



Confidential treatment has been requested by OPKO Health, Inc. pursuant to 17 C.F.R. § 200.83 for certain portions of this letter. This letter omits confidential information (denoted with [*]) included in the unredacted version of the letter delivered to the Division of Corporation Finance.**

December 4, 2018

Via: Email and EDGAR

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, 2017
Filed March 1, 2018
Form 10-Q for the Period Ended September 30, 2018
Filed November 9, 2018
File No. 001-33528**

Dear Sir/Madame:

On behalf of OPKO Health, Inc., a Delaware corporation (the "Company"), this letter is in response to the comments of the staff (the "Staff") of the United States Securities and Exchange Commission (the "Commission") contained in its letter to the Company, dated November 19, 2018, regarding the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Commission on March 1, 2018 (the "Annual Report"), and the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, filed with the Commission on November 9, 2018 (the "Quarterly Report") (File No. 001-33528).

Because of the confidential nature of information contained herein, this response letter includes a request for confidential treatment for selected portions of this letter, as indicated by [***], in accordance with the Freedom of Information Act, 5 U.S.C. § 552, as amended ("FOIA"). We have filed a separate letter with the Office of Freedom of Information and Privacy Act in connection with the confidential treatment request, pursuant to 17 C.F.R. § 200.83 ("Rule 83"). A complete version of this response letter has been separately furnished to the Commission. Please promptly inform the Company of any request for disclosure of the confidential portions herein made pursuant to FOIA or otherwise so that the undersigned may substantiate the foregoing request for confidential treatment in accordance with Rule 83.

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

Form 10-Q for the Period Ended September 30, 2018
Notes to Consolidated Financial Statements
Note 14 Segments, page 37

1. **Please tell us how you considered the requirements of ASC 280-10-50-40 in determining whether to provide the disclosure regarding your revenues from each product and service or each group of similar products and services. In this regard, we noted that your Diagnostics segment includes BioReference laboratory divisions in disclosure beginning on page 7 and separate disclosure with regards to your 4Kscore tests beginning on page 8 in your Form 10-K for the year ended December 31, 2017.**

Company's Response:

In response to the Staff's comments, the Company respectfully notes that it believes revenues generated by each of the thousands of diagnostic tests offered by BioReference, including the *4Kscore* test, are similar and therefore, discloses diagnostic services revenue as a group. The Company believes the disclosures in its Annual Report comply with ASC 280-10-50-40, which allows for revenues from similar services to be grouped.

With regard to the separate disclosure provided by the Company on the *4Kscore* test, the Company notes that the *4Kscore* test was internally developed and launched for commercial sale in 2014 (prior to its acquisition of BioReference). We believe the *4Kscore* test differentiates the Company from its competitors which do not offer an equivalent test. Since the acquisition of BioReference in 2015, the Company leverages the national marketing, sales and distribution resources of BioReference, along with its sales and marketing team, to manage the sales, laboratory testing and reimbursement for its *4Kscore* test. The *4Kscore* test is part of a comprehensive suite of laboratory testing services offered by BioReference in the detection, diagnosis, evaluation, monitoring, and treatment of diseases. The Company has continued to provide separate information regarding the *4Kscore* test solely because management believes it is useful information and of interest to investors.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 42

2. **For each of the periods presented, please provide us with proposed disclosure to be included in future filings beginning with your next Form 10-K to further clarify, as noted in prior responses, the following:**
- **why genomics reimbursement decreased from the prior periods and**
 - **why test volumes decreased from prior periods**

Company's Response:

In response to the Staff's comment, the Company proposes including disclosure substantially similar to the following in its Annual Report on Form 10-K for the fiscal year ended December 31, 2018:

*Revenue from services for the year ended December 31, 2017 decreased approximately \$123.1 million compared to 2016. The decrease in revenue from services is attributable to approximately [***] within our [***] as a result of an increase in denial rates and changes to payor medical and procedural requirements, approximately [***] of adjustments to the estimated collection amounts from third-party payors for our genomics testing, and [***]. Revenue from services also declined by approximately [***] as a result of increased competition and approximately [***] related to changes in the estimated collection amounts from third-party payors for our clinical testing, which was partially offset by [***] of improved collections for our clinical testing resulting from improvements in our billing cycle. Revenue from services for the year ended December 31, 2017 was also affected by claims of overpayment as a result of payor error of approximately \$30.0 million.*

*Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when estimating variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known based on actual collection experience. For the year ended December 31, 2017, changes to estimated collection amounts from third-party payors negatively affected revenue by [***] and [***]. The adjustments for our genomics testing primarily relate to changes in payor medical and procedural requirements for our genomics testing. The adjustments for our clinical testing primarily relate to delays in the billing cycle resulting from our implementation of a new clinical testing billing system in late 2016.*

We may have an obligation to reimburse Medicare, Medicaid, and third-party payors for overpayments regardless of fault. We have periodically identified and reported overpayments, reimbursed payors for overpayments and taken appropriate corrective action. Settlements with third-party payors for retroactive adjustments due to audits, reviews or investigations are considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews, and investigations. During the year ended December 31, 2017, a payor informed us it had overpaid BioReference due to an error on its part over a period of several years, including multiple years prior to the acquisition of BioReference by OPKO in August 2015. For the year ended December 31, 2017, Revenue from services was reduced by approximately \$30.0 million related to claims of overpayment as a result of payor error.

