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

January 6, 2023

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 December 12, 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 November 9, 2022

Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation, page Table 3

1. ***We note your non-GAAP adjustment for In-process research and development in the three months ended September 30, 2022. We believe the adjustment is inconsistent with Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretation. Please confirm to us you will no longer include the adjustment in any non-GAAP financial measure presented in accordance with Item 10(e) of Regulation S-K or Regulation G.***

RESPONSE: We acknowledge your comment and in our future Form 8-K filings, earnings releases and other presentations that include non-GAAP financial measures, for all periods presented, we will no longer adjust for in-process research and development expense in the calculation of our Adjusted Non-GAAP EBITDA, Non-GAAP Research and Development Expense, and Adjusted Non-GAAP Diluted Earnings per Share. We will recast prior period information to conform to current year presentation. In addition, we will provide a footnote to the non-GAAP reconciliation tables addressing the change as compared to previously furnished information; please refer to our response to question 3 below for draft language.

Correspondence dated December 5, 2022

Non-GAAP Financial Measures, page 6

2. ***You state in response to comment 1 that in connection with the November 2021 acquisition of Novitium Pharma LLC you acquired a fourth pharmaceutical manufacturing plant. During the integration of Novitium you determined that three manufacturing plants would support your manufacturing capacity needs and you thus decided to close the Canada plant and move the majority of production being undertaken in Canada to the remaining U.S. based manufacturing plants. As the operations appear to be continuing, although at a different manufacturing facility, it is unclear why it is appropriate to include a non-GAAP adjustment for the Canada operations. Please confirm you will revise your presentation in the future, or clarify to us further why you believe revenues and expenses relating to products previously manufactured at the Canada facility will not continue at the new manufacturing facility.***

RESPONSE: We appreciate the opportunity to further clarify our position regarding our non-GAAP adjustment of Canadian operations. While 13 of the products historically manufactured in Canada have been moved to other manufacturing facilities, the revenues and corresponding cost of goods sold for those products have not been subject to adjustment in our presentation of non-GAAP financial measures. We have only adjusted for aspects of running the Canada operations that will not recur once the closure of the Canada facility is complete (expected to be March 31, 2023). The below details are intended to clarify this point.

ANI's principal business is the manufacture, marketing, and sale of pharmaceutical products in its own label to direct wholesale and retail customers (sales of 'ANI Labeled Product'). For the nine months ended September 30, 2022, $202.9 million, or 91.3%, of our total net revenues of $222.2 million were derived from sales of ANI Labeled Product. We also derive revenues from contract development and manufacturing activities ('CDMO'), where ANI manufactures pharmaceutical products on behalf of other pharmaceutical companies ('CDMO Product'). During the same nine-month period we generated $12.1 million, or 5.4%, of our total revenues from CDMO activities.

Our Canada manufacturing facility has historically performed two core activities: a) the manufacture of ANI Labeled Product on behalf of ANI parent company and b) the manufacture of CDMO Product for third party customers. During the nine months ended September 30, 2022, third party sales of CDMO Product generated from Canada operations was $2.7 million of the $12.1 million contract manufacturing revenues reported. Revenues related to third party sales of ANI Labeled Product are not recorded by the Canada operations. Instead, they are accounted for as intercompany sales to the U.S. parent company and eliminated in our consolidated results. Subsequent third-party sales of ANI labeled inventory manufactured by Canada is recognized by the U.S parent company and presented as Generic pharmaceutical product revenue in our GAAP financial statements and disclosures (see page 47 of MD&A in our third quarter Form 10-Q as filed on November 8, 2022).

From an operational perspective, at the onset of 2022, ANI had excess manufacturing capacity in its manufacturing network of four manufacturing facilities. This excess capacity created the opportunity for us to close one facility, which was determined to be our Canada operations. Importantly, each of our facilities has available capacity to absorb more volume, and thus the transfer of Canada manufacturing to one of the remaining three facilities will not result in any incremental costs or headcount at the receiving facilities in functions that are being adjusted for in our non-GAAP measures. While direct manufacturing labor expense utilized to produce ANI Labeled product is being transferred from Canada to other facilities, we have not adjusted out expenses related to direct manufacturing of ANI Labeled Product that will be on-going post Canada closure. This detail is further discussed below.

The following details the approximate size and capacity of our four manufacturing facilities:

Manufacturing Site	Square Footage	Annual Solid Dose Capacity
Main Street, Baudette, MN	130,000	2.5 billion doses
Containment facility, Baudette, MN	47,000	2.5 billion doses
East Windsor, NJ	120,000	3.0 billion doses
Canada operations	101,000	1.0 billion doses

Canada was producing approximately 120 million doses per year, a volume that is readily absorbed into the Main Street and East Windsor facilities.

During the nine-month period ended September 30, 2022:

- ANI sold approximately 109 product families of ANI Labeled Product.

- Of this amount, 16 product families were manufactured in Canada. Of this amount, we have moved production to our other manufacturing facilities for thirteen and the remaining three products families have been discontinued.

- ANI sold approximately 30 product families of CDMO Product of which eight were manufactured in Canada. ANI has discontinued its contracts and will no longer manufacture these products on behalf of CDMO customers post closure of our Canada operations.

- ANI had approximately 600 employees of which approximately 128 were employees of our Canada operation. After the closure of Canada, all but one employee will be terminated with no increase in headcount at our remaining facilities in functions that are being adjusted for in our non-GAAP financial measures. For completeness: the one employee retained by ANI was repurposed into a pre-existing U.S. opening for an IT systems implementation.

