

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**

September 27, 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 August 16, 2023 (the "**August Commission Comment Letter**"), as discussed with Mr. Vaughn on September 18, 2023, 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 responses from our letter dated July 28, 2023, which addressed the items raised in the Commission's letter dated July 14, 2023, are incorporated herein by reference.

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. Please address the following regarding your response to comment one of our letter dated July 14, 2023:**

***Regarding your response to the second bullet of prior comment one, clarify in your response as well as in your future filings the extent you continue to use industry data to estimate returns for OLINVYK given the disconnect you experienced between the actual returns and expected returns based on industry data. If you do continue to use industry data, explain how you determined that was appropriate and the extent to which you now adjust such data for the higher actual returns experienced in the fourth quarter of 2022 when developing your return estimates for the most recent quarters.***

**RESPONSE:** Trevena does not currently use industry data, such as sales of other conventional IV opioids and the performance of broadly comparable hospital-based analgesic product launches, in its returns estimates. The Company previously used such industry data at the time of the OLINVYK launch in Q1 2021 and during OLINVYK's early launch phase. At the time, Trevena believed that industry data was a relevant consideration in the absence of any history of OLINVYK sales or returns that the Company could use to benchmark returns estimates.

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Trevena currently estimates returns based on factors including historical OLINVYK purchasing, projected demand from hospitals and ambulatory surgical centers (“*ASCs*”), the amount of OLINVYK held by wholesalers, OLINVYK shelf life, and return patterns and feedback from its wholesalers.

The Company respectfully acknowledges the Staff’s comments and will clarify in future filings that it does not currently rely on industry data, but rather on the factors listed in the above paragraph with respect to returns estimates. Sample disclosure is set forth below, marked to show changes from disclosure in the Company’s quarterly report on Form 10-Q filed with the Commission on August 14, 2023.

Generally, the Company’s customers have the right to return any unopened product during the eighteen (18) month period beginning six (6) months prior to the labeled expiration date and ending twelve (12) months after the labeled expiration date. Since the Company did not have a history of OLINVYK returns when the product was launched, the Company estimated returns based on industry data for comparable products in the market. **The Company does not currently rely on industry data in its analysis of returns reserve.** As the Company ~~sells~~ sold OLINVYK and ~~establishes~~ established historical sales over a longer period of time, the Company ~~places~~ placed more reliance on historical purchasing, demand ~~from hospitals and ambulatory surgical centers~~, return patterns of its customers and the amount of OLINVYK held by wholesalers, when evaluating reserves for product returns. OLINVYK has a forty-eight (48) month shelf life.

- ***Regarding the third and fourth bullets to prior comment one, please explain how you determined whether, based on your actual return experience beginning in November 2022, sales of OLINVYK should be constrained for subsequent interim periods.***

**RESPONSE:** As background, in October 2022, for the first time, the Company received feedback from one of its wholesalers (“*Wholesaler #1*”) that it intended to return a significant portion of its supply of OLINVYK. As a result, the Company updated its estimates to reflect this expected return and, in addition, the Company increased the probability of returns from its other two wholesalers at the time to approximately 50%, resulting 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 9, 2022.

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In the three months ended December 31, 2022, the Company recorded no product sales, and therefore no constraints were required. In connection with preparing its financial statements for the year ended December 31, 2022, the Company reviewed its returns reserve and other gross-to-net (“**GTN**”) adjustments and did not identify other factors that would result in a material change.

In the three months ended March 31, 2023, the Company recorded approximately \$7,000 in gross product sales, primarily to a newly contracted wholesaler (“**Wholesaler #4**”). Based on discussions with Wholesaler #4, the Company understood that these sales were due to demand and orders that Wholesaler #4 had received for OLINVYK from its customers. As a result, the Company estimated returns of approximately 2% for the \$7,000 in gross product sales. The Company recorded approximately \$6,000 in net product sales in the three months ended March 31, 2023. The Company reviewed its returns reserve and other GTN adjustments in connection with preparing its financial statements for the quarter ended March 31, 2023 and did not identify other factors that would result in a material change.

For the three months ended June 30, 2023, the Company recorded approximately \$25,000 in gross product sales to Wholesaler #1, and approximately \$2,000 in gross product sales to Wholesaler #4. Notably, Wholesaler #1 had previously indicated its intent to return its supply of OLINVYK in October 2022 (at which point the Company recorded an adjustment to its returns reserve as described above) and in fact carried out the return of substantially all of its supply of OLINVYK in February 2023.

Based on discussions with Wholesaler #1 and Wholesaler #4, the Company understood that these sales during the three months ended June 30, 2023 were due to demand and orders that Wholesaler #1 and Wholesaler #4 had received for OLINVYK from their respective customers. In addition, due to its recent return of OLINVYK in February 2023, Wholesaler #1 effectively had no other supply of OLINVYK with which to fulfill such demand and orders from its customers.

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As a result, Trevena estimated returns of approximately 2% for the gross product sales to Wholesaler #1 and Wholesaler #4. The Company recorded approximately \$21,000 in net product sales in the three months ended June 30, 2023. The Company reviewed its returns reserve and other GTN adjustments in connection with preparing its financial statements for the quarter ended June 30, 2023 and did not identify other factors that would result in a material change.

