August 7, 2019

OPKO Health Reports 2019 Second Quarter Business Highlights and Financial Results

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

MIAMI, Aug. 07, 2019 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended June 30, 2019.

Business Highlights

- **RAYALDEE total prescriptions reported by IQVIA increased 92% in 2Q 2019 compared with 2Q 2018:** Total prescriptions for the three months ended June 30, 2019 increased to approximately 12,700, compared with approximately 6,600 (as adjusted by IQVIA) during the comparable period of 2018.

- ***4Kscore*® receives a new proposed local coverage determination from Novitas Solutions and utilization remained strong during 2Q 2019 with approximately 18,800 tests performed**: Novitas Solutions, Inc. has issued a new proposed local coverage determination (LCD) for the *4Kscore*® test, with defined coverage criteria. Under the LCD, Medicare proposes reimbursing the test for patients who meet the defined criteria. The LCD is subject to a comment period ending August 11, 2019.

- **OPKO Plans to Refile *4Kscore* De Novo Submission as PreMarket Approval Application (PMA):** The Company plans to refile its *4Kscore*® test submission as a PMA application based on FDA feedback to the Company's de novo request for this test, which has now been withdrawn. The FDA did not request any additional clinical data or any additional clinical trials in connection with a PMA submission. The Company currently anticipates submitting the PMA application in August 2019.

- **BioReference Laboratories formed a strategic collaboration with SOMOS, New York City's largest multi-cultural physician led network:** BioReference is now SOMOS' preferred provider of diagnostic testing and will assist with data analytics for its patients. This collaboration is designed to streamline patient care and offer communication efficiencies between BioReference and the SOMOS network. SOMOS will leverage its relationship with BioReference to improve patient outcomes among its participants while decreasing the overall cost of care.

- **BioReference and its GeneDx subsidiary expand access to commercially insured lives:** BioReference and GeneDx have been selected for inclusion in the UnitedHealthcare Preferred Lab Network beginning July 1, 2019. This was a comprehensive process that evaluated service standards, turnaround time, quality and

accreditation. More than 300 laboratories were invited to apply; only 100 submitted applications due to the complexity of the requirements, and BioReference and GeneDx, along with five other laboratories, earned a place in the Preferred Lab Network. In addition, effective April 1, 2019, BioReference and GeneDx are now in-network providers with Humana, which provides access to 11 million additional lives.

- **Pharmaceutical pipeline continues to progress.** Last patient, last visit for our pivotal global Phase 3 clinical trial for hGH-CTP in growth hormone deficient children is expected this month. Topline data from the trial are expected to be announced by the end of 2019. The ongoing open-label phase 2 trial for RAYALDEE in hemodialysis patients is progressing well and initial data are expected by the end of 2019.

- **RAYALDEE Marketing Authorization Application filed by Vifor Fresenius in Switzerland.** With several Marketing Authorization Applications already accepted and under review in other European countries, Vifor expects to receive approvals in several European countries to market RAYALDEE for the treatment of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease during 2020.

Financial Highlights

- Consolidated revenues for the second quarter of 2019 were $226.4 million, compared with $263.7 million for the comparable period of 2018. During the 2019 quarter, revenue from services was $178.5 million, revenue from products was $28.7 million, including RAYALDEE net revenue of $5.7 million, and revenue from licensing and intellectual property was $19.2 million.

- Operating expenses for the second quarter of 2019 were $273.6 million. This included continued investment in the company's pharmaceutical pipeline, with R&D expense of $28.3 million, principally for pediatric trials with the hGH-CTP long-acting human growth hormone product.

- The net loss for the three months ended June 30, 2019 was $59.8 million, compared with a net loss of $6.2 million for the comparable period of 2018 principally as a result in the decrease in revenue from services as wells as the comparable period of 2018 including a $15.4 million reversal of contingent consideration expense compared to $3.8 million for the 2019 period.

- Cash, cash equivalents and marketable securities were $111.1 million as of June 30, 2019, which includes the repayment of a line of credit during the second quarter of approximately $40 million.

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. The conference call dial-in and webcast information is as follows:

DOMESTIC DIAL-IN: 866-634-2258

INTERNATIONAL DIAL-IN:	330-863-3454
PASSCODE:	7984069
WEBCAST:	OPKO 2Q19 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 7984069. The replay can be accessed for a period of time on OPKO's website at OPKO 2Q19 Results Conference Call.

