

February 23, 2023



OPKO Health Reports Fourth Quarter 2022 Business Highlights and Financial Results

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

MIAMI, Feb. 23, 2023 (GLOBE NEWSWIRE) -- **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® (somatrogon) 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.

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.

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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	<u>\$ (85.2)</u>	<u>\$ (73.8)</u>	<u>\$ (328.4)</u>	<u>\$ (30.1)</u>
Loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.11)</u>	<u>\$ (0.46)</u>	<u>\$ (0.05)</u>
Weighted average common shares outstanding, basic and diluted	750,169,485	651,775,740	719,060,942	648,077,716



Source: OPKO Health, Inc.