
**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 27, 2025

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 February 27, 2025, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended December 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 fourth quarter ended December 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

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release of the Company dated February 27, 2025</u>
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: February 27, 2025



OPKO Health Reports Fourth Quarter 2024 Business Highlights and Financial Results

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

MIAMI (February 27, 2025) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three and 12 months ended December 31, 2024.

Highlights from the fourth quarter of 2024 and recent weeks include the following:

- **Enrollment and dosing underway by Merck in the Phase 1 Epstein-Barr virus (EBV) vaccine trial.** Dosing of patients has commenced for the Phase I study (NCT06655324) of an EBV vaccine candidate being developed in collaboration with Merck. The investigational vaccine, based on ModeX's ferritin nanoparticle vaccine platform, is being evaluated for safety and tolerability in up to 200 healthy adults. Commencement of this study triggered a milestone payment to ModeX.
- **Awarded \$51 million of additional funding under an existing BARDA contract to develop COVID multispecific antibodies and to initiate an influenza program.** ModeX Therapeutics was awarded \$26.9 million of new funding under an existing contract with the Biomedical Advanced Research and Development Authority (BARDA). This funding supports the development of a second novel multispecific antibody to SARS-CoV-2 from preclinical through Phase 1 trials, as well as preclinical work on gene-based expression of multispecific antibodies to SARS-CoV-2 including mRNA and DNA vectors. In addition, BARDA activated an option for the second phase of funding totaling \$24.1 million for ModeX to begin development of influenza multispecifics with gene and protein delivery modalities. Together, these funds bring the total awarded to ModeX to \$110 million (and ModeX could receive up to \$205 million if all options are executed).
- **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 while preventing tumor antigen escape. This Phase 1 open-label trial is expected to enroll up to 45 patients at four clinical sites. The Phase 1a portion is primarily designed to evaluate the safety and immunogenicity of ascending doses of MDX2001 in patients with various solid tumors.
- **Pfizer's global commercialization of NGENLA® continues; available in all major markets.** OPKO is entitled to a share of gross profits based on sales of both NGENLA and Pfizer's daily growth hormone product, Genotropin®.
- **BioReference Health made significant strides toward near-term profitability.** With the goal of achieving profitability for 2025, BioReference continued to reduce costs and improve productivity by enhancing innovation of its higher-value specialty testing segments. In September 2024 OPKO sold a portion 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. This transaction accelerated the path to sustained growth and profitability while retaining core laboratory services operations.

- **Capital structure realignment through a series of transactions providing the Company with the liquidity and flexibility to execute its long-term plans.** During the fourth quarter of 2024 the Company repurchased \$17.0 million of principal convertible notes for \$25.0 million and repurchased an additional 10.9 million common shares for \$16.5 million. Under its previously announced stock repurchase program, OPKO has repurchased 25.8 million shares for \$40.2 million with \$59.8 million remaining under the program. During 2024, the Company reduced its common share count by 81.0 million shares, or 10% of shares outstanding. In addition, the Company received \$166.6 million of proceeds from the sale of GeneDx Holdings Corp. ("GeneDx") shares as well as \$51.7 million after December 31, 2024.

Fourth Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the fourth quarter of 2024 were \$183.6 million compared with \$181.9 million for the comparable period of 2023. Net income for the fourth quarter of 2024 was \$14.0 million, or \$0.01 per diluted share, compared with net loss of \$66.5 million, or \$0.09 per share, for the 2023 quarter. Operating loss for the fourth quarter of 2024 was \$33.1 million compared with operating loss of \$69.1 million for the 2023 quarter. The fourth quarter of 2024 included a realized gain of \$54.1 million from the sale of shares of GeneDx, as well as non-cash other income of \$21.4 million compared with non-cash other expense of \$3.2 million in the comparable quarter related to the change in the fair value of the GeneDx shares.
- **Pharmaceuticals:** Revenue from products in the fourth quarter of 2024 was \$37.4 million compared with \$43.0 million in the fourth quarter of 2023, primarily reflecting unfavorable foreign currency exchange fluctuations. Revenue from sales of *Rayaldee* was \$9.1 million compared with \$9.3 million in the same period in 2023. Revenue from the transfer of intellectual property and other was \$43.1 million in the fourth quarter of 2024 compared with \$14.7 million in the 2023 period. This increase was driven by revenue from the BARDA contract of \$23.8 million in 2024 compared with \$1.2 million in 2023, as well as \$9.8 million from contract manufacturers' commercial milestones, compared with \$0.4 million in 2023, and a \$12.5 million milestone from Merck. This increase was partially offset by a decrease in gross profit share payments for NGENLA, which totaled \$9.6 million in the 2024 period compared with \$12.2 million in the 2023 period. Total costs and expenses increased to \$82.6 million in the fourth quarter of 2024 from \$73.8 million in the prior-year period, primarily due to higher research and development expenses related primarily to increased activity within the ModeX development programs. Operating loss was \$2.1 million in the fourth quarter of 2024, which included \$18.1 million of depreciation and amortization expense, compared with \$16.0 million in the fourth quarter of 2023, which included \$17.9 million of depreciation and amortization expense.
- **Diagnostics:** Revenue from services in the fourth quarter of 2024 was \$103.1 million compared with \$124.2 million in the prior-year period, with the decrease primarily due to lower clinical test volume principally as a result of the sale of certain BioReference assets. Total costs and expenses were \$124.8 million in the fourth quarter of 2024 compared with \$166.4 million in the fourth quarter of 2023. The decrease was primarily attributable to the aforementioned asset sales and continued cost-reduction initiatives at BioReference, which included a reduction in employee headcount and the streamlining of certain smaller operations, resulting in operating efficiencies. Operating loss was \$21.7 million in the fourth quarter of 2024, which included \$7.4 million in adjustments to the life of certain leases and the associated expense, compared with a loss of \$42.3 million in the 2023 period, which included \$4.7 million of non-recurring expenses and \$5.4 million of revenue adjustments.

