May 6, 2020

OPKO Health Reports 2020 First Quarter Business Highlights and Financial Results

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

MIAMI, May 06, 2020 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended March 31, 2020.

Business Highlights

- **BioReference Laboratories launched COVID-19 testing nationwide:** On March 13, 2020, BioReference Laboratories launched a Real-Time Reverse Transcription Polymerase Chain Reaction assay with an approximate 24-72 hour turnaround time to promote earlier diagnosis of the SARS-CoV-2 virus to aid in limiting the spread of infection. In addition to its nationwide COVID-19 test offering, BioReference announced testing partnerships with the New York State Department of Health, New York City Health and Hospital Corporation, the State of New Jersey, the State of Florida and the cities of Detroit and Miami, among others. Additionally, Rite Aid Corporation selected BioReference to provide COVID-19 laboratory testing to its drive-up locations with the goal of flattening the curve through widely accessible diagnostic testing. To date, BioReference has run approximately 700,000 COVID-19 tests and currently has a COVID-19 testing capacity of 35,000 tests per day. As of April 27, 2020, BioReference Laboratories started offering COVID-19 antibody testing, a semi-quantitative immunoassay that measures SARS-CoV-2 specific IgG antibody levels, correlating with the patient's immune response after COVID-19 infection. Within the next two weeks, BioReference expects to expand its capacity to be able to process up to 400,000 tests per day.

- **Somatrogon abstract to be presented at Endocrine Society's ENDO Online 2020:** On April 22, 2020, OPKO announced the data from its two abstracts regarding the global Phase 3 pediatric trial evaluating somatrogon dosed once weekly in pre-pubertal children with growth hormone deficiency will be combined into a single presentation at ENDO Online 2020, a virtual event being held June 8 through 22 featuring on-demand and live programming. The results of the pivotal Phase 3 study will be delivered on June 8, 2020 at 11:00 a.m. Eastern time by Dr. Cheri Deal, the Principal Investigator of the pediatric study. The two abstracts entitled "Somatrogon Growth Hormone in the Treatment of Pediatric Growth Hormone Deficiency: Results of the Pivotal Phase 3" and "Interpretation of Insulin-like Growth Factor (IGF-1) Levels Following Administration of Somatrogon (a long-acting Growth Hormone-hGH-CTP)" will be published online in the April-May supplemental issue of the *Journal of Endocrine Society*.

- **Somatrogon global regulatory submissions:** Somatrogon regulatory submission in the U.S. is anticipated to occur in the second half of 2020. In Europe, regulatory

submission will follow completion of the open-label study demonstrating benefit and compliance with reduced treatment burden, which is expected to be completed in the third quarter of 2020. The registration study in Japan for pediatric growth hormone deficiency patients was completed in early March and topline data is expected in mid-2020.

- **RAYALDEE total prescriptions reported by IQVIA increased 78% in the first quarter of 2020 compared with the first quarter in 2019:** Total prescriptions for the three months ended March 31, 2020 increased to approximately 18,327, compared with approximately 10,307 during the comparable period of 2019.

- **Interim results from two ongoing RAYALDEE studies reported:** On March 25, 2020, OPKO announced positive preliminary data from the ongoing Phase 4 comparative trial, which suggest that RAYALDEE may be more effective in raising serum total 25-hydroxyvitamin D to the level required to effectively suppress elevated plasma intact parathyroid hormone (iPTH) in stage 3 or 4 chronic kidney patients. Final results are expected in the second half of 2020. In addition, OPKO announced positive proof-of-concept data from the ongoing Phase 2 trial in patients with stage 5 chronic kidney disease demonstrating RAYALDEE may be useful in treating secondary hyperparathyroidism in dialysis patients. The Phase 2 trial in hemodialysis patients is on track to complete enrollment in the third quarter of 2020 with full topline data expected in the first quarter of 2021.

- **Nearly 16,000 4Kscore® tests performed during the first quarter of 2020:**Novitas Solutions issued its final Local Coverage Determination for Medicare payments for the 4Kscore test with defined coverage criteria, effective December 30, 2019. With Medicare reimbursement in place, the Company began its salesforce expansion for the 4Kscore during the first quarter of 2020; however, COVID-19 impacted utilization during the month of March.

Financial Results

- Consolidated revenues for the first quarter of 2020 were $211.5 million compared with $222.5 million for the comparable period of 2019. The net loss for the first quarter of 2020 was $59.1 million, or $0.09 per share, compared with a net loss of $80.8 million, or $0.14 per share, for the comparable period of 2019.

- **Diagnostics:** Revenue from services in the first quarter of 2020 was $170.8 million compared with $178.9 million for the comparable period in 2019. Although revenue from services was positively affected by increased reimbursement amounts and improved operational procedures, in the last two weeks of March 2020, the Company experienced a decline in testing volumes net of COVID-19 testing services due to the COVID-19 pandemic. Total costs and expenses were $189.0 million in the first quarter of 2020 compared with $212.5 million for the comparable period in 2019 with the reduction primarily attributable to lower selling, general and administrative expenses due to cost-reduction initiatives. In addition, the 2019 period included a $10.6 million legal accrual. As a result, operating loss was $18.1 million in the first quarter of 2020 compared with $33.6 million in the first quarter of 2019.

