November 5, 2019

OPKO Health Reports 2019 Third Quarter Business Highlights and Financial Results

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

MIAMI, Nov. 05, 2019 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** reports business highlights and financial results for the three months ended September 30, 2019.

Business Highlights

- **Somatrogon meets primary and key secondary endpoints in global Phase 3 trial:** On October 21, OPKO and Pfizer announced that the global Phase 3 trial evaluating somatrogon dosed once weekly in pre-pubertal children with growth hormone deficiency met its primary endpoint of non-inferiority to GENOTROPIN® (somatropin) injected daily, as measured by annual height velocity at 12 months. Key secondary endpoints including change in height standard deviation scores at six and 12 months, and change in height velocity at six months, were also higher in the somatrogon group.

- **RAYALDEE total prescriptions reported by IQVIA increased 83% in 3Q 2019 compared with 3Q 2018:** Total prescriptions for the three months ended September 30, 2019 increased to approximately 14,600, compared with approximately 8,000 during the comparable period of 2018.

- **BioReference Laboratories continued to establish new alliances:** During the third quarter BioReference Laboratories formed a strategic collaboration with SOMOS, New York City's largest multicultural physician-led network, and was named the preferred provider for the IPA Association of America in laboratory services and, also, to assist with data analytics for member patients. These wins build upon successes earlier in the year, including selection as part of the preferred lab network with UnitedHealthcare and new in-network status with Humana.

- ***JAMA Oncology* published data from a GeneDx study addressing cancer risk estimates for gastric cancers in patients with gene variants of CDH1:** Results indicated that the lifetime risk of gastric cancer for individuals with pathogenic variants in the *CDH1* gene is significantly lower than previously described; the lifetime risk of gastric cancer associated with pathogenic *CDH1* variants was 42% in men and 33% in women, compared to published estimates of 40-70% in men and 56-83% in women. These results allow for a more personalized risk assessment and better informed decision making for patients at risk for hereditary gastric cancer.

- **Pharmaceutical pipeline continues to advance:**
    - The open-label Phase 2 trial for RAYALDEE in hemodialysis patients is progressing and initial data are expected in 1Q 2020.
    - The somatrogon registration study in Japanese pediatric GHD patients to assess

pharmacokinetics and compare efficacy of weekly somatrogon to daily GENOTROPIN is on track for data readout in 2020.

Financial Highlights

- Consolidated revenues for the third quarter of 2019 were $228.8 million, compared with $249.8 million for the comparable period of 2018. Revenue from services in the third quarter was $181.1 million, revenue from products was $26.2 million, including RAYALDEE net revenue of $7.4 million, and revenue from licensing and intellectual property was $21.5 million.

- Operating expenses for the third quarter of 2019 were $267.8 million. This included R&D expenses of $30.0 million, principally for the completion of the pediatric Phase 3 study for our long-acting human growth hormone product and other ongoing clinical trials.

- Accounting rules require marking strategic investments to market at the end of each quarter, which had a negative impact on the net loss for the third quarter of 2019 of $13.6 million, or $0.02 per share. The net loss for the third quarter of 2019, after giving effect to the decrease in market value of our strategic investments, was $62.0 million, or $0.11 per share, compared with a net loss of $27.7 million, or $0.05 per share, for the comparable period of 2018. The 2018 period's net loss benefited from an $11.6 million income tax benefit primarily resulting from a change in state income tax rates during that period.

- Cash, cash equivalents and marketable securities were $64.7 million as of September 30, 2019. Subsequent to the close of the third quarter, the Company raised gross proceeds of $75.0 million from an underwritten public offering of common stock.

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, Tuesday, November 5, 2019. The conference call dial-in and webcast information is as follows:

DOMESTIC DIAL-IN:	866-634-2258
INTERNATIONAL DIAL-IN:	330-863-3454
PASSCODE:	7270239
WEBCAST:	OPKO 3Q19 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 7270239. The replay can be accessed for a period of time on OPKO's website at OPKO 3Q19 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, 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 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 regarding timing for commencing and concluding our clinical trials and releasing data, 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 under the heading "Risk Factors" 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, 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)

	As of September 30, 2019	As of December 31, 2018
Assets:		
Cash, cash equivalents and marketable securities	$ 64.7	$ 96.5
Other current assets	228.1	221.2
Total Current Assets	292.8	317.7
In-process Research and Development and Goodwill	1,330.8	1,335.8
Other assets	745.9	797.6
Total Assets	$ 2,369.5	$ 2,451.1
Liabilities and Equity:		
Current liabilities	$ 270.1	$ 288.3
Convertible Notes	208.7	57.3
Deferred tax liabilities[, net]	113.5	115.2
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	135.3	199.0
Total Liabilities	727.6	659.8
Equity	1,641.9	1,791.3

Total Liabilities and Equity	$ 2,369.5	$ 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 September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Revenues				
Revenue from services	$ 181.1	$ 202.8	$ 538.5	$ 630.2
Revenue from products	26.2	25.4	80.1	81.8
Revenue from transfer of intellectual property	21.5	21.6	59.0	56.4
Total revenues	228.8	249.8	677.6	768.4
Costs and expenses				
Cost of revenues	141.9	150.9	430.2	455.1
Selling, general and administrative	80.6	84.1	264.2	263.2
Research and development	30.0	30.2	94.8	92.3
Contingent consideration	(1.1)	1.2	(0.1)	(12.4)
Amortization of intangible assets	16.4	16.9	49.4	51.4
Asset impairment charges	0.0	0.0	0.7	0.0
Total Costs and expenses	267.8	283.3	839.2	849.6
Operating loss	(39.0)	(33.5)	(161.6)	(81.2)
Other income and (expense), net	(20.9)	(3.9)	(35.0)	5.4
Loss before income taxes and investment losses	(59.9)	(37.4)	(196.6)	(75.8)
Income tax benefit (provision)	(1.8)	11.6	(3.6)	10.4
Loss before investment losses	(61.7)	(25.8)	(200.2)	(65.4)
Loss from investments in investees	(0.3)	(1.9)	(2.4)	(11.6)
Net loss	$ (62.0)	$ (27.7)	$ (202.6)	$ (77.0)
Loss per share, basic and diluted	$ (0.11)	$ (0.05)	$ (0.35)	$ (0.14)
Weighted average common shares outstanding, basic and diluted	586,351,045	559,786,382	586,348,791	559,601,097

Source: OPKO Health, Inc.