OPKO Health Reports 2018 Fourth Quarter Business Highlights and Financial Results

Conference Call begins today at 4:30 p.m. Eastern Time

MIAMI (February 27, 2019) – OPKO Health, Inc. (NASDAQ: OPK) reports business highlights and financial results for the three months ended December 31, 2018.

Business Highlights

- **RAYALDEE total prescriptions reported by IQVIA increased 166% in 4Q 2018 compared with 4Q 2017**: Total prescriptions were approximately 9,300 during the fourth quarter of 2018. As of January 1, 2019, approximately 80% of prospective U.S. patients have access to RAYALDEE under their insurance plans. The Company continues to increase its commercial reach through expansion of its sales force.

- **Topline data from the global Phase 3 clinical trial for hGH-CTP in growth hormone deficient children is expected by the end of 2019; Enrollment completed in Japanese registration study**: The global pediatric study is a pivotal, non-inferiority design comparing a single weekly administration of hGH-CTP with daily injections of a currently marketed growth hormone product. The global and Japanese pediatric studies utilize the pen device and formulation that will be launched commercially upon approval. The pediatric segment represents more than 80% of the commercial market for treatment of hGH deficiency.

- **RAYALDEE line extension trial initiated in hemodialysis patients with SHPT**: Together with its partners, Vifor Fresenius and Japan Tobacco, OPKO is developing RAYALDEE for patients with Stage 5 CKD who have secondary hyperparathyroidism (SHPT) and vitamin D insufficiency and are undergoing regular hemodialysis. A Phase 2 trial in this population is currently underway in the United States.

- **Topline data from the Phase 2b study with OPK88003, a once-weekly oxyntomodulin dual GLP1-Glucagon agonist for type 2 diabetes and obesity, is anticipated during 1Q 2019**: The last patient, last visit of this Phase 2b dose-escalation study occurred in February 2019. In an earlier, 420-patient Phase 2 trial in patients with type 2 diabetes, OPK88003 was similar to exenatide extended-release (Ex ER) in reducing HbA1c levels. OPK88003 showed statistically significantly greater weight loss and lowering of total cholesterol and triglycerides compared to once-weekly Ex ER, with a good safety profile.

- **Appointed Jon R. Cohen, M.D. Executive Chairman and promoted Geoff Monk as President, both for BioReference Laboratories:** Dr. Cohen brings more than 30 years of healthcare experience as a seasoned strategic leader with extensive and diverse experience; his track record of expanding existing business and developing new ventures, while dealing effectively with the payor universe, is well recognized in the diagnostics industry.

- **4Kscore® utilization remained strong during 4Q 2018 with nearly 20,000 tests performed**: The 4Kscore test is a blood test that gives a man with elevated prostate specific antigen (PSA) levels a personalized prediction of his chance of having or developing an aggressive form of prostate cancer. The Company is pursuing U.S. Food and Drug Administration (FDA) approval with a submission expected in the first half of 2019. OPKO announced on January 31, 2019 that Novitas Solutions, Inc. issued a notice of a future non-coverage determination for 4Kscore effective March 20, 2019. The Company is currently making efforts to have the determination rescinded or reversed.

- **FDA approved Claros® point-of-care (POC) PSA test**: On February 1, 2019, OPKO announced that the FDA approved the Company's point-of-care Sangia Total PSA Test using the Claros 1 Analyzer. The Company is taking steps to obtain CLIA waiver for the test and analyzer, which would permit the test to be performed by most medical office personnel with minimal training, and is also planning for scale up of manufacturing capacity during 2019. OPKO plans to expand the testing menu and the next test under development is testosterone, with clinical trials currently scheduled to commence in mid-2019.

Financial Highlights

- Net loss for the fourth quarter of 2018 of $76.1 million compared to $217.9 million for the comparable quarter of 2017. Net loss for both periods included unusual or non-cash items consisting of:

    - During the fourth quarter of 2018, the Company recorded $21.8 million of non-cash impairment to Goodwill and in-process research and development related to its active pharmaceutical ingredient business and the suspension of the Phase 2b clinical trial for its selective androgen receptor antagonist for benign prostatic hyperplasia. In the comparable period of 2017, the Company recorded a $13.2 million impairment resulting from the discontinuation by its licensee of the intravenous formulation of VARUBI;

    - During the fourth quarter of 2018, the Company incurred approximately $8.0 million of expenses related to defense and investigation of actions brought by the U.S. Securities and Exchange Commission (SEC) and related civil lawsuits. The Company reached a settlement agreement with the SEC in the fourth quarter of 2018, which was finalized in January 2019; and

    - During the fourth quarter of 2017, the Company recorded $73.3 million of adjustments to revenue from services.

