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): February 26, 2026

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

(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 February 26, 2026, OPKO Health, Inc. (the "Company") issued a press release announcing operating and financial highlights for the quarter and year ended December 31, 2025. The press release also contains information on how to access the conference call the Company is hosting to discuss its financial and operating results for the fourth quarter and year ended December 31, 2025, as well as provide business updates and 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 February 26, 2026
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 26, 2026

Exhibit 99.1

OPKO Health Reports Fourth Quarter 2025 Business Highlights and Financial Results

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

MIAMI, February 26, 2026 – OPKO Health, Inc. (NASDAQ: OPK) (OPKO) reports business highlights and financial results for the three and 12 months ended December 31, 2025, and introduces financial guidance for the first quarter and full year 2026.

Highlights from the fourth quarter of 2025 and recent weeks include the following:

- **Entered into a research collaboration with Regeneron Pharmaceuticals to develop multispecific antibodies.** This new partnership leverages ModeX's MSTAR technology platform with Regeneron's proprietary binders to develop single molecule candidates that target multiple distinct biological pathways in several clinical indications. ModeX received an upfront payment and is entitled to potential milestone payments exceeding $200 million for each program. The overall potential value of the collaboration exceeds $1 billion if multiple products from the collaboration are successful. In addition, ModeX is eligible to receive tiered royalties on global net sales, reaching low double digits at the highest tier. Regeneron is responsible for funding all preclinical and clinical development, as well as all commercialization activities.

- **Merck completed the Phase 1 Epstein-Barr virus vaccine trial (NCT06655324).** This investigational vaccine candidate is being developed in collaboration with Merck and the Phase 1 trial is evaluating safety and tolerability in over 200 healthy adults was completed in the fourth quarter of 2025. Additional studies are in progress to inform dose and adjuvant selection for potential Phase 2 studies.

- **MDX2003, a first-in-class trispecific T-cell engager-expander for the treatment of leukemia and lymphoma, was approved for Phase 1 studies in Australia, which are expected to begin in the first half of 2026. Also, an abstract was presented at 2025 ASH Annual Meeting.** In November, an abstract titled "MDX2003, a novel tetraspecific T cell engager-expander targeting CD19xCD20xCD3xCD28, demonstrates potent preclinical activity against B cell malignancies" was presented at the American Society of Hematology's 67th ASH Annual Meeting and Exposition. In an animal model, MDX2003 prevented further tumor growth at low doses and was well-tolerated with low levels of cytokines in the blood and no observable toxicity.

- **Abstract for MDX2004, a first-in-class trispecific antibody-fusion protein immune rejuvenator, was presented at SITC 2025.** In November, an abstract titled "MDX2004, a novel immune rejuvenator targeting CD3, CD28, and 4–1BB, augments tumor immunity in preclinical animal models" was presented at SITC 2025, the annual meeting of the Society for Immunotherapy of Cancer. The ongoing Phase 1/2a study (NCT07110584) is designed to evaluate the safety, tolerability and biologic activity of MDX2004 as an immunotherapy for advanced cancers.
- **Abstract for MDX2001 cMet-Trop2/CD3-CD28, a first-in-class tetraspecific T-cell engager, was presented at ESMO 2025.** In October, an abstract titled "A phase I/IIa, multicenter, first-in-human,

open-label clinical trial evaluating MDX2001, a tetraspecific T cell engager-expander in patients with advanced solid tumors" was presented at ESMO Congress 2025, the annual meeting of the European Society for Medical Oncology. The MDX2001 cMet-Trop2/CD3-CD28 tetraspecific antibody has advanced to the fifth dose level in its Phase 1 clinical trial, with Phase 1b studies in select solid tumors expected to begin in the first half of 2026.

- **FDA permission to proceed to Phase 1 granted to MDX2301, a tetravalent bispecific antibody that neutralizes all known strains of SARS-CoV2, for the prevention and treatment of COVID-19 infection.** Supported by non-dilutive funding from BARDA, the clinical trial in healthy volunteers is scheduled to begin in the second quarter of 2026, with pharmacokinetic and immunogenicity data expected later this year.
- **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% pro-rata ownership interest in the long-acting PTH hypoparathyroidism program and each is responsible for 50% of the program's development costs.

Fourth Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the fourth quarter of 2025 were $148.5 million compared with $183.6 million for the 2024 period, with the decrease principally resulting from the sale of certain BioReference assets in 2025. Operating loss for the fourth quarter of 2025 was $38.3 million compared with operating loss of $33.1 million for the 2024 quarter. Net loss for the fourth quarter of 2025 was $31.3 million, or $0.04 per share, compared with net income of $14.0 million, or $0.01 per diluted share, for the 2024 quarter. Net income for 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.

