

Christine Torney and Kevin Vaughn
Division of Corporation Finance
Office of Life Sciences
U.S. Securities & Exchange Commission
100 F Street N.E.
Washington, D.C. 20549

Re: Trevena, Inc.
Form 10-K for Fiscal Year Ended December 31, 2022
Filed March 30, 2023
File No. 001-36193

July 28, 2023

Dear Ms. Torney and Mr. Vaughn:

Please allow this letter to serve as Trevena's response to the comment of the Staff (the "**Staff**") of the Division of Corporation Finance of the U.S. Securities and Exchange Commission (the "Commission") contained in its letter, dated July 14, 2023 (the "**Commission Comment Letter**") in connection with the Company's Form 10-K for the fiscal year ended December 31, 2022, filed with the Commission on March 30, 2023. When used in this letter, "**Trevena**," the "**Company**," "**we**," and "**our**" refer to Trevena, Inc.

The Company's response to the Commission Comment Letter is set forth below. For ease of reference, the Staff's comment is printed in bold, italicized font and followed by the Company's response.

Form 10-K for the fiscal year ended December 31, 2022

Notes to Consolidated Financial Statements

10. Product Revenue

Variable Consideration, page 114

1. ***Given the significant returns adjustment in 2022, please address the following regarding your revenue recognition policies and how they comply with the specific applicable guidance in ASC 606:***

- ***At the time you recorded revenue from sales of OLINVYK in 2021, explain how you evaluated the probability that a significant reversal in the product revenue recognized would not occur before the uncertainty associated with the variable consideration was subsequently resolved (e.g., when the right of return expired).***

RESPONSE: As background, OLINVYK is an opioid agonist indicated in adults for the management of acute pain severe enough to require an IV analgesic and for whom alternative treatments are inadequate. OLINVYK is a Schedule II controlled substance.

Trevena recorded approximately \$0.5 million of revenue from sales of OLINVYK in 2021.

Trevena's distributors received return rights consistent with the standards for the industry. In 2021, the Company did not have a history of OLINVYK returns as it was a newly launched product and therefore estimated returns using the expected value method based on industry data for comparable products in the market, as discussed in more detail below.

At the time of sale, the Company did not believe it was probable that a significant reversal in the amount of cumulative product revenue recognized would occur prior to the expiration of the distributor return rights. When evaluating the probability that a significant reversal in the amount of cumulative product revenue recognized would not occur before the uncertainty associated with the variable consideration was subsequently resolved, the Company considered a range of factors including, among other things (i) the limited amounts of product the Company shipped to its three distributors relative to the Company's estimation of expected demand in an effort to limit the product in the pipeline during the early stages of the product launch, (ii) the size of the overall US IV opioid market, with approximately 45 million patients treated annually, dosed with an estimated 170 million units of IV opioids, (iii) the Company's commercial efforts, including an approximately 40-person customer-facing team that launched OLINVYK in February 2021, (iv) OLINVYK's profile, which the Company believes is meaningfully differentiated from existing conventional IV opioids such as IV morphine and IV hydromorphone (together, "Conventional IV Opioids"), and (v) broadly comparable products and product launches to use as reference, as further described in response to your bullet below.

- ***As part of your response, specifically address how you determined that it was appropriate to use industry data when estimating returns and that such products were sufficiently comparable to OLINVYK.***

RESPONSE: Trevena considered in its analysis, among other things, the significant sales of other Conventional IV Opioids. Trevena considered Conventional IV Opioids sufficiently comparable as IV OLINVYK also targets the mu opioid receptor and is used (i) in similar settings (generally hospitals and ambulatory surgical centers ("ASCs")), (ii) for similar purposes (generally to treat post-operative pain), (iii) with the same DEA Schedule II status, and (iv) with similar dosing protocols, including both bolus dosing and patient-controlled analgesia, as Conventional IV Opioids. The FDA-approved OLINVYK label notes that "an initial 1mg dose of OLINVYK is approximately equipotent to morphine 5mg," which Trevena believes further supports the comparability of OLINVYK with Conventional IV Opioids. Notably, these Conventional IV Opioids are frequently on the FDA's Drug Shortages Database, and these shortages are well documented in the public literature.

Trevena also considered sales of broadly comparable hospital-based analgesic product launches. Trevena believed these hospital launches were informative and sufficiently comparable due to (i) the formulary review process, in which a new medication must be reviewed and approved by a hospital formulary panel before it can be prescribed at that institution, and (ii) the multi-modal nature of post-operative pain management, in which health care providers use a combination of non-opioid and, if needed, opioid analgesics in the treatment of post-operative pain.

