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): September 16, 2024

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 September 16, 2024, ANI Pharmaceuticals, Inc., issued a press release announcing the completion of the previously announced acquisition of Alimera Sciences, Inc., pursuant to the terms of the Agreement and Plan of Merger, dated as of June 21, 2024. A copy of the press release is furnished herewith as Exhibit 99.1.

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of the Company, dated September 16, 2024
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: September 16, 2024

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, Inc. Completes Acquisition of Alimera Sciences

- *Strengthens Rare Disease segment as largest driver of future growth, adding approximately $105 million in 2024 revenue on a pro forma basis*
- *Adds two durable commercial assets ILUVIEN® and YUTIQ® with significant growth potential, expanding ANI's foothold in strategic therapeutic area of ophthalmology*
- *Anticipated to drive high single-digit to low double-digit accretion in adjusted non-GAAP EPS in 2025 and to be substantially accretive thereafter*
- *New capital structure in place, reducing interest expense by approximately $39 million on an annualized basis* [(1)]
- *ANI maintains its 2024 financial guidance for the standalone Company based on continued momentum across Purified Cortrophin® Gel (Cortrophin Gel) and Generics*

PRINCETON, N.J., September 16, 2024 (GLOBE NEWSWIRE)—ANI Pharmaceuticals, Inc. ("ANI" or "the Company") (Nasdaq: ANIP) today announced the completion of its previously announced acquisition of Alimera Sciences, Inc. (Nasdaq: ALIM) ("Alimera").

Nikhil Lalwani, President and CEO of ANI, stated, "Today marks a major milestone in our strategy to expand our Rare Disease business and deliver on our purpose of 'Serving Patients, Improving Lives.' Alimera is highly synergistic to our Rare Disease business, and we believe our proven commercial execution capabilities can further unlock the value of ILUVIEN and YUTIQ, two growing and durable assets, as well as accelerate the growth of Cortrophin Gel in ophthalmology. We continue to expect the transaction to create substantial shareholder value and generate high single-digit to low double-digit accretion in 2025 adjusted non-GAAP EPS with substantially higher accretion thereafter."

"With this acquisition, ANI now has three commercial rare disease assets, an expanded global footprint, and a robust Rare Disease team covering the specialties of ophthalmology, neurology, nephrology, rheumatology, and pulmonology. I want to thank the employees of both companies and our advisors for their cooperation and diligence in closing this transformational transaction. We are thrilled to welcome Alimera to the ANI team," concluded Lalwani.

Stephen Carey, Senior Vice President and Chief Financial Officer of ANI said, "ANI's new capital structure provides us significant financial flexibility to support the integration of Alimera and continue investing in organic growth initiatives while also significantly reducing our interest expense and increasing cash flow."

[(1)] As compared to estimated interest expense that would have been incurred if the new principal amount of debt was subject to rates that would have applied under the previous debt capital structure

Transaction Rationale

- **Solidifies Rare Disease segment as the largest driver of future growth:** The combination with Alimera creates an attractive Rare Disease growth platform, adding approximately $105 million in 2024 revenue on a pro forma basis and expanding the Rare Disease segment to approximately 45% of pro forma 2024 revenues. The transaction also expands ANI's footprint beyond the U.S. to 20 countries in Europe and beyond.

- **Adds two durable commercial products with significant growth potential that leverage the Company's existing Rare Disease infrastructure**: ILUVIEN and YUTIQ are durable assets with high barriers to genericization which the Company believes have a clear role for patients in need of alternative therapeutic options. ANI sees the potential to unlock significant additional growth for both ILUVIEN and YUTIQ through commercial synergies and execution.

