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): October 2, 2023

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)	(I.R.S. 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**

Not Applicable
(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 (see General Instruction A.2. below):

☐ 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(b))

☐ 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 October 2, 2023, ANI Pharmaceuticals, Inc. issued a press release announcing U.S. Food and Drug Administration (FDA) approval and commercial availability of a 1-mL vial (80 USP units/1 mL) of Purified Cortrophin® Gel (repository corticotropin injection USP). A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release, dated October 2, 2023
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

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 hereunto duly authorized.

Dated: October 2, 2023

ANI PHARMACEUTICALS, INC.

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

For Immediate Release

ANI Pharmaceuticals Announces FDA Approval and Commercial Availability of New 1-mL Vial Size of Purified Cortrophin® Gel, Appropriate for Adjunctive Treatment of Certain Patients with Acute Gouty Arthritis Flares

Cortrophin Gel is the only FDA-approved purified corticotropin (ACTH) indicated for the treatment of appropriate patients with acute gouty arthritis flares

New 1-mL size furthers ANI's commitment to providing ACTH options for appropriate acute gouty arthritis flare patients and their healthcare providers; available through distributors to help enable in-office administration and through specialty pharmacies

Cortrophin Gel will now be available in two sizes, including the 5-mL vial size launched in January 2022

BAUDETTE, Minn.— October 2, 2023 (BUSINESS WIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced U.S. Food and Drug Administration (FDA) approval and commercial availability of a 1-mL vial (80 USP units/1 mL) of Purified Cortrophin® Gel (repository corticotropin injection USP) (Cortrophin Gel). The 1-mL vial is now available via Cortrophin Gel's existing specialty pharmacy network and will also be available for ordering via national specialty distributors. Cortrophin Gel is already available in a 5-mL vial. Cortrophin Gel is indicated for short-term administration as an adjunctive therapy during an acute episode or exacerbation in acute gouty arthritis. Cortrophin Gel is contraindicated for intravenous administration. For additional important safety information, please see below.

ANI reintroduced Cortrophin Gel to the market in January 2022. At that time, Cortrophin Gel became the first newly commercialized drug indicated for appropriate patients with acute gouty arthritis flares in 12 years. This smaller 1-mL product configuration was developed with the goal of helping enable rapid time to therapy, at point-of-care, for appropriate patients with acute gouty arthritis flares.

"More than 9 million people in the US are affected by gout, and each year a portion of these patients experience acute gouty arthritis flares as a symptom of their underlying disease. For some of these patients, Cortrophin Gel may be an appropriate additional treatment option for their flares. The approval of the 1-mL vial for Cortrophin Gel is another step forward in our mission to increase access for appropriate acute gouty arthritis flare patients in need. Scaling up our Rare Disease business is ANI's largest growth driver and key to achieving our goal of building a high-growth biopharma company," stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

"With this approval, we look forward to continuing the Cortrophin Gel launch momentum we have seen to date," Lalwani continued. "The commercial launch of the 1-mL vial will be supported by ANI's existing Cortrophin Gel field sales force, which is already engaging rheumatologists and nephrologists who treat patients with acute gouty arthritis flares. Importantly, we are enhancing *Cortrophin in Your Corner™*, our reimbursement and access hub, to include support for this new 1-mL configuration of Cortrophin Gel."

"Gout is the most common type of inflammatory arthritis," said Mary Pao, MD, PhD, Chief Medical Officer of ANI. "Acute gouty arthritis flare patients who are in need of an additional flare treatment options, beyond currently recommended first line therapies, have a need for alternatives. The development of the 1-mL vial represents ANI's commitment to this patient population."

Cortrophin Gel is an adrenocorticotropic hormone (ACTH), also known as purified corticotropin, and it is approved for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis (MS) and rheumatoid arthritis (RA), in addition to excess urinary protein due to nephrotic syndrome. Cortrophin Gel is the only FDA-approved ACTH therapy indicated for the treatment of appropriate patients with acute gouty arthritis flares. For a full list of indications, please see below.

Indications

Cortrophin Gel is a prescription medicine that is injected subcutaneously or intramuscularly. It is indicated for:

- Short-term administration as an adjunctive therapy during an acute episode or exacerbation in:

    - acute gouty arthritis
    - rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; and ankylosing spondylitis.
- Exacerbations or as maintenance therapy in select cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- Severe erythema multiforme (Stevens-Johnson syndrome) and severe psoriasis.
- Atopic dermatitis and serum sickness.
- Severe acute and chronic allergic and inflammatory conditions affecting the eye and its adnexa, such as allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.
- Symptomatic sarcoidosis.
- Inducing a diuresis or remission of proteinuria due to nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
- Acute exacerbations of multiple sclerosis.