*Revise your future filings to provide a tabular breakdown of your gross sales as reduced by various adjustments, including reductions for future estimated returns, to reconcile to net revenue as presented on your Statement of Operations for all periods presented. In your response, provide us with sample disclosure for the first and second quarters of 2023.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments and will provide a tabular breakdown of gross sales as reduced by various adjustments, including reductions for future estimated returns, to reconcile to net revenue for all periods presented. As requested by the Staff, a sample of such disclosure is provided below.

For the three months ended March 31, 2023, the Company recorded gross sales of approximately \$7,000, and GTN adjustments of \$1,000 resulting in net sales of approximately \$6,000. The amounts in the following table are in thousands.

	Three Months Ended March 31,	
	2023	2022
Product revenue, gross	\$ 7	\$ -
GTN adjustments		
Chargebacks and cash discounts	(1)	-
Returns	(0)	-
Other rebates, discounts and adjustments	(0)	-
Total GTN adjustments	(1)	-
Product revenue, net	\$ 6	\$ -

For the three months ended June 30, 2023, the Company recorded gross sales of approximately \$27,000, and GTN adjustments of approximately \$6,000 resulting in net sales of approximately \$21,000. For the six months ended June 30, 2023, the Company recorded gross sales of approximately \$34,000, and GTN adjustments of approximately \$7,000 resulting in net sales of approximately \$27,000. The amounts in the following table are in thousands.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Product revenue, gross	\$ 27	\$ -	\$ 34	\$ -
GTN adjustments				
Chargebacks and cash discounts	(2)	-	(3)	-
Returns	(1)	-	(1)	-
Other rebates, discounts and adjustments	(3)	-	(4)	-
Total GTN adjustments	(6)	-	(7)	-
Product revenue, net	\$ 21	\$ -	\$ 27	\$ -

- As noted in your response to the sixth bullet of prior comment one, you disclose in your Form 10-Q for the period ended June 30, 2023 that sales from wholesalers to hospitals and ambulatory surgical centers have occurred, at a low level, every quarter since your commercial launch of OLINVYK. Please tell us the amount of quarterly sales by the wholesalers to end customers for each of the quarters since its commercial launch, and revise your future filings to provide quantified disclosure for the periods presented. As part of such disclosure, discuss the trends in sales levels to the end user and how you considered such trends in determining the amount of reduction of revenue for future returns.

**RESPONSE:** Sales from wholesalers to hospitals and ambulatory surgical centers (ASCs) have occurred, at a low level, every quarter since the commercial launch of OLINVYK. Trevena receives reports on orders that the wholesalers fulfill. Based on these reports, starting from the first quarter of launch in Q1 2021, commercial sales of OLINVYK to hospitals and ASCs were approximately as follows: \$300 (1Q 21), \$9,700 (2Q 21), \$3,700 (3Q 21), \$8,700 (4Q 21), \$12,400 (1Q 22), \$4,700 (2Q 22), \$7,600 (3Q 22), \$11,000 (4Q 22), \$14,700 (1Q 23) and \$23,800 (2Q 23). While there is a general quarterly upward trend from 1Q 22 through 2Q 23, the overall level of these sales remains low.

The Company respectfully acknowledges the Staff's comments and will provide quantified disclosure for the periods presented. As part of such disclosure, the Company will discuss trends in sales levels to the end user and how the Company considered such trends in determining the amount of reduction of revenue for future returns.

*In response to the seventh bullet of prior comment one, as well as the related disclosure added in your Form 10-Q for the period ended June 30, 2023, you list multiple positive factors that might affect or have affected sales of OLINVYK. To the extent you are aware of negative data, perceptions of your product, or other information that may be negatively affecting the level of sales to end customer hospitals, revise your future filings to clearly disclose such information. Provide us with your proposed revised disclosure as part of your response.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments and will revise future filings to clearly disclose negative data, perceptions of the Company's product, or other information that may be negatively affecting the level of sales to end customer hospitals. The proposed revised disclosure is set forth below, which shows the text from our quarterly report on Form 10-Q filed with the Commission on August 14, 2023, with marked changes to highlight the Company's proposed revisions.

In our returns reserve analysis, we also consider feedback from our wholesalers, group purchasing organizations and users of OLINVYK, as well as additional factors such as new safety data, or clinical or health economic data for OLINVYK that may affect future adoption and sales trends. Examples include OLINVYK data we announced in April 2022 with respect to respiratory physiology, and in July 2022 with respect to cognitive function. More recently in July 2023, we also announced OLINVYK data with respect to reduced cost per admission for hospitals and reduced average length of hospital stay, for OLINVYK-treated patients compared to matched patients treated with other IV opioids. **We also consider factors that may negatively affect sales of OLINVYK, such as the price of OLINVYK compared to conventional IV opioids, which are generally generic and available at a lower initial cost relative to OLINVYK. Other factors may include the public perception of opioids in general, as well as the FDA's and HHS' policy initiatives that may limit the promotion and marketing of opioids.**

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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

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