April 30, 2025

OPKO Health Reports First Quarter 2025 Business Highlights and Financial Results

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

MIAMI, April 30, 2025 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended March 31, 2025.

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

- **Signed definitive agreement with Labcorp to sell oncology and related clinical testing assets of BioReference Health (BioReference).** The transaction includes the sale of BioReference's laboratory testing businesses focused on oncology and oncology-related clinical testing services for up to $225 million, including $192.5 million payable at closing and up to $32.5 million in an earnout based on performance. BioReference will continue to offer urology diagnostic services nationwide, as well as maintain its core clinical testing operations in New York and New Jersey, which represented approximately $300 million in revenue for 2024. The transaction is anticipated to close in the second half of 2025.
- **Entered into collaboration agreement with Entera Bio to advance oral GLP-1/glucagon tablet candidate into the clinic to treat obesity and metabolic disorders.** This program combines OPKO's proprietary long-acting oxyntomodulin analog (OPK-88006) and Entera's proprietary N-Tab™ technology. Under the terms of the agreement, OPKO and Entera will hold 60% and 40% ownership interests, respectively, in the orally administered product and will be responsible for 60% and 40%, respectively, of the program's development costs. In connection with the execution of the agreement, OPKO purchased approximately 3.7 million ordinary shares of Entera for a purchase price equal to $2.17 per share. Entera agreed to utilize the proceeds from this share purchase to fund its 40% share of the program's development costs through the completion of Phase 1.
- **Enrollment and dosing underway by Merck in the Phase 1 Epstein-Barr virus (EBV) vaccine trial.** Dosing of patients commenced for the Phase 1 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.
- **ModeX continued to advance its immuno-oncology and immunology portfolio with four potential clinical candidates progressing in the pipeline.** The MDX2001 CMet-Trop2/CD3-CD28 tetraspecific antibody advanced to the fourth dose level in its Phase 1 clinical trial, with Phase 1B studies in selected solid tumors expected in early 2026. The MDX2003 tetraspecific antibody for lymphoma/leukemia and the MDX2004 immune rejuvenator are expected to begin human trials in late 2025/early 2026. Development of multispecific antibodies for immune impaired patients at risk for COVID and influenza A and B continues to progress with support from the Biomedical

Advanced Research and Development Authority (BARDA).

- **OPKO's Board of Directors authorized an additional $100 million for its common stock repurchase program, bringing total capacity to $200 million.** Approximately $40.2 million of OPKO's common stock has been repurchased under the prior program since its authorization in July 2024. This increased authorization, along with the prior authorization, represents approximately 14% of OPKO's common shares outstanding at the current stock price.

First Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the first quarter of 2025 were $149.9 million compared with $173.7 million for the comparable period of 2024. Operating loss for the first quarter of 2025 was $67.2 million compared with $71.5 million for the 2024 quarter. The first quarter of 2025 included a realized gain of $3.9 million from the sale of shares of GeneDx Holdings Corp. (GeneDx) compared with $22.7 million in the year-ago period primarily reflecting an unrealized gain in the fair value of GeneDx. In addition, other expense in the first quarter of 2024 included a non-cash, non-recurring expense of $26.3 million related to an embedded derivative as part of the 2029 convertible debt. Net loss for the first quarter of 2025 was $67.6 million, or $0.10 per share, compared with net loss of $81.8 million, or $0.12 per share, for the 2024 quarter.
- **Pharmaceuticals:** Revenue from products in the first quarter of 2025 was $34.8 million compared with $38.1 million in the first quarter of 2024, reflecting unfavorable foreign currency exchange rates and a decrease in *Rayaldee* sales. Revenue from sales of *Rayaldee* was $6.3 million compared with $6.9 million in the same period in 2024. Revenue from the transfer of intellectual property and other was $12.3 million in the first quarter of 2025 compared with $8.7 million in the 2024 period. This increase was driven by revenue from the BARDA contract of $7.0 million in 2025 compared with $2.2 million in 2024. This increase was partially offset by a decrease in gross profit share payments for NGENLA, which totaled $4.5 million in the 2025 period compared with $5.6 million in the 2024 period. Total costs and expenses increased to $81.9 million in the first quarter of 2025 from $74.5 million in the prior-year period, primarily due to higher research and development expenses related to increased activity within the ModeX development programs. Operating loss was $34.8 million in the first quarter of 2025, which included $17.8 million of depreciation and amortization expense, compared with $27.7 million in the first quarter of 2024, which included $18.0 million of depreciation and amortization expense.
- **Diagnostics:** Revenue from services in the first quarter of 2025 was $102.8 million compared with $126.9 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, partially offset by higher clinical test reimbursement rates. Total costs and expenses were $126.8 million in the first quarter of 2025, which included $7.3 million of non-recurring facility closure and severance costs, compared with $161.3 million in the first quarter of 2024. The decrease was primarily attributable to the assets sold and continued cost-reduction initiatives at BioReference. Operating loss was $23.9 million in the first quarter of 2025 compared with a loss of $34.4 million in the 2024 period. The first quarter of 2025 included revenue of $25.1 million and costs and expenses of $32.4 million from the oncology assets pending sale to Labcorp. Both periods include $5.7 million and $7.9 million of depreciation and amortization expense, respectively,

