OPKO Health Reports Third Quarter 2018 Financial Results

Conference Call begins today at 4:15 p.m. Eastern Time

MIAMI (November 9, 2018) – OPKO Health, Inc. (NASDAQ: OPK) reports financial results and business highlights for the three months ended September 30, 2018.

Financial Highlights

- Net loss for the three months ended September 30, 2018 decreased by 23% to $27.7 million or $0.05 a share compared to net loss of $35.9 million or $0.06 per share for the comparable 2017 period. Total revenues improved to $249.8 million during the three months ended September 30, 2018 compared to $246.0 million for the comparable period of 2017.
- Revenues from products during the three months ended September 30, 2018 include $5.8 million from *RAYALDEE* and revenues from services were $202.8 million for the 2018 period compared with $200.9 million for the corresponding 2017 period.
- During the three months ended September 30, 2018, costs of revenue and selling, general and administrative expenses decreased by approximately 8%, or $19.5 million, compared to the 2017 period. Research and Development expenses were $30.2 million compared to $32.5 million for the corresponding 2017 period.
- On November 8, 2018, OPKO secured approximately $150 million of additional capital, consisting of a private placement of common stock resulting in proceeds of $92.5 million, and an unsecured credit line of $60 million.

Business Highlights

- ***RAYALDEE* total prescriptions reported by IMS for Q3 2018 increased 222% compared with Q3 2017 and 18% compared with Q2 2018**: As of November 1, 2018, approximatley 79% of patients have access to *RAYALDEE* under their insurance plans.
- **Initiated the Phase 2 clinical trial to study the safety and efficacy of *RAYALDEE* as a new treatment for secondary hyperparathyroidism (SHPT) in adults with vitamin D insufficiency and stage 5 chronic kidney disease (CKD) requiring hemodialysis.** The trial will be conducted at multiple dialysis centers in the U.S. in two sequential cohorts. The first cohort of approximately 44 patients will be treated for 26 weeks in a randomized, open-label fashion with either *RAYALDEE* or placebo to identify the appropriate dosing to be studied in the second cohort. Data readout for this first cohort is expected in 2019. The second cohort of more than 200 patients will be treated for 26 weeks in a randomized, double-blind fashion with one of three different doses of *RAYALDEE* or placebo. The primary efficacy endpoint will be correction of vitamin D

insufficiency and control of SHPT. Patients will then be treated with *RAYALDEE* for another 26 weeks in an open-label extension.

- **4Kscore utilization in Q3 2018 was approximately 18,700 tests compared to 18,900 during Q3 2017**. Utilization of the 4Kscore remains strong while we continue to work with our Medicare administrator, Novitas, on their proposed local coverage determination. During this process, Novitas has continued to provide coverage of the 4Kscore to Medicare beneficiaries.
- **Completed the enrollment of a Global Phase 3 study of somatrogon (hGH-CTP) in Growth Hormone Deficient Children:** The somatrogon Phase 3 trial is a randomized, open-label study comparing once-weekly somatrogon to once daily Genotropin®. This study has enrolled 228 treatment naïve children with growth hormone deficiency (GHD) in 21 countries. The primary endpoint of the trial is height velocity at 52 weeks. Secondary endpoints are safety and pharmacodynamics.
- **Enrollment in Japanese Phase 3 registration trial of somatrogon in growth hormone deficient children expected to complete by year end:** The global and Japanese pediatric studies utilize the multiple dose pen device that will be launched commercially upon approval.
- **Completed the enrollment of a Phase 2b clinical trial for our once-weekly oxyntomodulin dual GLP1-Glucagon agonist to treat type 2 diabetes and obesity**: In a previous Phase 2 trial in 420 overweight patients with type 2 diabetes, the drug was shown to be safe and effective. The current trial is to study a new dosing schedule to achieve even greater weight loss and topline results are anticipated during 1Q 2019.
- **Advanced the Phase 2b trial for our SARM (selective androgen receptor modulator) to treat benign prostatic hyperplasia (BPH)**: Enrollment of approximately 110-120 patients in this dose ranging study of our orally administered SARM is expected to be completed by the end of this year.
- **Premarket Approval (PMA) application for Claros® point-of-care PSA test under review by FDA; decision anticipated during 1H 2019**: OPKO has completed a PMA submission to FDA for Sangia, our point of care PSA test utilizing the Claros 1 immunoassay analyzer. This is the first test on our proprietary diagnostic platform that can provide rapid, quantitative blood test results in the physician's office with only a finger stick drop of whole blood. Several biomarkers and biological meaningful chemistry tests such as testosterone and Vitamin D utilizing the Claros platform are advancing toward a 510(k) submission to the FDA.

