

**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 6, 2023

OPKO Health, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-33528

(Commission
File Number)

75-2402409

(IRS Employer
Identification No.)

4400 Biscayne Blvd. Miami, Florida

(Address of Principal Executive Offices)

33137

(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 6, 2023, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended September 30, 2023. 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 third quarter ended September 30, 2023, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated November 6, 2023.
104	Cover Page Interactive Data File-the cover page XBRL tags are 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

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

Date: November 6, 2023



OPKO Health Reports Third Quarter 2023 Business Highlights and Financial Results

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

MIAMI (November 6, 2023) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three and nine months ended September 30, 2023.

Business highlights from the third quarter and subsequent weeks included the following:

- ModeX Therapeutics Inc. (ModeX) was awarded a contract from the Biomedical Advanced Research and Development Authority (BARDA) to develop novel multispecific antibodies against viral infectious disease threats.** BARDA awarded a contract to ModeX to advance a platform and specific therapeutic candidates designed to address a range of public health threats in viral infectious diseases. The BARDA contract includes an initial \$59 million award for the development, manufacturing and execution of a Phase 1 clinical trial for a next-generation MSTAR multispecific antibody with broad neutralizing activity against known variants of SARS-CoV-2. ModeX may be eligible to receive up to an additional \$109 million from BARDA upon achieving milestones to develop multispecific antibodies targeting other viral pathogens, such as influenza.
- ModeX advanced its antiviral and immune-oncology product pipeline.** ModeX advanced its pipeline of antiviral and immune-oncology programs utilizing its next-generation multispecific antibodies. ModeX's oncology programs are in the preclinical stage and at least one program is expected to enter the clinic in 2024. ModeX's collaboration with Merck to develop MDX-2201, its vaccine for Epstein-Barr virus, is advancing. ModeX's antiviral program is focused on developing multiple indications, including HIV, as well as other potential viral pathogens funded by BARDA.
- NGENLA has now been approved in 48 markets including the U.S., Japan, EU Member States, Canada and Australia; sales are underway by Pfizer in over 23 countries including all priority global markets.** NGENLA is the first once-weekly product approved for the treatment of pediatric growth hormone deficiency in Japan, Canada, Australia, the United Kingdom, Taiwan, United Arab Emirates and Brazil. OPKO is entitled to gross profit sharing in all global markets based on regional, tiered gross profit for both NGENLA and Genotropin. The U.S. region commenced gross profit sharing in August 2023.
- New clinical data on RAYALDEE® presented at Kidney Week 2023.** OPKO Health presented late-breaking clinical data on RAYALDEE extended-release calcifediol in a poster presentation at the American Society of Nephrology Kidney Week. The data indicate that early, sustained and effective treatment of secondary hyperparathyroidism (SHPT) with RAYALDEE is associated with significantly slower progression of chronic kidney disease (CKD) in pre-dialysis patients. Data presented in an additional poster demonstrated that effective control of SHPT was achieved with RAYALDEE in both randomized clinical trials and in a real-world clinical experience trial.
- OPKO Biologics entered into a research collaboration agreement with Entera Bio Ltd. to develop oral peptide tablet formulations for obesity and intestinal malabsorption syndromes.** Under the agreement, OPKO will supply its long-acting GLP-2 peptide and certain oxyntomodulin (OXM) analogs for the development of oral tablet formulations using Entera's proprietary oral delivery technology. Treatment with glucagon-like peptide-2 (GLP-2) analogs has been shown to improve the absorption of nutrients in patients with short bowel syndrome and to reduce parenteral support requirements. OXM is a naturally occurring peptide hormone found in the colon, with glucagon-like peptide-1 (GLP-1) and glucagon dual agonist activity that suppresses appetite and induces weight loss. OPKO has developed several proprietary, modified OXM analogs as potential candidates for treating obesity, including an injectable pegylated peptide that demonstrated significant reductions in weight loss and decreased plasma triglyceride levels in a 420-patient Phase 2b study.
- BioReference Health continued executing its plan to improve operational efficiencies and enhance productivity, and is on track to return to profitability.** BioReference continued to implement initiatives to reduce costs and rationalize its business in line with current testing volumes. Additionally, BioReference is focused on improving productivity and enhancing innovation of its higher-value specialty testing segments. Other efforts to return this business to profitability include expanding into new market segments, such as providing information for the pharmaceutical market.

