

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): **January 24, 2022**

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-31812
(Commission File Number)

58-2301143
(I.R.S. Employer
Identification Number)

210 Main Street West
Baudette, Minnesota
(Address of principal executive offices)

56623
(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(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 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 January 24, 2022, ANI Pharmaceuticals, Inc. issued a press release announcing the U.S. commercial availability of Purified Cortrophin™ Gel (Repository Corticotropin Injection USP) 80 U/mL. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|------------------------|---|
| 99.1 | Press release dated January 24, 2022. |
| 104 | Cover Page Interactive Data File (embedded within the inline XBRL document) |

SIGNATURE

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.

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Stephen P. Carey

Senior Vice President, Finance and Chief Financial Officer

Dated: January 24, 2022



<https://www.anipharmaceuticals.com>

**ANI Pharmaceuticals Announces Commercial Availability of Purified
Cortrophin™ Gel (Repository Corticotropin Injection USP) for Multiple Chronic
Autoimmune Disorders**

BAUDETTE, Minn., January 24, 2022 — ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced the U.S. commercial availability of Purified Cortrophin™ Gel (Repository Corticotropin Injection USP) 80 U/mL. The commercial launch of Cortrophin Gel, an adrenocorticotrophic hormone (ACTH), also known as purified corticotropin, is being led by ANI's recently established rare disease business unit. Cortrophin Gel is indicated for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis (MS) and rheumatoid arthritis (RA), and excess urinary protein due to nephrotic syndrome. For full list of indications, please see below.

"Patients with certain chronic autoimmune conditions often need additional treatment options," said Dr. Mary Pao Seideman, Chief Medical Officer of ANI. "ACTH therapy can be effective across a number of inflammatory diseases. The reintroduction of Cortrophin Gel gives prescribers another ACTH option, which can mean a greater chance for an effective treatment for some patients."

"Choice in the ACTH category is long overdue, with only one available treatment option for over two decades. With today's full-scale commercial launch of Cortrophin Gel, an established treatment, healthcare professionals now have another ACTH therapy option, with U.S.-based development, supply chain and manufacturing," said Nikhil Lalwani, President and Chief Executive Officer of ANI. "This milestone is the culmination of six years of hard work and dedication from ANI employees and external partners, building on ANI's long history and mission to create high-quality medicines for patients in need. I am extremely proud of the high-degree of technical excellence employed by our team in reintroducing this important treatment to a community long in need of alternatives."

"Our goal from the start has been to ensure that Cortrophin Gel is available to as many patients who need it as possible," said Christopher Mutz, Head of Rare Disease for ANI. "As part of our commitment to supporting meaningful access to Cortrophin Gel, we've launched our reimbursement and access support hub, Cortrophin in Your Corner™ to provide commercial copay support and other reimbursement assistance for eligible patients."

Cortrophin Gel is now available to healthcare providers through a network of specialty pharmacies and distributors. For appropriate patients, physicians can submit a prescription and initiate access to treatment through a specialty pharmacy by visiting www.cortrophin.com.

ANI is committed to establishing meaningful access to Cortrophin Gel and has created *Cortrophin In Your Corner*, a dedicated program for patients and their caregivers throughout the treatment journey that includes one-on-one access and reimbursement support, financial assistance for eligible patients, and nurse-provided injection training. *Cortrophin In Your Corner* also provides access and reimbursement support for healthcare professionals and their staff. To get started with Cortrophin Gel, call *Cortrophin In Your Corner* (available Monday–Friday from 8 AM - 8 PM ET) at 1-800-805-5258.

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 reinstated 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; impaired wound healing; hypertension; convulsions; headache; development of Cushingoid state; and suppression of growth in children. These are not all the adverse reactions reported with Cortrophin Gel.

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 rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; and acute gouty arthritis.
- 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.

Please click [here](#) for full prescribing information for Cortrophin Gel.

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals 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 building a successful Purified Cortrophin™ Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. For more information, please visit www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release relate to information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words 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, the potential benefit of Cortrophin Gel to patients as a new treatment option, and the size of the market opportunity for Cortrophin Gel. 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 that are described in ANI’s Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the U.S. Securities and Exchanges Commission.

Any 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. Except as required by law, 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 details, visit www.cortrophin.com.

Investor Contact

Lisa M. Wilson
In-Site Communications, Inc.
212-452-2793
lwilson@insitecony.com

Media Contact

Angela Salerno-Robin
dna Communications
212-445-8219
ASalerno-Robin@dna-comms.com

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