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 4:15 p.m. Eastern time today. The conference call dial-in and webcast information is as follows:

WHEN: Friday, November 9, 2018 at 4:15 p.m. Eastern time
DOMESTIC DIAL-IN: (866) 634-2258
INTERNATIONAL DIAL-IN: (330) 863-3454
PASSCODE: 3487296
WEBCAST: www.investor.opko.com/events

For those unable to participate in the live conference call or webcast, a replay will be available beginning November 9, 2018 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: 3487296. The replay can be accessed for a period of time on OPKO's website at www.investor.opko.com/events.

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 PSA and testosterone as the most advanced 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) for treating BPH (Benign Prostatic Hypertrophy), urinary incontinence, and other conditions, is in clinical trials. 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 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 Novitas will continue to provide coverage of the 4kscore test for Medicare beneficiaries, whether OPK88004 will improve the symptoms of BPH by reducing prostate size and increase muscle mass and bone strength and decrease body fat, 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, 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 success of our relationship with Pfizer and our other partners, integration challenges for Bio-Reference, EirGen, Transition, 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.

CONTACTS:

Investors
LHA Investor Relations
Miriam W. Miller, 212-838-3777
MMiller@lhai.com
or
Bruce Voss, 310-691-7100
bvoss@lhai.com

—Tables to Follow—

OPKO Health, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in millions)

	As of	
	September 30, 2018	December 31, 2017
Assets:		
Cash, cash equivalents and marketable securities	$ 43.7	$ 91.5
Other current assets	246.1	257.4
Total Current Assets	289.8	348.9
In-process Research and Development and Goodwill	1,360.0	1,364.4
Other assets	831.2	876.7
Total Assets	$ 2,481.0	$ 2,590.0
Liabilities and Equity:		
Current liabilities	$ 286.9	$ 316.5
2033 Senior Notes and 5% Convertible Notes	87.6	29.2
Deferred tax liabilities	134.1	148.7
Other long-term liabilities, principally deferred revenue, contingent consideration and lines of credit	183.8	240.0
Total Liabilities	692.4	734.4
Equity	1,788.6	1,855.6
Total Liabilities and Equity	$ 2,481.0	$ 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 September 30,		For the nine months ended September 30,	
	2018	2017	2018	2017
Revenues				
Revenue from services	$ 202.8	$ 200.9	$ 630.2	$ 663.3
Revenue from products	25.4	22.8	81.8	74.0
Revenue from transfer of intellectual property	21.6	22.3	56.4	67.7
Total revenues	249.8	246.0	768.4	805.0
Costs and expenses				
Cost of revenues	150.9	151.3	455.1	463.5
Selling, general and administrative	84.1	103.2	263.2	318.7
Research and development	30.2	32.5	92.3	92.2
Contingent consideration	1.2	(11.2)	(12.4)	(4.5)
Amortization of intangible assets	16.9	18.0	51.4	53.9
Total Costs and expenses	283.3	293.8	849.6	923.8
Operating loss	(33.5)	(47.8)	(81.2)	(118.8)
Other income and (expense), net	(3.9)	(8.5)	5.4	1.0
Loss before income taxes and investment losses	(37.4)	(56.3)	(75.8)	(117.8)
Income tax benefit (provision)	11.6	24.4	10.4	42.3
Income (loss) before investment losses	(25.8)	(31.9)	(65.4)	(75.5)
Loss from investments in investees	(1.9)	(4.0)	(11.6)	(11.8)
Net loss	$ (27.7)	$ (35.9)	$ (77.0)	$ (87.3)
Loss per share, basic and diluted	$ (0.05)	$ (0.06)	$ (0.14)	$ (0.16)

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