April 28, 2021

OPKO Health Reports 2021 First Quarter Business Highlights and Financial Results

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

MIAMI, April 28, 2021 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended March 31, 2021.

Business Highlights

- **BioReference Laboratories test volume increased 158% compared with the first quarter of 2020.** During the first quarter of 2021, BioReference Laboratories (BRL) processed approximately 4.3 million COVID-19 PCR tests and has current capacity to process more than 100,000 PCR tests per day. In addition, during the quarter, BRL performed approximately 200,000 COVID-19 serology tests to measure SARS-CoV-2 antibody levels and currently has significant additional capacity.

  BRL continues to provide COVID-19 solutions to meet the testing needs of physicians, health systems, long-term care facilities, governments, schools, employers, professional sports leagues and entertainment venues, as well as the general public through relationships with retail pharmacy chains including Rite-Aid and CVS. In April 2021, BRL announced a COVID-19 testing agreement for players and staff, stadium employees and league staff for the 2021 Major League Baseball season and the renewal of a similar agreement for the 2021 Major League Soccer season.

  In March 2021, BRL announced expansion of its COVID-19 school testing program to support return to in-person classroom instruction across the country. For two of the nation's largest school systems, BRL provides testing services to nearly 200 schools every day and has tested nearly 500,000 public school students, teachers and principals.

- **Topline results reported from first cohort of Phase 2 trial with Rayaldee in patients with stage 5 chronic kidney disease (CKD) on dialysis.** Cohort 1 of the Phase 2 clinical trial explored the safety and efficacy of a high-strength formulation of Rayaldee (calcifediol) as a new treatment for secondary hyperparathyroidism (SHPT) in adults with vitamin D insufficiency and stage 5 CKD who require hemodialysis. Topline results from 44 subjects (33 Rayaldee; 11 placebo) demonstrated that the prohormone Rayaldee was well tolerated at a dose of 900 mcg/week, decreased intact parathyroid hormone (iPTH) versus placebo, and was activated to calcitriol (the active hormone) despite the lack of functional kidneys. A full analysis of the data is underway and will be reviewed with both FDA and OPKO's development partners.

- **Regulatory submission for somatrogon by Pfizer, OPKO's commercial partner, accepted by the European Medicines Agency (EMA).** In February 2021, the EMA

validated for review the Marketing Authorization Application (MAA) for somatrogon, a long-acting recombinant human growth hormone intended to be administered once-weekly to treat pediatric patients with growth hormone deficiency (GHD). Pfizer expects a decision from the European Commission in 2022. In January 2021, the FDA accepted for filing the initial Biologics License Application for somatrogon with a target Prescription Drug User Fee Act action date in October 2021. Pfizer also submitted a New Drug Application for somatrogon to the Pharmaceuticals and Medical Devices Agency in Japan.

- **Multiple presentations highlighting somatrogon clinical data were presented at two endocrinology conferences.** Data from OPKO's somatrogon clinical studies were presented virtually at ENDO 2021, the Endocrine Society's 2021 Annual Meeting held March 20-23, 2021, and at ICE 2021, the 19th International Congress of Endocrinology Annual Meeting held February 24-28, 2021. Utilizing OPKO's proprietary long-acting technology, somatrogon represents a significant advancement to increase patient adherence and improve quality of life compared with daily injections. Posters and abstracts from the endocrinology conferences can be viewed on the Company's website in the Investors section. In addition, OPKO will be participating in the 2021 Pediatric Endocrine Society Virtual Annual Meeting to be held today through May 3, 2021.

- **Phase 2 trial with RAYALDEE in COVID-19 outpatients is 71% enrolled and ongoing at 10 U.S. sites.** The trial is a randomized, double-blind, placebo-controlled study and is expected to enroll approximately 160 outpatients, including some with stage 3 or 4 CKD who are at higher risk for developing more severe illness. The qualified outpatients are being randomized one-to-one to four weeks of daily treatment with either RAYALDEE or placebo, and then monitored for another two weeks. Topline data from this trial are expected in the third quarter and, if sufficiently positive, will form the basis for an immediate request to FDA for an Emergency Use Authorization.

First Quarter Financial Results

- Consolidated revenues for the first quarter of 2021 were $545.2 million compared with $211.5 million for the comparable period of 2020. Net income for the first quarter of 2021 was $31.1 million, or $0.05 per diluted share, compared with a net loss of $59.1 million, or $0.09 per share, for the comparable period of 2020.

- **Diagnostics:** Revenue from services in the first quarter of 2021 increased to $507.0 million from $170.8 million in the prior-year period, primarily due to COVID-19 testing, partially offset by lower revenue in our base testing business reflecting the negative impact of the COVID-19 pandemic. Total costs and expenses were $439.9 million in the first quarter of 2021 compared with $189.0 million in the first quarter of 2020, resulting in operating income of $67.0 million compared with an operating loss of $18.1 million in the 2020 period. The increase in operating income of $85.1 million reflects the increased demand for COVID-19 PCR testing.

