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): March 14, 2025

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 March 14, 2025, ANI Pharmaceuticals, Inc., issued a press release announcing that the U.S. Food and Drug Administration has approved an expanded label for ILUVIEN® (fluocinolone acetonide intravitreal implant) that includes an indication for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. 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 March 14, 2025
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: March 14, 2025

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Name: Stephen P. Carey

Title: Senior Vice President Finance and Chief Financial Officer

ANI Pharmaceuticals Announces FDA Approval for Expansion of ILUVIEN® Label

- *ILUVIEN now approved for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (NIU-PS) in addition to diabetic macular edema (DME)*
- *ANI plans to begin marketing ILUVIEN in the U.S. under the combined label later this year*

BAUDETTE, Minn.— (GLOBE NEWSWIRE) – March 14, 2025 – ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded label for ILUVIEN (fluocinolone acetonide intravitreal implant) that includes an indication for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (NIU-PS). The approval also included other updates to the label including to the Warnings and Precautions section. As previously announced, the Company plans to market ILUVIEN for chronic NIU-PS in addition to its current indication of diabetic macular edema (DME) in the U.S. ILUVIEN is already approved for both DME and NIU-PS outside the U.S., including in seventeen European countries.

Nikhil Lalwani, President and CEO of ANI stated, “ILUVIEN’s expanded label and the strengthening of our partnership with long-standing ILUVIEN contract manufacturer, Seigfried, will enhance supply security and access for appropriate NIU-PS and DME patients in need.”

ANI previously announced that it extended its supply agreement for ILUVIEN with a subsidiary of Siegfried Holding AG (Seigfried) through 2029. Siegfried and ANI also agreed to upgrade equipment on the existing manufacturing line and significantly expand capacity.

INDICATIONS

ILUVIEN is a corticosteroid indicated for:

- the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.
- the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ILUVIEN is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- ILUVIEN is contraindicated in patients with glaucoma who have cup to disc ratios of greater than 0.8.
- ILUVIEN is contraindicated in patients with known hypersensitivity to any components of this product.

WARNINGS AND PRECAUTIONS

- **Intravitreal Injection-related Effects:** Intravitreal injections, including those with ILUVIEN, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. For patients with non-infectious uveitis affecting the posterior segment, hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection. Patients may experience temporary blurred vision after injection of the implant.
- **Intraocular Pressure (IOP) Increase:** Prolonged use of corticosteroids may result in the development of glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be routinely monitored during the course of the treatment.
- **Cataracts:** Use of corticosteroids including ILUVIEN may produce posterior subcapsular cataracts.
- **Delayed Corneal Wound Healing:** The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.
- **Corneal and Scleral Melting:** Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of ophthalmic corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation of the globe.
- **Bacterial Infections:** Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. Acute purulent or parasitic infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated.
- **Viral Infections:** Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.
- **Fungal Infections:** Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.
- **Risk of Implant Migration:** Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

ADVERSE REACTIONS

Diabetic Macular Edema

Ocular adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of ILUVIEN for diabetic macular edema include: cataract (82%), myodesopsia (21%), eye pain (15%), conjunctival hemorrhage (13%), posterior capsule opacification (9%), eye irritation (8%), vitreous detachment (7%), conjunctivitis (4%), corneal oedema (4%), foreign body sensation in eyes (3%), eye pruritus (3%), ocular hyperaemia (3%), optic atrophy (2%), ocular discomfort (2%), photophobia (2%), retinal exudates (2%), anterior chamber cell (2%), and eye discharge (2%). Non-ocular adverse reactions reported by greater than or equal to 5% of patients include: anemia (11%), headache (9%), renal failure (9%), and pneumonia (7%)

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 34% of ILUVIEN patients versus 10% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 20% of ILUVIEN patients versus 4% of sham patients. 38% of the patients who received ILUIVEN were subsequently treated with IOP-lowering medications during the study versus 14% of sham patients. 5% of the patients who received ILUIVEN needed surgical intervention for elevated IOP versus 1% of sham patients

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the ILUVIEN group (82%) compared with Sham (50%). The median time of cataract being reported as an adverse event was approximately 12 months in the ILUVIEN group and 19 months in the Sham group. Among these patients, 80% of ILUVIEN subjects versus 27% of sham-controlled subjects underwent cataract surgery, generally within the first 18 Months (Median Month 15 for both ILUIVEN group and for Sham) of the studies.

Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye

Ocular adverse reactions reported by greater than or equal to 1% of patients in the three combined clinical trials through 12 months following injection of fluocinolone acetonide intravitreal implant: cataract (56%), visual acuity reduced (15%), macular edema (11%), uveitis (10%), conjunctival hemorrhage (8%), eye pain (8%), hypotony of eye (7%), anterior chamber inflammation (5%), dry eye (4%), vitreous opacities (4%), conjunctivitis (4%), posterior capsule opacification (4%), ocular hyperemia (4%), vitreous haze (3%), foreign body sensation in eyes (3%), vitritis (3%), vitreous floaters (3%), eye pruritus (3%), conjunctival hyperemia (2%), ocular discomfort (2%), macular fibrosis (2%), glaucoma (2%), photopsia (2%), vitreous hemorrhage (2%), iridocyclitis (1%), eye inflammation (1%), choroiditis (1%), eye irritation (1%), visual field defect (1%), and lacrimation increased (1%). Non-ocular adverse reactions reported by greater than or equal to 2% of patients include: nasopharyngitis (5%), hypertension (3%), and arthralgia (2%).

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 22% of fluocinolone acetonide patients versus 12% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 12% of fluocinolone acetonide patients versus 3% of sham patients. 43% of the patients who received fluocinolone acetonide were subsequently treated with IOP-lowering medications during the study versus 41% of sham patients. 2% of the patients who received fluocinolone acetonide needed surgical intervention for elevated IOP versus 2% of sham patients.

Please see full Prescribing Information.

About ANI

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified biopharmaceutical company committed to its mission of “Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high-quality therapeutics. The Company is focused on delivering sustainable growth through its Rare Disease business, which markets novel products in the areas of ophthalmology, rheumatology, nephrology, neurology, and pulmonology; its Generics business, which leverages R&D expertise, operational excellence, and U.S.-based manufacturing; and its Brands business. For more information, visit 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, 2025 guidance, 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 ability of our approved products, including Cortrophin Gel, ILUVIEN and YUTIQ, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, including the acquisition of Alimera, in a timely manner or at all; the limitation of our cash flow as a result of the indebtedness and liabilities incurred from the recent acquisition of Alimera; the risks that our acquisitions and investments, including the recent acquisition of Alimera, could disrupt our business and harm our financial position and operating results; delays and disruptions in production of our approved products, increased costs and potential loss of revenues if we need to change suppliers due to the limited number of suppliers for our raw materials, active pharmaceutical ingredients, expedients, and other materials; delays and disruptions in production of our approved products as a result of our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel, ILUVIEN and YUTIQ; delays or failure in obtaining and maintaining approvals by the FDA of the products we sell; changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration and other regulatory agencies, and the focus of the current U.S. presidential administration, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions; risks that we may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason; the ability of our manufacturing partners to meet our product demands and timelines; the impact of changes or fluctuations in exchange rates; our ability to develop, license or acquire, and commercialize new products; our obligations in agreements under which we license, develop or commercialize rights to products or technology from third parties and our ability to maintain such licenses; the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products; our ability to protect our intellectual property rights; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the impact of any litigation to which we are, or may become, a party; our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; our ability to maintain the services of our key executives and other personnel; and general business and economic conditions, such as inflationary pressures, geopolitical conditions including but not limited to the conflict between Russia and the Ukraine, the conflict in the Middle East, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies, 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 Securities and Exchange Commission.

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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SOURCE: ANI Pharmaceuticals, Inc.