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): August 4, 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	
(Address of Principal E	xecutive Offices)	(Zi

(Zip Code)

33137

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:

 \Box W ritten communications pursuant to Rule425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Procommencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Precommencement 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 \Box

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 August 4, 2022, OPKO Health, Inc. (the "Company") issued a press release announcing operating and financial highlights for the quarter ended June 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 second quarter ended June 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 August 4, 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 August 4, 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: August 4, 2022

By: /s/ Adam Logal

Name:Adam LogalTitle:Senior Vice President, Chief Financial Officer



OPKO Health Reports 2022 Second Quarter Business Highlights and Financial Results

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

MIAMI (August 4, 2022) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three and six months ended June 30, 2022.

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

- Acquired ModeX Therapeutics, Inc. (ModeX), gained proprietary immunotherapy technology, seasoned scientific team, new executives and Directors. ModeX is focused on developing uniquely designed multi-specific immune therapies for cancer and infectious diseases. In connection with the acquisition, Dr. Elias Zerhouni joined OPKO as President and Vice Chairman of the Board of Directors, Dr. Gary Nabel joined as Chief Innovation Officer and a member of OPKO's Board of Directors, and Alexis Borisy joined OPKO's Board. The company acquired ModeX for \$300 million in OPKO common stock.
- Pfizer launched NGENLA[®] (somatrogon) in Germany, Japan and additional global markets. NGENLA treats pediatric patients with decreased growth due to insufficient secretion of growth hormone and it reduces the frequency of required injections from once daily to once weekly. In the second quarter, OPKO received \$85 million in milestone payments from Pfizer, OPKO's global commercial partner, related to the launching of NGENLA in Europe and Japan.
- Completed sale of GeneDx LLC (formerly GeneDx, Inc.) to Sema4 Holdings Corp. (Sema4). Sema4 acquired GeneDx for an upfront cash payment of \$150 million, subject to adjustments, plus 80 million shares of Sema4 Class A 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 Class A common stock on April 29, 2022, the date the transaction closed, the total upfront consideration was approximately \$322 million and the total aggregate consideration including potential milestones was approximately \$472 million.
- BioReference Laboratories' (BRL) Scarlet Health[®] announced a collaboration with Teladoc Health. Under the collaboration with Teladoc Health, a global leader in whole-person virtual care, BRL will offer in-home, on-demand phlebotomy service from Scarlet Health. The collaboration removes barriers to access and increases convenience through a seamless, comprehensive experience that meets people at their location. With Scarlet's at-home, on-demand phlebotomy service, Teladoc Health saw laboratory order completion rates increase by 22.5% in an initial trial.

Second Quarter Financial Results

- Pharmaceuticals: Revenue in the second guarter of 2022 increased to \$35.9 million from \$35.7 million in the second quarter of 2021, primarily attributable to higher RAYALDEE sales, partially offset by a decrease in OPKO's pharmaceutical business in Chile, due to foreign exchange fluctuations. Revenue from sales of RAYALDEE in the second guarter of 2022 was \$6.2 million compared with \$5.0 million in the prior-year period. Revenue from the transfer of intellectual property was \$87.2 million in the second quarter of 2022 compared with \$9.5 million in the 2021 period. During the second quarter of 2022, OPKO received \$85.0 million in milestone payments from Pfizer related to the commencement of NGENLA sales in Europe and Japan. The second quarter of 2021 included a \$5.0 million non-refundable upfront payment under the license agreement with Nicoya Therapeutics. Total costs and expenses were \$67.7 million in the second quarter of 2022 compared with \$58.9 million in the prior-year period. This increase was primarily attributable to higher amortization expense related to the reclassification of NGENLA's in-process research and development upon its approval in Europe and Japan during the first quarter of 2022 and spending related to the ModeX acquisition, partially offset by lower RAYALDEE cost per unit and foreign exchange fluctuations at OPKO's international operating companies. Operating income was \$55.4 million in the second quarter of 2022 compared with an operating loss of \$13.7 million in the second quarter of 2021.
- Diagnostics: Revenue from services in the second quarter of 2022 was \$186.8 million compared with \$397.2 million in the prior-year period, the decrease primarily due to lower COVID-19 testing volume. BRL processed approximately 0.9 million COVID-19 PCR tests in the second quarter of 2022 versus 2.8 million in the second quarter of 2021. Total costs and expenses were \$244.3 million in the second quarter of 2022 compared with \$367.2 million in the second quarter of 2021, resulting in an operating loss of \$57.5 million compared with operating income of \$30.0 million in the 2021 period. Significant investments in growth initiatives, principally our digital health platforms and non-traditional COVID lines of business negatively impacted operating margins at BRL. Operating loss for the second quarter of 2022 includes a \$15.4 million gain on the sale of GeneDx, partially offset by \$5.8 million of operating losses prior to closing in April 2022.
- Consolidated: Consolidated total revenues for the second quarter of 2022 were \$309.9 million compared with \$442.4 million for the comparable period of 2021. Operating loss for the second quarter of 2022 was \$10.7 million compared with operating income of \$5.6 million for the 2021 quarter. Net loss for the second quarter of 2022 includes non-cash expense of \$71.2 million related to a decrease in Sema4's stock price at June 30, 2022. After giving effect to this non-cash expense, net loss for the three months ended June 30, 2022 was \$101.7 million, or \$0.14 per share, compared with net loss of \$16.2 million, or \$0.03 per diluted share, for the 2021 quarter.
- **Cash and equivalents:** Cash and cash equivalents were \$210.5 million as of June 30, 2022. In addition, OPKO has \$53.1 million available under its line of credit with JP Morgan.