The disclosure above reflects the Company's revenues as reported in its Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Effective January 1, 2018, the Company adopted Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, using the full retrospective transition method. The above disclosure will be revised to reflect the impact of adopting Topic 606 when presented in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

3. Please provide us with the proposed disclosure to include in future filings beginning with your next Form 10-K disaggregating the adjustments to estimated collection amounts from third-party payors by each significant factor noted.

Company's Response:

In response to the Staff's comment, the Company proposes including disclosure substantially similar to the disclosure included in the response to question 2 above in its Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

4. We noted in your third quarter 2018 earnings call transcript that you continue to see improvements in your overall volumes within your clinical lab testing and double-digit growth within your genomics testing. Please reconcile for us your statements to the disclosure provided on page 42 noting "Revenue from services for the three months ended September 30, 2018 were negatively affected by \$3.5 million as a result of reduction in test volumes..."

Company's Response:

In response to the Staff's comment, the Company respectfully advises the Staff that the disclosure on page 42 of the Company's Quarterly Report "Revenue from services for the three months ended September 30, 2018 were negatively affected by \$3.5 million as a result of reduction in test volumes" is comprised of [***], which was partially offset by [***]. This disclosure is a comparison of test volume for the three months ended September 30, 2018 to the comparable period in 2017. The statement in the Company's third quarter 2018 earnings call "we continue to see improvements in our overall volumes within our clinical laboratory testing" is in reference to volume trends for BioReference's clinical laboratory testing that improved sequentially from the fourth quarter of 2017 through October 2018 as follows:

| Favorable (unfavorable) to comparative period in prior year | Quarter ending | | | | Month Ended |
|--|----------------------|-------------------|------------------|-----------------------|---------------------|
| | December 31, 2017 | March 31, 2018 | June 30, 2018 | September 30, 2018 | October 31, 2018 |
| [***] | [***] | [***] | [***] | [***] | [***] |

Going forward, the Company will modify the language in its earnings calls to provide greater clarity to the trend line comparisons on testing volume at BioReference to reduce the chance of misinterpretation. The Company also notes that it provided revenue guidance for BioReference in its earnings call for the fourth quarter 2018, which indicated that revenues for the fourth quarter are expected to be flat or down slightly from the third quarter of 2018.

Critical Accounting Policies and Estimates
Goodwill and intangible assets, page 52

5. **Given the decreases in revenues at Biologics and the local draft determination issued by Novitas Solutions, Inc. proposing not to provide coverage for your 4Kscore test, combined with recurring historical operating losses in your Diagnostics segment, please tell us the following regarding your testing of goodwill for impairment for the reporting units in your Diagnostics segment:**

- **The date you last tested goodwill for impairment for the reporting units.**
- **Whether any of your reporting units had a fair value that was not substantially in excess of carrying value.**
- **For those reporting units, the percentage by which fair value exceeded carrying value as of the date of the most recent test.**
- **The amount of goodwill allocated to each reporting unit.**
- **A description of the methods and key assumptions used and how the key assumptions were determined.**
- **A discussion of the degree of uncertainty associated with key assumptions. The discussion regarding uncertainty should provide specifics to the extent possible (e.g., the valuation model assumes recovery from a business downturn within a defined period of time).**

Company's Response:

In response to the Staff's comments, the Company respectfully advises the Staff the BioReference and OPKO Diagnostics reporting units are included in the Diagnostics segment and carry goodwill. The Diagnostics reporting segment primarily consists of the clinical laboratory operations at BioReference and has a goodwill balance of \$434.8 million. OPKO Diagnostics performs research and development on the Company's Claros 1 in-office immunoassay diagnostic testing platform, currently generates no revenue, and has goodwill of \$18.0 million.

The Company evaluates goodwill on an annual basis as of October 1st. As permitted by ASC 350-20-35-3B, the Company bypassed the qualitative assessment for goodwill for BioReference as of October 1, 2017, and proceeded directly to performing the first step of the goodwill impairment test. In response to challenges in BioReference's operating performance in the fourth quarter of 2017, the Company updated the valuation of BioReference as of December 31, 2017. For OPKO Diagnostics, the Company performed a qualitative assessment for goodwill as of October 1, 2017. The most recent quantitative assessment of OPKO Diagnostics was as of October 1, 2016. None of the Company's reporting units had a fair value that was not substantially in excess of carrying value.

The income approach was used to determine the fair values of the Company's reporting units. Using this approach, the reporting unit's value was determined by discounting future debt-free cash flows to present value at rates of return commensurate with the business and financial risks associated with the achievement of the projected cash flows.

The December 2017 valuation included in our impairment analysis for Bio Reference assumed a stabilization of the business for both volumes and reimbursement levels during 2018 in comparison to the 2017 period and substantially lower volumes and reimbursement levels compared to 2016 levels with modest improvements for future years. Our long-term forecast and budget includes assumptions of the market, competitor landscape, new products and reimbursement trends.

With respect to coverage for the *4Kscore* test, Novitas Solutions, Inc. (“Novitas”) has been reimbursing for the *4Kscore* test for approximately three years. In May 2018, Novitas issued a draft local coverage determination (“LCD”) that proposed no reimbursement coverage for the *4Kscore* test. The Company submitted comments to the draft LCD during the public comment period, which ended on July 13, 2018. Novitas continues to reimburse for the *4Kscore* test. Based on the results of the latest goodwill test and the overall performance against plans in 2018, the draft LCD was not considered an interim indicator of impairment.

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) 575-4148.

Sincerely,

/s/ Adam Logal

Adam Logal

Chief Financial Officer

KI/dmr