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**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): February 23, 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. ☐

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**ITEM 2.02. Results of Operations and Financial Condition.**

On February 23, 2023, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended December 31, 2022. The Company is hosting a conference call to provide a business update and discuss its financial and operating results for the fourth quarter and full year ended December 31, 2022, as well as discuss financial guidance. The press release contains information on how to access the conference call. 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 February 23, 2023
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

## Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated February 23, 2023

## **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: February 23, 2023

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer



## **OPKO Health Reports Fourth Quarter 2022 Business Highlights and Financial Results**

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

**MIAMI (February 23, 2023) – OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended December 31, 2022.

Business highlights include the following:

- **Sales are underway by Pfizer for NGENLA® (somatrogen) in 15 countries including Japan, Germany and the United Kingdom; Pfizer expects to launch in all priority ex-U.S. markets by year-end and is continuing to work with the FDA to obtain approval in the U.S.** NGENLA treats pediatric patients with decreased growth due to insufficient growth hormone and reduces the injection frequency from once daily to once weekly. NGENLA is the first once-weekly product approved for the treatment of pediatric growth hormone deficiency in Japan, Canada, Australia, Taiwan, United Arab Emirates and Brazil. Its European Union marketing authorization is valid in all EU Member States, as well as in Iceland, Norway and Liechtenstein.
- **BioReference Health advances its cost-cutting initiatives.** BioReference continues to implement significant initiatives to reduce costs and rationalize its business following the decline of COVID-19 testing volume. In addition, BioReference is driving innovation to its portfolio and exploring other revenue sources to return the business to profitability.

### **Fourth Quarter Financial Results**

- **Pharmaceuticals:** Revenue from products in the fourth quarter of 2022 increased to \$37.9 million from \$35.3 million in the fourth quarter of 2021, driven by sales in our international operating companies and revenue from sales of RAYALDEE. Revenue from sales of RAYALDEE in the fourth quarter of 2022 was \$9.1 million compared with \$7.7 million in the prior-year period. Revenue from the transfer of intellectual property was \$8.1 million in the fourth quarter of 2022 compared with \$3.2 million in the 2021 period. Furthermore, during the fourth quarter of 2022, OPKO received \$2.5 million from Nicoya, tied to the first anniversary of the agreement's effective date. Total costs and expenses were \$68.0 million in the fourth quarter of 2022 compared with \$53.3 million in the prior-year period. The increase was primarily attributable to higher amortization expenses related to the reclassification of NGENLA's in-process research and development upon its approval in Europe and Japan, higher employee expenses associated with the ModeX acquisition and the impact of foreign exchange at our international operating companies. The operating loss was \$22.0 million in the fourth quarter of 2022 compared with an operating loss of \$14.8 million in the fourth quarter of 2021.

- **Diagnostics:** Revenue from services in the fourth quarter of 2022 was \$139.4 million compared with \$362.8 million in the prior-year period. The decrease was primarily due to lower COVID-19 testing volume. BioReference processed approximately 0.1 million COVID-19 PCR tests in the fourth quarter of 2022 versus 2.7 million tests in the fourth quarter of 2021. Total costs and expenses were \$162.5 million in the fourth quarter of 2022 compared with \$381.4 million in the fourth quarter of 2021, resulting in an operating loss of \$23.1 million compared with an operating income of \$18.6 million in the 2021 period. BioReference continues to implement significant cost-reduction initiatives and has scaled back its digital health investments as it looks to return to profitability following the decline of COVID-19 testing.
- **Consolidated:** Consolidated total revenues for the fourth quarter of 2022 were \$185.4 million compared with \$401.3 million for the comparable period of 2021. The operating loss for the fourth quarter of 2022 was \$55.3 million compared with an operating loss of \$63.1 million for the 2021 quarter. Net loss for the fourth quarter of 2022, which included a non-cash expense of \$49.1 million due to a decrease in the fair value of OPKO's GeneDx Holdings (formerly Sema4 Holdings Corp.) investment, was \$85.2 million, or \$0.11 per share, compared with a net loss of \$73.8 million, or \$0.11 per share, for the 2021 quarter. Net loss for the fourth quarter of 2021 included non-recurring legal expenses and expenses related to the sale of GeneDx, Inc.
- **Cash and cash equivalents:** Cash and cash equivalents were \$153.2 million as of December 31, 2022.

### Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss fourth 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 March 2, 2023 by dialing (877) 344-7529 (U.S.) or (412) 317-0088 (International) and providing the passcode 3187296. 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](http://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, the ability to get beneficial pricing approvals, our product development efforts and the expected benefits of our products, whether the relationship with our business partners will be successful, whether our business 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 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

	As of	
	December 31, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	\$ 153.2	\$ 134.7
Assets held for sale	0.0	315.0
Other current assets	241.3	373.3
Total current assets	394.5	823.0
In-process research and development and goodwill	790.9	1,110.8
Other assets	981.9	465.9
Total Assets	<u>\$ 2,167.3</u>	<u>\$ 2,399.7</u>
Liabilities and Equity:		
Accounts payable	\$ 67.0	\$ 82.0
Accrued expenses	98.3	193.5
Current portion of convertible notes	3.1	0.0
Liabilities associated with assets held for sale	0.0	28.2
Other current liabilities	45.1	26.3
Total current liabilities	213.5	330.0
Long term portion of convertible notes	210.4	187.9
Deferred tax liabilities	126.4	148.5
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	55.4	48.2
Total Liabilities	605.7	714.6
Equity	1,561.6	1,685.1
Total Liabilities and Equity	<u>\$ 2,167.3</u>	<u>\$ 2,399.7</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 December 31,		For the year ended December 31,	
	2022	2021	2022	2021
Revenues				
Revenue from services	\$ 139.4	\$ 362.8	\$ 755.6	\$ 1,607.1
Revenue from products	37.9	35.3	142.9	141.8
Revenue from transfer of intellectual property and other	8.1	3.2	105.7	25.8
Total revenues	185.4	401.3	1,004.2	1,774.7
Costs and expenses				
Cost of revenues	129.4	292.8	716.0	1,193.2
Selling, general and administrative	74.0	138.2	372.7	468.9
Research and development	19.5	21.0	73.9	76.8
Contingent consideration	(0.6)	(0.1)	(1.3)	(1.7)
Amortization of intangible assets	21.6	12.5	87.8	50.3
Gain on sale of assets	(3.2)	0.0	(18.6)	(31.5)
Total costs and expenses	240.7	464.4	1,230.5	1,756.0
Operating income (loss)	(55.3)	(63.1)	(226.3)	18.7
Other expense, net	(46.9)	(2.7)	(165.2)	(32.7)
Loss before income taxes and investment losses	(102.2)	(65.8)	(391.5)	(14.0)
Income tax (provision)	17.0	(7.5)	63.5	(15.5)
Loss before investment losses	(85.2)	(73.3)	(328.0)	(29.5)
Loss from investments in investees	(0.0)	(0.5)	(0.4)	(0.6)
Net loss	\$ (85.2)	\$ (73.8)	\$ (328.4)	\$ (30.1)
Loss per share, basic and diluted	\$ (0.11)	\$ (0.11)	\$ (0.46)	\$ (0.05)
Weighted average common shares outstanding, basic and diluted	750,169,485	651,775,740	719,060,942	648,077,716

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