
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): April 28, 2026

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

(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	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 April 28, 2026, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended March 31, 2026. 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, 2026, 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
<u>99.1</u>	<u>Press Release of the Company dated April 28, 2026</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: April 28, 2026



OPKO Health Reports First Quarter 2026 Business Highlights and Financial Results

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

MIAMI, April 28, 2026 – OPKO Health, Inc. (NASDAQ: OPK) (OPKO) reports business highlights and financial results for the three months ended March 31, 2026.

Highlights from the first quarter of 2026 and recent weeks included the following:

- **Initiated and completed first dose cohort of MDX2301 Phase 1 clinical trial for the prevention of COVID-19.** MDX2301 is a tetravalent bispecific antibody that neutralizes all known variants of SARS-CoV-2 and also has the potential to delay resistance by emerging variants. The Phase 1 clinical trial ([NCT07445971](#)) is evaluating the safety, pharmacokinetics and tolerability of MDX2301 administered via different routes in healthy volunteers and in immune impaired adults at high risk for severe COVID-19. By combining multiple antibody binding domains in a single molecule, MDX2301 is designed to provide high potency and greater breadth compared with conventional monoclonal antibodies. This trial is being funded by the Biomedical Advanced Research and Development Authority (BARDA).
- **Initiated MDX2003 Phase 1 clinical trial in relapsed or refractory B-cell lymphoma.** MDX2003 (CD19xCD20xCD3xCD28) is a novel tetraspecific T-cell engager-expander designed to optimize sustained T-cell function and address the two most common and validated targets in lymphomas and leukemias. The MDX2003 Phase 1 study ([NCT07249905](#)) is designed to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of MDX2003 in adults with various types of B-cell lymphoma. The study includes dose-escalation and dose-expansion phases. B-cell lymphoma, a form of non-Hodgkin lymphoma arising from B lymphocytes, represents the most common lymphoma subtype, accounting for approximately 85% of cases.
- **ModeX to present data on multispecific antibody targeted *in vivo* CAR T cell programs at the American Society of Gene + Cell Therapy (ASGCT) Annual Meeting with plans to enter Phase 1 studies later this year.** Built on its multispecific technology, ModeX recently developed an *in vivo* CAR-T and gene delivery platform that it believes is highly differentiated compared with *ex vivo* and other *in vivo* CAR-T approaches. Using antibody-targeted lipid nanoparticles, this platform can deliver genes encoding chimeric antigen receptors (CARs) directly to specific immune cell subsets that generate functional CAR-T cells *in vivo*.
- **Presented two posters highlighting MDX2003 and MDX2004 at the ESMO Targeted Anticancer Therapies Congress 2026.** In March, an abstract titled “MDX2003, a First-in-Class CD19xCD20xCD3xCD28 Tetraspecific T-Cell Engager with Potent Preclinical Activity against B Cell Malignancies and Promise in Autoimmunity” was presented at the European Society for Medical

Oncology's (ESMO) Targeted Anticancer Therapies Congress 2026 in Paris. An abstract titled "A phase 1/2a, multicenter, first-in-human, open-label clinical trial evaluating monotherapy with MDX2004, a trispecific antibody-fusion protein in patients with advanced tumors" was also presented at the Congress.

- **Expanded partnership with Entera Bio to advance first-in-class oral long-acting PTH tablet for patients with hypoparathyroidism.** This third program under the collaboration combines OPKO's proprietary long-acting PTH variants with Entera's proprietary N-Tab® technology. Following favorable pharmacodynamic and pharmacokinetic data reported in December 2025, the companies have jointly decided to accelerate development and expect to file an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) in late 2026. OPKO and Entera Bio each hold a 50% ownership interest in the long-acting PTH hypoparathyroidism program and each is responsible for 50% of the program's development costs.

First Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the first quarter of 2026 were \$124.2 million compared with \$149.9 million for the 2025 period, with the decrease principally resulting from the sale of certain BioReference assets in 2025. Operating loss for the first quarter of 2026 improved to \$51.0 million compared with operating loss of \$67.2 million for the 2025 quarter. Net loss for the first quarter of 2026 was \$54.8 million, or \$0.07 per share, compared with net loss of \$67.6 million, or \$0.10 per share, for the 2025 quarter. The prior year results included a \$3.9 million realized gain from the sale of shares of GeneDx Holdings Corp.
- **Pharmaceuticals:** Revenue from products in the first quarter of 2026 was \$38.0 million compared with \$34.8 million in the first quarter of 2025, driven by higher sales volumes from OPKO's Spanish operations and by a positive net foreign exchange impact of \$2.4 million. Revenue from *Royaldee* remained consistent at \$6.3 million in the first quarter of both 2026 and 2025. Revenue from the transfer of intellectual property and other rose to \$14.0 million, up from \$12.3 million in 2025. This was highlighted by an increase in gross profit share payments for NGENLA, which totaled \$6.4 million compared with \$4.5 million in the 2025 quarter. The increase was partially offset by a decrease in revenue recognized under the BARDA contract, which totaled \$4.1 million in the first quarter of 2026 compared with \$7.0 million for the same period in 2025. Total costs and expenses were \$81.7 million in the first quarter of 2026 compared with \$81.9 million in the prior-year period. Operating loss narrowed by 15% to \$29.7 million in the first quarter of 2026, which included \$18.3 million in depreciation and amortization expense, compared with operating loss of \$34.8 million in the first quarter of 2025, which included \$17.8 million of depreciation and amortization expense.
- **Diagnostics:** Revenue from services in the first quarter of 2026 was \$72.2 million compared with \$102.8 million in the prior-year period, which included \$25.9 million of revenue related to the oncology assets sold to Labcorp in September 2025. The remaining decrease was principally a result of lower clinical test reimbursement rates as a result of exiting certain higher priced, but lower or negative gross margin test offerings, as well as a slight decrease in overall testing volumes. Total costs and expenses were \$85.1 million in the first quarter of 2026 compared with \$126.8 million in the first quarter of 2025, which included \$31.3 million of costs and expenses related to oncology assets that were sold to Labcorp. Operating loss narrowed by more than 45% to \$13.0 million in the first quarter of 2026, which included \$3.9 million of depreciation and

amortization expense, compared with operating loss of \$23.9 million in the 2025 period, which included \$5.7 million of depreciation and amortization expense.

