

[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested by Supernus Pharmaceuticals, Inc. with respect to portions of this letter.

November 16, 2018

VIA EDGAR and Overnight Delivery

United States Securities and Exchange Commission  
Division of Corporation Finance  
Office of Healthcare & Insurance  
100 F Street, NE  
Washington, DC 20549

**FOIA Confidential Treatment Request by  
Supernus Pharmaceuticals, Inc. Pursuant to  
Rule 83 (17 C.F.R. § 200.83)**

Re: Supernus Pharmaceuticals, Inc.  
Form 10-K for the Fiscal Year Ended December 31, 2017  
Filed March 1, 2018  
File No. 001-35518

Dear Ms. Baynes:

This letter sets forth the responses of Supernus Pharmaceuticals, Inc. (the "Company," "we" or "our") to the comment letter received from the Staff of the Division of Corporation Finance (the "Staff") of the Securities and Exchange Commission on November 2, 2018 (the "Letter") concerning the Staff's review of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed on March 1, 2018.

To assist your review, we have reproduced in bold below the text of the Staff's comments. The headings and numbered paragraphs in this letter correspond to the headings and numbered paragraphs in the Comment Letter. Unless otherwise noted, references to page numbers and sections herein are to the above referenced Form 10-K. Capitalized terms used but not defined herein have the meanings ascribed to them in the Form 10-K.

**Form 10-K for the Fiscal Year Ended December 31, 2017**

**Management's Discussion and Analysis of Financial Condition and Results of Operation**

**Critical Account Policies and Use of Estimates**

**Revenue Recognition, page 64.**

1. **It appears from your response to prior comment 1 that your gross-to-net adjustments recorded in 2016 related to sales of prior years was significant to your operating earnings and earnings before income taxes in 2016. To the extent that re-estimates of prior year gross-to-net variable consideration is significant in future periods, please**

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**represent to us that you will disclose herein the impact on your product sales and operating results and include in your financial statement the disclosure required by ASC 606-10-50-12A.**

The Company acknowledges the Staff's comment regarding the required disclosures under ASC 606-10-50-12A. The Company adopted ASC 606 at January 1, 2018, the effective date of the standard. Quarterly, the Company evaluates the adjustments of prior year gross-to-net variable considerations and to the extent that these adjustments are determined to be significant, the Company will disclose any such adjustments in its current financial statements. The Company notes that we have included a disclosure in the footnotes section of the Form 10-Q reports filed in 2018 specifically disclosing the results of our evaluation that revenue recognized from performance obligations related to prior periods were not material. See references below:

- Page 11 of report on Form 10-Q for the Quarterly Period Ended March 31, 2018
- Page 12 of report on Form 10-Q for the Quarterly Period Ended June 30, 2018
- Page 12 of report on Form 10-Q for the Quarterly Period Ended September 30, 2018

The Company confirms that it will continue to disclose the impact of changes to prior year gross-to-net variable considerations, to the extent these are significant, and include the disclosures in the financial statements as required by ASC 606-10-50-12A.

- 2. It appears from your response to prior comment 1 that your gross-to-net adjustment for sales returns of Oxtellar XR recorded in 2016 related to prior period was significant to your net product sales for Oxtellar XR in 2016 and to your estimated reserve balance at December 31, 2015. Given the magnitude of this adjustment recorded in 2016, please tell us how you were able to make reasonable estimates of product returns in order to recognize product sales of Oxtellar XR revenue upon product shipment under ASC 605-15-25-1f applicable at the time.**

The Company advises the staff that we believe that recognition of revenue for our Oxtellar XR product at the time of shipment to wholesalers / distributors meets the condition for revenue recognition under ASC 605-15-25-1f.

The Company believes we have consistently applied a reasonable and supportable basis for determining our estimate for future product returns and that the magnitude of the adjustment in 2016 was not material to our overall financial results.

**EXPIRED PRODUCT RETURNS POLICY:**

Oxtellar XR is a medication for treatment of epilepsy. Epilepsy is a chronic condition, with patients maintaining once daily dosing until or unless being switched to an alternative therapy. Failure to maintain daily dosing greatly increases the likelihood of seizure(s).

Consistent with the pharmaceutical industry practice, our returned goods policy allows for undamaged and unused product to be returned six months prior to and 12 months post expiry date of that lot. Prior to expiry, neither wholesalers nor pharmacies can

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return undamaged or unused product. At launch in 2013, Oxtellar XR had three year dating. Product dating has subsequently been increased to four years. Due to the expiration dating of Oxtellar XR, wholesalers and distributors typically have 18 months to 42 months to sell product before it is eligible for return.

