ANI Pharmaceuticals, Inc.
210 Main Street West
Baudette, Minnesota 56623

December 5, 2022

Division of Corporation Finance
Office of Life Sciences
United States Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Re: **ANI Pharmaceuticals, Inc.**
Form 10-K for Fiscal Year Ended December 31, 2021
Filed March 15, 2022
Form 8-K furnished August 8, 2022
File No. 001-31812

Ladies and Gentlemen:

Set forth below are the responses of ANI Pharmaceuticals, Inc. (the "Company," "ANI," "we," "us" or "our") to comments received from the staff of the Division of Corporation Finance (the "Staff") of the Securities and Exchange Commission (the "Commission") by letter, dated November 1, 2022. For your convenience, each response is prefaced by the exact text of the Staff's corresponding comment in bold, italicized text.

Form 8-K Furnished August 8, 2022

Non-GAAP Financial Measures, page 6

1. ***Your non-GAAP reconciliation includes an adjustment for the Impact of Canada operations. You disclose that you intend to consolidate manufacturing operations and cease operations at your Oakville, Ontario, Canada manufacturing. You also state that you plan to support future growth and continue serving customers through your remaining facilities. Please tell us why you believe the adjustment for operational synergies is consistent with Question 100.01 of the Division's Compliance & Disclosure Interpretations ("C&DI") on Non-GAAP Financial Measures.***

RESPONSE: ANI is a marketer of pharmaceutical products in the United States and during the period of August 2018 through November of 2021, owned and operated three pharmaceutical manufacturing plants, including our facility in Oakville, Ontario, Canada ("Canada"). In November of 2021, ANI acquired Novitium Pharma LLC ("Novitium"), and in conjunction with the acquisition obtained a fourth pharmaceutical manufacturing plant. During the integration of Novitium, we determined that three manufacturing plants would support our manufacturing capacity needs and that to retain a fourth plant would result in idle capacity. Thus, it was decided to close the Canada plant and move the majority of production being undertaken in Canada to the remaining U.S based manufacturing plants.

When preparing our financial statements for the three-month period ended June 30, 2022, we considered the proper presentation and disclosure of the closure of Canada and determined that the actions being taken did not meet the criteria of ASC 205 – Discontinued Operations. The principal factors that led to this conclusion were that the disposal of Canada did not represent a strategic shift in operations, nor did it have a major effect on the overall operation of the Company. The Canada manufacturing facility was one of four facilities and did not have any particular attribute nor was it associated with a particular segment, product line, technology, etc. As such, we continue to report the impact of Canada operations in our Loss Before Benefit for Income Taxes (from continuing operations) in our Statement of Operations.

We believe, however, that the activities and associated Revenues and Expenses during the wind-down period of Canada represents non-recurring activities and corresponding financial results that will cease as of March 31, 2023. And while the action did not rise to Discontinued Operations presentation for the GAAP financial statements, we believe that highlighting the non-recurring nature of the financial impact of Canada during the wind-down period in our non-GAAP financial measures would be useful to the readers of our financial statement in addition to the disclosures provided in Footnote 4 “Restructuring” of our Form 10-Q for the second quarter of 2022 as filed on August 8, 2022 (“Footnote 4”).

The intent of the disclosure is to provide readers of our financial statements an understanding of our non-GAAP results excluding the non-recurring impact of Canada operations. As disclosed in our August 8th Earnings Release and detailed on Table 3 to such release, we have removed all effect of Canada operations through the subtraction of Canada cost of sales, SG&A expense, R&D expense, restructuring charges, stock-based compensation, and depreciation and amortization in calculating non-GAAP Adjusted EBITDA (and similar for non-GAAP Net Income and non-GAAP Diluted Earnings per Share as disclosed in Table 4). In addition, to be balanced and consistent, we have also excluded third party revenue generated from Canada in our non-GAAP results (which will also not recur upon closure).

As highlighted in Question 100.01 of the Division’s Compliance & Disclosure Interpretations on Non-GAAP Financial Measures:

“Certain adjustments may violate Rule 100(b) of Regulation G because they cause the presentation of the non-GAAP measure to be misleading. For example, presenting a performance measure that excludes normal, recurring, cash operating expenses necessary to operate a registrant’s business could be misleading. [May 17, 2016]”

Given that we anticipate that revenues and expenses relating to Canada will be de minimis (nearly zero) by April 1, 2023, we believe that revenues and expenses during the wind-down phase of the business (from June date of announcement through March 2023 closure) should be viewed as non-recurring in context of our non-GAAP measures as such revenue and expense will not recur in the period beginning April 1, 2023. We also believe that we have provided adequate transparency and detail to the reader of our non-GAAP financial metrics to understand the intent of our treatment. Finally, we take care to closely align the non-GAAP financial metrics that we present to the public with the metrics that are provided to our Board of Directors (“Board”) in discussing the performance of our business internally, and the key metrics on which the Board evaluates management’s performance including for executive compensation as will be disclosed in our CD&A in the 2023 Proxy Statement.