Important Safety Information

Contraindications

- Cortrophin Gel is contraindicated for intravenous administration.
- Cortrophin Gel is contraindicated in patients who have any of the following conditions: scleroderma; osteoporosis; systemic fungal infections; ocular herpes simplex; recent surgery; history of or the presence of a peptic ulcer; congestive heart failure; hypertension; primary adrenocortical insufficiency; adrenocortical hyperfunction; or sensitivity to proteins derived from porcine sources.

Warnings and Precautions

- **Infections:** Corticotropin therapy may increase susceptibility to infections and may mask the symptoms of infections.
- **Adrenal insufficiency:** Prolonged corticotropin therapy can increase the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by gradually reducing the corticotropin dosage. Hormone therapy should be reinstituted if stressful situations arise during discontinuation.
- **Elevated blood pressure, salt and water retention, and hypokalemia:** Corticotropin can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium or calcium.
- **Masking symptoms of other diseases:** Corticotropin may only suppress signs and symptoms of chronic disease without altering the natural course of disease.

- **Psychiatric reactions:** Psychic derangements may appear when corticotropin is used, ranging from euphoria, insomnia, mood swings, personality changes, and depression to psychosis. Existing conditions may be aggravated.
- **Ophthalmic reactions:** Prolonged use of corticotropin may produce posterior subcapsular cataracts and glaucoma with possible damage to the optic nerves.
- **Immunogenicity potential:** Prolonged administration of Cortrophin Gel may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH and Cortrophin Gel activity.
- **Vaccination:** Patients should not be vaccinated against smallpox while on corticotropin therapy. Other immunizations should be undertaken with caution due to possible neurologic complications and lack of antibody response.
- **Use in patients with hypothyroidism and cirrhosis:** There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis.
- **Use in patients with latent tuberculosis or tuberculin reactivity:** Closely observe for reactivation of the disease.
- **Comorbid diseases:** Corticotropin should be used with caution in patients with diabetes, abscess, pyogenic infections, diverticulitis, renal insufficiency, and myasthenia gravis.
- **Growth and development:** Carefully observe growth and development of infants and children on prolonged corticotropin therapy.
- **Acute gouty arthritis:** Treatment of acute gouty arthritis should be limited to a few days. Conventional concomitant therapy should be administered during corticotropin treatment and for several days after it is stopped.
- **Drug interactions:** Aspirin should be used cautiously with corticotropin in hypoprothrombinemia.
- **Pregnancy:** Since fetal abnormalities have been observed in animals, Cortrophin Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Adverse Reactions

Adverse reactions for Cortrophin Gel include fluid or sodium retention; muscle weakness; osteoporosis; peptic ulcer with possible perforation and hemorrhage; injection site reactions; impaired wound healing; hypertension; convulsions; headache; development of Cushingoid state; suppression of growth in children; and weight gain. These are not all the adverse reactions reported with Cortrophin Gel.

Please click here for full prescribing information for Cortrophin Gel.

About ANI

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by scaling up our Rare Disease business through successful launch of our lead asset, Purified Cortrophin® Gel, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. 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, those relating to the commercialization and potential sales of the product and any additional product launches from the Company's generic pipeline, 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.

These forward-looking statements include statements regarding the commercial launch of Cortrophin Gel and the potential benefit of Cortrophin Gel to patients as a treatment option. Risks and uncertainties that may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements include, but are not limited to, the costs involved in commercializing Cortrophin Gel, the ability to maintain regulatory approval of the product and maintain sufficiency of the product, the ability to obtain reimbursement from third-party payors for this product, evolving government legislation, the opinions and views of key opinion leaders and physicians who treat patients with chronic diseases and who may prescribe Cortrophin Gel, manufacturing difficulties or delays, ANI's ability to generate projected net product revenue and gain market share on the timeline expected, actions taken by competitors in response to a new market entrant, ANI's reliance on third parties over which it may not always have full control, costs and regulatory requirements relating to contract manufacturing arrangements, increased competition and strategies employed by competitors, uncertainties regarding the COVID-19 pandemic, market trends for our products, regulatory environment and changes, and other risks and uncertainties. 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 ("SEC"), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. 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.

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