October 29, 2025

OPKO Health Reports Third Quarter 2025 Business Highlights and Financial Results

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

MIAMI, Oct. 29, 2025 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** (OPKO) reports business highlights and financial results for the three and nine months ended September 30, 2025.

Highlights from the third 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 indications. ModeX is entitled to receive an upfront payment and potential milestone payments exceeding $200 million for each program. The overall value of the collaboration potentially exceeds $1 billion if multiple products from the collaboration are successful. In addition, ModeX is eligible to receive tiered royalties on global net sales, up to low double digits at the highest tier. Regeneron is responsible for funding all preclinical and clinical development, as well as all commercialization activities.
- **Completed the sale of BioReference Health (BioReference) oncology and related clinical assets to Labcorp for $225 million.** The purchase included $192.5 million that was paid at closing and up to $32.5 million in a performance-based earnout. BioReference will continue to offer its core clinical testing services in the New York and New Jersey region and its 4Kscore® Test franchise, which represented approximately $300 million in revenue for 2024. This transaction streamlines BioReference's laboratory services business and better positions the company to optimize its test menu and achieve sustained profitability. OPKO intends to utilize a portion of the proceeds to fund its share repurchase program.
- **Merck advanced the Phase 1 Epstein-Barr virus vaccine trial (NCT06655324).** This investigational vaccine candidate is being developed in collaboration with Merck and evaluates safety and tolerability in up to 200 healthy adults. Enrollment in this ongoing trial is progressing well and the safety and immunogenicity data obtained from this trial will inform the Phase 2 trial design.
- **First patient dosed in MDX2004 Phase 1/2a study for the treatment of advanced cancers (NCT07110584).** This study is designed to evaluate the safety, tolerability and biologic activity of MDX2004, a first-in-class trispecific antibody-fusion protein, as an immunotherapy for advanced cancers. Preclinical proof-of-concept data, as well as clinical dose selection analyses to support MDX2004 development will be showcased in two poster presentations at the 40th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), being held November 5-9, 2025.
- **Abstract for MDX-2001 CMet-Trop2/CD3-CD28, a first-in-class tetraspecific T-cell engager, was presented at ESMO 2025.** In October, the 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 early 2026.

- **Abstract for first-in-class dual GLP-1/glucagon tablet candidate was presented at the ENDO 2025 annual meeting.** In July, the abstract titled "First-in-Class Oral Dual GLP-1/Glucagon Agonist for Patients with Obesity and Metabolic Disorders: In Vivo Pharmacokinetic and Pharmacodynamic Results" highlighting preclinical animal data was presented at ENDO 2025, the annual meeting of the Endocrine Society. Oral OPK-88006 is being developed pursuant to a collaboration and license agreement between OPKO and Entera Bio (Entera) whereby the companies are advancing a proprietary novel dual agonist GLP-1/glucagon peptide as a once-daily tablet treatment with OPK-88006 and Entera's proprietary N-Tab™ technology.
- **Abstract on the pharmacokinetics/pharmacodynamics of oral GLP-2 tablet for the treatment of short bowel syndrome was presented at the 2025 ESPEN Congress.** In September, the abstract "A First-in-Class Oral GLP-2 Analog for Treatment of Short Bowel Syndrome" highlighting *in vivo* animal data was presented at the 47th European Society for Clinical Nutrition & Metabolism (ESPEN) Congress. Pursuant to a research collaboration agreement with Entera, the companies are developing an oral GLP-2 tablet that combines a proprietary long-acting GLP-2 agonist developed by OPKO with Entera's proprietary N-Tab™ technology, for patients suffering from short bowel syndrome and additional disorders involving gastrointestinal mucosal inflammation and nutrient malabsorption.
- **FDA approved the supplemental application for the 4Kscore® Test regarding the availability of digital rectal examination information.** In July, the U.S. Food and Drug Administration (FDA) approved OPKO's supplemental application enabling the performance of the 4Kscore® Test without digital rectal examination (DRE) information. The 4Kscore® Test is indicated for the assessment of the likelihood of aggressive prostate cancer in men age 45 and older who have age-specific elevated/abnormal screening PSA results. Two prospective controlled clinical studies (n=937) concluded that the 4Kscore® Test is a reliable (>96% sensitivity and accuracy) blood test to assess the probability of aggressive prostate cancer, before biopsy decisions. In the U.S., over 90% of PSA screening tests are ordered by primary care providers, potential users of the 4Kscore® Test who don't routinely perform a DRE.

Third Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the third quarter of 2025 were $151.7 million compared with $173.6 million for the comparable period of 2024. Operating income for the third quarter of 2025 was $48.1 million compared with $14.2 million for the 2024 quarter. Net income for the third quarter of 2025 included a gain of $101.6 million from the sale of the BioReference oncology assets. The prior-year period included a gain of $121.5 million from the sale of certain BioReference clinical assets and income of $45.9 million related to the investment in GeneDx shares. Net income for the third quarter of 2025 was $21.6 million, or $0.03 per diluted share, compared with $24.9 million, or $0.03 per diluted share, for the 2024 quarter.