- **Pharmaceuticals:** Revenue from products in the fourth quarter of 2025 was $43.7 million compared with $37.4 million in the fourth quarter of 2024, driven by a positive net foreign exchange impact of $4.0 million and by higher sales volumes in our international operations. Revenue from *Rayaldee* was $8.8 million compared with $9.1 million in the comparable prior-year quarter. Revenue from the transfer of intellectual property and other was $33.7 million in the fourth quarter of 2025 compared with $43.1 million in the 2024 period. Gross profit share payments for NGENLA, which totaled $12.5 million in the 2025 period compared with $9.6 million in the 2024 period, reflect the global commercial progress by Pfizer. In addition, the fourth quarter of 2025 included $4.3 million in royalty revenue from Eli Lilly following the commercial launch of mazdutide in China by their partner Innovent Biologics and a $7.0 million upfront payment from Regeneron. The comparable period of 2024 included a $12.5 million milestone payment from Merck, as well as a $7.0 million decrease in commercial milestones at our Eirgen business and a $4.1 million decrease in revenue from our contract with BARDA. Total costs and expenses increased to $88.0 million in the fourth quarter of 2025 from $82.6 million in the prior-year period, primarily due to higher cost of revenue related to higher sales volume, higher research and development expenses driven by advancements in early-stage programs and employee-related expenses reflecting an increase in headcount to support ongoing clinical

activities. Operating loss was $10.7 million in the fourth quarter of 2025, which included $18.3 million in depreciation and amortization expense, compared with operating loss of $2.1 million in the fourth quarter of 2024, which included $18.1 million of depreciation and amortization expense.

- **Diagnostics:** Revenue from services in the fourth quarter of 2025 was $71.1 million compared with $103.1 million in the prior-year period. The decrease was principally a result of the sale of certain BioReference assets in 2025 and the resulting decline in clinical test volume, and lower clinical test reimbursement rates, partially offset by increased demand and higher average reimbursement for the 4Kscore test, resulting in a 16% increase in revenue to $7.0 million in the 2025 quarter compared with $6.0 million in revenue in the 2024 quarter. Total costs and expenses were $89.4 million in the fourth quarter of 2025 compared with $124.8 million in the fourth quarter of 2024. The decrease was primarily attributable to the assets sold and to continued cost-reduction initiatives at BioReference. Operating loss was $18.3 million in the fourth quarter of 2025, which included $4.1 million of depreciation and amortization expense, compared with operating loss of $21.7 million in the 2024 period, which included $6.0 million of depreciation and amortization expense. The fourth quarter of 2025 was impacted by non-recurring transition-related adjustments of $5.8 million, primarily from severance, asset write-offs, third-party revenue adjustments, and capital tax expense. The fourth quarter of 2024 included revenue of $26.3 million and costs and expenses of $32.9 million from the oncology assets that were sold to Labcorp on September 15, 2025.

- **Cash, cash equivalents, marketable securities and restricted cash:** Cash, cash equivalents and restricted cash were $369.1 million as of December 31, 2025. As of December 31, 2025, approximately $87.3 million of OPKO's common stock had been repurchased, including $13.5 million in the fourth quarter of 2025, under the program since its authorization in July 2024. Approximately $112.7 million remained authorized and available for future repurchases.

- **2026 Financial Guidance:** The table below reflects financial guidance for the first quarter and full year 2026 (in millions):

	For the three months ended March 31, 2026		For the year ended December 31, 2026	
	Low	High	Low	High
Revenue				
Services revenue	$ 71	$ 75	$ 300	$ 312
Product revenue	38	45	160	170
IP and other revenue	15	20	70	80
Total revenues	125	140	530	560
Included in revenue				
Pfizer profit share	5	6	34	37
BARDA contract	7	9	18	22
Total costs and expenses	170	180	725	750
R&D included in costs and expenses	30	32	125	135

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 5, 2026, by dialing 855-669-9658 (U.S.) or 412-317-0088 (International) and providing the passcode 2367034. 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 the collaboration with Regeneron will be successful and whether we will receive milestone payments and/or royalties as a result of that collaboration, whether the remaining BioReference business will become profitable, whether we will be able to submit Investigational New Drug applications for the oral and subcutaneous forms of GLP-1/glucagon and GLP-2 tablet and the timing of those submissions, whether we will have a successful collaboration with Entera, whether our product development efforts will be successful and whether the expected benefits of our products will be realized, including whether the data for MDX2004 will be positive, whether preclinical data will be indicative of clinical data should any of our preclinical programs progress into clinical development, whether the trial for MDX2001 and EBV will continue to progress and whether the data will be positive for all trials, including the EBV Vaccine trial, 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, 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
Summary of Revenues
(in millions)
Unaudited

