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 24, 2022

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 February 24, 2022, OPKO Health, Inc. (the "Company") issued a press release announcing operating and financial highlights for the quarter ended December 31, 2021. 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 fourth quarter and full year ended December 31, 2021, 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 February 24, 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 February 24, 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.

By: /s/ Adam Logal

Date: February 24, 2022

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

OPKO Health Reports 2021 Fourth Quarter Business Highlights and Financial Results

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

MIAMI (February 24, 2022) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three months ended December 31, 2021.

Business Highlights

Business highlights for the fourth quarter of 2021 and subsequent weeks include the following:

- **NGENLA® (somatrogon) injection granted regulatory approvals in Europe, Japan, Australia and Canada for pediatric growth hormone deficiency.** NGENLA® is a once-weekly, long-acting recombinant human growth hormone for the long-term treatment of growth hormone deficiency (GHD) in pediatric patients. NGENLA® has been approved in the European Union, including Iceland, Norway and Liechtenstein, Japan, Australia and Canada. Under the worldwide agreement with Pfizer Inc., OPKO is eligible to receive a milestone payment after regulatory approvals and pricing determinations are obtained in major markets outside of the U.S. NGENLA® became commercially available in Canada to patients with pediatric growth hormone deficiency on February 16, 2022, the product's first commercial launch.

  In the U.S., the Food and Drug Administration (FDA) issued a Complete Response Letter for the Biologics License Application for somatrogon. Pfizer is evaluating the FDA's comments and intends to work with the Agency to determine an appropriate path forward in the U.S.

- **RAYALDEE® launched in Germany by OPKO's licensee, Vifor Fresenius Medical Care Renal Pharma (VFMCRP).** VFMCRP has initiated the commercial launch of RAYALDEE (extended-release calcifediol) in Germany, the first launch of RAYALDEE outside the U.S. VFMCRP is OPKO's commercial partner for RAYALDEE in Europe and selected markets outside the U.S. The sales kick-off in Germany began with presentations from several nephrology key opinion leaders. VFMCRP has received marketing authorizations for RAYALDEE in 11 European countries and expects to launch the product in additional markets.

- **Topline results reported from a Phase 2 clinical trial evaluating RAYALDEE as a treatment for symptomatic COVID-19 outpatients.** Topline data indicate that improving vitamin D status with oral RAYALDEE results in earlier resolution of respiratory symptoms associated with mild-to-moderate COVID-19. A preprint manuscript summarizing the topline results is available on medRxiv. This manuscript is currently under review for publication in a peer-reviewed medical journal. We plan to discuss potential next steps with the FDA.

- **Definitive agreement signed for Sema4 Holdings Corp. (Sema4) to acquire GeneDx, Inc., a leader in genomic testing and analysis.** Upon completion of the transaction, OPKO anticipates Sema4 and GeneDx will be one of the largest and most advanced providers of genomic clinical testing in the U.S., with a projected $350 million in pro forma 2022 revenue. Under the terms of the agreement, Sema4 will acquire GeneDx for an upfront payment of $150 million in cash plus 80 million shares of Sema4 common stock, with up to an additional $150 million in revenue-based milestones over the next two years (payable in cash or Sema4 shares at Sema4's discretion). Based on the closing price of Sema4's common stock on January 14, 2022, the total upfront consideration is approximately $473 million and the total aggregate consideration including potential milestones is approximately $623 million. As part of the transaction, Sema4 also entered into definitive agreements for a $200 million private placement of Sema4 stock from a syndicate of institutional investors, including Pfizer. The acquisition and the private placement are expected to close in the second quarter of 2022, subject to customary closing conditions including approval by Sema4 stockholders.

- **BioReference Laboratories (BRL) processed approximately 2.7 million COVID-19 PCR tests in the fourth quarter of 2021 versus 2.2 million in the third quarter of 2021.** Demand for COVID-19 PCR tests increased significantly due to the Omicron variant beginning late in the fourth quarter of 2021 and continuing into the first quarter of 2022.

