October 29, 2020

OPKO Health Reports 2020 Third Quarter Business Highlights and Financial Results

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

MIAMI, Oct. 29, 2020 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended September 30, 2020.

Third Quarter Business Highlights

- **BioReference Laboratories' COVID-19 PCR testing volume increased 61% over the second quarter of 2020.** During the third quarter, BioReference Laboratories (BRL) processed approximately 3.5 million COVID-19 PCR tests and currently has the capacity to process more than 70,000 tests per day. In addition, the laboratory performed approximately 300,000 COVID-19 serology tests to measure SARS-CoV-2 specific antibody levels with the capacity to process more than 400,000 serology tests per day.

  BRL announced additional COVID-19 testing agreements for New York City schools through a continued collaboration with New York City, the Department of Health and Hospital Corporation, the Test & Trace Corp. and the Department of Education. Through these agreements, BRL is testing students, teachers and staff in nearly 1,000 public schools across New York. BRL continues to provide COVID-19 testing services to numerous states, cities, professional sports associations and healthcare organizations, as well as to over 600 drive-thru and retail pharmacy testing sites nationwide.

- **Positive somatrogon Phase 3 topline results reported from crossover pediatric study.** A global Phase 3 study of somatrogon administered once-weekly to children 3 to <18 years of age with growth hormone deficiency met its primary objective of improved treatment burden compared to daily injection of Genotropin® as measured by the mean overall Life Interference total score after 12 weeks of treatment.

- **Somatrogon global regulatory submissions:** Pfizer remains on schedule with respect to its regulatory submissions for marketing approval of somatrogon for children with growth hormone deficiency in the U.S. in the fourth quarter of this year and in Europe and Japan in the first half of 2021.

- **RAYALDEE has received marketing authorizations in seven European countries.** Vifor Fresenius Medical Care Renal Pharma, OPKO's commercial partner for RAYALDEE in Europe, has received marketing authorizations for RAYALDEE for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency in the United Kingdom, Germany, Sweden, Norway, Ireland, Denmark and the Netherlands. Market authorizations from Spain,

Portugal, Italy and Switzerland are still pending. Market launch of RAYALDEE in authorized countries is expected to begin next year.

- **RAYALDEE total prescriptions reported by IQVIA increased 13% compared with the third quarter of 2019.** Total prescriptions for the three months ended September 30, 2020 increased to approximately 16,700, compared with approximately 14,800 for the third quarter of 2019. During the third quarter of 2020, demand for RAYALDEE was impacted by challenges in onboarding new patients because of the COVID-19 pandemic.

- **RAYALDEE Phase 2 clinical trial initiated in patients with mild-to-moderate COVID-19.** OPKO initiated a Phase 2 clinical trial with RAYALDEE as a treatment for mild to moderate COVID-19. The trial, "A Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Safety and Efficacy of **R**AYALDEE (calcifediol) **E**xtended-relea**s**e **C**aps**u**l**e**s to Treat Symptomatic Patients Infected with SARS-CoV-2 (**REsCue**)," is expected to enroll approximately 160 subjects, many with stage 3 or 4 CKD who are at increased risk for developing more severe illness. The REsCue trial will randomize COVID-19 outpatients in a 1:1 ratio to 4 weeks of treatment with RAYALDEE or placebo, and 2 weeks of follow-up. Primary efficacy endpoints are raising and maintaining serum total 25-hydroxyvitamin D within the range of 50-100 ng/mL and time to resolution of COVID-19 symptoms. Numerous independent studies report a correlation between vitamin D status and COVID-19 risk and severity.

- **GeneDx enters into agreement with Pediatrix Medical Group to offer neonatal genomic services.** In August 2020, BRL's GeneDx subsidiary announced an agreement with Pediatrix Medical Group, the nation's leading provider of maternal-fetal, and pediatric medical and surgical subspecialty physician services, to offer state-of-the-art, next-generation genomic sequencing to support clinical diagnosis in neonatal intensive care units staffed by neonatologists affiliated with Pediatrix. The sequencing is designed to enhance diagnostic capabilities in order to lessen the impact of disease and to facilitate the development of novel precision medicine solutions for pediatric care.

- **BioReference Laboratories launches best-in-class next-generation sequencing assay.** In September 2020, BRL, along with its GenPath specialty oncology division, announced the launch of OnkoSight Advanced™, a next-generation sequencing (NGS) assay that enables revolutionary deoxyribonucleic acid (DNA) mutational profiling of tumor samples. OnkoSight Advanced NGS testing provides targeted gene content that is aligned with the latest National Comprehensive Cancer Network and World Health Organization guideline recommendations to provide critical insight into many of the most common cancer types. Each OnkoSight Advanced panel includes key biomarkers – Tumor Mutation Burden and Tumor-Only Microsatellite, critical when profiling advanced-stage malignancies to guide potential immunotherapy.

