

**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): August 7, 2024

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 August 7, 2024, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended June 30, 2024. 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 second quarter ended June 30, 2024, 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 August 7, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 7, 2024



OPKO Health Reports Second Quarter 2024 Business Highlights and Financial Results

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

MIAMI (August 7, 2024) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three and six months ended June 30, 2024.

Highlights from the second quarter and recent weeks include the following:

- **Enrollment underway in the MDX2001 Phase 1 trial for the treatment of solid tumor cancers.** MDX2001, a tetraspecific antibody, is designed to optimize T-cell function to stimulate tumor regression while minimizing the likelihood of antigen escape. This Phase 1 open-label trial is expected to enroll 45 cancer patients with a variety of solid tumors at six clinical trial sites, and to evaluate safety, tolerability, pharmacokinetics and early evidence of anti-tumor activity.
- **The global commercial launch of NGENLA® is ongoing by OPKO's partner, Pfizer. NGENLA has been launched in all major markets.** OPKO is entitled to gross profit sharing based on sales of both NGENLA and Pfizer's daily growth hormone product, Genotropin®. In addition, OPKO is entitled to an additional \$100 million in potential milestone payments associated with approvals for an adult indication for growth hormone deficiency and additional pediatric indications.
- **Entered into a \$250 million note purchase agreement with HealthCare Royalty secured by profit share payments related to NGENLA.** Under the terms of the agreement, OPKO retains a significant portion of the profit share payments from Pfizer received pursuant to its license agreement relating to NGENLA in the near term with upside over the long term, as well as the full \$100 million of remaining potential milestone payments.
- **OPKO's Board of Directors authorized a \$100 million share repurchase program.** Under the program, OPKO may repurchase shares of its common stock from time to time through open market purchases, block trades, privately negotiated transactions, accelerated share repurchase transactions and/or pursuant to Rule 10b5-1 plans, in compliance with applicable securities laws and other legal requirements. The Company had approximately 697 million shares outstanding as of June 30, 2024. This new authorization represented approximately 10.1% of shares outstanding at the stock price at the time of the announcement.
- **Sale of select assets of BioReference Health expected to close toward the end of the third quarter.** OPKO entered into an agreement in March 2024 to sell BioReference Health's laboratory testing businesses focused on clinical diagnostics and women's health, excluding operations in New York and New Jersey, for \$237.5 million. BioReference Health will continue to offer oncology and urology diagnostic services nationwide, as well as maintain its full operations in New York and New Jersey. Continuing operations accounted for net sales of more than \$400 million in 2023. This transaction is expected to streamline BioReference Health's laboratory services business while retaining its core operations to better position the division for sustained growth and profitability.

Second Quarter Financial Results

- **Pharmaceuticals:** Revenue from products in the second quarter of 2024 was \$40.5 million compared with \$43.5 million in the second quarter of 2023, reflecting lower sales in OPKO's international operating companies primarily due to foreign currency exchange fluctuations. Revenue from sales of *Rayaldee* was \$7.2 million compared with \$7.7 million in the same period in 2023. Revenue from the transfer of intellectual property and other was \$12.3 million in the second quarter of 2024, which included \$5.0 million from the BARDA contract, compared with \$94.9 million in the 2023 period, which included milestone revenue of \$90.0 million triggered by the FDA approval of NGENLA. Gross profit share and royalty payments for NGENLA and Pfizer's Genotropin was \$6.3 million in the 2024 quarter compared with \$3.8 million in the same period for 2023. Total costs and expenses increased to \$77.6 million in the second quarter of 2024 from \$74.7 million in the prior-year period primarily due to higher research and development expenses related to increased activity within the ModeX development programs. Operating loss was \$24.8 million in the second quarter of 2024, which included \$17.9 million of depreciation and amortization expense, compared with operating income of \$63.6 million in the second quarter of 2023, after giving effect to the \$90.0 million milestone payment as described above and also included \$17.8 million of depreciation and amortization expense.
- **Diagnostics:** Revenue from services in the second quarter of 2024 was \$129.4 million compared with \$127.0 million in the prior-year period, with the increase primarily due to higher clinical test reimbursement partially offset by lower clinical test volume. Total costs and expenses were \$156.0 million in the second quarter of 2024 compared with \$171.3 million in the second quarter of 2023, reflecting continued progress with cost-reduction initiatives. Included in second quarter 2024 results were revenue from services of approximately \$25.5 million and total costs and expenses of approximately \$32.5 million related to assets being acquired by Labcorp. Operating loss was \$26.6 million in the second quarter of 2024 compared with \$44.3 million in the 2023 period and included \$6.2 million and \$8.6 million of depreciation and amortization expense, respectively.