Third Quarter Financial Results

- Pharmaceuticals:** Revenue from products in the third quarter of 2023 increased to \$40.7 million from \$32.4 million in the third quarter of 2022, driven by higher sales in OPKO's international operating companies positively impacted by foreign currency exchange fluctuations of \$2.9 million, and by an increase in sales of RAYALDEE to \$7.3 million from \$6.9 million in the prior-year period. Revenue from the transfer of intellectual property was \$6.2 million in the third quarter of 2023 compared with \$4.5 million in the 2022 period, which included revenue of \$4.9 million and \$1.4 million, respectively, of gross profit share for NGENLA in Europe and Japan and does not include an estimate from gross profit in the U.S. as our partner has not yet provided details post their launch in August 2023. Total costs and expenses were \$72.3 million in the third quarter of 2023, up from \$65.2 million in the prior-year period. The increase was mainly from the cost of revenue due to higher sales in OPKO's international operating companies, higher inventory costs compared with the 2022 third quarter and unfavorable foreign currency exchange fluctuations of \$2.2 million. Operating loss was \$25.4 million in the third quarter of 2023 compared with \$28.3 million in the third quarter of 2022.
- Diagnostics:** Revenue from services in the third quarter of 2023 was \$131.7 million compared with \$142.9 million in the prior-year period. Revenue decreased \$10.0 million due to lower COVID-19 testing volume and reimbursement. Furthermore, clinical test reimbursement decreased by \$6.6 million due to the mix of testing ordered, partially offset by a \$5.4 million increase in clinical test volume. Total costs and expenses were \$160.8 million in the third quarter of 2023 compared with \$192.3 million in the third quarter of 2022, resulting in an operating loss of \$29.1 million compared with an operating loss of \$49.5 million in the 2022 period, an improvement of 41%. Operating loss improved primarily due to continued cost-reduction initiatives at BioReference as we strive to return to profitability.
- Consolidated:** Consolidated total revenues for the third quarter of 2023 were \$178.6 million compared with \$179.7 million for the comparable 2022 period. Operating loss for the third quarter of 2023 was \$64.4 million compared with an operating loss of \$87.8 million for the 2022 quarter. Net loss for the third quarter of 2023 included a mark-to-market adjustment of \$8.3 million compared with \$30.6 million in the 2022 period related to the decrease in the share price of GeneDx, resulting in a net loss of \$84.5 million, or \$0.11 per share, compared with a net loss of \$86.1 million, or \$0.11 per share, for the 2022 quarter.
- Cash and cash equivalents:** Cash and cash equivalents were \$138.6 million as of September 30, 2023.

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 audio webcast today beginning at 4:30 p.m. Eastern time. Participants are encouraged to pre-register for the conference call using this link. 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 can 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 13, 2023 by dialing 877-344-7529 (U.S.) or 412-317-0088 (International) and providing the passcode 8299382. A webcast replay will be available beginning approximately one hour after the completion of the live conference call here.

About OPKO Health

OPKO Health 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 its 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 products will launch in all the territories in which they have been approved for sale, the timing of such launches, our product development efforts and the expected benefits of our products, 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 attract new commercial and strategic partners, 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, our expectations about RAYALDEE, the therapeutic benefits or effectiveness of RAYALDEE or whether early initiation of SHPT treatment with RAYALDEE would delay disease progression, whether BioReference's cost-cutting initiatives and attempts at returning to its core business 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.

Contacts:

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—Tables to Follow—

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

	September 30, 2023	As of December 31, 2022
Assets:		
Cash and cash equivalents	\$ 138.6	\$ 153.2
Other current assets	218.6	241.3
Total current assets	<u>357.2</u>	<u>394.5</u>
In-process research and development and goodwill	789.5	790.9
Other assets	910.0	981.9
Total Assets	<u>\$ 2,056.7</u>	<u>\$ 2,167.3</u>
Liabilities and Equity:		
Accounts payable	\$ 66.8	\$ 67.0
Accrued expenses	92.4	98.3
Current portion of convertible notes	0.0	3.1
Other current liabilities	41.4	45.1
Total current liabilities	<u>200.6</u>	<u>213.5</u>
Long-term portion of convertible notes	213.3	210.4
Deferred tax liabilities, net	138.0	126.4
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	60.2	55.4
Total Liabilities	<u>612.1</u>	<u>605.7</u>
Equity	1,444.6	1,561.6
Total Liabilities and Equity	<u>\$ 2,056.7</u>	<u>\$ 2,167.3</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 September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Revenues				
Revenue from services	\$ 131.7	\$ 142.8	\$ 391.1	\$ 616.3
Revenue from products	40.7	32.4	124.6	104.9
Revenue from transfer of intellectual property and other	6.2	4.5	165.9	97.7
Total revenues	<u>178.6</u>	<u>179.7</u>	<u>681.6</u>	<u>818.9</u>
Costs and expenses				
Cost of service revenues	106.4	128.2	333.5	521.3
Cost of product revenues	24.5	20.2	74.7	65.4
Selling, general and administrative	72.3	79.7	227.7	298.7
Research and development	19.4	18.8	70.2	54.4
Contingent consideration	(1.1)	(0.8)	(1.0)	(0.7)
Amortization of intangible assets	21.5	21.4	64.5	66.2
Gain on sale of assets	0.0	0.0	0.0	(15.4)
Total costs and expenses	<u>243.0</u>	<u>267.5</u>	<u>769.6</u>	<u>989.9</u>
Operating loss	<u>(64.4)</u>	<u>(87.8)</u>	<u>(88.0)</u>	<u>(171.0)</u>
Other expense, net	<u>(14.0)</u>	<u>(38.6)</u>	<u>(23.8)</u>	<u>(118.3)</u>
Loss before income taxes and investment losses	<u>(78.4)</u>	<u>(126.4)</u>	<u>(111.8)</u>	<u>(289.3)</u>
Income tax benefit (provision)	<u>(6.1)</u>	<u>40.3</u>	<u>(10.5)</u>	<u>46.5</u>
Loss before investment losses	<u>(84.5)</u>	<u>(86.1)</u>	<u>(122.3)</u>	<u>(242.8)</u>
Loss from investments in investees	<u>(0.0)</u>	<u>(0.0)</u>	<u>(0.1)</u>	<u>(0.4)</u>
Net loss	<u>\$ (84.5)</u>	<u>\$ (86.1)</u>	<u>\$ (122.4)</u>	<u>\$ (243.2)</u>
Loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.11)</u>	<u>\$ (0.16)</u>	<u>\$ (0.34)</u>
Weighted average common shares outstanding, basic and diluted	751,525,007	750,396,263	751,716,692	708,121,980

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