- Consolidated revenues for the fourth quarter of 2018 were $221.9 million compared with $161.0 million for the comparable period of 2017. During the 2018 quarter, revenue from services was $183.1 million, revenue from products was $25.4 million, including RAYALDEE revenue of $6.0 million, and revenue from licensing and intellectual property was $13.4 million.

- During the fourth quarter of 2018, total operating expenses were $311.9 million, including the aforementioned impairment charges of $21.8 million as well as continued investment in the Company's pharmaceutical pipeline, with R&D expense of $33.3 million.

- The Company recorded a $28.3 million income tax benefit during the fourth quarter of 2018 primarily as a result of valuation allowance releases in foreign jurisdictions. The comparable period of 2017 includes a $61.2 million income tax provision, principally as a result of the Tax Cuts and Jobs Act ($31.8 million) as well as recording a valuation allowance against U.S. based deferred tax assets.

- Subsequent to the close of the fourth quarter, on February 5, 2019, OPKO completed the sale of $200 million aggregate principal amount of 4.5% Convertible Senior Notes due 2025.

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:	4254518
WEBCAST:	http://investor.opko.com/events.cfm.

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 4254518. The replay can be accessed for a period of time on OPKO's website at http://investor.opko.com/events.cfm.

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 in Phase 2 clinical trials, is among a new class of GLP-1/glucagon receptor dual agonists. OPK88004, a SARM (selective androgen receptor modulator) has been studied for benign prostatic hyperplasia but we are exploring other 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 we will be able to reverse or rescind the Novitas non coverage decision for the 4kscore test for Medicare beneficiaries, statements regarding our planned submission for FDA approval of the 4kscore test and the timeline for the submission, whether we will be able to develop OPK88004 for additional indications, whether OP88003 will be shown to be safe and effective and achieve even greater weight loss, the expected timing for launch of our products in development, 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, our ability to increase our commercial reach through expansion our RAYALDEE commercial sales force, our ability to expand the testing menu for the Claros® system and plans for scale up of our manufacturing capacity, 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 BioReference, 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, OPK88003, OPK88004, 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, 2018	December 31, 2017
Assets:		
Cash, cash equivalents and marketable securities	$ 96.5	$ 91.5
Other current assets	221.2	257.4
Total Current Assets	317.7	348.9
In-process Research and Development and Goodwill	1,335.8	1,364.4
Other assets	797.6	876.7
Total Assets	$ 2,451.1	$ 2,590.0
Liabilities and Equity:		
Current liabilities	$ 256.8	$ 312.0
2033 Senior Notes, net of discount	31.6	29.2
Deferred tax liabilities	115.2	148.7
Other long-term liabilities, principally deferred revenue, contingent consideration and lines of credit	256.2	256.5
Total Liabilities	659.8	746.4
Equity	1,791.3	1,843.6
Total Liabilities and Equity	$ 2,451.1	$ 2,590.0

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,	
	2018	2017	2018	2017
Revenues				
Revenue from services	$ 183.1	$ 119.4	$ 813.3	$ 782.7
Revenue from products	25.4	33.8	107.1	107.8
Revenue from transfer of intellectual property	13.4	7.8	69.9	75.5
Total revenues	221.9	161.0	990.3	966.0
Costs and expenses				
Cost of revenues	149.6	156.6	604.6	620.1
Selling, general and administrative	95.1	95.9	358.4	414.6
Research and development	33.3	34.2	125.6	126.4
Contingent consideration	(4.4)	1.1	(16.8)	(3.4)
Amortization of intangible assets	16.5	17.6	67.9	71.5
Asset impairment charges	21.8	13.2	21.8	13.2
Total Costs and expenses	311.9	318.6	1,161.5	1,242.4
Operating loss	(90.0)	(157.6)	(171.2)	(276.4)
Other income and (expense), net	(11.4)	3.6	(6.0)	4.5
Loss before income taxes and investment losses	(101.4)	(154.0)	(177.2)	(271.9)
Income tax benefit (provision)	28.3	(61.2)	38.7	(18.9)
Loss before investment losses	(73.1)	(215.2)	(138.5)	(290.8)
Loss from investments in investees	(3.0)	(2.7)	(14.5)	(14.5)
Net loss	$ (76.1)	$ (217.9)	$ (153.0)	$ (305.3)
Loss per share, basic and diluted	$ (0.13)	$ (0.39)	$ (0.27)	$ (0.55)

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