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): July 31, 2025

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 July 31, 2025, OPKO Health, Inc. (the "Company") issued a press release announcing operating and financial highlights for the quarter ended June 30, 2025. 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 second quarter ended June 30, 2025, 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	Description
99.1	Press Release of the Company dated July 31, 2025
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.

Date: July 31, 2025

By: /s/ Adam Logal
Name: Adam Logal
Title: Senior Vice President, Chief Financial Officer

Exhibit 99.1

OPKO Health Reports Second Quarter 2025 Business Highlights and Financial Results

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

MIAMI, July 31, 2025 – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three and six months ended June 30, 2025.

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

- **Merck advanced 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. Based on analysis of these results, Merck will determine whether and how to proceed with Phase 2 studies.

- **ModeX continued to advance its immuno-oncology and immunology portfolio with four potential clinical candidates progressing.** 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 selected solid tumors expected in 2026. MDX2004, a multispecific immune rejuvenator, is expected to enter the clinic later this year. Human clinical trials with the MDX2003 tetraspecific antibody for lymphoma/leukemia are expected to begin in early 2026. Development of multispecific antibodies for immune impaired patients at risk for COVID and influenza continued to progress with support from the Biomedical Advanced Research and Development Authority (BARDA).

- **Presented preclinical data on OPK-88006, OPKO's novel long-acting glucagon-like peptide-1 receptor/glucagon receptor dual agonist in a poster presentation at the American Diabetes Association 85th Scientific Sessions in June.** Clinical pharmacology assessments of OPK-88006 in disease models of obesity and energy expenditure activities were encouraging. The presented data compared the 12-week daily treatment outcomes of OPK-88006, semaglutide and survodutide in a GAN diet induced obese and biopsy confirmed mouse model of metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis. In this study, the therapeutic benefits of OPK-88006 on quantitative biological hallmarks of MASH were superior to semaglutide and survodutide, suggesting that OPK-88006 is a promising GLP-1/glucagon receptor dual agonist for the treatment of MASH.

- **Abstract for first-in-class dual GLP-1/glucagon tablet candidate for patients with obesity and metabolic disorders selected for presentation at the ENDO 2025 annual meeting.** New pharmacologic and pharmacokinetic *in vivo* data for the investigational oral OPK-88006 tablet

formulation was selected for presentation 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 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 pharmacokinetics/pharmacodynamics of oral GLP-2 tablet for the treatment of short bowel syndrome selected for 2025 ESPEN Congress.** The abstract "First-in-Class Oral GLP-2 Analog for Treatment of Short Bowel Syndrome" submitted jointly by OPKO and Entera Bio was selected for a poster presentation at the 47thEuropean Society for Clinical Nutrition & Metabolism (ESPEN) Congress, taking place September 13–16, 2025, in Prague. Pursuant to a research collaboration agreement with Entera Bio, the companies are developing an oral GLP-2 tablet, which 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.** 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 45 years old and above and reported to have age-specific elevated/abnormal screening PSA results. Two prospective controlled clinical studies (n=937) conclude that the 4Kscore®Test is a reliable (greater than 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 performed by primary care providers, potential users of the 4Kscore®Test, who don't routinely perform a DRE.

- **OPKO's Board of Directors authorized an additional $100 million for its common stock repurchase program, bringing total capacity to $200 million.** As of June 30, 2025, approximately $58.5 million of OPKO's common stock has been repurchased under the 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.

Second Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the second quarter of 2025 were $156.8 million compared with $182.2 million for the comparable period of 2024. Operating loss for the second quarter of 2025 was $60.0 million compared with $61.7 million for the 2024 quarter. Net loss during the second quarter of 2025 included $91.7 million of non-recurring expense related to the convertible note exchange that closed on April 1, 2025, including unamortized debt discount, debt issuance costs and inducement expense. The prior-year period included $60.5 million of unrealized gain in the fair value of GeneDx Holdings Corp. Net loss for the second quarter of 2025 was $148.4 million, or $0.19 per share, compared with net loss of $10.3 million, or $0.01 per share, for the 2024 quarter.