The Company's product returns policy generally permits returns to be processed at current wholesaler price, rather than at historical purchase price. Consequently, any price increase(s) taken during the current period increases our provision for product returns, for both sales made in the current period as well as sales made in prior periods.

#### RETURNS METHODOLOGY AND PROCESS FOR RETURNS PROVISIONING:

Our methodology for establishing the allowance for product returns is based on two factors. First, actual returns data generated by our commercial products. Second, industry returns experience for similar products; i.e., ambient temperature storage of oral formulations. Our methodology is further informed by prescription data and inventory held in the supply chain. The Company calculates the estimated provision for returns quarterly, by lot and for each individual product. Our estimates have been refined as new returns information is gained.

Regarding actual returns data, our methodology calculates, for each lot, the number of units returned as a percentage of the total number of units shipped. On a quarterly basis, we compute the actual return rate for that lot, as of quarter end, and project the return rate for that lot through 12 months post expiry; i.e., through to its ultimate return date. As we generate additional actual returns experience, we increasingly rely on the actual data set of information, and consequently rely diminishingly on industry experience.

For lots which have not yet reached expiry, the Company uses both actual returns data generated in preceding Oxtellar XR lots, as well as industry returns experience for products similar to Oxtellar XR; e.g., ambient storage; oral formulation; comparable shelf life, and same dosage form. Based on information provided by the three major pharmaceutical product wholesalers / distributors (i.e., McKesson Corporation, Cardinal Health, Inc. and Amerisource Bergen Corporation, collectively "the Three Major Wholesalers / Distributors"), we ascertained that the return rate at 'steady state' (i.e., 5+ years post launch) for a product such as Oxtellar XR is expected to range from [\*\*\*] to [\*\*\*] of each lot.

In January 2014, product dating was extended for Oxtellar XR to four years. Extended dating affords pharmacists greater opportunity to fill prescriptions from stock on hand and thereby reduce the exposure for returns because there is a longer period during which pharmacies can sell the product.

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Oxtellar XR is still in the process of maturing in the marketplace. Consequently, as we gain additional returns experience, we adjust our allowance for product returns as applied to both sales consummated in the current period as well as sales consummated in prior periods.

ASC 605 FACTORS (ASC 605-15-25-3A THROUGH 3D) AND SAB TOPIC 13(A)(4)(B).

The Company reviewed ASC 605 factors as well as SAB Topic 13 in assessing factors which would allow determination of product returns.

- Susceptibility of product to significant external factors, such as technological obsolescence or changes in demand.<sup>(1)</sup>

Oxtellar XR is a branded pharmaceutical product and has multiple Orange Book listed patents that do not expire until 2027, which we believe should inhibit generic entry. To our knowledge, there are no products which would render Oxtellar XR technologically obsolete, either in the market or under development. We believe we have significant visibility on new potential market entrants.

Based on our assessment, we believe this factor is not present and therefore does not impede our ability to make reasonable estimates of product returns.

- Relatively long periods in which a particular product may be returned.

As explained in our returns policy, we allow product to be returned 6 months prior to and up to 12 months post expiration. These are standard terms within the pharmaceutical industry and therefore are customary and not atypically long.

Based on our assessment, we believe this factor is not present and therefore does not impede our ability to make reasonable estimates of product returns.

- Absence of historical experience with similar type of sales of similar products, or inability to apply such experience because of changing circumstances, for example changes in selling enterprise's marketing policies or relationships with customers.

For lots which have not yet reached expiry, the Company uses both actual returns data generated in preceding Oxtellar XR lots, as well as industry returns experience for products similar to Oxtellar XR; e.g., ambient storage; oral formulation; comparable shelf life, and dosage form. Based on information provided by the three major pharmaceutical product wholesalers / distributors, we ascertained that the

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- (1) We have considered similar additional factors under SAB Topic 13(A)(4)(b) pertaining to expected introductions of new products or competitor's products that may result in the technological obsolescence and for same reason as indicated in our response above, determined these factors are not present and therefore do not impact our ability to estimate returns.

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return rate at 'steady state' (i.e., 5+ years post launch) for a product such as Oxtellar XR is expected to range from [\*\*\*] to [\*\*\*] of each lot.

There are numerous other branded extended release anti-epileptic products within the industry. Our product is not unique in that regard.<sup>(2)</sup>

Although the Company's historical return experience in 2016 for Oxtellar XR was limited, there was available industry data for products similar to Oxtellar XR to support the estimated return rate, as discussed. Therefore, we believe this factor does not impede our ability to make reasonable estimates of product returns.

· Absence of large volume of relatively homogenous transactions:

Oxtellar XR is a drug in oral dosage form (i.e., tablet) which is packaged with a regulatory approved NDC number for each dosage form and sold in large volumes of homogenous transactions.

