

February 26, 2026



OPKO Health Reports Fourth Quarter 2025 Business Highlights and Financial Results

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

MIAMI, Feb. 26, 2026 (GLOBE NEWSWIRE) -- **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. The Phase 1 trial 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 *Royaldee* 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

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.

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—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
<i>Royaldee</i>	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	<u>\$ 1,931.9</u>	<u>\$ 2,200.2</u>
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	<u>146.6</u>	<u>193.1</u>
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	<u>663.9</u>	<u>834.8</u>
Equity	1,268.0	1,365.4
Total Liabilities and Equity	<u>\$ 1,931.9</u>	<u>\$ 2,200.2</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,	
	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	<u>148.5</u>	<u>183.6</u>	<u>606.9</u>	<u>713.1</u>
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	<u>\$ (31.3)</u>	<u>\$ 14.0</u>	<u>\$ (225.7)</u>	<u>\$ (53.2)</u>
(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



Source: OPKO Health, Inc.