Conference Call and Webcast Information

OPKO's senior management will provide a business update, discuss second 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 <u>link</u>. Callers who pre-register will be given 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 may also be accessed at OPKO's Investor Relations <u>page</u> and <u>here</u>.

A telephone replay will be available until August 11, 2022 by dialing (877) 344-7529 (U.S.) or (412) 317-0088 (International) and providing the passcode 5775821. A webcast replay will be available beginning approximately one hour after the completion of the live conference call <u>here</u>.

About OPKO Health

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industryleading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit <u>www.opko.com</u>.

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 the acquisition of ModeX, including the expansion of the executive management team, will positively impact the Company, whether expectations after completion of the merger will be met, whether we will receive milestone payments under the Sema4 transaction, the benefits of NGENLA, 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 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 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.

<u>Contacts:</u> LHA Investor Relations

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

<u>—Tables to Follow—</u>

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

	As of					
		June 30, 2022		December 31, 2021		
Assets:						
Cash and cash equivalents	\$	210.5	\$	134.7		
Assets held for sale		0.0		315.0		
Other current assets		284.3		373.3		
Total current assets		494.8		823.0		
In-process research and development and goodwill		773.8		1,110.8		
Other assets		1,101.0		465.9		
Total Assets	\$	2,369.6	\$	2,399.7		
Liabilities and Equity:						
Current liabilities	\$	215.5	\$	301.8		
Liabilities associated with assets held for sale		0.0		28.2		
Convertible notes		211.5		187.9		
Deferred tax liabilities, net		176.7		148.5		
Other long-term liabilities, principally contract liabilities,						
leases, contingent consideration and lines of credit		47.1		48.2		
Total Liabilities		650.8		714.6		
Equity		1,718.8		1,685.1		
Total Liabilities and Equity	\$	2,369.6	\$	2,399.7		

OPKO Health, Inc. and Subsidiaries Condensed Consolidated Statements of Operations (in millions, except share and per share data) Unaudited

	For the three months ended June 30,			For the six months ended June 30,				
	2022		2021		2022		2021	
Revenues								
Revenue from services	\$	186.8	\$	397.2	\$	473.4	\$	904.2
Revenue from products		35.9		35.7		72.5		69.6
Revenue from transfer of intellectual								
property and other		87.2		9.5		93.2		13.8
Total revenues		309.9		442.4		639.1		987.6
Costs and expenses								
Cost of revenues		194.3		292.9		438.2		656.5
Selling, general and administrative		101.5		113.2		219.0		225.5
Research and development		17.2		18.2		35.6		37.5
Contingent consideration		0.2		(0.1)		0.1		(1.1)
Amortization of intangible assets		22.8		12.6		44.8		25.2
Gain on sale of assets		(15.4)		0.0		(15.4)		0.0
Total costs and expenses		320.6		436.8		722.3		943.6
Operating income (loss)		(10.7)		5.6		(83.2)		44.0
Other expense, net		(75.6)		(16.9)		(79.8)		(23.7)
Income (loss) before income taxes and								
investment losses		(86.3)		(11.3)		(163.0)		20.3
Income tax benefit (provision)		(15.1)		(4.8)		6.2		(5.3)
Income (loss) before investment losses		(101.4)		(16.1)		(156.8)		15.0
Loss from investments in investees		(0.3)		(0.1)		(0.3)		(0.1)
Net income (loss)	\$	(101.7)	\$	(16.2)	\$	(157.1)	\$	14.9
Income (loss) per share,		·		<u> </u>				
basic and diluted	\$	(0.14)	\$	(0.03)	\$	(0.23)	\$	0.02
Weighted average common shares								
outstanding, basic and diluted	7	12,548,661	e	646,996,891	6	86,597,899	6	44,001,280

#