About OPKO Health, Inc.

OPKO Health is a diversified healthcare company. In diagnostics, its BioReference Laboratories is the nation's third largest clinical laboratory; GeneDx is a rapidly growing genetic testing business; the *4Kscore*® prostate cancer test is used to confirm an elevated PSA 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 and testosterone as the most advanced test in development. In our pharmaceutical pipeline, RAYALDEE is our first pharmaceutical product to be marketed. OPK88003, a once-weekly oxyntomodulin for type 2 diabetes and obesity recently 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, is in Phase 3 trials and is partnered with Pfizer. OPKO also has research, development, production and distribution facilities abroad. More information is available at 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, our product development efforts and the expected benefits of our products, including whether our 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 about reimbursement for the 4Kscore test and the recent Novitas LCD proposing certain coverage criteria for the test, statements regarding our planned PMA submission for FDA approval of the 4Kscore test and the timeline for the submission, whether the relationship with SOMOS will improve patient outcomes among its participants while decreasing the overall cost of care, whether Vifor will receive approvals in several European countries to market RAYALDEE for the treatment of secondary hyperparathyroidism (SHPT) in adult non-dialysis patients with chronic kidney disease during 2020, expectations regarding the topline data from the hGH-CTP and timing for the announcement, the expected timing of commencing and concluding our clinical trials, expected enrollment in clinical trials, the timing of our regulatory

submissions, 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 in our other filings with the Securities and Exchange Commission, as well as the continuation and success of our relationship with Pfizer and our other partners, integration challenges for Bio-Reference, and other acquired businesses, 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 the 4Kscore, RAYALDEE, hGH-CTP, 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)

	As of

	June 30, 2019	December 31, 2018
Assets:		
Cash, cash equivalents and marketable securities	$ 111.1	$ 96.5
Other current assets	233.1	221.2
Total Current Assets	344.2	317.7
In-process Research and Development and Goodwill	1,335.4	1,335.8
Other assets	776.6	797.6
Total Assets	$ 2,456.2	$ 2,451.1
Liabilities and Equity:		
Current liabilities	$ 283.4	$ 288.3
Convertible Notes	206.2	57.3
Deferred tax liabilities, net	113.3	115.2
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	144.4	199.0
Total Liabilities	747.3	659.8
Equity	1,708.9	1,791.3
Total Liabilities and Equity	$ 2,456.2	$ 2,451.1

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

	For the three months ended June 30,		For the six months ended June 30,	
	2019	2018	2019	2018
Revenues				
Revenue from services	$ 178.5	$ 216.1	$ 357.3	$ 427.4
Revenue from products	28.7	28.5	54.0	56.4
Revenue from transfer of intellectual property	19.2	19.1	37.5	34.8
Total revenues	226.4	263.7	448.8	518.6
Costs and expenses				
Cost of revenues	144.2	150.1	288.3	304.1
Selling, general and administrative	88.5	87.7	183.6	179.2
Research and development	28.3	29.2	64.8	62.1
Contingent consideration	(3.8)	(15.4)	1.0	(13.6)
Amortization of intangible assets	16.4	17.2	33.0	34.5

Asset impairment charges	0.0	0.0	0.7	0.0
Total Costs and expenses	273.6	268.8	571.4	566.3
Operating loss	(47.2)	(5.1)	(122.6)	(47.7)
Other income and (expense), net	(11.2)	8.1	(14.0)	9.2
Income (loss) before income taxes and investment losses	(58.4)	3.0	(136.6)	(38.5)
Income tax provision	(1.1)	(2.0)	(1.9)	(1.1)
Income (loss) before investment losses	(59.5)	1.0	(138.5)	(39.6)
Loss from investments in investees	(0.3)	(7.2)	(2.1)	(9.7)
Net loss	$ (59.8)	$ (6.2)	$ (140.6)	$ (49.3)
Loss per share, basic and diluted	$ (0.10)	$ (0.01)	$ (0.24)	$ (0.09)
Weighted average common shares outstanding, basic and diluted	586,351,045	559,541,253	586,347,645	559,507,732

Source: OPKO Health, Inc.