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

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 29, 2020

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-31812**	**58-2301143**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

210 Main Street West **Baudette, Minnesota**	**56623**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(218) 634-3500**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading Symbol(s):**	**Name of each exchange on which registered:**
Common Stock	ANIP	Nasdaq Stock Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2)

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On April 29, 2020, ANI Pharmaceuticals, Inc. (the "Company") announced that it received a Refusal to File ("RTF") letter from the U.S. Food and Drug Administration ("FDA") regarding its supplemental New Drug Application ("sNDA") for Cortrophin Gel. Upon its preliminary review, the FDA determined that certain portions of the Chemistry, Manufacturing and Controls section in the sNDA were not sufficiently complete to permit a substantive review. The Company will seek immediate guidance, which potentially includes requesting a Type A meeting with the FDA, to clarify and respond to the issues identified in the RTF letter.

Forward-Looking Statements

To the extent any statements made in this report deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the Company's planned response to the RTF letter and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates. Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. The Company's business generally is subject to a number of risks which are described more fully in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this report speak only as of the date of this report and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits

Exhibit	Description
99.1	Press release dated April 29, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey
Stephen P. Carey
Vice President Finance, and Chief Financial Officer

Dated: April 29, 2020

Exhibit 99.1

ANI Receives Refusal to File Letter from FDA for Cortrophin® Gel

BAUDETTE, Minnesota (April 29, 2020) - ANI Pharmaceuticals, Inc. ("ANI") (Nasdaq: ANIP) today announced that it received a Refusal to File (RTF) letter from the U.S. Food and Drug Administration (FDA) regarding its supplemental new drug application (sNDA) for Cortrophin® Gel. Upon its preliminary review, the FDA determined that certain portions of the Chemistry, Manufacturing and Controls section in the sNDA were not sufficiently complete to permit a substantive review. ANI will seek immediate guidance, which potentially includes requesting a Type A meeting with the FDA, to clarify and respond to the issues identified in the RTF letter.

Arthur S. Przybyl, ANI's President and CEO commented, "We remain highly confident in our Cortrophin Gel filing and are fully committed to working with the FDA as quickly as possible to address their letter. We believe that the majority of items mentioned have already been addressed in our original March 23rd sNDA filing and that the remaining items can be reasonably addressed. We look forward to clarifying certain aspects of the filing with the agency."

About Cortrophin® Gel

Purified Cortrophin® Gel (Repository Corticotropin Injection USP) (80 U/ml) has 54 indications on its previously approved label, including but not limited to acute exacerbations of multiple sclerosis, rheumatoid arthritis, systemic lupus erythematous and ulcerative colitis. For more information, including the complete list of indications and usages, please see the Full Prescribing Information. An sNDA for Cortrophin® Gel was filed with the FDA on March 23, 2020. The current annual market for Cortrophin® Gel is approximately $950 million and has only one competitor.

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about ANI's planned response to the RTF letter, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

For more information about ANI, please contact:
Investor Relations
IR@anipharmaceuticals.com