- *Explain how you determined that, based on the information available at the time of initial recognition, the variable consideration was not constrained under ASC 606.*

RESPONSE: Trevena determined that the approximately \$0.5 million of revenue from sales of OLINVYK recognized in 2021 faced a low probability of potential returns based on the factors outlined above which were known at the time of initial recognition, including the large 45-million patient market opportunity, the Company's 40-person customer-facing product launch team, OLINVYK's differentiated profile, shortages in Conventional IV Opioids, and review of comparable product sales and launches.

- *Tell us and revise your future filings to more clearly describe the steps you took to reevaluate the likelihood of significant product returns in each quarter subsequent to its initial sale.*

RESPONSE: Trevena considered the existing supply of OLINVYK at its distributors, communications with, and feedback from, these distributors, as well as the pace of ordering of OLINVYK by hospitals and ASCs in reevaluating the likelihood of significant product returns each quarter subsequent to initial sale. The Company also considered additional factors such as new and differentiating clinical or health economic data for OLINVYK that may drive further adoption. Trevena incorporated these factors as it considered the need for any adjustments to the amount of cumulative product revenue recognized on a quarterly basis.

The Company respectfully acknowledges the Staff's comments and will revise future filings to more clearly describe the steps taken to reevaluate the likelihood of significant product returns in each quarter subsequent to the initial sale of OLINVYK.

- **Identify in your response as well as your future filings the nature of the information which was available to you and the information which you reviewed as part of your estimation of product returns. Specifically address the extent to which you were privy to the levels of quarterly sales of OLINVYK by your distributors.**

RESPONSE: As described above, the information Trevena had available included the existing supply of OLINVYK at its distributors. Trevena receives weekly reports on the level of sales from its distributors to hospitals and ASCs. The Company believes it used all reasonably available information to make its estimate of product returns.

The Company respectfully acknowledges the Staff's comments and will revise future filings to more clearly detail the nature of the information available to it as part of its review of the estimation of product returns and the judgments made in assessing variable consideration.

- **Tell us and revise your future filings to disclose what information led you to record the significant adjustment for product returns in the third quarter 2022. Clarify the extent to which that information was previously unavailable to you.**

RESPONSE: The Company's commercial efforts were ongoing in 2022, and the Company published further positive data for OLINVYK with respect to respiratory physiology (April 2022) and cognitive function (July 2022). The Company also entered into a contract (July 2022) with Vizient, a large group purchasing organization ("**GPO**") serving over 50% of US acute care providers and 20% of US ASCs. While the Company was aware of the relatively low levels of sales by its distributors to hospitals and ASCs, it continued to believe that these positive data and the GPO contract would drive adoption of OLINVYK.

In October 2022, for the first time, the Company received feedback from one of its distributors that the distributor intended to return a significant portion of its supply of OLINVYK. As a result, the Company reevaluated its returns methodology and updated its estimates to reflect this expected return, as well as potential increased probability of returns from other distributors. This resulted in the Company recording an approximately \$0.4 million returns reserve adjustment in its quarterly report on Form 10-Q filed with the Commission on November 15, 2022.

The Company respectfully acknowledges the Staff's comments and will revise future filings to more clearly detail the nature of the information available to it as part of its review of the estimation of product returns and the judgments made in assessing variable consideration.

- ***Revise the MD&A of your future filings to more clearly address the underlying trends in OLINVYK sales and potential for their returns since its approval. To the extent known or estimated, clearly address the trends in patient use of the product for the periods since approval. Include a summary of any other relevant data, including safety data, that may have an impact on customer use that you believe is affecting sales trends (both sales by the Company and sales by distributors).***

RESPONSE: The Company respectfully acknowledges the Staff's comments and will revise the MD&A of its future filings to address the areas set forth in the sub-bullet above. The Company believes that the data it has produced to date, including safety data, are a positive, differentiating aspect of OLINVYK.

If you have any questions regarding the information contained in this letter, or need further information, please do not hesitate to call me at 610-727-0545.

Very truly yours,

/s/ Barry Shin

Barry Shin
CFO

cc:

Joel Solomon, General Counsel and Chief Compliance Officer

Troutman Pepper Hamilton Sanders LLP
Brian M. Katz
Cody Mathis