More specifically, we are only adjusting for what we believe to be the non-recurring portion of Canada operations. The following is a summary of statement of operations line items for Canada operations and their treatment for purposes of our reported non-GAAP financial measures beginning with our second quarter 2022 financial statements:

P&L Line Item	**Non-recurring?**	**Adjusted in Non-GAAP Measure?**
Third Party CDMO Revenue and Costs of Sales ('COS')	Yes; CDMO contracts have been cancelled and manufacturing will cease; third party revenues and related COS will not recur post Canada closure	Yes
ANI Labeled Product Revenue and COS recorded by Parent company	No; revenue streams and related direct costs to manufacture will continue for 13 of 16 product families. Labor, overhead and input costs will move from Canada to U.S. and thus are recurring.	No
SG&A	Yes; all Canada based activities will cease and Canada employees will be terminated with no increase in expense or headcount at the remaining facilities	Yes
Research & Development	Yes; Canada only performed R&D for its CDMO customers therefore all Canada based activities will cease and Canada employees will be terminated with no increase in expense or headcount at the remaining facilities	Yes

The Canada closure remains on track to be completed by the originally disclosed date of March 31, 2023. In fact, as of the date of this response, all manufacturing activities are complete.

Lastly, ANI does not have a history of undertaking significant restructurings. The June 2022 announcement of the closure of the Canada operations is the first action in the Company's history as a public company to warrant presentation on the face of our GAAP Statement of Operations as a restructuring. Given the materiality of the annual losses being generated at the Oakville facility relative to our overall company profitability metrics commonly utilized to communicate with the analyst and investor community ($7 - $8 million of annualized savings announced on June 2, 2022, as compared to projected full year 2022 adjusted non-GAAP EBITDA of $54 - $60 million at the time) and the unique (for ANI) nature of the action, we believe that the presentation of our non-GAAP measures as a supplement to our GAAP financial results further enhances the disclosures contained in our Form 10-Q and highlights the impact of the actions being undertaken of our results of operations.

Our intent is that the above details will provide the Staff further context and support for the Company's position that the amounts being adjusted in our non-GAAP measures are non-recurring and that activities that are to be recurring are not being adjusted in our non-GAAP measures. In addition, that the adjustments presented for Canada operations are directly attributable to the decision to close the facility, are incremental to our normalized operations and based directly on amounts recorded in our GAAP financial statements. In order to further clarify these items for the users of our financial statements and financial disclosures, we will edit the existing footnote to the non-GAAP reconciliation tables to read as follows:

"Impact of Canada operations includes CDMO revenues, cost of sales relating to CDMO revenues, all selling, general and administrative expenses, and all research and development expenses recorded in Canada in the period presented, exclusive of restructuring activities, stock-based compensation and depreciation and amortization, which are included within their respective lines above. The adjustment of Canada operations represents revenues, cost of sales and expense that will not recur after the completion of the closure of our Canada operations, expected to be complete by March 31, 2023. The adjustment of Canada operations does not adjust for revenues, cost of sales, and expense that will recur at our other manufacturing facilities after the transfer of certain manufacturing activities is complete."

In addition, we will clarify in our "Restructuring" footnote to our financial statements as well as in any applicable sections of MD&A that we have cancelled the CDMO contracts that were previously being supplied from the Canada operations.

We appreciate the opportunity to further clarify our position regarding our non-GAAP adjustment of Canadian operations and welcome further engagement with the Staff if there are further questions or clarifications warranted.

3. ***We acknowledge your response to comment 2. Although you are no longer adjusting for Cortrophin pre-launch charges and sales and marketing expenses, we continue to believe that the non-GAAP adjustments in prior periods are not appropriate since these costs are normal costs incurred in your business to achieve FDA approval, regardless of whether or not regulatory approval is ultimately obtained. Please confirm you will revise to eliminate these adjustments in future filings or tell us why these costs are different from costs incurred by other companies in your industry to obtain regulatory approval.***

RESPONSE: To further clarify our previous response, the $13.5 million of Sales, General and Administrative pre-launch sales and marketing expenses for Cortrophin that were adjusted in our non-GAAP results for the twelve months ended December 31, 2021, were related to establishing our sales and marketing team and launch strategy and were not related to achieving FDA approval. Costs related to achieving FDA approval for Cortrophin were recorded to the Research and Development expense and are fully recognized in both our GAAP and non-GAAP results in 2021.

Nonetheless, we acknowledge your comment and in our future Form 8-K filings, earnings releases and other presentations that include non-GAAP financial measures, for all periods presented, we will no longer adjust for pre-launch charges and sales and marketing expenses in the calculation of our Adjusted Non-GAAP EBITDA, Non-GAAP SG&A Expense, and Adjusted Non-GAAP Diluted Earnings per Share. We will recast prior period information to conform to current year presentation.

In addition, we will provide the following footnote to the non-GAAP reconciliation tables addressing both this change and the change for IPR&D in response number 1 above:

"Beginning in the fourth quarter of 2022, ANI will no longer exclude expenses for In-Process Research & Development or Cortrophin pre-launch charges and sales and marketing expenses from its non-GAAP results. Historically, the company excluded these charges. These changes are being made at the request of the U.S. Securities and Exchange Commission. Prior periods have been recast to reflect these changes.

- For the period ended December 31, 2022, non-GAAP financial measures have been recast to include $1.15 million of incremental R&D expense and a related reduction in full year Adjusted non-GAAP Diluted Earnings per Share of $0.06 as compared to amount reported in our third quarter 2022 earnings release and associated Form 8-K.

- For the period ended December 31, 2021, non-GAAP results have been recast to include $780K of additional Purified Cortrophin Gel pre-launch charges and $13.4 million of Cortrophin related SG&A expense, and a related reduction in full year Adjusted non-GAAP Diluted Earnings per Share of $0.86, resulting in a revised 2021 Adjusted non-GAAP Diluted Earnings per Share of $2.36."

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Should you have any questions 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 609-759-1810 ext. 1001.

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