within the operating loss.

- **Cash, cash equivalents, marketable securities and restricted cash:** Cash, cash equivalents and restricted cash were $449.7 million as of March 31, 2025, including the receipt of $51.7 million from the sale of all of OPKO's remaining GeneDx shares. Subsequent to the first quarter of 2025, OPKO completed an exchange agreement with certain institutional holders to purchase $159.2 million of the Company's outstanding convertible notes, including accrued and unpaid interest, for 121.4 million shares and approximately $63.5 million in cash.

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 7, 2025, by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 3746692. 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 anticipated sale of assets to Labcorp will close and the remaining BioReference business will be successful, whether we will be able to submit an Investigational New Drug application for the oral GLP-1/glucagon and the timing of that submission, in addition to whether we will have a successful collaboration with Entera Bio, whether our product development efforts will be successful and whether the expected benefits of our products will be realized, including the timing for when clinical trials for MDX2003 and MDX 2004 will commence and whether they will be successful, whether the trial for MDX2001 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
Condensed Consolidated Balance Sheets
(in millions)
Unaudited

	As of	
	March 31, 2025	December 31, 2024
Assets:		
Cash and cash equivalents	$ 436.0	$ 431.9
Assets held for sale	87.0	0.0
Other current assets	214.6	230.2
Total current assets	737.6	662.1

In-process research and development and goodwill	671.7	724.3
Other assets	719.1	813.8
Total Assets	$ 2,128.4	$ 2,200.2
Liabilities and Equity:		
Accounts payable	$ 59.4	$ 47.1
Accrued expenses	113.2	118.4
Current portion of convertible notes	101.2	0.2
Other current liabilities	22.1	27.4
Total current liabilities	295.9	193.1
Long-term portion of convertible notes	77.2	173.6
Senior secured notes	245.8	245.6
Deferred tax liabilities, net	129.4	140.8
Other long-term liabilities, principally leases	68.4	81.7
Total Liabilities	816.7	834.8
Equity	1,311.7	1,365.4
Total Liabilities and Equity	$ 2,128.4	$ 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 March 31,	
	2025	2024
Revenues		
Revenue from services	$ 102.8	$ 126.9
Revenue from products	34.8	38.1
Revenue from transfer of intellectual property	12.3	8.7
Total revenues	149.9	173.7
Costs and expenses		
Cost of service revenues	84.5	109.9
Cost of product revenues	22.8	21.8
Selling, general and administrative	59.1	70.2
Research and development	30.8	21.9
Amortization of intangible assets	19.9	21.4
Total costs and expenses	217.1	245.2
Operating loss	(67.2)	(71.5)
Other expense, net	(6.2)	(11.7)

Loss before income taxes and investment losses	(73.4)	(83.2)
Income tax benefit	5.8	1.4
Net loss before investment losses	(67.6)	(81.8)
Loss from investments in investees	(0.0)	(0.0)
Net loss	$ (67.6)	$ (81.8)
Loss per share, basic and diluted	$ (0.10)	$ (0.12)
Weighted average common shares outstanding, basic and diluted	671,577,429	706,882,189

Source: OPKO Health, Inc.