  In December 2021, BRL announced a collaboration with MVP Health Care (MVP) to offer MVP's members medically necessary COVID-19 testing, bloodwork and other diagnostic tests in the comfort of their homes. MVP, the first insurer in New York and Vermont to offer this service, is utilizing Scarlet Health®, BRL's seamlessly integrated digital platform that provides specimen collection for laboratory diagnostic services conducted by a Scarlet Health professional in a patient's home or office.

- **FDA approved the Premarket Approval Application (PMA) of the 4Kscore® Test.** This test is approved for use in men aged 45 years and older who have not had a prior prostate biopsy or are biopsy negative and have an age-specific abnormal total prostate specific antigen (PSA) and/or abnormal digital rectal exam. The 4Kscore Test in the intended use population, when used in conjunction with other clinical factors and patient preferences, can contribute to a properly informed decision as to whether or not to proceed with a prostate biopsy. The regulatory approval provides further validation of the 4Kscore Test as an important diagnostic tool and should assist in expanding reimbursement coverage.

Fourth Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the fourth quarter of 2021 were $401.3 million compared with $494.6 million for the comparable period of 2020. Operating loss for the fourth quarter of 2021 was $63.1 million compared with operating income of $49.3 million for the comparable period of 2020. Net loss for the fourth quarter of 2021 was $73.8 million, or $0.11 per share, compared with net income of $32.3 million, or $0.05 per diluted share, for the comparable period of 2020. Operating loss for the fourth quarter of 2021 included non-recurring legal expenses, as well as expenses related to the GeneDx transaction.

- **Diagnostics:** Revenue from services in the fourth quarter of 2021 were to $362.8 million compared to $457.9 million in the prior-year period, primarily due to a decrease in COVID-19

testing volume. Total costs and expenses were $381.4 million in the fourth quarter of 2021 compared to $388.0 million in the fourth quarter of 2020, resulting in an operating loss of $18.6 million compared to operating income of $69.9 million in the 2020 period. The lower operating income is primarily due to a decline in COVID-19 test volume and increased investment in BRL's base business and digital health activities, principally related to Scarlet. Included in the fourth quarter 2021 results were revenue of $33.1 million and costs and expenses of $43.4 million at GeneDx compared with revenue of $20.3 million and costs and expenses of $36.6 million for the fourth quarter of 2020.

- **Pharmaceuticals:** Revenue from products in the fourth quarter of 2021 increased nearly 15% to $35.3 million compared to $30.8 million in the fourth quarter of 2020, with the increase primarily attributable to the accelerating growth of OPKO's international pharmaceutical businesses. Revenue from sales of RAYALDEE in the fourth quarter of 2021 was $7.7 million compared to $10.1 million in the prior-year period. Sales of RAYALDEE were negatively impacted by challenges in onboarding new patients due to the COVID-19 pandemic. Revenue from the transfer of intellectual property was $3.3 million in the fourth quarter of 2021 compared to $5.9 million in the 2020 period. Total costs and expenses were $53.3 million in the fourth quarter of 2021 compared to $45.7 million in the prior-year period, reflecting an increase in the cost of product revenue at OPKO's international operating companies related to higher sales and ongoing expenses for the somatrogon program to support open-label extension studies, as well as the preparation of applications for marketing approvals. Operating loss was $14.8 million in the fourth quarter of 2021 compared to an operating loss of $9.0 million in the fourth quarter of 2020.

- **Cash and equivalents:** Cash, cash equivalents and marketable securities were $134.7 million as of December 31, 2021. In addition, the Company has $64.8 million available under its line of credit with JP Morgan.

CONFERENCE CALL & WEBCAST INFORMATION

OPKO's senior management will provide a business update, discuss fourth 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 requested to pre-register for the conference call using the link here. Upon registering, participants will receive dial-in numbers, an event passcode and a unique registrant ID to gain immediate access to the call and bypass the live operator. Participants may pre-register at any time, including up to and after the start of the call. Alternatively, please dial (888) 869-1189 or (706) 643-5902 and use conference ID 4489338.

To access the live call via webcast, please click on the link OPKO 4Q21 Results Conference Call. Individual investors and investment community professionals who do not plan to ask a question during the call's Q&A session are encouraged to listen to the call via the webcast.