- **Cash, cash equivalents, marketable securities and restricted cash:** Cash, cash equivalents, marketable securities and restricted cash were \$341.9 million as of March 31, 2026. As of March 31, 2026, approximately \$92.0 million of OPKO's common stock had been repurchased under the program since its authorization in July 2025, including \$4.8 million in the first quarter of 2026. Approximately \$108.0 million remained authorized and available for future repurchases.

Financial Guidance

The table below contains financial guidance for the 2026 second quarter and the unchanged full year financial guidance (in millions):

	For the three months ended June 30, 2026		For the year ended December 31, 2026	
	Low	High	Low	High
Revenue:				
Services revenue	\$ 72	\$ 76	\$ 300	\$ 312
Product revenue	38	42	160	170
IP and other revenue	15	19	70	80
Total revenue	127	132	530	560
Included in revenue				
Pfizer gross profit share	6	8	34	37
BARDA	5	7	18	22
Total costs and expenses	180	190	725	750
R&D included in costs and expenses	32	38	125	135

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 March 5, 2026, by dialing 855-669-9658 (U.S.) or 412-317-0088 (International) and providing the passcode 2140261. 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, please 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, including whether and when we will complete the clinical studies initiated for each of MDX2301 and MDX2003, and whether final study data will be positive for one or both studies, whether data will support marketing approval, our ability to develop and commercialize each of MDX2301 and MDX2003, whether MDX2301 is capable of effectively preventing COVID-19, whether each of MDX2301 and MDX2003 will be safe and tolerable, or have any impact on the severity of disease, expectations regarding the products, their efficacy and market potential, whether the in vivo CAR-T and gene delivery platform is highly differentiated and whether we will initiate a Phase 1 trial in connection therewith, whether we will be able to submit Investigational New Drug application for the oral long-acting PTH tablet and the timing of that submission, whether our expanded collaboration with Entera will be successful, whether our product development efforts will be successful and whether the expected benefits of our products will be realized, including whether preclinical data will be indicative of clinical data should any of our preclinical programs progress into clinical development, 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 we will continue to successfully advance products in our pipeline and whether they can be commercialized, 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
Summary of Revenues
(in millions)
Unaudited

	For the three months ended March 31,	
	2026	2025
Diagnostics revenue		
Core diagnostics	\$ 65.8	\$ 70.4
4Kscore Test	6.4	6.5
Divested revenue	0.0	25.9
Revenue from services	72.2	102.8
Pharmaceutical revenue		
International operations	31.7	28.5
<i>Royaldee</i>	6.3	6.3
Revenue from products subtotal	38.0	34.8
NGENLA royalty and profit sharing, and cost sharing	6.4	4.5
BARDA	4.1	7.0
Regeneron	0.9	-
Other royalties and milestones	2.6	0.8
Revenue from transfer of intellectual property and other subtotal	14.0	12.3
Total pharmaceutical revenue	52.0	47.1
Total revenues	\$ 124.2	\$ 149.9

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

	As of	
	March 31, 2026	December 31, 2025
Assets:		
Cash, cash equivalents, and current restricted cash	\$ 341.9	\$ 369.1
Accounts receivable, net	79.6	90.3
Inventory, net	64.4	65.8
Other current assets	49.4	56.7
Total current assets	535.3	581.9
In-process research and development and goodwill	677.3	679.3
Other assets	644.2	670.7
Total Assets	<u>\$ 1,856.8</u>	<u>\$ 1,931.9</u>
Liabilities and Equity:		
Accounts payable	\$ 44.2	\$ 41.1
Accrued expenses	83.5	84.4
Other current liabilities	20.7	21.1
Total current liabilities	148.4	146.6
Long-term portion of convertible notes	87.4	85.0
Senior secured royalty financing	246.6	246.4
Deferred tax liabilities, net	114.6	126.3
Other long-term liabilities, principally leases, and lines of credit	55.2	59.6
Total Liabilities	652.2	663.9
Equity	1,204.6	1,268.0
Total Liabilities and Equity	<u>\$ 1,856.8</u>	<u>\$ 1,931.9</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,	
	2026	2025
Revenues		
Revenue from services	\$ 72.2	\$ 102.8
Revenue from products	38.0	34.8
Revenue from transfer of intellectual property	14.0	12.3
Total revenues	<u>124.2</u>	<u>149.9</u>
Costs and expenses		
Cost of service revenues	56.1	84.5
Cost of product revenues	22.3	22.8
Selling, general and administrative	48.6	59.1
Research and development	29.2	30.8
Amortization of intangible assets	19.0	19.9
Total costs and expenses	<u>175.2</u>	<u>217.1</u>
Operating loss	(51.0)	(67.2)
Other expense, net	(9.9)	(6.2)
Loss before income taxes and investment losses	(60.9)	(73.4)
Income tax benefit	6.1	5.8
Net loss before investment losses	(54.8)	(67.6)
Loss from investments in investees	(0.0)	(0.0)
Net loss	<u>\$ (54.8)</u>	<u>\$ (67.6)</u>
Loss per share, basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.10)</u>
Weighted average common shares outstanding, basic and diluted	758,876,415	671,577,429

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