	For the three months ended December 31,		For the twelve months ended December 31,	
	2025	2024	2025	2024
Diagnostics revenue				
Core diagnostics	$ 64.1	$ 70.8	$ 273.5	$ 274.6
4Kscore Test	7.0	6.0	27.1	23.9
Divested revenue	-	26.3	69.7	182.2
Service revenue subtotal	71.1	103.1	370.3	480.7
Pharmaceutical revenue				
International operations	34.7	28.3	127.1	126.3
Rayaldee	8.8	9.1	29.8	28.8
Revenue from products subtotal	43.7	37.4	156.9	155.1
Pfizer milestone, royalty and profit sharing, and cost sharing	12.5	9.6	31.9	30.0
BARDA	6.9	11.0	28.5	23.8
Merck	-	12.5	-	12.5
Regeneron	7.2	-	7.2	-
Other royalties and milestones	7.1	10.0	12.1	11.0
Revenue from transfer of intellectual property and other subtotal	33.7	43.1	79.7	77.3
Total pharmaceutical revenue	77.4	80.5	236.6	232.4
Total revenues	$ 148.5	$ 183.6	$ 606.9	$ 713.1

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

	As of December 31, 2025	December 31, 2024
Assets:		
Cash, cash equivalents, and current restricted cash	$ 369.1	$ 431.9
Accounts receivable, net	90.3	118.0
Inventory, net	65.8	56.8
Other current assets	56.7	55.4
Total current assets	581.9	662.1
In-process research and development and goodwill	679.3	724.3
Other assets	670.7	813.8
Total Assets	$ 1,931.9	$ 2,200.2
Liabilities and Equity:		
Accounts payable	$ 41.1	$ 47.1
Accrued expenses	84.4	118.4
Current portion of convertible notes	0.0	0.2
Other current liabilities	21.1	27.4
Total current liabilities	146.6	193.1
Long-term portion of convertible notes	85.0	173.6
Senior secured notes	246.4	245.6
Deferred tax liabilities, net	126.3	140.8
Other long-term liabilities, principally leases, and lines of credit	59.6	81.7
Total Liabilities	663.9	834.8
Equity	1,268.0	1,365.4
Total Liabilities and Equity	$ 1,931.9	$ 2,200.2

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,	
	2025	2024	2025	2024
Revenues				
Revenue from services	$ 71.1	$ 103.1	$ 370.3	$ 480.7
Revenue from products	43.7	37.4	156.9	155.1
Revenue from transfer of intellectual property and other	33.7	43.1	79.7	77.3
Total revenues	148.5	183.6	606.9	713.1
Costs and expenses				
Cost of service revenues	60.0	76.3	307.4	402.1
Cost of product revenues	24.4	22.7	93.6	92.5
Selling, general, and administrative	50.5	67.0	223.0	304.2
Research and development	32.8	30.4	124.0	105.2
Amortization of intangible assets	19.1	20.3	77.9	82.7
Gain on sale of assets	0.0	0.0	(101.6)	(121.5)
Total costs and expenses	186.8	216.7	724.3	865.2
Operating loss	(38.3)	(33.1)	(117.4)	(152.1)
Other (expense) income, net	(8.6)	68.0	(124.0)	141.7
(Loss) income before income taxes and investment losses	(46.9)	34.9	(241.4)	(10.4)
Income tax benefit (provision)	15.7	(20.9)	15.7	(42.8)
(Loss) income before investment losses	(31.2)	14.0	(225.7)	(53.2)
Loss from investments in investees	(0.1)	(0.0)	(0.0)	(0.0)
Net (loss) income	$ (31.3)	$ 14.0	$ (225.7)	$ (53.2)
(loss) income per share, basic	$ (0.04)	$ 0.02	$ (0.30)	$ (0.08)
(loss) income per share, diluted	$ (0.04)	$ 0.01	$ (0.30)	$ (0.08)
Weighted average common shares outstanding, basic	765,519,363	676,788,895	751,132,891	694,019,535
Weighted average common shares outstanding, diluted	765,519,363	951,837,287	751,132,891	594,019,535

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