- **Cash, cash equivalents, marketable securities and restricted cash:** Cash, cash equivalents, and current restricted cash were \$431.9 million, marketable securities, principally shares of GeneDx, were \$54.6 million and long term restricted cash and escrow was \$37.2 million as of December 31, 2024.

Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss fourth 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 March 6, 2025, by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 8087517. 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 product development efforts will be successful and whether the expected benefits of our products will be realized, including whether enrollment in a clinical trials for MDX2001 and MDX 2201 will be successful and whether the data will be positive, whether we will receive additional funding from BARDA, 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, whether our partner will be able to continue to successfully commercialize NGENLA and the NGENLA profits will provide adequate upside, whether we will continue to repurchase shares under a buyback program, 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 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.

Contacts:

Alliance Advisors IR

Yvonne Briggs, 310-691-7100

ybriggs@allianceadvisors.com

or

Bruce Voss, 310-691-7100

bvoss@allianceadvisors.com

—Tables to Follow—

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

	As of	
	December 31, 2024	December 31, 2023
Assets:		
Cash, cash equivalents, and current restricted cash	\$ 431.9	\$ 95.9
Other current assets	230.2	213.6
Total current assets	662.1	309.5
In-process research and development and goodwill	724.3	793.3
Other assets	813.8	908.9
Total Assets	<u>\$ 2,200.2</u>	<u>\$ 2,011.7</u>
Liabilities and Equity:		
Accounts payable	\$ 47.1	\$ 69.7
Accrued expenses	118.4	90.1
Current portion of convertible notes	0.2	0.0
Other current liabilities	27.4	40.3
Total current liabilities	193.1	200.1
Long-term portion of convertible notes	173.6	214.3
Senior secured notes	245.6	0.0
Deferred tax liabilities, net	140.8	126.8
Other long-term liabilities, principally leases, and lines of credit	81.7	81.3
Total Liabilities	834.8	622.5
Equity	1,365.4	1,389.2
Total Liabilities and Equity	<u>\$ 2,200.2</u>	<u>\$ 2,011.7</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 December 31,		For the twelve months ended December 31,	
	2024	2023	2024	2023
Revenues				
Revenue from services	\$ 103.1	\$ 124.2	\$ 480.7	\$ 515.3
Revenue from products	37.4	43.0	155.1	167.5
Revenue from transfer of intellectual property and other	43.1	14.7	77.3	180.7
Total revenues	183.6	181.9	713.1	863.5
Costs and expenses				
Cost of service revenues	76.3	112.4	402.1	445.8
Cost of product revenues	22.7	24.8	92.5	99.5
Selling, general, and administrative	67.0	72.9	304.2	300.6
Research and development	30.4	19.4	105.2	89.6
Contingent consideration	0.0	(0.0)	0.0	(1.0)
Amortization of intangible assets	20.3	21.5	82.7	86.0
Gain on sale of assets	0.0	0.0	(121.5)	0.0
Total costs and expenses	216.7	251.0	865.2	1,020.5
Operating loss	(33.1)	(69.1)	(152.1)	(157.0)
Other income (expense), net	68.0	(3.4)	141.7	(27.4)
Income (loss) before income taxes and investment losses	34.9	(72.5)	(10.4)	(184.4)
Income tax (provision) benefit	(20.9)	6.0	(42.8)	(4.4)
Income (loss) before investment losses	14.0	(66.5)	(53.2)	(188.8)
Loss from investments in investees	(0.0)	(0.0)	(0.0)	(0.1)
Net income (loss)	\$ 14.0	\$ (66.5)	\$ (53.2)	\$ (188.9)
Income (loss) per share, basic	\$ 0.02	\$ (0.09)	\$ (0.08)	\$ (0.25)
Income (loss) per share, diluted	\$ 0.01	\$ (0.09)	\$ (0.08)	\$ (0.25)
Weighted average common shares outstanding, basic	676,788,895	751,506,257	694,019,535	751,765,915
Weighted average common shares outstanding, diluted	951,837,287	751,506,257	694,019,535	751,765,915