UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): November 7, 2024

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

Not Applicable
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, par value $0.01 per share	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 November 7, 2024, OPKO Health, Inc. (the "Company") issued a press release announcing operating and financial highlights for the quarter ended September 30, 2024. 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 September 30, 2024, 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 No.	Description
99.1	Press Release of the Company dated November 7, 2024
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

Date: November 7, 2024

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

Exhibit 99.1

OPKO Health Reports Third Quarter 2024 Business Highlights and Financial Results

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

MIAMI (November 7, 2024) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three and nine months ended September 30, 2024.

Highlights from the third quarter of 2024 and recent weeks include the following:

- **Completed sale of select assets of BioReference Health to Labcorp for $237.5 million**. OPKO completed the sale of BioReference Health's laboratory testing businesses focused on clinical diagnostics and women's health, excluding operations in New York and New Jersey, for $237.5 million. BioReference Health will continue to offer oncology and urology diagnostic services nationwide, as well as maintain its full operations in New York and New Jersey. This transaction streamlines BioReference Health's laboratory services business while retaining its core operations to better position the division for sustained growth and profitability. Net sales from operations continuing at BioReference Health exceeded $400 million in 2023.

- **Entered into a $250 million note purchase agreement with HealthCare Royalty secured by profit share payments related to NGENLA.** Under the terms of the note purchase agreement, in the near term OPKO retains a significant portion of the profit share payments from Pfizer received pursuant to its license agreement relating to NGENLA with upside over the long term, as well as the full $100 million of remaining potential milestone payments.

- **OPKO's Board of Directors authorized a $100 million share repurchase program.** Under the program, OPKO may repurchase shares of its common stock from time to time through open-market purchases, block trades, privately negotiated transactions, accelerated share repurchase transactions and/or pursuant to Rule 10b5-1 plans, in compliance with applicable securities laws and other legal requirements. The Company repurchased and retired 14.9 million shares for approximately $23.8 million during the three months ended September 30, 2024, and thereafter, through November 6, 2024 repurchased and retired an additional 8.7 million shares for approximately $13.0 million. In addition, the Company repurchased approximately $3.5 million in principal of its Convertible Notes.

- **Enrollment and dosing underway in the MDX2001 Phase 1 trial for the treatment of solid tumor cancers.** MDX2001**,** a tetraspecific antibody, is designed to optimize T-cell function while preventing tumor antigen escape. This Phase 1 open-label trial is expected to enroll up to 45 patients at four clinical trial sites. The Phase 1a portion is primarily designed to evaluate the safety and immunogenicity of ascending doses of MDX2001 in patients with various solid tumors.

- **Awarded $51 million of additional funding under an existing BARDA contract to develop COVID multispecific antibodies and to initiate an influenza program**. ModeX Therapeutics was awarded $26.9 million of additional funding under an existing contract with the Biomedical Advanced Research and Development Authority (BARDA). This funding will support the development of a second novel multispecific antibody to SARS-CoV-2 from preclinical through Phase 1 trials, as well as preclinical work on gene-based expression of multispecific antibodies to SARS-CoV-2 including mRNA and/or DNA vectors. In addition, BARDA activated an option for the second phase of funding totaling $24.1 million for ModeX to begin development of influenza multispecifics with gene and/or protein delivery modalities. Together, these funds bring the total support awarded to ModeX to $110 million, with up to $205 million in total, if all options are executed.

- **Announced promising results of an orally delivered oxyntomodulin analog.** OPKO is continuing to progress development of its long-acting oxyntomodulin analog in both its subcutaneous and oral formulations. The polyethylene glycol (PEG) linked peptide was studied and progressed to Phase 2 clinical trials before it was suspended due to dose limiting its formulation. The same key peptide as an acylated compound, OPK-88006, has been confirmed in in vitro assays and animal disease models to be a strong candidate for once-weekly subcutaneous administration. Entera and OPKO recently announced results from their ongoing collaborative research combining OPK-88006 and Entera's proprietary N-Tab™ technology. The program is focused on developing the first oral dual-agonist GLP-1/glucagon peptide as a potential once-daily treatment for patients with obesity and metabolic disorders. In vivo studies in rodent and pig models showed single dose administration, delivered orally, resulted in a desirable PK profile and bioavailability.

Third Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the third quarter of 2024 were $173.6 million compared with $178.6 million for the comparable period of 2023. Operating income for the third quarter of 2024 was $14.2 million compared with operating loss of $64.4 million for the 2023 quarter. The third quarter of 2024 included a gain of $121.5 million from the sale of certain BioReference assets and a gain of $10.5 million from the sale of shares of GeneDx, as well as non-cash other income of $35.4 million compared with non-cash other expense of $8.3 million in the year-ago quarter related to the change in the fair value of the GeneDx Holdings investment. As a result, net income for the third quarter of 2024 was $24.9 million, or $0.03 per diluted share, compared with net loss of $84.5 million, or $0.11 per share, for the 2023 quarter.

- **Pharmaceuticals:** Revenue from products in the third quarter of 2024 was $39.1 million compared with $40.7 million in the third quarter of 2023, reflecting lower Rayaldee sales and foreign currency exchange fluctuations. Revenue from sales of Rayaldee was $5.8 million compared with $7.3 million in the same period in 2023. Revenue from the transfer of intellectual property and other was $13.2 million in the third quarter of 2024 compared with $6.2 million in the 2023 period, primarily attributable to $5.5 million related to the BARDA contract. Gross profit share and royalty payments for NGENLA and Pfizer's Genotropin was $7.0 million in the 2024 quarter compared with $4.9 million in the same period for 2023. Total costs and expenses increased to $84.6 million in the third quarter of 2024 from $72.3 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 $32.2 million in the third quarter of 2024, which included $18.0 million of depreciation and amortization expense, compared with $25.4 million in the third quarter of 2023, which included $17.8 million of depreciation and amortization expense.