2. ***We acknowledge that you state in footnote 3 that beginning in 2022, you no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP EBITDA. However, we note that you continue to include the adjustment in prior periods. Since it appears that these costs fall under C&DI Question 100.01, please confirm you will eliminate the adjustment in future filings or tell us why you believe it is appropriate to continue to adjust for these normal cash operating costs.***

RESPONSE: Since 2016, ANI has been working toward FDA approval of Purified Cortrophin Gel ("Cortrophin"), its first rare disease (branded) pharmaceutical product. Prior to 2021, ANI, as a predominately Generic pharmaceutical company, had no Rare Disease Sales and Marketing headcount, infrastructure, or expertise. In the first quarter of 2021, in anticipation of FDA approval of Cortrophin, ANI began to hire employees and build an internal Rare Disease management team and prepare for launch of the product. During the twelve months ended December 31, 2021, ANI incurred $13.5 million of SG&A pre-launch expenses for Cortrophin. These efforts were undertaken with significant uncertainty as to whether the product would be approved for sale by the United States Food and Drug Administration ("FDA"). If Cortrophin was ultimately not approved by the FDA, we would be forced to cease significant portions of our pre-launch efforts and the pre-launch spend would not have recurred in future periods.

Given the magnitude of this effort and corresponding expense in relation to ANI's existing SG&A base (2021 pre-launch SG&A expense of $13.5 million as compared to $61.5 of 2021 SG&A excluding this spend), we believed that it was useful to the readers of our financial statements to add back this expense in calculating our non-GAAP results. With this treatment, comparison of our 2021 non-GAAP results to our prior year non-GAAP results would be more comparable. Further, by highlighting the 2021 expense in the non-GAAP tables, it gave the Company's efforts and the corresponding expense of such efforts further prominence and thus provided management a further basis to discuss the impact of the Rare Disease team buildout with our constituents in the investment community.

Cortrophin was approved by the FDA in October of 2021, and we launched the product in the first quarter of 2022. From this point forward, all Cortrophin related SG&A was no longer pre-launch, and therefore beginning in our first quarter 2022 earnings release, and corresponding 8-K we ceased adding back Rare Disease SG&A in our non-GAAP results as the expense is now normal and recurring.

As highlighted in Question 100.01 of the Division's Compliance & Disclosure Interpretations on Non-GAAP Financial Measures:

"Certain adjustments may violate Rule 100(b) of Regulation G because they cause the presentation of the non-GAAP measure to be misleading. For example, presenting a performance measure that excludes normal, recurring, cash operating expenses necessary to operate a registrant's business could be misleading. [May 17, 2016]"

As per the above description, in 2021, we believed that the pre-launch expenses incurred during the year were non-recurring due to the uncertainty of receiving FDA approval to market Cortrophin. If the product were not approved, all of the 2021 spending would be worthless and we would cease any further spend. Once Cortrophin was approved by the FDA, our SG&A expenses in support of the product became recurring and as such, we ceased the add back of such spend in presentation of our non-GAAP results.

In addition, we considered Question 100.02 of the Division's Compliance & Disclosure Interpretations on Non-GAAP Financial Measures:

Question: Can a non-GAAP measure be misleading if it is presented inconsistently between periods?

Answer: Yes. For example, a non-GAAP measure that adjusts a particular charge or gain in the current period and for which other, similar charges or gains were not also adjusted in prior periods could violate Rule 100(b) of Regulation G unless the change between periods is disclosed and the reasons for it explained. In addition, depending on the significance of the change, it may be necessary to recast prior measures to conform to the current presentation and place the disclosure in the appropriate context. [May 17, 2016]

As described above, in 2021 the Company did not believe the SG&A costs incurred related to Cortrophin were recurring in nature, due to the uncertainty of the receiving of FDA approval. Upon receipt of FDA approval in late 2021 and subsequent product launch in January 2022, this uncertainty was resolved and the Company believes the SG&A costs related to Cortrophin will be recurring, and are considered necessary to operate the Company's business. We did not recast 2021 non-GAAP results as we believe that the discrete treatment of these activities in both 2021 and 2022 as historically presented are logical and consistent with the development of events as Cortrophin moved through the FDA regulatory pathway to commercialization and believe that recasting prior year non-GAAP results would be inconsistent and create confusion for the readers of our financial disclosures.

In addition, upon further review of footnote (3) to Table 3 and Table 4 of our non-GAAP reconciliation as presented in our first, second and third quarter tables to our earnings release, we believe that our rationale could be disclosed in a more complete manner, and suggest that the existing language be replaced by the following in our fourth quarter earnings release:

"For the three- and twelve-month period ended December 31, 2021, we add back Cortrophin pre-launch SG&A expenditures based upon the premise that these activities were undertaken with significant uncertainty of FDA approval of Purified Cortrophin Gel. Beginning in the first quarter of 2022, and in all subsequent periods, we no longer add back Cortrophin SG&A expenditures due to the fact that the product was approved by the FDA and a commercial launch of the product ensued in January of 2022. As such, for the three- and twelve-month period ended December 31, 2022, Cortrophin SG&A expenditures are included in our non-GAAP results."

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Please direct any questions that you have with respect to the foregoing or if any additional supplemental information is required by the Staff, please contact Meredith W. Cook, SVP, General Counsel and Corporate Secretary of ANI Pharmaceuticals, Inc. at 609-917-4893.

Sincerely,

ANI Pharmaceuticals, Inc.

By: /s/ Stephen P. Carey
Name: Stephen P. Carey
Title: Senior Vice President Finance and Chief Financial Officer

Enclosures

cc: Nikhil Lalwani, ANI Pharmaceuticals, Inc.
Meredith W. Cook, ANI Pharmaceuticals, Inc.
Karen Dempsey, Orrick Herrington & Sutcliffe LLP