OPKO Health Reports 2019 Fourth Quarter Business Highlights and Financial Results

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

MIAMI (February 26, 2020) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three months ended December 31, 2019.

Business Highlights

- **Successful Phase 3 results for Somatrogon, an investigational long-acting human growth hormone to treat children with growth hormone deficiency:** On October 21, 2019, OPKO and Pfizer announced the global Phase 3 trial evaluating somatrogon dosed once-weekly in pre-pubertal children with growth hormone deficiency (GHD) met its primary endpoint of non-inferiority to daily GENOTROPIN® (somatropin) for injection, as measured by annual height velocity at 12 months.

- **Somatrogon Phase 3 clinical trial data to be presented at ENDO on March 28, 2020:** Two oral presentations will be delivered at the Endocrine Society's ENDO 2020 meeting, to be held March 28-31, 2020:
    - "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)"

- **Somatrogon regulatory submissions:** Regulatory submission in the U.S. is anticipated in 2H 2020: Europe is expected to follow upon 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 pediatric GHD patients in Japan is on track for completion in the first quarter of 2020.

- **RAYALDEE total prescriptions reported by IQVIA increased 89% in 4Q 2019 compared with 4Q 2018:** Total prescriptions for the three months ended December 31, 2019 increased to more than 17,700, compared with approximately 9,400 during the comparable period of 2018.

- **RAYALDEE Phase 2 trial:** Interim readout is expected in 1Q 2020 of the open-label Phase 2 trial with RAYALDEE in adults with vitamin D insufficiency and stage 5 chronic kidney disease (CKD) requiring dialysis.

- ***4Kscore*® test receives final Local Coverage Determination for Medicare payments:** On November 15, 2019, OPKO announced that Novitas Solutions issued its final Local Coverage Determination for Medicare payments for the *4Kscore* test with defined coverage criteria, effective December 30, 2019. *4Kscore* utilization remained strong with nearly 18,000 tests performed during the fourth quarter of 2019. A premarket approval submission for the *4Kscore* test was accepted for review by the U.S. Food and Drug Administration (FDA) in December 2019.

Financial Highlights

- Consolidated revenues for the fourth quarter of 2019 increased to $224.3 million compared with $221.9 million for the comparable period of 2018. Revenue from services in the fourth quarter of 2019 was $177.9 million, revenue from products was $32.0 million including RAYALDEE net revenue of $12.6 million, and revenue from licensing and intellectual property was $14.4 million.

- Operating expenses for the fourth quarter of 2019 were $336.8 million compared with $311.9 million during the fourth quarter of 2018. Operating expenses during the three months ended December 31, 2019 included a non-cash impairment charge of $91.8 million for goodwill and intangible assets related to the acquisitions of Claros, CURNA and Transition Therapeutics, while the 2018 period included a $21.8 million non-cash impairment charge. Selling, general and administrative expenses decreased during the 2019 period by $16 million to $79.1 million, while research and development expenses decreased to $23.0 million from $33.3 million for the 2018 period, primarily due to the completion of the pediatric Phase 3 study for OPKO's long-acting human growth hormone product and other ongoing clinical trials.

- The net loss for the fourth quarter of 2019, which includes a non-cash impairment charge of $91.8 million, was $112.4 million, or $0.18 per share, compared with a net loss of $76.1 million, or $0.13 per share, for the comparable period of 2018. The 2018 reported net loss benefited from inclusion of an income tax benefit of $28.3 million whereas the 2019 period included an income tax expense of $3.4 million.

- Cash, cash equivalents and marketable securities were $85.5 million as of December 31, 2019. In the fourth quarter of 2019, the Company raised gross proceeds of $81.3 million from an underwritten public offering of common stock. On February 25, 2020, the Company entered into an unsecured credit facility providing $100 million of incremental capital on a non-dilutive basis. The credit facility is with Phillip Frost, MD, the Company's Chairman and CEO.

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, Wednesday, February 26, 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:	9678678
WEBCAST:	OPKO 4Q19 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 9678678. The replay can be accessed for a period of time on OPKO's website at OPKO 4Q19 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, 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 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 December 31, 2019	December 31, 2018
Assets:		
Cash, cash equivalents and marketable securities	$ 85.5	$ 96.5
Other current assets	238.5	221.2
Total Current Assets	324.0	317.7
In-process Research and Development and Goodwill	1,262.1	1,335.8
Other assets	723.2	797.6
Total Assets	$ 2,309.3	$ 2,451.1
Liabilities and Equity:		
Current liabilities	$ 249.1	$ 256.8
Convertible Notes	211.2	88.9
Deferred tax liabilities, net	118.7	115.2
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	115.5	198.9
Total Liabilities	694.5	659.8
Equity	1,614.8	1,791.3
Total Liabilities and Equity	$ 2,309.3	$ 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 December 31,		For the twelve months ended December 31,	
	2019	2018	2019	2018
Revenues				
Revenue from services	$ 177.9	$ 183.1	$ 716.4	$ 813.3
Revenue from products	32.0	25.4	112.2	107.1
Revenue from transfer of intellectual property	14.4	13.4	73.3	69.9
Total revenues	224.3	221.9	901.9	990.3
Costs and expenses				
Cost of revenues	142.3	149.6	572.5	604.6
Selling, general and administrative	79.1	95.1	343.3	358.4
Research and development	23.0	33.3	117.9	125.6
Contingent consideration	(14.8)	(4.4)	(14.9)	(16.8)
Amortization of intangible assets	15.4	16.5	64.8	67.9
Asset impairment charges	91.8	21.8	92.4	21.8
Total Costs and expenses	336.8	311.9	1,176.0	1,161.5
Operating loss	(112.5)	(90.0)	(274.1)	(171.2)
Other income and (expense), net	4.0	(11.4)	(30.8)	(6.0)
Loss before income taxes and investment losses	(108.5)	(101.4)	(304.9)	(177.2)
Income tax benefit (provision)	(3.4)	28.3	(7.1)	38.7
Loss before investment losses	(111.9)	(73.1)	(312.0)	(138.5)
Loss from investments in investees	(0.5)	(3.0)	(2.9)	(14.5)
Net loss	$ (112.4)	$ (76.1)	$ (314.9)	$ (153.0)
Loss per share, basic and diluted	$ (0.18)	$ (0.13)	$ (0.53)	$ (0.27)
Weighted average common shares outstanding, basic and diluted	622,474,281	573,655,844	595,454,394	563,143,663

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