Based on our assessment, we believe this factor is not present and therefore does not impede our ability to make reasonable estimates of product returns.

· Lack of visibility into or the inability to determine or observe the levels of inventory in a distribution channel and the current level of sales to end user:

Since launch, we observed stable growth in patient usage of the product, stable product ordering patterns and stable weeks of coverage at our wholesalers / distributors. We have a high degree of visibility with regard to inventory levels and throughput of wholesalers/distributors.

We regularly monitor channel quantities by reviewing the weekly supply reports from the Three Major Wholesalers / Distributors, which represents 96% of sales in 2015 and 2016, and by purchasing third party prescription data to monitor inventory and throughput at the pharmacy level.

Based on this monitoring, we estimate product held at distributors and on pharmacy shelves in 2015 and 2016. Because inventory held by wholesalers consists of relatively recently manufactured product, and therefore has several years of remaining dating, the risk of expired product returns from distributors is minimal. Based upon our historical review of the morgue reports (i.e., nonsalable inventory) from the wholesalers / distributors, we observed little/no inventory being held for return.

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(2) We have considered the newness of the product factor under Topic 13(A)(4)(b) and for same reason as indicated in our response above, determined this factor is not present and therefore does not impact our ability to estimate returns.

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Based on our assessment, we believe this factor is not present and therefore does not impede our ability to make reasonable estimates of product returns.

· Significant increases in or excess levels of inventory in a distribution channel (aka channel stuffing):

We regularly monitor channel quantities by reviewing the weekly supply reports from the Three Major Wholesalers / Distributors, which represents 96% of sales in 2015 and 2016, and by purchasing third party prescription data to monitor inventory and throughput at the pharmacy level. Based on this information, we have not seen any significant increases or excess levels of inventory at any stage of the distribution channel.

We have not sold short-dated product nor engaged in pricing or promotional activities which could result in channel stuffing.

Based on our assessment, we believe this factor is not present and therefore does not impede our ability to make reasonable estimates of product returns.

· The significance of a particular distributor to the registrant's (or a reporting segment's) business, sales and marketing:

We sell our products to wholesalers / distributors including the nationally recognized big Three Major Wholesalers / Distributors, as well as other approved wholesalers / distributors. The number of distributors has not been a significant factor in our ability to estimate returns.

Based on our assessment, we believe this factor is not present and therefore does not impede our ability to make reasonable estimates of product returns.

OXTELLAR XR RETURNS HISTORY

Oxtellar XR was launched in February 2013. The initial lots sold in 2013 had expiration dates ranging from 3Q2015 to 1Q2016. Prior to 3Q2015, as we expected, product return activity was limited. Consequently, prior to 3Q2015, our returns reserve was based primarily on industry experience.

Industry experience demonstrates that lots which are shipped upon launch (i.e., 'load-in' lots) typically experience higher rates of return due to product expiry. This occurs because it is difficult to predict, a priori, which pharmacies are likely to experience significant demand for the product and, conversely, which pharmacies will experience little demand. Product returns due to expiry of load-in lots are overwhelmingly driven by returns from 'slow moving pharmacies'.

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## 2015 Experience

We, in fact, anticipated that the returns data for load-in lots would be atypically high and reflected this expectation in the return reserve. However, actual returns data for lots expiring in 3Q2015 exceeded our returns estimates. Consequently, we increased our reserve for returns for load-in lots as of mid-2015 to reflect this experience.

Lots shipped subsequent to load in are generally expected to experience substantially lower levels of expiry-driven returns. This occurs primarily because of a self-selection phenomena, whereby only pharmacies that are experiencing demand for product will place a follow on order. Inventory at these pharmacies should be relatively fast moving because there is an underlying base of active patients. Conversely, pharmacies experiencing little/no demand will place few, if any, follow on orders.

Because the return rate for load-in lots exceeded our initial estimates, we also increased our estimates for follow-on lots in 3Q2015, but to a lesser extent.

Throughout this period, we consistently applied our methodology for estimating returns, and accounted for these adjustments as a change in estimate.

## 2016 Experience

During 2016, we continued to gain additional experience for returns of expired product associated with both the load-in and follow-on lots. The additional experience for the load-in lots was not significantly different than our expectations as of year-end 2015, as we had received [\*\*\*] of the actual total returns as of December 31, 2015. Consequently, the adjustment in 2016 to the returns reserve for the load-in lots was *de minimis*.

As of December 31, 2015, we anticipated the returns rates for the follow-on lots would be less than for the load-in lots but greater than the steady-state return rate. However, actual returns data for lots expiring in 2016 exceeded our returns estimates. Therefore, we recognized out of period expense in 2016 as we continued to increase our reserve for returns for these lots, as well as lots expiring in 2017.

