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): October 28, 2021

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 October 28, 2021, OPKO Health, Inc. (the "Company") issued a press release announcing operating and financial highlights for the quarter ended September 30, 2021. In the press release, the Company also provided information about its conference call during which it will provide a business update and discuss its third quarter ended September 30, 2021 financial and operating results, as well as provide 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 October 28, 2021
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 October 28, 2021

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: October 28, 2021

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

OPKO Health Reports 2021 Third Quarter Business Highlights and Financial Results

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

MIAMI (October 28, 2021) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three months ended September 30, 2021.

Business Highlights

- **Health Canada approved NGENLA™ (somatrogon) injection for pediatric growth hormone deficiency. NGENLA** is a once-weekly, long-acting recombinant human growth hormone, for the long-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (growth hormone deficiency, or GHD). Please click here to view Pfizer Canada's news release issued earlier today. Global regulatory applications for somatrogon continue to advance with action dates in the U.S., Europe and Japan expected during the first half of 2022.

- **BioReference Laboratories (BRL) processed approximately 2.2 million COVID-19 PCR tests in the third quarter of 2021.** In addition, during the quarter BRL performed approximately 158,100 COVID-19 serology tests to measure SARS-CoV-2 antibody levels and currently has significant additional capacity. In August 2021 Rite Aid, the U.S. Department of Health and Human Services, and BRL announced a "Back to School" COVID-19 testing program offering students at New York State public schools the opportunity for free COVID-19 testing prior to or at the start of the 2021-2022 school year. Students will be tested using highly accurate RT-PCR laboratory-based COVID-19 tests.

- **BRL acquired the U.S. Ariosa centralized laboratory prenatal testing business from Roche.** Ariosa's noninvasive prenatal screening (NIPS) test, the Harmony Prenatal Test, is one of the most widely studied tests utilized in prenatal screening. This test has been performed in more than 1.5 million patients. The acquisition of Ariosa will complement the current NIPS offering at GenPath, BRL's specialty health division.

- **Completed enrollment in Phase 2 trial evaluating RAYALDEE® as a treatment for symptomatic COVID-19 outpatients.** The U.S. trial, "A Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Safety and Efficacy of RAYALDEE (calcifediol) Extended-release Capsules to Treat Symptomatic Patients Infected with SARS-CoV-2," completed final enrollment with 171 subjects, including some with stage 3 or 4 chronic kidney disease who are at higher risk for developing more severe illness. Topline data are expected later this year.

- **Formed a joint venture with LeaderMed Group to develop, manufacture and commercialize oxyntomodulin and Factor VIIa-CTP in China and other Asian territories.** Under the terms of the agreements, OPKO granted the joint venture exclusive rights to develop, manufacture and

commercialize OPK88003, an oxyntomodulin analog being developed for the treatment of obesity and diabetes, and Factor VIIa-CTP, a novel long-acting coagulation factor being developed to treat hemophilia, in exchange for a 47% ownership interest in the joint venture. LeaderMed will be responsible for funding the joint venture's operations, development and commercialization efforts. OPKO retains full rights to oxyntomodulin and Factor VIIa-CTP in all other geographies.

- **Executed exclusive worldwide agreement with CAMP4 Therapeutics Corporation (CAMP4) for the development, manufacture and commercialization of therapeutics utilizing the AntagoNAT technology.** This technology is an oligonucleotide platform developed under OPKO CURNA. CAMP4 has prioritized OPKO's lead AntagoNAT compound to progress into clinical trials for the treatment of Dravet syndrome. Under the terms of the agreement, OPKO received an upfront payment and shares of privately held CAMP4. In addition, OPKO will be eligible to receive up to $93.5 million and additional shares upon the achievement of certain development and sales milestones for products developed from this technology and associated intellectual property. CAMP4 will also pay OPKO double-digit royalties on product sales.

Third Quarter Financial Results

- **Consolidated:** Consolidated total revenues for the third quarter of 2021 were $385.8 million compared with $428.1 million for the comparable period of 2020. Operating income for the third quarter of 2021 increased 72% to $37.8 million compared with $21.9 million, for the comparable period of 2020. Net income for the third quarter of 2021 was $28.7 million, or $0.04 per diluted share, compared with $23.7 million, or $0.04 per diluted share, for the comparable period of 2020.

- **Diagnostics:** Revenue from services in the third quarter of 2021 decreased to $340.1 million from $382.5 million in the prior-year period, primarily due to a decrease in COVID-19 testing volume, which was partially offset by an improvement in COVID-19 test reimbursement and an increase in clinical and genomic test revenue. Total costs and expenses were $320.5 million in the third quarter of 2021 compared with $346.4 million in the third quarter of 2020, resulting in operating income of $19.7 million compared with $46.2 million in the 2020 period. The decrease in operating income is primarily due to a decline in COVID-19 test volume and an increased level of investment in our commercial organization for our base business and digital health activities resulting in increased professional fees and personnel expenses. During the third quarter of 2020, BioReference received a $10.0 million non-recurring grant under the CARES Act.

- **Pharmaceuticals:** Revenue from products in the third quarter of 2021 increased almost 29% to $36.9 million compared with $28.7 million in the third quarter of 2020, with the increase primarily attributable to accelerating growth within OPKO's international pharmaceutical businesses. Total prescriptions for RAYALDEE in the third quarter of 2021 decreased to approximately 11,500 from approximately 16,700 in the third quarter of 2020. Revenue from sales of RAYALDEE in the third quarter of 2021 was $8.5 million compared with $8.1 million in the prior-year period, with the increase reflecting a higher net realized price as a result of lower Medicare Part D rebates. Revenue from the transfer of intellectual property was $8.8 million in the third quarter of 2021 compared with $6.8 million for the 2020 period. The increase reflects the CAMP4 and LeaderMed agreements partially offset by a decrease in revenue related to the Pfizer transaction. Total costs and expenses were $17.0 million in the third quarter of 2021 compared with $49.9 million in the prior-year period, primarily due to a $31.5 million gain on the sale of assets to Horizon Therapeutics plc for OPKO's sterile-fill-finish manufacturing facility

in Ireland. Operating income was $28.6 million in the third quarter of 2021 compared with an operating loss of $14.4 million in the third quarter of 2020.

- **Cash and equivalents:** Cash, cash equivalents and marketable securities were $148.6 million as of September 30, 2021. In addition, the Company has $64.3 million availability under its line of credit with JP Morgan.

CONFERENCE CALL & 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 requested to pre-register for the conference call using the link here. Upon pre-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 6958207

To access the live call via webcast, please click on the link OPKO 3Q21 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 3Q21 Results Conference Call. A telephone replay will be available beginning approximately two hours after the completion of the conference call. To access the replay, please dial (855) 859-2056 or (404) 537-3406, and use conference ID 6958207.

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 final study data for RAYALDEE will be available, our ability to commercialize RAYALDEE for COVID-19 patients, 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, 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	
	September 30, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 148.6	72.2
Other current assets	408.9	451.0
Total current assets	557.5	523.2
In-process research and development and goodwill	1,264.8	1,270.8
Other assets	595.3	679.1
Total Assets	$ 2,417.6	$ 2,473.1
Liabilities and Equity:		
Current liabilities	$ 283.0	$ 375.5
Convertible notes	185.5	222.0
Deferred tax liabilities, net	134.2	137.2
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	49.3	66.8
Total Liabilities	652.0	801.5
Equity	1,765.6	1,671.6
Total Liabilities and Equity	$ 2,417.6	$ 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 September 30,		For the nine months ended September 30,	
Revenues				
Revenue from services	$ 340.1	$ 382.5	$ 1,244.3	$ 804.3
Revenue from products	36.9	28.7	106.5	89.1
Revenue from transfer of intellectual property and other	8.8	16.9	22.6	47.3
Total revenues	385.8	428.1	1,373.4	940.7
Costs and expenses				
Cost of revenues	244.0	272.8	900.4	575.7
Selling, general and administrative	105.1	99.9	330.6	253.7
Research and development	18.3	18.5	55.8	57.9
Contingent consideration	(0.5)	1.1	(1.6)	1.3
Amortization of intangible assets	12.6	13.9	37.8	43.8
Gain on sale of asset	(31.5)	0.0	(31.5)	0.0
Total costs and expenses	348.0	406.2	1,291.5	932.4
Operating income	37.8	21.9	81.9	8.3
Other income and (expense), net	(6.4)	(1.3)	(30.1)	(5.6)
Income before income taxes and investment losses	31.4	20.6	51.8	2.7
Income tax benefit (provision)	(2.7)	3.2	(8.0)	(4.0)
Income (loss) before investment losses	28.7	23.8	43.8	(1.3)
Loss from investments in investees	(0.0)	(0.1)	(0.2)	(0.4)
Net income (loss)	$ 28.7	$ 23.7	$ 43.6	$ (1.7)
Income (loss) per share, basic and diluted	$ 0.04	$ 0.04	$ 0.07	$ (0.00)
Weighted average common shares outstanding, basic and diluted	651,843,074	640,699,982	646,710,240	640,619,485

# # #