July 30, 2020

OPKO Health Reports 2020 Second Quarter Business Highlights and Financial Results

Conference call begins at 4:45 p.m. Eastern time today

MIAMI , July 30, 2020 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended June 30, 2020.

Second Quarter Business Highlights

- **BioReference Laboratories increased COVID-19 testing nationwide:** During the second quarter, BioReference Laboratories (BRL) announced numerous partnerships and testing agreements with states, cities, professional sports associations and healthcare organizations, including the New York State Department of Health, New York City Health and Hospital Corporation and MagnaCare. Further, BRL provided testing services for more than 500 drive-thru and retail testing sites around the country. In July 2020, the Company announced that the Centers for Disease Control and Prevention (CDC) awarded BRL an Indefinite Delivery Indefinite Quantity contract to provide Commercial Surge Capacity Testing for COVID-19, under which BRL will perform antibody testing to determine COVID-19 seroprevalence and other testing with key demographic data for the next four months.

  BRL processed approximately 2.2 million COVID-19 molecular tests during the second quarter and currently has a capacity of more than 50,000 daily. Since late April, when BRL began offering COVID-19 serology testing to measure SARS-CoV-2 specific antibody levels, it has performed approximately 331,600 tests with a significantly greater capacity.

- **Successful 4Kscore® Medicare appeal for tests performed during 2019:** As previously announced, Novitas Solutions issued its final Local Coverage Determination for Medicare payments for the 4Kscore test with defined coverage criteria, effective December 30, 2019. The Company received a favorable Medicare appeal decision from Novitas for previously denied Medicare claims for 4Kscore tests performed in 2019. The COVID-19 pandemic impacted utilization of 4Kscore during the second quarter as many urology practices were either closed or operating at reduced capacity. More than 8,400 tests were performed during the quarter despite fewer patient visits and access to physicians. The volume of 4Kscore tests has been increasing in recent weeks with the gradual re-opening of the economy and patients resuming visits to their physicians.

- **Positive somatrogon topline results reported from Japan pediatric Phase 3 efficacy and safety study:** In June, OPKO announced that its Japan Phase 3 clinical

trial met its primary and secondary objectives, and demonstrated that the efficacy and safety of somatrogon administered once-weekly were comparable to GENOTROPIN® (somatropin) administered once-daily as measured by annual height velocity after 12 months of treatment in treatment-naïve Japanese pre-pubertal children with growth hormone deficiency. The findings were consistent with the results previously reported from the Company's global Phase 3 study.

- **Somatrogon abstracts presented at Endocrine Society's ENDO Online 2020:** Two abstracts regarding the somatrogon global Phase 3 trial were presented at ENDO Online 2020 by Cheri Deal, PhD, MD, FRCPC, Chief of Pediatric Endocrinology and Diabetes at CHU Sainte-Justine and Tenured Professor of Pediatrics at Université de Montréal, the Principal Investigator of the study. The two abstracts, "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)," were published online in the April-May supplemental issue of the *Journal of Endocrine Society*. Dr. Deal's presentation included data demonstrating that somatrogon administered once weekly, met its endpoint of non-inferiority to daily GENOTROPIN® (somatropin) in height velocity and height standard deviation score (SDS). In addition, Dr. Deal presented new data demonstrating that over 95% of patients had mean IGF-1 SDS levels within the normal range. IGF-1 SDS is a biomarker to evaluate efficacy and safety of human growth hormone replacement therapy.

- **Somatrogon global regulatory submissions:** The somatrogon Biologics License Application (BLA) submission in the U.S. is anticipated to occur in the fall of 2020. In Europe, the Company's open-label study demonstrating benefit and compliance with reduced treatment burden will be completed this quarter, enabling Pfizer to submit for regulatory approval in Europe early next year. The somatrogon regulatory submission in Japan is expected during the first half of 2021.

- **RAYALDEE total prescriptions reported by IQVIA increased 45% in the second quarter of 2020 compared with the second quarter of 2019:** Total prescriptions for the three months ended June 30, 2020 increased to approximately 18,400, compared to approximately 12,700 for the second quarter of 2019. During the second quarter of 2020, demand for RAYALDEE remained strong but prescription growth was impacted by limited access to physician offices by both patients and OPKO's sales representatives.

- **RAYALDEE authorized for Phase 2 clinical trial in patients with mild-to-moderate COVID-19:** On June 1, 2020, OPKO announced that the U.S. Food and Drug Administration (FDA) authorized the Company to undertake a Phase 2 trial with RAYALDEE as a treatment for patients with mild-to moderate COVID-19. The trial, entitled "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 (REsCue)," will enroll approximately 160 subjects, including many with stage 3 or 4 chronic kidney disease. The REsCue trial will have four weeks of treatment with RAYALDEE or placebo and two weeks of follow-up. There are two primary efficacy endpoints: time to resolution of COVID-19

symptoms; and consistent attainment of serum total 25-hydroxyvitamin D levels greater than or equal to 50 ng/mL during the last week of treatment. The trial is expected to begin enrolling subjects later this quarter.