For those unable to listen to the live conference call, a replay can be accessed for a period of time on OPKO's website at OPKO 4Q21 Results Conference Call. A telephone replay will be available beginning approximately two hours after the close of the conference call. To access the replay, please dial (855) 859-2056 or (404) 537-3406, and use conference ID 4489338.

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, expectations about COVID-19 testing, the demand for testing, our capacity for testing, the impact of COVID-19 on all of our businesses, positively and negatively, whether and when the FDA will approve somatrogon for the treatment of pediatric patients with growth hormone deficiency for sale in the U.S., whether the sale of GeneDx to Sema4 will be consummated, the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement, the ability to implement business plans, forecasts, and other expectations after the completion of the transactions, and identify and realize additional opportunities, the risk of downturns and a changing regulatory landscape in the highly competitive healthcare industry, whether our products will launch in the territories in which they have been approved for sale, the timing of such launches, the possibility of further analyses of existing clinical data, whether regulatory authorities will be satisfied with the design of and results from our clinical studies, whether RAYALDEE prescriptions will increase, the utility of the Scarlet Health mobile service, the availability of and demand for the service, whether the service and the integrated platform will function or perform as designed, the role and value of the service to patients and healthcare providers and whether the demand for at home health care will continue or increase as anticipated, whether FDA approval of the 4Kscore Test will assist in expanding reimbursement coverage, our product development efforts and the expected benefits of our products, whether our products in development will be commercialized, 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 ongoing effects of the COVID-19 pandemic, 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:
LHA Investor Relations

Yvonne Briggs, 310-691-7100
ybriggs@lhai.com
or
Bruce Voss, 310-691-7100
bvoss@lhai.com

—Tables to Follow—

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

	As of	
	December 31, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 134.7	$ 72.2
Assets held for sale	315.0	0.0
Other current assets	373.3	451.0
Total current assets	823.0	523.2
In-process research and development and goodwill	1,110.8	1,270.8
Other assets	465.9	679.1
Total Assets	$ 2,399.7	$ 2,473.1
Liabilities and Equity:		
Current liabilities	$ 301.8	$ 375.5
Liabilities associated with assets held for sale	28.2	0.0
Convertible notes	187.9	222.0
Deferred tax liabilities, net	148.5	137.2
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	48.2	66.8
Total Liabilities	714.6	801.5
Equity	1,685.1	1,671.6
Total Liabilities and Equity	$ 2,399.7	$ 2,473.1

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,	
	2021	2020	2021	2020
Revenues				
Revenue from services	$ 362.8	$ 457.9	$ 1,607.1	$ 1,262.2
Revenue from products	35.3	30.8	141.8	120.0
Revenue from transfer of intellectual property and other	3.2	5.9	25.8	53.2
Total revenues	401.3	494.6	1,774.7	1,435.4
Costs and expenses				
Cost of revenues	292.8	318.7	1,193.2	894.4
Selling, general and administrative	138.2	101.8	468.9	355.6
Research and development	21.0	17.5	76.8	75.3
Contingent consideration	(0.1)	(5.3)	(1.7)	(4.0)
Amortization of intangible assets	12.5	12.6	50.3	56.4
Gain on sale of asset	0.0	0.0	(31.5)	0.0
Total costs and expenses	464.4	445.3	1,756.0	1,377.7
Operating income (loss)	(63.1)	49.3	18.7	57.7
Other income and (expense), net	(2.7)	(3.4)	(32.7)	(9.0)
Income (loss) before income taxes and investment losses	(65.8)	45.9	(14.0)	48.7
Income tax (provision)	(7.5)	(13.6)	(15.5)	(17.6)
Income (loss) before investment losses	(73.3)	32.3	(29.5)	31.1
Loss from investments in investees	(0.5)	(0.0)	(0.6)	(0.5)
Net income (loss)	$ (73.8)	$ 32.3	$ (30.1)	$ 30.6
Income (loss) per share, basic and diluted	$ (0.11)	$ 0.05	$ (0.05)	$ 0.05
Weighted average common shares outstanding, basic and diluted	651,775,740	640,590,427	648,077,716	640,655,290

# # #