

September 25, 2017

Via: <u>Email</u>

Division of Corporation Finance Securities and Exchange Commission 100 F Street, NE Washington, DC 20549

Re: OPKO Health, Inc. Form 10-K for the Fiscal Year Ended December 31, 2016 Filed March 1, 2017 File No. 001-33528

Dear Sir/Madame:

On behalf of OPKO Health, Inc., a Delaware corporation (the "<u>Company</u>"), this letter is in response to the comments of the staff (the "<u>Staff</u>") of the United States Securities and Exchange Commission (the "<u>Commission</u>") contained in its letter to the Company, dated September 14, 2017, regarding the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the Commission on March 1, 2017 (File No. 001-33528) (the "<u>Annual Report</u>").

For your convenience, we have set forth the text of each of the Staff's comments in bold, followed in each case by the Company's response thereto.

Form 10-K for the Fiscal Year Ended December 31, 2016

Business

Pharmaceutical Business, page 9

1. We note your disclosure that you receive tiered, double digit royalties on sales of Rayaldee both under the collaboration agreement with Vifor Fresenius Medical Care Renal Pharma and the option granted to VFMCRP. Please provide us with disclosure to be included in future filings disclosing a range of royalties not to exceed 10 percent (e.g., "high single digits to teens" or "between 5 and 15 percent"). We also note that you receive a minimum royalty payment under the collaboration agreement. Please disclose this amount or tell us why you believe it this information is not material to investors.

OPKO Health, Inc. | 4400 Biscayne Boulevard, Miami, FL 33137 | fax 305.575.4140 | www.opko.com

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Company's Response:

In response to the Staff's comment, the Company proposes including disclosure substantially similar to the following in future filings.

In May 2016, we entered into a collaboration agreement with Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP) for the development and commercialization of Rayaldee in Europe, Canada, Mexico, Australia, South Korea and certain other international markets for the treatment of SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency. Under the terms of the agreement, OPKO received an upfront payment of \$50 million, and will receive up to \$232 million in regulatory and sales based milestones. In addition, VFMCRP will pay OPKO tiered royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon commencement of sales of the product. OPKO and VFMCRP will also collaborate to develop and commercialize a new dosage form of Rayaldee for the treatment of SHPT in hemodialysis patients. OPKO granted VFMCRP an option to acquire rights to this dosage form for the U.S. market; if exercised, OPKO will receive up to \$555 million in additional milestones and royalties on sales of the product at percentage rates that range rates that range from the mid-teens to the mid-twenties.

The Company respectfully acknowledges the Staff's comment regarding disclosure of the minimum royalty payments under the collaboration agreement, but we do not believe that the existence of minimum royalty payments or the amounts thereof are material to the Company or to investors' understanding of the transaction. Under the collaboration agreement, we are eligible to receive royalty payments at percentage rates that range from mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon commencement of sales of the Product within the Territory and in the Field (each as defined in the collaboration agreement). The minimum royalty obligation per year represents less than 1% of our total revenues based on the Company's \$1.2 billion in revenues for the year ended December 31, 2016. We have not received any royalty payments to date and do not believe the minimum royalties we could receive are material, given the overall value of the collaboration agreement and our total revenues. Further, VFMCRP has not obtained regulatory approval for the Product in any jurisdiction at this point, and, we do not expect the minimum royalty payments will have any financial impact on OPKO for the immediately foreseeable future. We believe that disclosing the minimum royalty terms would not provide meaningful information or provide clarity to investors and would cause competitive harm to both OPKO and VFMCRP.

Notes to Consolidated Financial Statements

Note 14 Strategic Alliances

Vifor Fresenius Medical Renal Care Pharma Ltd., page 116

2. Your letter agreement with VFMCRP grants an option to obtain an additional license. Please provide us with disclosure to be included in future filings disclosing the description of each milestone and the related consideration that may be received for each milestone under the additional license agreement. Refer to ASC 605-28-50-2b.

Company's Response:

The Company respectfully acknowledges the Staff's comment to disclose a description of each individual milestone and its related contingent consideration that may be received under the potential additional license agreement as required by ASC 605-28-50-2b. In applying the guidance in ASC 605-28-50-2b, the Company considered which individual milestones, if any, would be material from a disclosure perspective. As a result, the Company has concluded that the aggregation of milestones by category in its disclosure to be more meaningful to investors than disclosing individual milestones. In making this assessment, one of the factors that the Company considered is that it is not eligible to receive milestone payments unless and until VFMCRP exercises its option to acquire an exclusive license to use, import, offer for sale, sell, distribute and commercialize Rayaldee in the United States solely for the treatment of secondary hyperparathyroidism in dialysis patients with chronic kidney disease and vitamin D insufficiency (the "Dialysis Indication"). In addition, the Company considered that the first milestone is not payable until the first commercial sale of product for the Dialysis Indication.

Moreover, the Company believes that the disclosure of the individual milestones and the related contingent consideration may be misleading to investors because achievement of such milestones is subject to the successful development and commercialization of Rayaldee for the Dialysis Indication, which is subject to numerous risks and uncertainties, including uncertainties relating to:

- The progress and results of clinical trials,
- The timing and outcome of regulatory reviews,
- · The emergence of competing technologies and products and other adverse market developments,
- · Maintaining, enforcing and defending intellectual property-related claims, and

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• The skills, experience and efforts of VFMCRP's employees responsible for the project, VFMCRP's commitment to the arrangement, and the financial condition of VFMCRP.

These risks and uncertainties make it difficult to predict if any of the milestones will be achieved by the Company and when such milestones might be achieved. Providing a description of each potential milestone and the related contingent consideration could potentially mislead investors as the inclusion of such detailed information may imply that the Company has a substantial likelihood of achieving some or many of such milestones and receiving the related payments, while the actual prospects for achievement of such milestones is inherently uncertain and many milestones may never ultimately be achieved. Additionally, the Company believes that the individual milestones and payment amounts are not material to investors unless there is a high likelihood of achieving a particular milestone. As described above, the Company's prospects for achieving any of the milestones that would be included in any potential additional license agreement are both uncertain and difficult to determine.

The Company also believes that the expected time frame in which a milestone may be achieved is a relevant factor in determining whether disclosure of individual milestones and payment amounts are material to investors. The Company has not yet commenced its Phase 2 or 3 study for the Dialysis Indication. Accordingly, a substantial amount of time is expected to pass before the first commercial sale of product for the Dialysis Indication, which would trigger the first potential milestone payment if the option is exercised by VFMCRP. Therefore, the Company believes the disclosure of any individual milestone that is both highly uncertain and not achievable in the foreseeable future, if at all, is not material to investors.

As the Company approaches final development of, and approval for, the Dialysis Indication, the Company will reevaluate inclusion of appropriate disclosure about the specific terms of the milestones and the related payments, as required by ASC 605-28-50-2b.

If you or any other member of the Staff should have any further comments or questions regarding this response, please feel free to contact the undersigned by phone at (305) 575-4138.

Sincerely,

/s/ Kate Inman

Kate Inman General Counsel, Secretary

KI/dmr