- **Pharmaceuticals:** Revenue from products in the first quarter of 2021 was $33.9 million compared with $31.1 million in the first quarter of 2020, primarily attributable to an increase in sales at OPKO Chile and FineTech, partially offset by a decline in sales of

RAYALDEE, which were negatively impacted by the COVID-19 pandemic. Total prescriptions of RAYALDEE for the first quarter of 2021 decreased to approximately 12,300 from approximately 18,300 for the first quarter of 2020. Revenue from the transfer of intellectual property was $4.3 million in the first quarter of 2021 compared with $9.6 million in the first quarter of 2020, reflecting a decrease in the amortization of payments received from Pfizer with respect to somatrogon. Total costs and expenses were $57.4 million in the first quarter of 2021 compared with $54.8 million in the prior-year period, primarily due to increased sales and an inventory reserve for RAYALDEE. The operating loss was $19.2 million in the first quarter of 2021 compared with $14.1 million in the first quarter of 2020.

- **Cash and equivalents:** Cash, cash equivalents and marketable securities were $89.5 million as of March 31, 2021. In addition, the Company has availability under its present line of credit with JP Morgan of $64.7 million and an unutilized $100 million credit facility that provides access to incremental capital on a non-dilutive basis.

CONFERENCE CALL & WEBCAST INFORMATION

OPKO's senior management will provide a business update, discuss first quarter financial results and answer questions during a conference call and live audio webcast beginning at 4:30 p.m. Eastern time today, April 28, 2021. Participants are requested to pre-register for the conference call using the link here, or dialing (888) 869-1189 or (706) 643-5902 and using conference ID 9993698. 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.

To access the live call via webcast, please click on the linkOPKO 1Q21 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 1Q21 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 9993698.

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, our ability to expand our capacity should there be additional demand, the availability of resources, including labor, equipment and supplies, to meet demand for testing and the potential impact on us should these resources be constrained, our product development efforts and the expected benefits of our products, whether our products in development will be commercialized, the possibility of further analyses of existing clinical data, the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities, whether regulatory authorities will be satisfied with the design of and results from our clinical studies, whether RAYALDEE prescriptions will increase, 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 Pfizer, Vifor and our other partners, liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that somatrogon, RAYALDEE, and/or any of our compounds or diagnostic products under development may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications proposed or for other indications, that enrollment for our Phase 2 trial with RAYALDEE in COVID-19 may not complete and topline data may not be available when anticipated and may not, in any event, be positive such that an Emergency Use Authorization could be sought, that regulatory approvals for our products, particularly somatrogon, may not be received when anticipated or at all, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied. 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	
	March 31, 2021	December 31, 2020
Assets:		
Cash, cash equivalents and marketable securities	$ 89.5	$ 72.2
Other current assets	509.5	451.0
Total Current Assets	599.0	523.2
In-process Research and Development and Goodwill	1,266.4	1,270.8
Other assets	654.2	679.1
Total Assets	$ 2,519.6	$ 2,473.1
Liabilities and Equity:		
Current liabilities	$ 403.9	$ 375.5
Convertible Notes	224.8	222.0
Deferred tax liabilities, net	135.2	137.2
Other long-term liabilities, principally contract liabilities, leases, contingent consideration and lines of credit	59.2	66.8
Total Liabilities	823.1	801.5
Equity	1,696.5	1,671.6
Total Liabilities and Equity	$ 2,519.6	$ 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 March 31,	
	2021	2020
Revenues		
Revenue from services	$ 507.0	$ 170.8
Revenue from products	33.9	31.1

Revenue from transfer of intellectual property	4.3	9.6
Total revenues	545.2	211.5
Costs and expenses		
Cost of revenues	363.5	140.3
Selling, general and administrative	112.3	76.1
Research and development	19.3	21.8
Contingent consideration	(1.0)	(0.9)
Amortization of intangible assets	12.6	14.9
Total Costs and expenses	506.7	252.2
Operating income (loss)	38.5	(40.7)
Other income and (expense), net	(6.8)	(17.1)
Income (loss) before income taxes and investment losses	31.7	(57.8)
Income tax provision	(0.6)	(1.2)
Net income (loss) before investment losses	31.1	(59.0)
Loss from investments in investees	0.0	(0.1)
Net income (loss)	$ 31.1	$ (59.1)
Income (loss) per share, basic and diluted	$ 0.05	$ (0.09)
Weighted average common shares outstanding, basic and diluted	640,853,200	640,578,794

Source: OPKO Health, Inc.