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): June 1, 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**

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

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

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 June 1, 2020, ANI Pharmaceuticals, Inc. (the "Company") issued a press release providing an update on the timeline for resubmission of its supplemental New Drug Application ("sNDA") for Cortrophin® Gel. As previously disclosed, the Company received a Refusal to File ("RTF") letter regarding its sNDA for Cortrophin® Gel from the U.S. Food and Drug Administration ("FDA") in April 2020. The Company has decided to concentrate its efforts on a resubmission of its sNDA, which will address the items identified in the RTF letter, and will not request a Type A meeting with the FDA at this time. The Company has retained a prominent regulatory consulting firm to support its plan to conduct a comprehensive review of the sNDA before resubmission. The Company currently expects to resubmit its sNDA for Cortrophin® Gel upon completion of the review process. A copy of the Company's press release is attached hereto as Exhibit 99.1.

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 beliefs regarding its review and observations relating to its initial Cortophin® Gel sNDA filing, the Company's beliefs concerning its ability to satisfactorily respond to the matters raised in the FDA's RTF letter in a resubmission of the filing, the Company's beliefs concerning the information and activities required to resubmit to the FDA the Cortophin® Gel sNDA filing, the timing of resubmission of the Company's sNDA to the FDA and the timing and outcome of the FDA's review of any resubmitted sNDA relating to the Cortophin® Gel product.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which may cause the Company's actual results to be materially different from these forward-looking statements. There can be no assurances that the results of the additional review and refiling plan will be successful, that the Company will be able to successfully develop the additional information that may be required for resubmission of the sNDA, or concerning the timing of completion of development of any additional information for resubmission of the sNDA. In addition, there can be no assurance that the FDA will conclude that any sNDA that the Company resubmits will satisfactorily respond to the matters raised in the FDA's RTF letter, or concerning the timing of any resubmission by the Company of the sNDA, that the FDA will approve our sNDA relating to our Cortophin® Gel product or concerning the timing of any future action by the FDA on our sNDA, regarding the commercialization options that the Company will pursue if our sNDA is approved, or that the product will be able to compete successfully in the market if approved and launched.

Certain of these risks 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 June 1, 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: June 1, 2020

Exhibit 99.1

ANI Pharmaceuticals Provides Update on Recent Regulatory Filing

Baudette, Minnesota (June 1, 2020) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) announced today that it continues to make progress toward addressing items identified in the Refusal to File letter received from the FDA relating to its Cortrophin ® Gel sNDA filing.

"The most efficient path forward is to concentrate efforts on the preparation of the resubmission of the sNDA," commented ANI Pharmaceuticals Interim CEO Patrick Walsh. "As such, we decided to forego a request for a Type-A meeting with the FDA and respond to all observations as part of the comprehensive resubmission of the sNDA. To further support our efforts, we have retained a prominent regulatory consulting firm to support the company's re-filing plan, including a comprehensive review of the entire application before re-submission."

The Company plans on refiling its sNDA for Cortrophin® Gel with the FDA upon completion of the review process.

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include controlled substances, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit the Company's 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 the company's beliefs regarding its review and observations relating to its initial Cortophin® Gel sNDA filing, the company's beliefs concerning its ability to satisfactorily respond to the matters raised in the FDA's Refusal to File Letter in a re-submission of the filing, the company's beliefs concerning the information and activities required to resubmit to the FDA the Cortophin® Gel sNDA filing, the timing of resubmission of the company's sNDA to the FDA and the timing and outcome of the FDA's review of any resubmitted sNDA relating to the Cortophin® Gel product.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which may cause ANI's actual results to be materially different from these forward-looking statements. There can be no assurances that the results of the additional review and refiling plan will be successful, that the company will be able to successfully develop the additional information that may be required for resubmission of the sNDA, or concerning the timing of completion of development of any additional information for resubmission of the sNDA. In addition, there can be no assurance that the FDA will conclude that any sNDA that the company resubmits will satisfactorily respond to the matters raised in the FDA's Refusal To File letter, or concerning the timing of any resubmission by ANI of the sNDA, that the FDA will approve our sNDA relating to our Cortophin® Gel product or concerning the timing of any future action by the FDA on our sNDA, regarding the commercialization options that the company will pursue if our sNDA is approved, or that the product will be able to compete successfully in the market if approved and launched.

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 risks described above or that the Company may face with respect to importing raw materials; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approvals from the U.S. Food and Drug Administration; general business and economic conditions; market trends; regulatory environment; 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.. 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