
**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 8, 2022

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

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 8, 2022, OPKO Health, Inc. (the “Company”) issued a press release announcing operating and financial highlights for the quarter ended September 30, 2022. 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, 2022, as well as discuss 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 8, 2022
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 November 8, 2022

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: November 8, 2022

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer



OPKO Health Reports Third Quarter 2022 Business Highlights and Financial Results

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

MIAMI (November 8, 2022) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three months ended September 30, 2022.

Business highlights for the third quarter of 2022 and subsequent weeks include the following:

- **Pfizer's NGENLA® (somatrogen) launched in Japan, Germany and other global markets; Pfizer seeking pricing approvals in additional European countries and continuing to work with FDA to obtain approval in the U.S.** Pfizer's NGENLA® (somatrogen) launched in Japan, Germany and other global markets; Pfizer seeking pricing approvals in additional European countries and continuing to work with 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, UAE and Brazil. Its European Union marketing authorization is valid in all EU Member States as well as Iceland, Norway and Liechtenstein. In Australia, NGENLA is now offered through the Pharmaceutical Benefits Scheme, Australia's national drug subsidy program.
- **ModeX Therapeutics, Inc. (ModeX) progresses proprietary immunotherapy pipeline.** ModeX continues to advance its pipeline of antiviral and immune-oncology products utilizing its next generation multispecific antibodies. In addition, ModeX is pursuing potential licensing and collaboration arrangements with strategic partners for certain of its early stage pipeline candidates.
- **Innovation and cost cutting efforts continue at BioReference Laboratories (BRL).** BRL continues significant cost reduction and business rationalization efforts following the decline of COVID testing volume. These efforts have resulted in a reduction of more than \$100 million in annualized costs to date. Furthermore, BRL is exploring other revenue sources to work toward returning BRL to profitability.

Third Quarter Financial Results

- **Pharmaceuticals:** Revenue in the third quarter of 2022 decreased to \$32.4 million from \$36.9 million in the third quarter of 2021, driven by foreign currency exchange and lower sales of RAYALDEE. During the third quarter of 2022, OPKO received gross profit share and royalty payments from Pfizer related to sales of NGENLA. We expect these payments to increase as Pfizer receives additional pricing approvals and launches the product in other geographies. Revenue from sales of RAYALDEE in the third quarter of 2022 was \$6.9 million compared with \$8.5 million in the prior-year period; however, we also began to receive royalty payments from sales of RAYALDEE by CSL Vifor in Germany and Switzerland during the third quarter of 2022. We expect these payments to increase as CSL Vifor launches RAYALDEE in additional territories throughout Europe. There were several significant events that positively impacted third quarter 2021 results, and should be considered when comparing those results to 2022. Revenue from
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the transfer of intellectual property was \$4.5 million in the third quarter of 2022 compared with \$8.8 million in the 2021 period. The third quarter of 2021 also included \$4.9 million related to an exclusive license agreement with CAMP4 Therapeutics Corp. and \$1.0 million due to the joint venture with LeaderMed Health Group Ltd. Total costs and expenses were \$65.2 million in the third quarter of 2022 compared with \$17.0 million in the prior-year period, which included a \$31.5 million gain on the sale of OPKO's fill-finish manufacturing facility in Ireland to Horizon Therapeutics. In addition, the increase in total costs and expenses in the third quarter of 2022 were 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 higher research and development costs for somatrogon, partially offset by foreign currency exchange. The operating loss of \$28.3 million in the third quarter of 2022 compared to operating income of \$28.6 million in the third quarter of 2021 reflects these events.