Third Quarter Financial Results

- Net income for the third quarter of 2020 was $23.7 million, or $0.04 per diluted share, compared with a net loss of $62.0 million, or $0.11 per share, for the comparable

period of 2019. Consolidated revenues for the third quarter of 2020 were $428.1 million compared with $228.8 million for the comparable period of 2019.

- **Diagnostics:** Revenue from services in the third quarter of 2020 was $392.5 million compared with $181.1 million in the prior-year period, primarily due to increased COVID-19 testing volumes, partially offset by reduced clinical and genomic test volumes related to the pandemic and lower clinical and genomic test reimbursement. In addition, the Company received a $10.0 million grant from the CARES Act in the third quarter. Total costs and expenses were $346.4 million in the third quarter of 2020 compared with $197.5 million in the third quarter of 2019. This increase represents higher volumes from both COVID-19 testing and from the core testing business. Operating income was $46.2 million in the third quarter of 2020 compared with an operating loss of $16.4 million in the prior-year period, an improvement of $62.5 million.
- **Pharmaceuticals:** Revenue from products in the third quarter of 2020 was $28.7 million compared with $26.2 million in the third quarter of 2019, with the increase primarily attributable to higher sales at OPKO Chile and an increase in net sales of RAYALDEE to $8.1 million in the third quarter of 2020 compared with $7.4 million in the prior-year period. Revenue from transfer of intellectual property was $6.8 million in the third quarter of 2020 compared with $20.7 million in the third quarter of 2019 reflecting a decrease in the amortization of payments received from Pfizer with respect to somatrogon. Total costs and expenses were $49.9 million in the third quarter of 2020 compared with $61.1 million in the prior-year period, with the decline primarily attributable to lower research and development expenses due to the completion of the pediatric human growth hormone Phase 3 trial. The operating loss was $14.4 million in the third quarter of 2020 compared with $14.2 million in the third quarter of 2019.
- **Cash and equivalents:** Cash, cash equivalents and marketable securities were $36.3 million as of September 30, 2020, which reflects the repayment, in full, of its line of credit with JP Morgan utilizing cash generated from operations of $63.0 million during the three months ended September 30, 2020. In addition, the Company has availability under its 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 and discuss third quarter financial results in greater detail during a conference call and live audio webcast at 4:30 p.m. Eastern time today, October 29, 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 4542807. 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 3Q20 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 3Q20 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 4542807.

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, 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, 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
(in millions)

	As of September 30, 2020	As of December 31, 2019
Assets:		
Cash, cash equivalents and marketable securities	$ 36.3	$ 85.5
Other current assets	391.8	238.5
Total Current Assets	428.1	324.0
In-process Research and Development and Goodwill	1,266.0	1,262.1
Other assets	677.2	723.2
Total Assets	$ 2,371.3	$ 2,309.3
Liabilities and Equity:		
Current liabilities	$ 335.9	$ 249.1
Convertible Notes	219.2	211.2
Deferred tax liabilities, net	119.2	118.7
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	73.2	115.5

Total Liabilities	747.5	694.5
Equity	1,623.8	1,614.8
Total Liabilities and Equity	$ 2,371.3	$ 2,309.3

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2019	2020	2019
Revenues				
Revenue from services	$ 382.5	$ 181.1	$ 804.3	$ 538.5
Revenue from products	28.7	26.2	89.1	80.1
Revenue from transfer of intellectual property	16.9	21.5	47.3	59.0
Total revenues	428.1	228.8	940.7	677.6
Costs and expenses				
Cost of revenues	272.8	141.9	575.7	430.2
Selling, general and administrative	99.9	80.6	253.7	264.2
Research and development	18.5	30.0	57.9	94.8
Contingent consideration	1.1	(1.1)	1.3	(0.1)
Amortization of intangible assets	13.9	16.4	43.8	49.4
Asset impairment charges	0.0	0.0	0.0	0.7
Total Costs and expenses	406.2	267.8	932.4	839.2
Operating income (loss)	21.9	(39.0)	8.3	(161.6)
Other income and (expense), net	(1.3)	(20.9)	(5.6)	(35.0)
Loss before income taxes and investment losses	20.6	(59.9)	2.7	(196.6)
Income tax benefit (provision)	3.2	(1.8)	(4.0)	(3.6)
Loss before investment losses	23.8	(61.7)	(1.3)	(200.2)
Loss from investments in investees	(0.1)	(0.3)	(0.4)	(2.4)

Net income (loss)	$ 23.7	$ (62.0)	$ (1.7)	$ (202.6)
Income (loss) per share, basic and diluted	$ 0.04	$ (0.11)	$ (0.00)	$ (0.35)
Weighted average common shares outstanding, basic and diluted	640,699,982	586,351,045	640,619,485	586,348,791

Source: OPKO Health, Inc.