- **Expands foothold in ophthalmology and expected to accelerate growth of Cortrophin Gel in this key therapeutic area:** During the first quarter of 2024, ANI launched a targeted ophthalmology-focused sales force for Cortrophin Gel. The team has continued to gain momentum in ophthalmology, driving significant growth in the number of new patient starts in the second quarter and third quarter to date. Importantly, the addition of Alimera expands the reach of the ophthalmology sales team to over 3,600 physicians. The Company estimates that there is over 50% overlap between high potential prescribers of Cortrophin Gel, ILUVIEN and YUTIQ.

- **Offers potential for substantial shareholder value creation:** ANI continues to expect high single-digit to low double-digit accretion in 2025 adjusted non-GAAP EPS with substantial accretion thereafter. The transaction is anticipated to deliver an additional $35 - $38 million in 2025 adjusted non-GAAP EBITDA inclusive of approximately $10 million in identified cost synergies with additional EBITDA contribution expected from accelerated growth of Cortrophin Gel within ophthalmology.

Business Updates

- **Cortrophin Gel:** ANI continues to see momentum across all targeted specialties and prescription growth across both existing and new prescribers. In August, the Cortrophin Gel franchise experienced a record number of new patients starts and the Company believes there is significant room for future growth as the number of patients on ACTH therapy remains significantly lower it was than a few years ago.

- **Generics:** Strong R&D capabilities enabled ANI to launch four products in the third quarter to date, bringing the number of products launched year-to-date to fourteen. In addition, the Company's operational excellence leveraging its U.S. based manufacturing footprint and a robust FDA compliance track record continues to enable ANI to deliver high-single-digit to low double-digit growth in Generics.

- **Alimera Integration:** ANI has made substantial progress on integration planning and expects the combined ophthalmology commercial team to begin generating synergies across Cortrophin Gel, ILUVIEN and YUTIQ in the near-term. The Company will leverage its manufacturing, quality, and regulatory expertise to further strengthen supply-security for ILUVIEN and YUTIQ.

- **Guidance:** ANI is maintaining its 2024 guidance for the standalone Company based on continued momentum across Cortrophin Gel and Generics and plans to provide 2024 guidance for the combined Company by no later than the Company's third quarter earnings call.

Terms of the Transaction

- Under the terms of the merger agreement, ANI acquired all of the outstanding shares of Alimera for $5.50 per share. The Company also repaid $72.5 million of Alimera debt. Alimera investors received one non-tradable contingent value right (CVR) representing the right to receive up to $0.50 per share upon the achievement of certain net revenue targets in 2026 and 2027.

New Capital Structure

- ANI recently completed an offering of $316.25 million aggregate principal amount of 2.25% convertible senior notes due September 1, 2029. The Company utilized a majority of the net proceeds as well as cash from its balance sheet to repay in full its existing senior secured term loan facility ($292.5 million that carried an interest rate of SOFR+6.0%). The initial conversion price of the convertible notes is $74.11 per share. Concurrent with the convertible offering, the Company used $40.6 million of the net proceeds to enter into capped call transactions. The cap price of the capped call transactions is initially $114.02 per share, which represents a premium of 100% over the last reported sale price of the Company's common stock on August 7, 2024. The capped call transactions are expected generally to reduce the potential dilution to ANI's common stock upon any conversion of the notes up to the cap price of $114.02.

- To fund the acquisition of Alimera, ANI entered into a new senior secured credit agreement consisting of a $325 million delayed draw term loan facility and $75 million revolving credit facility (initial interest rate SOFR+2.75%). On September 16, 2024 the Company drew the full $325 million term loan; the $75 million revolving credit facility remains un-drawn.

- The Company expects these capital structure changes to reduce interest expense by approximately $39 million on an annualized basis as compared to estimated interest expense that would have been incurred if the new principal amount of debt was subject to rates that would have applied under the previous debt capital structure.

Advisors

Guggenheim Securities, LLC acted as lead financial advisor to ANI and Raymond James & Associates, Inc. also acted as financial advisor. Hughes Hubbard & Reed LLP acted as legal advisor to ANI. Centerview Partners LLC acted as lead financial advisor to Alimera, and Perella Weinberg Partners also acted as a financial advisor to Alimera. DLA Piper acted as legal advisor to Alimera.

