UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

December 12, 2022

Stephen P. Carey
Senior Vice President, Finance and Chief Financial Officer
ANI Pharmaceuticals, Inc.
210 Main Street West
dette , Minnesota 56623

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

Dear Stephen P. Carey:

We have reviewed your December 5, 2022 response to our comment letter and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments. Unless we note otherwise, our references to prior comments are to comments in our November 1, 2022 letter.

Form 8-K furnished November 9, 2022

Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation, page Table3

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.

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.

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.

You may contact Ibolya Ignat at 202-551-3636 or Mary Mast at 202-551-3613 with any questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences