

VIA EDGAR

September 18, 2018

Ms. Vanessa Robertson and Ms. Mary Mast
U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F. Street, N.E.
Washington, D.C. 20549

Re: ANI Pharmaceuticals, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2017
Filed February 27, 2018
File No. 001-31812

Dear Ms. Robertson and Ms. Mast:

We are hereby submitting this letter in response to your September 7, 2018 comment letter (the "**Comment Letter**") from the staff ("**Staff**") of the Securities and Exchange Commission ("**Commission**") to ANI Pharmaceuticals, Inc. (the "**Company**").

Paragraph No. 1 set forth below responds to the Staff's comment in the Comment Letter. Bold face type indicates the Staff's comment set forth in the Comment Letter.

5. Intangible Assets

Definite-lived Intangible Assets

Acquisition of New Drug Applications and Product Rights, page 89

1. You recorded the February and December 2017 acquisitions as asset acquisitions. Please tell us, for each acquisition, why you believe the acquisitions are not required to be recorded as an acquisition of a business pursuant to ASU 2017-01. In this regard, please specifically address the following:

- As it appears you acquired both tangible and intangible assets in the February acquisitions and the December acquisition appears to relate to assets with significantly different risks, please confirm our understanding that the acquisitions did not meet the "practical screen" in ASC 805-10-55-5A through 55-5C as the term is used in ASC 805-10-55-5. Refer also to the example in ASC 805-10-55-68.

- Please address each of the criteria in ASC 805-10-55-5E in determining whether or not a substantive process was acquired, that together with the input acquired, significantly contribute to the ability to create outputs.

RESPONSE:

We acknowledge the Staff's comment and the FASB requirements with respect to determining if a transaction is a business combination or an asset acquisition.

Inderal XL

In February 2017, we acquired a distribution license and trademark for the Inderal XL product, which we classify as a product rights intangible asset in accordance with ASC 805-20-55-18. In addition, we acquired finished goods inventory.

Per ASC 805-10-55-5Ba:

A single identifiable asset includes any individual asset or group of assets that could be recognized and measured as a single identifiable asset in a business combination. However, for purposes of this evaluation, the following should be considered a single asset:

a. A tangible asset that is attached to and cannot be physically removed and used separately from another tangible asset (or an intangible asset representing the right to use a tangible asset) without incurring significant cost or significant diminution in utility or fair value to either asset (for example, land and building)

Per ASC 805-20-55-18:

The terms *brand* and *brand name*, often used as synonyms for trademarks and other marks, are general marketing terms that typically refer to a group of complementary assets such as a trademark (or service mark) and its related trade name, formulas, recipes, and technological expertise. This Subtopic does not preclude an entity from recognizing, as a single asset separately from goodwill, a group of complementary intangible assets commonly referred to as a brand if the assets that make up that group have similar useful lives.

The finished goods inventory acquired in the asset acquisition cannot be marketed or sold by ANI Pharmaceuticals, Inc. ("ANI") without the related product rights. As a prescription pharmaceutical drug manufacturer and marketer focused on the United States domestic market, we operate in a highly regulated industry, and our business is directly regulated by the U.S. Food and Drug Administration (the "FDA"). The FDA grants rights to market and distribute pharmaceutical products in the form of an approved New Drug Application ("NDA") (among other FDA-mandated regulatory pathways). In this transaction, if we only acquired the inventory without the corresponding right to the NDA, we would have no lawful right to market or sell the inventory, as a pharmaceutical product, such as Inderal XL, can only be sold in the U.S. under the rights conferred by the approved NDA or a license thereto. As a result, we concluded that, in accordance with ASC 805-10-55-Ba, the product rights and the finished goods inventory together represent "a single identifiable asset," and therefore the acquisition met the "practical screen" and was accounted for as an asset acquisition.

InnoPran XL

In February 2017, we acquired the NDA and trademark for the InnoPran XL product, which we classify as a product rights intangible asset in accordance with ASC 805-20-55-18. In addition, we acquired finished goods inventory.

The finished goods inventory acquired in the asset acquisition cannot be sold or benefitted from in any way without the related product rights. As discussed above, our business is closely regulated by the FDA and the rights to market and distribute pharmaceutical products are granted by the FDA in the form of NDA filings. As a result, the InnoPran XL product can only be sold under the NDA filing or a license thereto. Accordingly, we concluded that, in accordance with ASC 805-10-55-Ba, the product rights and the finished goods inventory together represent a single identifiable asset, and therefore the acquisition meets the practical screen for the transaction to be accounted for as an asset acquisition. In this regard, the fact patterns for the acquisitions for the InnoPran XL and InnoPran XL assets were very similar, and the accounting treatment for the acquisitions was consistent.

