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 7, 2024

OPKO Health, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-33528**	**75-2402409**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 7, 2024, OPKO Health, Inc. (the "Company") issued a press release announcing operating and financial highlights for the quarter ended March 31, 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 first quarter ended March 31, 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

Exhibit No.	Description
99.1	Press Release of the Company dated May 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: May 7, 2024

OPKO Health Reports First Quarter 2024 Business Highlights and Financial Results

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

MIAMI (May 7, 2024) – **OPKO Health, Inc. (NASDAQ: OPK)**reports business highlights and financial results for the three months ended March 31, 2024.

First quarter business highlights include the following:

- **Entered into an agreement with Labcorp to sell select assets of BioReference Health.** The transaction includes the sale of 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. These assets comprise patient service centers, certain customer contracts and operating assets, which account for approximately $100 million in annualized revenue. 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. 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. The transaction is subject to customary closing conditions and applicable regulatory approvals, including under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. The transaction is anticipated to close in the second half of 2024.

- **The IND application for MDX2001, a tetraspecific antibody for the treatment of solid tumor cancers, received FDA clearance.** MDX2001 is designed to optimize T-cell function while preventing tumor antigen escape. The first patient is expected to be enrolled in a Phase 1 trial to evaluate safety, tolerability, pharmacokinetics and anti-tumor activity in the second quarter of 2024.

- **The global launch of NGENLA® is ongoing by OPKO's partner, Pfizer. NGENLA is approved in over 50 countries including the U.S., Japan, EU Member States, Canada and Australia.** 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.

First Quarter Financial Results

- **Pharmaceuticals:** Revenue from products in the first quarter of 2024 were $38.1 million compared to $40.4 million in the first quarter of 2023, resulting from lower sales in OPKO's international operating companies and foreign currency exchange fluctuations, partially offset by an increase in sales of *Rayaldee* to $6.9 million from $6.6 million. Revenue from the transfer of intellectual property and other was $8.7 million in the first quarter of 2024 compared with $64.8 million in the 2023 period, which included $5.6 million in gross profit share and royalty payments for NGENLA and Pfizer's Genotropin® in the 2024 quarter compared with $3.1 million in the same period for 2023. The decrease in revenue from the transfer of intellectual property and other is primarily attributable to one-time milestone payments received in 2023 including 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 for *Rayaldee* and a $2.5 million milestone payment from Nicoya Therapeutics for the submission of its IND application for *Rayaldee* to China's Center for Drug Evaluation. Total costs and expenses declined to $74.5 million in the first quarter of 2024 from $86.3 million in the prior-year period primarily due to a $10.6 million, or 33%, decrease in research and development expense as the 2023 period included a non-recurring payment to Sanofi related to our Merck collaboration, partially offset by increased activity within our ModeX development programs. Operating loss was $27.7 million in the first quarter of 2024 compared with operating income of $19.0 million in the first quarter of 2023, again with 2023 benefiting from over $59 million in milestones as described above.

- **Diagnostics:** Revenue from services in the first quarter of 2024 was $126.9 million compared with $132.4 million in the prior-year period, with the decline primarily due to lower clinical testing volume. Total costs and expenses were $161.3 million in the first quarter of 2024 compared with $172.4 million in the first quarter of 2023, reflecting the continued implementation of cost-reduction initiatives. Included in first quarter 2024 results were revenue from services of approximately $27.8 million and total costs and expenses of approximately $34.8 million related to assets being acquired by Labcorp. Operating loss was $34.4 million in the first quarter of 2024 compared with $40.0 million in the 2023 period.

- **Consolidated:** Consolidated total revenues for the first quarter of 2024 were $173.7 million compared with $237.6 million for the comparable period of 2023. Operating loss for the first quarter of 2024 increased to $71.5 million from $30.6 million for the 2023 quarter, with the 2023 quarter benefiting from the non-recurring license payments described above totaling $59.5 million. First quarter 2024 results included a non-cash, non-recurring expense of $26.3 million related to an embedded derivative as part of our convertible debt. In addition, both periods benefited from the increase of GeneDx's stock price of $22.7 million and $8.3 million, respectively, for 2024 and 2023. As a result, net loss for the first quarter of 2024 was $81.8 million, or $0.12 per share, compared with $18.3 million, or $0.02 per share, for the 2023 quarter.

- **Cash and cash equivalents:** Cash and cash equivalents were $75.6 million as of March 31, 2024. In January, OPKO completed the sale of $230.0 million aggregate principal amount of 3.75% Convertible Senior Notes due 2029 and exchanged approximately $144.4 million of the Company's outstanding 4.50% Convertible Senior Notes due 2025. The Company used approximately $50.0 million of the net proceeds to repurchase shares of the Company's common stock from purchasers of the notes. Additionally, OPKO issued and sold approximately $71.1 million aggregate principal amount of its 3.75% Convertible Senior Notes due 2029 to several holders, including Company affiliates, in exchange for the outstanding 5% Convertible Promissory Notes and accrued interest.

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 21, 2024 by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 6926223. 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 patients will be enrolled in a Phase 1 clinical trial for MDX2001 in the second quarter or if it all, 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, our expectations about RAYALDEE, whether the sale of selected BioReference assets will be completed within the second half of 2024 or at all, and if this transaction is completed, whether it will streamline BioReference Health's laboratory services business and better position the division for sustained growth and profitability, 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, 2024	As of December 31, 2023
Assets:		
Cash and cash equivalents	$ 75.6	$ 95.9
Assets held for sale	120.3	0.0
Other current assets	195.4	213.6
Total current assets	391.3	309.5
In-process research and development and goodwill	725.6	793.3
Other assets	857.1	908.9
Total Assets	$ 1,974.0	$ 2,011.7
Liabilities and Equity:		
Accounts payable	$ 71.2	$ 69.7
Accrued expenses	88.8	90.1
Liabilities associated with assets held for sale	9.7	0.0
Current portion of convertible notes	0.2	0.0
Other current liabilities	34.5	40.3
Total current liabilities	204.4	200.1
Long-term portion of convertible notes	323.1	214.3
Deferred tax liabilities, net	121.6	126.8
Other long-term liabilities, principally contract liabilities, leases, contingent consideration, and lines of credit	72.1	81.3
Total Liabilities	721.2	622.5
Equity	1,252.8	1,389.2
Total Liabilities and Equity	$ 1,974.0	$ 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 March 31,	
	2024	2023
Revenues		
Revenue from services	$ 126.9	$ 132.4
Revenue from products	38.1	40.4
Revenue from transfer of intellectual property	8.7	64.8
Total revenues	173.7	237.6
Costs and expenses		
Cost of service revenues	109.9	114.1
Cost of product revenues	21.8	24.2
Selling, general and administrative	70.2	75.7
Research and development	21.9	32.6
Contingent consideration	0.0	0.1
Amortization of intangible assets	21.4	21.5
Total costs and expenses	245.2	268.2
Operating loss	(71.5)	(30.6)
Other income and (expense), net	(11.7)	13.6
Loss before income taxes and investment losses	(83.2)	(17.0)
Income tax benefit (provision)	1.4	(1.2)
Net loss before investment losses	(81.8)	(18.2)
Loss from investments in investees	(0.0)	(0.1)
Net loss	$ (81.8)	$ (18.3)
Loss per share, basic and diluted	$ (0.12)	$ (0.02)
Weighted average common shares outstanding, basic and diluted	706,882,189	751,506,257

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