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified biopharmaceutical 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. ANI is focused on delivering sustainable growth by scaling up its Rare Disease business through its lead asset Purified Cortrophin® Gel, strengthening its Generics business with enhanced research and development capabilities, delivering innovation in Established Brands, and leveraging its U.S. based manufacturing footprint.

Forward-Looking Statements

This press release contains not only historical information, but also forward-looking statements made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements represent the Company’s expectations or beliefs concerning future events, including statements regarding the benefits of the acquisition of Alimera Sciences. These forward-looking statements generally are identified by the words “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “continue,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “shall,” “would” other words of similar meaning, derivations of such words and the use of future dates. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties.

The following factors, among others, could cause actual results to differ materially from those described in these forward-looking statements: (i) the ability to implement business plans, forecasts, and other expectations in connection with the acquisition and integration of Alimera Sciences, and identify and realize additional opportunities and, in particular, the possibility that the Company is unable to achieve anticipated synergies, (ii) costs and regulatory requirements relating to contract manufacturing arrangements, (iii) costs or delays associated with manufacturing (including the sources and any changes in sources thereof) of the Company’s products, (iv) delays or failures in retaining and obtaining continuing and future product approvals from the FDA, and other regulatory issues relating to the Company's business and products, (v) market trends for the Company’s products, including but not limited to, ILUVIEN, YUTIQ and Cortrophin Gel, and the ability to achieve anticipated sales for such products, (vi) risks that the acquisition of Alimera may disrupt current plans and operations of the Company and potential difficulties of the Company in retaining employees of Alimera and/or maintaining business relationships of Alimera, (vii) the impact of any litigation to which the Company is, or may become, a party, including in connection with the acquisition and integration thereof, (viii) volatility in the Company’s stock price, including as a result of the acquisition, (ix) changes in competitive and

regulated industries in which the Company operates, variations in operating performance across competitors, changes in laws and regulations affecting the Company's business, and changes in the Company's capital structure as a result of the acquisition, (x) regulatory and other approvals relating to product development and manufacturing, (xi) the Company's ability, and that of its suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries and/or the Company and its products, (xii) costs incurred in connection with the acquisition of Alimera and the possibility that the Company is unable to realize anticipated benefits of the acquisition or to realize estimated pro forma results and underlying assumptions, (xiii) delays in production, increased costs and potential loss of revenues if there is a change in manufacturers or manufacturing processes due to the limited number of suppliers for the Company's raw materials, active pharmaceutical ingredients, excipients and other materials, (xiv) the Company's reliance on single source third-party contract manufacturing supply for certain of its key products, including ILUVIEN, YUTIQ and Cortrophin Gel, (xv) changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration, and other regulatory agencies, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions, (xvi) the impact of legislative or regulatory reform on the pricing for the Company's products, (xvii) the Company' ability to maintain the services of its key executives and other personnel, and (xviii) 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 between Israel and Gaza, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies.

This press release refers to financial measures that are not in accordance with U.S. generally accepted accounting principles ("GAAP"). Because the non-GAAP financial measures are not calculated in accordance with GAAP, they should not be considered superior to or as a substitute for the related financial measures that are prepared in accordance with GAAP and are not intended to be considered in isolation and may not be the same as or comparable to similarly titled measures presented by other companies due to possible differences in method and in the items being adjusted. A reconciliation of the forward-looking non-GAAP measures presented in this communication is not provided due to the inherent difficulty in forecasting and quantifying items that are necessary for such reconciliation. In addition, the Company believes such a reconciliation would imply a degree of precision and certainty that could be confusing to investors. The variability of the specified items may have a significant and unpredictable impact on future financial performance. The financial guidance is subject to risks and uncertainties applicable to all forward-looking statements as described elsewhere in this communication.

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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