Product Rights Acquired from AstraZeneca

In December 2017, we acquired from AstraZeneca AB and AstraZeneca UK Limited the right, title, and interest in the NDAs and the U.S. rights to market Atacand®, Atacand HCT®, Arimidex®, and Casodex®, and also licensed the trademarks for these products. We classify NDAs, U.S. rights to market products, and trademarks for a product together as a product rights intangible asset for the product in accordance with ASC 805-20-55-18. In our analysis of the transaction, we determined that the four product rights intangible assets acquired form a group of similar assets with similar risks associated with the group.

Similar Assets

Per ASC 805-10-55-5C:

A group of similar assets includes multiple assets identified in accordance with paragraph 805-10-55-5B. When evaluating whether assets are similar, an entity should consider the nature of each single identifiable asset and the risks associated with managing and creating outputs from the assets (that is, the risk characteristics). However, the following should not be considered similar assets:

- a. A tangible asset and an intangible asset
- b. Identifiable intangible assets in different major intangible asset classes (for example, customer-related intangibles, trademarks, and in-process research and development)
- c. A financial asset and a nonfinancial asset
- d. Different major classes of financial assets (for example, accounts receivable and marketable securities)
- e. Different major classes of tangible assets (for example, inventory, manufacturing equipment, and automobiles)
- f. Identifiable assets within the same major asset class that have significantly different risk characteristics.

Per ASC 805-10-55-68:

Pharma Co. concludes that Project 1 and Project 2 are each separately identifiable intangible assets, both of which would be accounted for as a single asset in a business combination. Pharma Co. then considers whether Project 1 and Project 2 are similar assets. Pharma Co. notes that the nature of the assets is similar in that both Project 1 and Project 2 are in-process research and development assets in the same major asset class. However, Pharma Co. concludes that Project 1 and Project 2 have significantly different risks associated with creating outputs from each asset because each project has different risks associated with developing and marketing the compound to customers. The projects are intended to treat significantly different medical conditions, and each project has a significantly different potential customer base and expected market and regulatory risks associated with the assets. Thus, Pharma Co. concludes that substantially all of the fair value of the gross assets acquired is not concentrated in a single identifiable asset or group of similar identifiable assets and that it must further evaluate whether the set has the minimum requirements to be considered a business.

The product rights acquired in ANI's asset acquisition are for products with different indications. However, all four products share one important attribute in that they have been off-patent for several years and that they have been marketed in the U.S. for more than 17 years. Within the pharmaceutical industry, this type of product is referred to as a "tail brand", which signifies that the product is no longer promotionally sensitive. These products are well-established in the marketplace after years of promotion by the original marketer of the brand (in this case AstraZeneca) and have been subject to generic competition for numerous years and as such have a *de minimus* residual market share (as measured by volume). Tail brands are typically not heavily promoted and, as in this case, ANI does not support these brands with any significant promotional activity and does not detail the products with a sales force. As such, the marketing approach and corresponding risk is extremely low and is similar across all tail brand products despite their differing product indications. In addition, because the products have all been sold on the market for more than 17 years, their regulatory risk is minimal, and we concluded that the example in ASC 805-10-55-68 did not apply to these particular facts and circumstances. As a result, we concluded that the risks related to these four products are similar and therefore the assets acquired in the acquisition form a group of similar assets that meet the requirements for the practical screen. Based on this conclusion, we accounted for the transaction as an asset acquisition.

As described above, our internal analysis of each of these three transactions focused on applying the practical screen as the primary factor of our determination that these transactions were each an asset acquisition and not a business combination. As such, we respectfully have not specifically responded to the second bullet in your question relating to the criteria in ASC 805-10-55-5E because it was not a component of our internal determination of the accounting for these transactions. As discussed above, we determined that these transactions are properly accounted as asset acquisitions through the guidance included in the practical screen.

Thank you for reviewing our response. Should you have any questions, please do not hesitate to contact Brian Lee at (212) 768-6926.

Sincerely,

/s/ Stephen P. Carey

Stephen P. Carey

Vice President, Finance and CFO

cc: Arthur S. Przybyl, President and CEO
Paul A Gajer, Esq., Dentons US LLP
Brian Lee, Esq., Dentons US LLP