- **Diagnostics:** Revenue from services in the third quarter of 2024 was $121.3 million compared with $131.7 million in the prior-year period, with the decrease primarily due to lower clinical test volume, principally as a result of the Labcorp transaction and a reduction in reimbursement rates. Total costs and expenses, net of the gain on the sale of assets, were $62.7 million in the third quarter of 2024 compared with $160.8 million in the third quarter of 2023. The decrease in costs and expenses were primarily attributable to a $121.5 million gain on the Labcorp transaction, partially offset by severance expense of $26.3 million and costs related to the closure of an office building, which reflect the continued progress with cost-reduction initiatives. The third quarter of 2024 included revenue from services of approximately $19.9 million and total costs and expenses of approximately $31.7 million related to assets acquired by Labcorp. Operating income was $58.5 million in the third quarter of 2024 compared with a loss of $29.1 million in the 2023 period and included $6.1 million and $8.4 million of depreciation and amortization expense, respectively.

- **Cash, cash equivalents, marketable securities and restricted cash:** Cash and cash equivalents were $400.1 million, marketable securities, principally shares of GeneDx were $92.2 million and restricted cash and escrow was $43.7 million (including $6.3 million of current restricted cash) as of September 30, 2024. In the third quarter, OPKO entered into a $250 million note purchase agreement secured by OPKO's profit share payments to be received from Pfizer relating to NGENLA. In addition, OPKO received $237.5 million upon closing of the Labcorp transaction, of which $23.7 million was deposited in an escrow account and will be released upon the one-year anniversary of the transaction close less any outstanding adjustments or claims.

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 14, 2024, by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 6323665. 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 our product development efforts will be successful and whether the expected benefits of our products will be realized, including whether enrollment in a Phase 1 clinical trial for MDX2001 will be successful and whether the data will be positive, whether efforts to develop a daily oral dual-agonist GLP-1/glucagon peptide will succeed, whether and how many of our shares we will repurchase under a buyback program, whether NGENLA profits will be sufficient to provide long term upside after satisfying our obligations under the note purchase agreement, whether we can successfully progress the development of oxyntomodulin in both subcutaneous and oral formulations, 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, 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, whether BioReference will be able to streamline its laboratory services business and better position the division for sustained growth and profitability, whether BioReference's attempts at returning its core business to profitability will be successful, 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, 2024	December 31, 2023
Assets:		
Cash, cash equivalents, and current restricted cash	$ 406.4	$ 95.9
Accounts receivable, net	106.6	123.4
Other current assets	116.6	90.2
Total current assets	629.6	309.5
In-process research and development and goodwill	730.9	793.3
Other assets	895.6	908.9
Total Assets	$ 2,256.1	$ 2,011.7
Liabilities and Equity:		
Accounts payable	$ 62.7	$ 69.7
Accrued expenses	122.8	90.1
Current portion of convertible notes	0.2	0.0
Other current liabilities	25.9	40.3
Total current liabilities	211.6	200.1
Long-term portion of convertible notes	178.7	214.3
Senior secured notes	245.4	0.0
Deferred tax liabilities, net	128.4	126.8
Other long-term liabilities, principally leases, and lines of credit	88.6	81.3
Total Liabilities	852.7	622.5
Equity	1,403.4	1,389.2
Total Liabilities and Equity	$ 2,256.1	$ 2,011.7

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,	
	2024	2023	2024	2023
Revenues				
Revenue from services	$ 121.3	$ 131.7	$ 377.5	$ 391.1
Revenue from products	39.1	40.7	117.7	124.6
Revenue from transfer of intellectual property and other	13.2	6.2	34.3	165.9
Total revenues	173.6	178.6	529.5	681.6
Costs and expenses				
Cost of service revenues	108.8	106.4	325.8	333.5
Cost of product revenues	24.7	24.5	69.8	74.7
Selling, general and administrative	98.2	72.3	237.2	227.7
Research and development	28.8	19.4	74.8	70.2
Contingent consideration	0.0	(1.1)	0.0	(1.0)
Amortization of intangible assets	20.4	21.5	62.3	64.5
Gain on sale of assets	(121.5)	0.0	(121.5)	0.0
Total costs and expenses	159.4	243.0	648.4	769.6
Operating income (loss)	14.2	(64.4)	(118.9)	(88.0)
Other income (expense), net	34.2	(14.0)	73.6	(23.8)
Income (loss) before income taxes and investment losses	48.4	(78.4)	(45.3)	(111.8)
Income tax provision	(23.5)	(6.1)	(21.9)	(10.5)
Loss before investment losses	24.9	(84.5)	(67.2)	(122.3)
Loss from investments in investees	(0.0)	(0.0)	(0.0)	(0.1)
Net income (loss)	$ 24.9	$ (84.5)	$ (67.2)	$ (122.4)
Income (loss) per share, basic	$ 0.04	$ (0.11)	$ (0.10)	$ (0.16)
Income (loss) per share, diluted	$ 0.03	$ (0.11)	$ (0.10)	$ (0.16)
Weighted average common shares outstanding, basic	694,622,466	751,525,007	699,675,944	751,716,692
Weighted average common shares outstanding, diluted	998,363,636	751,525,007	699,675,944	751,716,692

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