- **Diagnostics:** Revenue from services in the third quarter of 2022 was \$142.8 million compared with \$340.1 million in the prior-year period, the decrease primarily due to lower COVID-19 testing volume. BRL processed approximately 0.2 million COVID-19 PCR tests in the third quarter of 2022 versus 2.2 million tests in the third quarter of 2021. Total costs and expenses were \$192.3 million in the third quarter of 2022 compared with \$320.5 million in the third quarter of 2021, resulting in an operating loss of \$49.5 million compared with operating income of \$19.7 million in the 2021 period. BRL continues to implement significant cost-reduction initiatives and scaled back digital health investments as it looks to return to profitability following the buildup and then decline of COVID-related testing. The third quarter of 2022 included \$5.1 million in severance costs as the company reduced employee costs on an annualized basis by over \$46 million.
- **Consolidated:** Consolidated total revenues for the third quarter of 2022 were \$179.7 million compared with \$385.8 million for the comparable period of 2021. Operating loss for the third quarter of 2022 was \$87.8 million compared with operating income of \$37.8 million for the 2021 quarter. Net loss for the third quarter of 2022 was \$86.1 million, or \$0.11 per share, compared with net income of \$28.7 million, or \$0.04 per diluted share, for the 2021 quarter. Net loss for the third quarter of 2022 included a non-cash expense of \$30.6 million due to a decrease in the fair value of OPKO's Sema4 investment, while the comparable quarter of 2021 included a \$31.5 million gain on the sale of the facility in Ireland.
- **Cash and cash equivalents:** Cash and cash equivalents were \$180.8 million as of September 30, 2022.

Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss third quarter financial results 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 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 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 15, 2022 by dialing (877) 344-7529 (U.S.) or (412) 317-0088 (International) and providing the passcode 5757952. 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, the risk of downturns and a changing regulatory landscape in the highly competitive healthcare industry, 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, whether RAYALDEE prescriptions will increase, 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, 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, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	\$ 180.8	\$ 134.7
Assets held for sale	0.0	315.0
Other current assets	233.2	373.3
Total current assets	414.0	823.0
In-process research and development and goodwill	768.5	1,110.8
Other assets	1,042.3	465.9
Total Assets	<u>\$ 2,224.8</u>	<u>\$ 2,399.7</u>
Liabilities and Equity:		
Accounts payable	\$ 49.8	\$ 82.0
Accrued expenses	112.0	193.5
Current portion of convertible notes	70.6	0.0
Liabilities associated with assets held for sale	0.0	28.2
Other current liabilities	34.8	26.3
Total current liabilities	267.2	330.0
Long term portion of convertible notes	141.8	187.9
Deferred tax liabilities	135.1	148.5
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	51.6	48.2
Total Liabilities	595.7	714.6
Equity	1,629.1	1,685.1
Total Liabilities and Equity	<u>\$ 2,224.8</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 September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Revenues				
Revenue from services	\$ 142.8	\$ 340.1	\$ 616.3	\$ 1,244.3
Revenue from products	32.4	36.9	104.9	106.5
Revenue from transfer of intellectual property and other	4.5	8.8	97.7	22.6
Total revenues	179.7	385.8	818.9	1,373.4
Costs and expenses				
Cost of revenues	148.4	244.0	586.7	900.4
Selling, general and administrative	79.7	105.1	298.7	330.6
Research and development	18.8	18.3	54.4	55.8
Contingent consideration	(0.8)	(0.5)	(0.7)	(1.6)
Amortization of intangible assets	21.4	12.6	66.2	37.8
Gain on sale of assets	0.0	(31.5)	(15.4)	(31.5)
Total costs and expenses	267.5	348.0	989.9	1,291.5
Operating income (loss)	(87.8)	37.8	(171.0)	81.9
Other expense, net	(38.6)	(6.4)	(118.3)	(30.1)
Income (loss) before income taxes and investment losses	(126.4)	31.4	(289.3)	51.8
Income tax benefit (provision)	40.3	(2.7)	46.5	(8.0)
Income (loss) before investment losses	(86.1)	28.7	(242.8)	43.8
Loss from investments in investees	(0.0)	(0.0)	(0.4)	(0.2)
Net income (loss)	\$ (86.1)	\$ 28.7	\$ (243.2)	\$ 43.6
Income (loss) per share, basic and diluted	\$ (0.11)	\$ 0.04	\$ (0.34)	\$ 0.07
Weighted average common shares outstanding, basic and diluted	750,396,263	651,843,074	708,121,980	646,710,240

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