- **Consolidated:** Consolidated total revenues for the second quarter of 2024 were \$182.2 million compared with \$265.4 million for the comparable period of 2023. Operating loss for the second quarter of 2024 was \$61.7 million compared with operating income of \$7.0 million for the 2023 quarter, with the 2023 quarter benefiting from the \$90.0 million milestone payment described above. The second quarter of 2024 included non-cash other income of \$60.5 million compared with non-cash other expense of \$19.9 million in the year-ago quarter related to the change in the fair value of the GeneDx Holdings investment. As a result, net loss for the second quarter of 2024 was \$10.3 million, or \$0.01 per share, compared with net loss of \$19.6 million, or \$0.03 per share, for the 2023 quarter.
- **Cash and cash equivalents:** Cash and cash equivalents were \$40.6 million as of June 30, 2024 and OPKO's Investments included liquid equity securities which had a market value of \$101.5 million, primarily from the ownership interest in GeneDx. Subsequent to the end of the second quarter, OPKO entered into a \$250 million note purchase agreement secured by OPKO's profit share payments to be received from Pfizer relating to NGENLA. OPKO is also entitled to receive \$237.5 million upon closing of the Labcorp transaction anticipated toward the end of the third quarter of 2024.

Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss second 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 August 14, 2024, by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 6314261. 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, whether Pfizer will obtain approvals for an adult indication for growth hormone deficiency or additional pediatric indications and accordingly, whether we will be entitled to any additional milestone payments, whether our product development efforts will be successful and whether the expected benefits of our products will be realized, including whether enrollment in a Phase 1 clinical trial for MDX2001 will be successful and whether the data will be positive, whether and how many of our shares we will repurchase under a buyback program, whether NGENLA profits will be sufficient to provide long term upside after satisfying our obligations under the note purchase agreement, whether the relationship with our commercial and strategic partners will be successful, whether our commercial and strategic 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 we will continue to successfully advance products in our pipeline and whether they can be commercialized, whether the sale of selected BioReference assets will be completed in the third quarter or at all, and if this transaction is completed, whether BioReference will be able to streamline its laboratory services business and better position the division for sustained growth and profitability, whether BioReference's attempts at returning its core business to profitability 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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OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in millions)
Unaudited

	As of	
	June 30, 2024	December 31, 2023
Assets:		
Cash and cash equivalents	\$ 40.6	\$ 95.9
Assets held for sale	119.7	0.0
Other current assets	197.7	213.6
Total current assets	358.0	309.5
In-process research and development and goodwill	725.1	793.3
Other assets	896.8	908.9
Total Assets	\$ 1,979.9	\$ 2,011.7
Liabilities and Equity:		
Accounts payable	\$ 82.2	\$ 69.7
Accrued expenses	94.5	90.1
Liabilities associated with assets held for sale	8.9	0.0
Current portion of convertible notes	0.2	0.0
Other current liabilities	33.7	40.3
Total current liabilities	219.5	200.1
Long-term portion of convertible notes	175.9	214.3
Deferred tax liabilities, net	119.1	126.8
Other long-term liabilities, principally leases, and lines of credit	70.1	81.3
Total Liabilities	584.6	622.5
Equity	1,395.3	1,389.2
Total Liabilities and Equity	\$ 1,979.9	\$ 2,011.7

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,	
	2024	2023	2024	2023
Revenues				
Revenue from services	\$ 129.4	\$ 127.0	\$ 256.3	\$ 259.4
Revenue from products	40.5	43.5	78.5	83.9
Revenue from transfer of intellectual property and other	12.3	94.9	21.1	159.7
Total revenues	<u>182.2</u>	<u>265.4</u>	<u>355.9</u>	<u>503.0</u>
Costs and expenses				
Cost of service revenues	107.1	113.0	216.9	227.1
Cost of product revenues	23.5	25.9	45.2	50.2
Selling, general and administrative	68.8	79.8	139.0	155.4
Research and development	24.1	18.2	46.0	50.8
Contingent consideration	0.0	(0.0)	0.0	0.1
Amortization of intangible assets	20.4	21.5	41.9	43.0
Total costs and expenses	<u>243.9</u>	<u>258.4</u>	<u>489.0</u>	<u>526.6</u>
Operating loss (income)	(61.7)	7.0	(133.1)	(23.6)
Other income (expense), net	51.1	(23.5)	39.4	(9.8)
Loss before income taxes and investment losses	(10.6)	(16.5)	(93.7)	(33.4)
Income tax benefit (provision)	0.3	(3.1)	1.6	(4.4)
Loss before investment losses	(10.3)	(19.6)	(92.1)	(37.8)
Loss from investments in investees	(0.0)	(0.0)	(0.0)	(0.1)
Net loss	<u>\$ (10.3)</u>	<u>\$ (19.6)</u>	<u>\$ (92.1)</u>	<u>\$ (37.9)</u>
Loss per share, basic and diluted	<u>\$ (0.01)</u>	<u>\$ (0.03)</u>	<u>\$ (0.13)</u>	<u>\$ (0.05)</u>
Weighted average common shares outstanding, basic and diluted	697,211,592	751,727,383	702,036,148	751,617,431

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