

**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 3, 2023

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

(Address of Principal Executive Offices)

33137

(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 3, 2023, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended March 31, 2023. 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, 2023, 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 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 May 3, 2023.
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 3, 2023.

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: May 3, 2023



OPKO Health Reports First Quarter 2023 Business Highlights and Financial Results

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

MIAMI (May 3, 2023) – **OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended March 31, 2023.

First quarter business highlights include the following:

- **OPKO Health’s ModeX Therapeutics, Inc. (ModeX) entered into an exclusive worldwide license and collaboration agreement with Merck to develop MDX-2201 for Epstein-Barr virus.** Under the terms of the agreement, OPKO received a \$50.0 million upfront payment and is eligible to receive up to an additional \$872.5 million upon the achievement of prespecified development and commercial milestones. In addition, upon commercial launch of MDX-2201, OPKO is eligible to receive royalties on global net sales. Merck will be responsible for clinical and regulatory costs and activities, as well as product commercialization.
 - **Sales are underway by Pfizer for NGENLA® (somatrogon) in 17 countries including Japan, Germany and the United Kingdom; NGENLA® has been approved in 41 countries and Pfizer continues to work with the FDA to obtain approval in the U.S.** NGENLA treats pediatric patients with decreased growth due to insufficient growth hormone and reduces the injection frequency from once daily to once weekly. NGENLA is the first once-weekly product approved for the treatment of pediatric growth hormone deficiency in Japan, Canada, Australia, the United Kingdom, Taiwan, United Arab Emirates and Brazil, and was recently approved in Korea and Turkey. Its European Union marketing authorization is valid in all EU Member States, as well as in Iceland, Norway and Liechtenstein. Pfizer expects to launch in all priority international markets by year-end.
 - **BioReference Health is one of the first commercial laboratories to offer a dual-stain triage test to enhance cervical cancer screenings.** The CINtec® PLUS Cytology test from Roche Diagnostics is the only approved dual-stain triage test for patients who have a high-risk human papillomavirus result. The dual-stain biomarker test allows healthcare providers to assess a patient’s risk for cervical pre-cancer more accurately and quickly. BioReference is driving innovation to its portfolio with new tests to provide valuable information for healthcare providers and their patients.
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First Quarter Financial Results

- **Pharmaceuticals:** Revenue from products in the first quarter of 2023 increased to \$40.4 million from \$36.6 million in the first quarter of 2022, driven by sales in our international operating companies and an increase in sales of *Royaldee* to \$6.6 million from \$5.1 million in the prior-year period. Revenue from the transfer of intellectual property was \$64.8 million in the first quarter of 2023 compared with \$6.0 million in the 2022 period. The increase in revenue from the transfer of intellectual property reflects a \$50.0 million upfront payment from Merck, a \$7.0 million milestone payment from Vifor Fresenius Medical Care Renal Pharma triggered by the German price approval related to *Royaldee* and a \$2.5 million milestone payment from Nicoya Therapeutics related to the submission of its investigational new drug application to China's Center for Drug Evaluation for *Royaldee*. Total costs and expenses were \$86.3 million in the first quarter of 2023, up from \$60.7 million in the prior-year period. The increase was mainly due to a \$12.5 million payment to Sanofi that accrued under a Sanofi In-License Agreement between ModeX and Sanofi, and research expenses at ModeX, which was acquired in May 2022. Operating income was \$19.0 million in the first quarter of 2023, compared with an operating loss of \$18.1 million in the first quarter of 2022.
- **Diagnostics:** Revenue from services in the first quarter of 2023 was \$132.4 million compared with \$286.6 million in the prior-year period. Revenue decreased due to lower COVID-19 testing volume. BioReference processed approximately 68,000 COVID-19 PCR tests in the first quarter of 2023, representing 4.8% of total volume, versus 2.0 million tests in the first quarter of 2022, representing 46.9% of total volume. Furthermore, revenue decreased by \$36.1 million due to the sale of GeneDx in April 2022. Total costs and expenses were \$172.4 million in the first quarter of 2023 compared with \$330.1 million in the first quarter of 2022, resulting in an operating loss of \$40.0 million compared with an operating loss of \$43.5 million in the 2022 period, which included approximately \$16.0 million from GeneDx. BioReference is implementing significant cost-reduction initiatives as it strives to return to profitability.
- **Consolidated:** Consolidated total revenues for the first quarter of 2023 were \$237.6 million compared with \$329.2 million for the comparable period of 2022. Operating loss for the first quarter of 2023 decreased \$41.8 million to \$30.6 million from \$72.4 million for the 2022 quarter. Net loss for the first quarter of 2023 was \$18.3 million, or \$0.02 per share, compared with a net loss of \$55.4 million, or \$0.08 per share, for the 2022 quarter. Net loss for the first quarter of 2023 included non-cash income of \$8.3 million due to an increase in the fair value of OPKO's GeneDx Holdings (formerly Sema4 Holdings Corp) investment and non-cash income of \$8.5 million as a result of GeneDx Holdings achieving specific revenue targets for the 2022 fiscal year.
- **Cash and cash equivalents:** Cash and cash equivalents were \$110.8 million as of March 31, 2023, which does not include the \$50 million upfront payment from Merck that was received in April 2023.

Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss first quarter financial results, provide financial guidance 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 here. Callers who pre-register will receive a unique PIN to gain immediate access to the call and bypass the live operator. Participants may register at any time, including up to and after the call start time. Those unable to pre-register may participate by dialing 833-630-0584 (U.S.) or 412-317-1815 (International). A webcast of the call can also be accessed at OPKO's Investor Relations page and here.

A telephone replay will be available until May 10, 2023 by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 4576780. 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 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, our product development efforts and the expected benefits of our products, 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, whether BioReference's cost-cutting initiatives and attempts at returning to its core business will be successful, 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

	As of	
	March 31, 2023	December 31, 2022
Assets:		
Cash and cash equivalents	\$ 110.8	\$ 153.2
Other current assets	295.6	241.3
Total current assets	406.4	394.5
In-process research and development and goodwill	792.4	790.9
Other assets	970.8	981.9
Total Assets	\$ 2,169.6	\$ 2,167.3
Liabilities and Equity:		
Accounts Payable	\$ 80.5	\$ 67.0
Accrued expenses	106.0	98.3
Current portion of convertible notes	0.0	3.1
Other current liabilities	35.9	45.1
Total current liabilities	222.4	213.5
Long term portion of convertible notes	211.3	210.4
Deferred tax liabilities, net	129.7	126.4
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	54.4	55.4
Total Liabilities	617.8	605.7
Equity	1,551.8	1,561.6
Total Liabilities and Equity	\$ 2,169.6	\$ 2,167.3

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,	
	2023	2022
Revenues		
Revenue from services	\$ 132.4	\$ 286.6
Revenue from products	40.4	36.6
Revenue from transfer of intellectual property	64.8	6.0
Total revenues	237.6	329.2
Costs and expenses		
Cost of revenues	138.3	243.9
Selling, general and administrative	75.7	117.5
Research and development	32.6	18.3
Contingent consideration	0.1	(0.1)
Amortization of intangible assets	21.5	22.0
Total costs and expenses	268.2	401.6
Operating loss	(30.6)	(72.4)
Other income and (expense), net	13.6	(4.2)
Loss before income taxes and investment losses	(17.0)	(76.7)
Income tax benefit (provision)	(1.2)	21.3
Net loss before investment losses	(18.2)	(55.3)
Loss from investments in investees	(0.1)	(0.1)
Net loss	\$ (18.3)	\$ (55.4)
Loss per share, basic and diluted	\$ (0.02)	\$ (0.08)
Weighted average common shares outstanding, basic and diluted	751,506,257	660,302,426

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