- **Pharmaceuticals:** Revenue from products in the third quarter of 2025 was $37.7 million compared with $39.1 million in the third quarter of 2024, reflecting lower sales volumes in certain international operations primarily due to the timing of customer orders and product mix, partially offset by an increase in *Rayaldee* sales. Revenue from sales of *Rayaldee* was $7.5 million compared with $5.8 million in the comparable prior-year period. Revenue from the transfer of intellectual property and other was $18.8 million in the third quarter of 2025 compared with $13.2 million in the 2024 period. The increase was driven by higher revenue from the BARDA contract and higher gross profit share payments for NGENLA, which totaled $8.8 million in the 2025 period compared with $7.0 million in the 2024 period. Total costs and expenses decreased to $80.6 million in the third quarter of 2025 from $84.6 million in the prior-year period, primarily due to lower cost of revenue related to lower sales volume and reduced employee-related expense, partially offset by higher research and development expenses driven by progress in the BARDA collaboration and advancements in early-stage programs. Operating loss was $24.2 million in the third quarter of 2025 compared with $32.2 million in the third quarter of 2024, with both periods including $18.0 million of depreciation and amortization expense.
- **Diagnostics:** Revenue from services in the third quarter of 2025 was $95.2 million compared with $121.3 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 in 2024, partially offset by higher clinical test reimbursement rates. Total costs and expenses, net of the gain on the sale of assets in both periods, were $13.6 million in the third quarter of 2025 compared with $62.7 million in the third quarter of 2024. The decrease was primarily attributable to the assets sold and continued cost-reduction initiatives at BioReference. Operating income was $81.6 million in the third quarter of 2025, which included $4.7 million of depreciation and amortization expense, compared with $58.5 million in the 2024 period, which included $6.1 million of depreciation and amortization expense. The third quarter of 2025 included revenue of $19.5 million and costs and expenses of $25.2 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 $428.9 million as of September 30, 2025. In September 2025, OPKO received $173.3 million in cash consideration and an escrow of $19.2 million subject to any outstanding indemnity claims upon closing of the Labcorp transaction. As of September 30, 2025, approximately $73.8 million of OPKO's common stock had been repurchased under the program since its authorization in July 2024, and approximately $126.2 million remains authorized and available for future repurchases.

Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss third 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 November 5, 2025, by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 8678248. 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 the approved supplemental application for 4Kscore will further increase use of the test without DRE information, 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.

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—Tables to Follow—

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

	As of September 30, 2025	As of December 31, 2024
Assets:		
Cash and cash equivalents	$ 415.2	$ 431.9
Accounts receivable, net	94.6	118.0
Inventory, net	65.0	56.8
Other current assets and prepaid expenses	52.4	55.4
Total current assets	627.2	662.1
In-process research and development and goodwill	679.0	724.3
Other assets	689.3	813.8
Total Assets	$ 1,995.5	$ 2,200.2
Liabilities and Equity:		
Accounts payable	$ 50.8	$ 47.1
Accrued expenses	95.6	118.4
Current portion of convertible notes	0.0	0.2
Other current liabilities	22.9	27.4
Total current liabilities	169.3	193.1
Long-term portion of convertible notes	82.7	173.6
Senior secured notes	246.2	245.6

Deferred tax liabilities, net	130.3	140.8
Other long-term liabilities, principally leases	61.5	81.7
Total Liabilities	690.0	834.8
Equity	1,305.5	1,365.4
Total Liabilities and Equity	$ 1,995.5	$ 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 September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Revenues				
Revenue from services	$ 95.2	$ 121.3	$ 299.2	$ 377.5
Revenue from products	37.7	39.1	113.2	117.7
Revenue from transfer of intellectual property and other	18.8	13.2	46.0	34.3
Total revenues	151.7	173.6	458.4	529.5
Costs and expenses				
Cost of service revenues	80.4	108.8	247.3	325.8
Cost of product revenues	21.4	24.7	69.2	69.8
Selling, general and administrative	53.8	98.2	172.5	237.2
Research and development	30.1	28.8	91.3	74.8
Amortization of intangible assets	19.5	20.4	58.8	62.3
Gain on sale of assets	(101.6)	(121.5)	(101.6)	(121.5)
Total costs and expenses	103.6	159.4	537.5	648.4
Operating Income (loss)	48.1	14.2	(79.1)	(118.9)
Other expense (income), net	(6.7)	34.2	(115.4)	73.6
Income (loss) before income taxes and investment losses	41.4	48.4	(194.5)	(45.3)
Income tax (provision) benefit	(19.8)	(23.5)	0.1	(21.9)

Income (loss) before investment losses	21.6	24.9	(194.4)	(67.2)
Loss from investments in investees	(0.0)	(0.0)	(0.0)	(0.0)
Net income (loss)	$ 21.6	$ 24.9	$ (194.4)	$ (67.2)
Income (loss) per share, basic	$ 0.03	$ 0.04	$ (0.26)	$ (0.10)
Income (loss) per share, diluted	$ 0.03	$ 0.03	$ (0.26)	$ (0.10)
Weighted average common shares outstanding, basic	777,154,808	694,622,466	746,136,135	699,675,944
Weighted average common shares outstanding, diluted	779,919,259	998,363,636	746,136,135	699,675,944

Source: OPKO Health, Inc.