- **Pharmaceuticals:** Revenue from products in the second quarter of 2025 was $40.7 million compared with $40.5 million in the second quarter of 2024, reflecting higher sales volumes in certain international operations partially offset by reduced sales in our Chilean subsidiary due to the impact of foreign currency and a mild winter cold and flu season. Revenue from sales of *Rayaldee* was $7.2 million for both the current and comparable period. Revenue from the transfer of intellectual property and other was $15.0 million in the second quarter of 2025 compared with $12.3 million in the 2024 period. The increase was driven by higher revenue from the BARDA contract and contract manufacturers' commercial milestones, partially offset by slightly lower gross profit share payments for NGENLA, which totaled $6.1 million in the 2025 period compared with $6.3 million in the 2024 period. Total costs and expenses increased to $84.4 million in the second quarter of 2025 from $77.6 million in the prior-year period, primarily due to higher research and development expenses driven by growth in our BARDA collaborations and early-stage programs as we prepare for several investigational new drug application filings later this year. Operating loss was $28.7 million in the second quarter of 2025, which included $18.1 million of depreciation and amortization expense, compared with $24.8 million in the second quarter of 2024, which included $17.9 million of depreciation and amortization expense.

- **Diagnostics:** Revenue from services in the second quarter of 2025 was $101.1 million compared with $129.4 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 $119.3 million in the second quarter of 2025 compared with $156.0 million in the second quarter of 2024. The decrease was primarily attributable to the assets sold and continued cost-reduction initiatives at BioReference. Operating loss was $18.2 million in the second quarter of 2025, which included $4.9 million of depreciation and amortization expense, compared with $26.6 million in the 2024 period, which included $6.2 million of depreciation and amortization expense. The second quarter of 2025 included revenue of $24.9 million and costs and expenses of $29.4 million from the oncology assets that are pending sale to Labcorp.

- **Cash, cash equivalents, marketable securities and restricted cash:** Cash, cash equivalents and restricted cash were $285.4 million as of June 30, 2025. In the second 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 of common stock and approximately $63.5 million in cash.

Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss second 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 August 7, 2025, by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 3096711. 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 Investigational New Drug applications for the oral and subcutaneous forms of GLP-1/glucagon and the timing of those submissions, 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 preclinical data will be indicative of clinical data should any of our preclinical programs progress into clinical development, 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 June 30, 2025	As of December 31, 2024
Assets:		
Cash and cash equivalents	$ 271.7	$ 431.9
Assets held for sale	87.0	0.0
Other current assets	224.6	230.2
Total current assets	583.3	662.1
In-process research and development and goodwill	679.2	724.3
Other assets	710.5	813.8
Total Assets	$ 1,973.0	$ 2,200.2
Liabilities and Equity:		
Accounts payable	$ 56.7	$ 47.1
Accrued expenses	90.6	118.4
Current portion of convertible notes	0.0	0.2
Other current liabilities	23.9	27.4
Total current liabilities	171.2	193.1
Long-term portion of convertible notes	80.5	173.6
Senior secured notes	246.0	245.6
Deferred tax liabilities, net	113.3	140.8
Other long-term liabilities, principally leases	65.1	81.7
Total Liabilities	676.1	834.8
Equity	1,296.9	1,365.4
Total Liabilities and Equity	$ 1,973.0	$ 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 June 30,		For the six months ended June 30,	
	2025	2024	2025	2024
Revenues				
Revenue from services	$ 101.1	$ 129.4	$ 204.0	$ 256.3
Revenue from products	40.7	40.5	75.6	78.5
Revenue from transfer of intellectual property and other	15.0	12.3	27.2	21.1
Total revenues	156.8	182.2	306.8	355.9
Costs and expenses				
Cost of service revenues	82.4	107.1	166.9	216.9
Cost of product revenues	25.0	23.5	47.8	45.2
Selling, general and administrative	59.6	68.8	118.7	139.0
Research and development	30.3	24.1	61.2	46.0
Contingent consideration	0.0	0.0	0.0	0.0
Amortization of intangible assets	19.5	20.4	39.3	41.9
Total costs and expenses	216.8	243.9	433.9	489.0
Operating loss	(60.0)	(61.7)	(127.1)	(133.1)
Other income (expense), net	(102.5)	51.1	(108.8)	39.4
Loss before income taxes and investment losses	(162.5)	(10.6)	(235.9)	(93.7)
Income tax benefit	14.1	0.3	19.8	1.6
Loss before investment losses	(148.4)	(10.3)	(216.1)	(92.1)
Loss from investments in investees	(0.0)	(0.0)	(0.0)	(0.0)
Net loss	$ (148.4)	$ (10.3)	$ (216.1)	$ (92.1)
Loss per share, basic and diluted	$ (0.19)	$ (0.01)	$ (0.31)	$ (0.13)
Weighted average common shares outstanding, basic and diluted	788,006,992	697,211,592	700,684,863	702,036,148

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