- **Pharmaceuticals:** Revenue from products in the first quarter of 2020 was $31.1 million compared with $25.3 million in the first quarter of 2019 with the increase primarily attributable to higher sales of RAYALDEE of $9.9 million in the first quarter of 2020 compared with $5.8 million in the prior year period. Revenue from licensing and intellectual property was $9.6 million in the first quarter of 2020 compared to $18.3 million in the first quarter of 2019 with the reduction primarily due to a decrease in the amortization of payments received from Pfizer, OPKO's commercial partner for its long-acting human growth hormone product, Somatrogon. Total cost and expenses were $54.8 million in the first quarter of 2020 compared with $73.0 million for the prior year period, with the decline primarily attributable to lower research and development expenses due to the completion of the pediatric Phase 3 study for somatrogon. The operating loss was $14.1 million in the first quarter of 2020 compared to $29.5 million in the first quarter of 2019.

- **Cash and equivalents:** Cash, cash equivalents and marketable securities were $34.5 million as of March 31, 2020. In addition, the Company has an unutilized $100 million credit facility which provides the company with access to incremental capital on a non-dilutive basis. In April 2020, the Company also accessed additional capital available under the CARES Act which provided the company with approximately $30 million of short-term liquidity through various provisions under the Act.

CONFERENCE CALL & WEBCAST INFORMATION

OPKO's senior management will provide a business update and discuss results in greater detail in a conference call and live audio webcast at 4:30 p.m. Eastern time today, May 6, 2020. The conference call dial-in and webcast information is as follows:

DOMESTIC DIAL-IN:	(877) 783-8475
INTERNATIONAL DIAL-IN:	(614) 999-1827
PASSCODE:	9095275
WEBCAST:	OPKO 1Q20 Results Conference Call

For those unable to participate in the live conference call or webcast, a replay will be available beginning approximately two hours after the close of the conference call. To access the replay, dial 855-859-2056 or 404-537-3406. The replay passcode is 9095275. The replay can be accessed for a period of time on OPKO's website at OPKO 1Q20 Results Conference Call.

About OPKO Health

OPKO Health is a diversified healthcare company. In diagnostics, its BioReference Laboratories is one of the nation's largest full-service clinical laboratories; GeneDx is a rapidly growing genetic testing business; the 4Kscore® test is used to assess a patient's individual risk for aggressive prostate cancer following an elevated PSA and to help decide about next steps such as prostate biopsy; Claros® 1 is a point-of-care diagnostics platform with a total PSA test approved by the FDA. In our pharmaceutical pipeline, RAYALDEE is our first pharmaceutical product to be marketed. OPK88003, a once-weekly oxyntomodulin for type 2 diabetes and obesity - reported positive data from a Phase 2 clinical trial. It's

among a new class of GLP-1/glucagon receptor dual agonists. OPK88004, a SARM (selective androgen receptor modulator) is currently being studied for various potential indications. The Company's most advanced product utilizing its CTP technology, a once-weekly human growth hormone for injection, successfully met its primary endpoint and key secondary endpoints in a Phase 3 study and is partnered with Pfizer. OPKO also has research, development, production and distribution facilities abroad.

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, our capacity for testing and expected turnaround time, our ability to expand our capacity to be able to process up to 400,000 antibody tests per day, our product development efforts and the expected benefits of our products, whether our products in development will be commercialized, the possibility of unfavorable new clinical data and 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 the two Rayaldee studies or our other ongoing and future clinical trials will be successfully enrolled or completed on a timely basis or at all and whether the data from any of our trials will support submission or approval, validation and/or reimbursement for our products, whether RAYALDEE prescriptions will continue to increase, expectations regarding timing for commencing and concluding our clinical trials and releasing data, the timing of our regulatory submissions, including for somatrogon, our ability to market and sell any of our products in development, and expectations about developing RAYALDEE for dialysis patients, 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 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, the 4Kscore, 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 being studied or for other indications, 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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OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets (Unaudited)
(in millions)

	March 31, 2020	As of December 31, 2019
Assets:		
Cash, cash equivalents and marketable securities	$ 34.5	$ 85.5
Other current assets	239.9	238.5
Total Current Assets	274.4	324.0
In-process Research and Development and Goodwill	1,259.8	1,262.1
Other assets	698.3	723.2
Total Assets	$2,232.5	$ 2,309.3
Liabilities and Equity:		
Current liabilities	$ 245.1	$ 249.1
Convertible Notes	213.8	211.2
Deferred tax liabilities, net	118.6	118.7
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	106.4	115.5
Total Liabilities	683.9	694.5
Equity	1,548.6	1,614.8
Total Liabilities and Equity	$2,232.5	$ 2,309.3

OPKO Health, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations (Unaudited)
(in millions, except share and per share data)

	For the three months ended March 31,	
	2020	2019
Revenues		
Revenue from services	$ 170.8	$ 178.9
Revenue from products	31.1	25.3
Revenue from transfer of intellectual property	9.6	18.3
Total revenues	211.5	222.5
Costs and expenses		
Cost of revenues	140.3	144.0
Selling, general and administrative	76.1	95.2
Research and development	21.8	36.5
Contingent consideration	(0.9)	4.8
Amortization of intangible assets	14.9	16.6
Asset impairment charges	0.0	0.7
Total Costs and expenses	252.2	297.8
Operating loss	(40.7)	(75.3)
Other income and (expense), net	(17.1)	(2.8)
Loss before income taxes and investment losses	(57.8)	(78.1)
Income tax provision	(1.2)	(0.8)
Loss before investment losses	(59.0)	(78.9)
Loss from investments in investees	(0.1)	(1.9)
Net loss	$ (59.1)	$ (80.8)
Loss per share, basic and diluted	$ (0.09)	$ (0.14)
Weighted average common shares outstanding, basic and diluted	640,578,794	586,344,207

Source: OPKO Health, Inc.