During 2016, the Company consistently applied the same methodology in determining our returns allowance. We continued to adjust our reserve to take into account the most recent actual returns information.

In 2016, we recorded a current provision related to sales made in prior periods of [\*\*\*], as described in our previous comment letter. As mentioned in that letter, this [\*\*\*] year over year change was comprised of both price and volume adjustments. Of the [\*\*\*] total, [\*\*\*] was related to price increases taken during 2016 which affected the returns allowance for sales consummated prior to 2016. The right of return at the new price only

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became effective in 2016; therefore, we do not consider this to be an out-of-period adjustment. The remainder, [\*\*\*], was attributable to adjustments to the returns reserve to reflect the higher return rates for both load-in and follow-on lots.

The Company concluded that, the [\*\*\*] adjustment was a refinement in estimate and was accounted for as a change in estimate. Additionally, the Company determined that this amount was not material, either quantitatively or qualitatively, to our overall financial results.

Given that we had actual data from both load-in lots and follow-on lots, and that these data showed that the actual results varied from our estimates by an immaterial amount of [\*\*\*], the Company continues to conclude we had a strong basis for estimating expected future product returns throughout the year.

#### SUMMARY AND MATERIALITY ASSESSMENT

During 2016, the Company consistently applied the same methodology in determining our returns allowance. We continued to adjust our reserve to take into account the most recent actual returns experience and information.

In 2016, we recorded a current provision related to sales made in prior periods of [\*\*\*], as described in our previous comment letter. As mentioned in that letter, this [\*\*\*] year over year change was comprised of both price and volume adjustments. Of the [\*\*\*] total, [\*\*\*] related to price increases taken during 2016 which affected the returns allowance for sales consummated prior to 2016. We do not consider this to be an out-of-period adjustment. The remainder, [\*\*\*], was attributable to adjustments to the returns reserve for both load-in and follow-on lots.

We considered the materiality of the approximately [\*\*\*] remaining adjustment (i.e., [\*\*\*] less the [\*\*\*] impact of price increase). While we believe that our reported net product sales figure is important to investors, we also believe that the precision of any estimate used in the preparation of financial statements needs to be evaluated in the context of materiality of the overall financial statement preparation. We assessed the materiality and degree of precision of this estimate as compared to the key financial amounts reported in our financial statements. We assessed materiality using quantitative metrics which we actively use in monitoring our business and which we also believe are critical quantitative metrics to investors.

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The impact of this adjustment to the calendar year 2016 is shown in the table below.

(\$ in Millions)	Period 2016
Impact of Oxtellar XR 2016 recorded current provision related to prior period sales (excluding price increase impact)	\$ [***]
As percentage of Balance Sheet Amounts	
Total Accrued Sales Deductions	[***]
Total Liabilities	[***]
As percentage of Income Statement Amounts	
Oxtellar XR Net Product Sales	[***]
Total Net Product Sales	[***]
Total Operating Income	[***]
As percentage of Total Gross-to-Net Deductions*	
Oxtellar XR Gross Sales	[***]
Oxtellar XR Gross-to-Net Deductions	[***]
Total Gross Product Sales	[***]
Total Gross-to- Deductions	[***]

\* Note that these amounts are not presented in the financial statements and are included herein for analysis only.

Our analysis, as shown above, shows that the incremental impact of the referenced adjustment is [\*\*\*] or less in 2016, as measured against reported financial statement amounts. As shown above, the impact of the [\*\*\*] adjustment is below [\*\*\*] of total Oxtellar XR net product sales, total net product sales and operating income for 2016. In addition, it represents about [\*\*\*] of the total gross-to-net deductions for Oxtellar XR and less when compared to total gross-to-net deductions. The impact to other qualitative metrics that both management as well as investors normally use in monitoring progress of our business i.e., current ratio, quick ratio, operating margin, debt service coverage ratio, and debt to equity ratio measures are affected to only a de *minimis* amount by this change.

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Given that we had actual data from both load-in lots and follow-on lots, and that these data showed that the actual results varied from our estimates by an immaterial amount of [\*\*\*], the Company continues to conclude we had a strong basis for estimating expected future product returns throughout 2016.

Based on discussion above, we believe that Company has a reasonable methodology and strong basis to estimate returns for Oxtellar XR, that the amount of future returns can be reasonably estimated at the time of sale and therefore, continue to believe we can recognize product sales of Oxtellar XR upon product shipment.

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If you have any questions or comments regarding the response or require additional information, please do not hesitate to contact me at (301) 838- 2522.

Sincerely,

/s/ Gregory S. Patrick

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Gregory S. Patrick

Vice President and Chief Financial Officer

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