Second Quarter Financial Results

- Consolidated revenues for the second quarter of 2020 were $301.2 million compared with $226.4 million for the comparable period of 2019. Net income for the second quarter of 2020 was $33.7 million, or $0.05 per diluted share, compared with a net loss of $59.8 million, or $0.10 per share, for the comparable period of 2019.

- **Diagnostics:** Revenue from services in the second quarter of 2020 was $251.0 million compared with $178.5 million in the prior-year period, primarily due to increased COVID-19 testing volumes, partially offset by reduced clinical and genomic test volumes due to physician office closures and stay-at-home orders relating to the pandemic. In addition, the Company received a $6.2 million grant from the CARES Act in the second quarter. Total costs and expenses were $216.2 million in the second quarter of 2020 compared with $206.5 million in the second quarter of 2019. Operating income was $40.9 million in the second quarter of 2020 compared with an operating loss of $28.0 million in the prior-year period, an improvement of $68.9 million.

- **Pharmaceuticals:** Revenue from products in the second quarter of 2020 was $29.3 million compared with $28.7 million in in the second quarter of 2019, with the increase primarily attributable to higher sales of RAYALDEE of $8.6 million in the second quarter of 2020 compared with $5.7 million in the prior-year period. Revenue from licensing and intellectual property was $14.7 million in the second quarter of 2020 compared with $19.2 million in the second 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 costs and expenses were $50.0 million in the second quarter of 2020 compared with $56.5 million in the prior-year period, with the decline primarily attributable to lower research and development expenses due to the completion of the pediatric Phase 3 trial. The operating loss was $6.0 million in the second quarter of 2020 compared with $8.6 million in the second quarter of 2019.

- **Cash and equivalents:** Cash, cash equivalents and marketable securities were $21.6 million as of June 30, 2020. In addition, the Company has availability under its line of credit with JP Morgan of $15.3 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 and discuss results in greater detail during a conference call and live audio webcast at 4:45 p.m. Eastern time today, July 30, 2020. 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 6946539. 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 2Q20 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 2Q20 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 6946539.

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 and expected turnaround time, 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, whether our turnaround time be extended or our performance quality decline, 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 we will be able to make the expected regulatory submissions for somatrogon during the expected time periods or at all, whether the applicable regulatory agencies will accept our submissions, whether the Rayaldee study for patients with mild-to moderate COVID-19 will initiate or begin enrolling subjects later this quarter or be completed at all, whether 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, our ability to market and sell any of our products in development, whether the volume of 4Kscore tests will increase 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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—Tables to Follow—

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

	As of	
	June 30, 2020	December 31, 2019
Assets:		
Cash and cash equivalents	$ 21.6	$ 85.5
Other current assets	338.4	238.5
Total Current Assets	360.0	324.0
In-process Research and Development and Goodwill	1,261.8	1,262.1
Other assets	701.9	723.2

Total Assets	$ 2,323.7	$ 2,309.3
Liabilities and Equity:		
Current liabilities	$ 279.5	$ 249.1
Convertible Notes	216.5	211.2
Deferred tax liabilities, net	119.0	118.7
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	120.4	115.5
Total Liabilities	735.4	694.5
Total Equity	1,588.3	1,614.8
Total Liabilities and Equity	$ 2,323.7	$ 2,309.3

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,	
	2020	2019	2020	2019
Revenues				
Revenue from services	$ 251.0	$ 178.5	$ 421.8	$ 357.3
Revenue from products	29.3	28.7	60.4	54.0
Revenue from transfer of intellectual property	20.9	19.2	30.5	37.5
Total revenues	301.2	226.4	512.7	448.8
Costs and expenses				
Cost of revenues	162.7	144.2	302.9	288.3
Selling, general and administrative	77.7	88.5	153.8	183.6
Research and development	17.6	28.3	39.4	64.8
Contingent consideration	1.1	(3.8)	0.3	1.0
Amortization of intangible assets	14.9	16.4	29.9	33.0
Asset impairment charges	0.0	0.0	0.0	0.7
Total Costs and expenses	274.0	273.6	526.3	571.4
Operating income (loss)	27.2	(47.2)	(13.6)	(122.6)
Other income and (expense), net	12.7	(11.2)	(4.3)	(14.0)

Income (loss) before income taxes and investment losses	39.9	(58.4)	(17.9)	(136.6)
Income tax provision	(6.0)	(1.1)	(7.2)	(1.9)
Net income (loss) before investment losses	33.9	(59.5)	(25.1)	(138.5)
Loss from investments in investees	(0.2)	(0.3)	(0.3)	(2.1)
Net income (loss)	$ 33.7	$ (59.8)	$ (25.4)	$ (140.6)
Income (loss) per share, basic and diluted	$ 0.05	$ (0.10)	$ (0.04)	$ (0.24)
Weighted average common shares outstanding, basic and diluted	640,578,794	586,351,045	640,578,794	586,347,645

Source: OPKO Health, Inc.