
**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): February 28, 2025

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 No.)

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

56623
(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 2.02 Results of Operations and Financial Condition

On February 28, 2025, ANI Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2024. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company, dated February 28, 2025
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

* The information in Item 2.02 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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: February 28, 2025

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 Reports Record Fourth Quarter and Full-Year 2024 Financial Results and Raises 2025 Guidance

- *Generated record quarterly net revenues of \$190.6 million, representing year-over-year growth of 44.8%*
- *Total Rare Disease quarterly net revenue of \$87.0 million, which includes:*
 - *Record quarterly net revenue for Purified Cortrophin® Gel of \$59.4 million, an increase of 42.3% year-over-year, and*
 - *ILUVIEN® and YUTIQ® net revenues of \$27.6 million in the first full quarter of ownership following the acquisition of Alimera Sciences*
- *Delivered record quarterly adjusted non-GAAP EBITDA of \$50.0 million, an increase of 65.7% year-over-year*
- *Diluted GAAP loss per share of \$(0.55) and adjusted non-GAAP diluted earnings per share of \$1.63*
- *Increased 2025 guidance with expected net revenues of \$756.0 million to \$776.0 million and adjusted non-GAAP EBITDA of \$190.0 million to \$200.0 million; announced adjusted non-GAAP diluted earnings per share guidance of \$6.12 to \$6.49*
- *Rare Disease net revenues expected to represent 48% to 49% of total Company net revenues in 2025, including:*
 - *Purified Cortrophin Gel net revenues of \$265.0 million to \$274.0 million, representing year-over-year growth of 33.8% to 38.3%, and*
 - *ILUVIEN and YUTIQ net revenues of \$97.0 million to \$103.0 million*

BAUDETTE, Minn.— (GLOBE NEWSWIRE) – February 28, 2025 – ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced financial results and business highlights for the fourth quarter and full year ended December 31, 2024.

Nikhil Lalwani, President and CEO of ANI stated, “We’re thrilled to report another year of strong execution for ANI, capped by our record fourth quarter results, with total net revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted EPS all finishing above our previously announced guidance for the full year. Cortrophin Gel generated nearly \$200 million in sales during 2024, in just the third year since launch, and our Generics business delivered its third straight year of double-digit growth. In addition, we expanded our Rare Disease business with the addition of the durable ophthalmology franchise of ILUVIEN and YUTIQ, through the acquisition of Alimera Sciences in September.”

“With our business off to a strong start in 2025, particularly Cortrophin Gel, Generics, and Brands, we are raising our 2025 guidance for total net revenues and adjusted non-GAAP EBITDA. On the heels of what was a transformative year for our company, I’d like to thank the ANI team as well as our customers, suppliers, partners, and investors for helping us deliver on our purpose of ‘Serving Patients, Improving Lives,’” concluded Mr. Lalwani.

Change in Segment Reporting

Following the acquisition of Alimera and in accordance with FASB ASC 280, *Segment Reporting*, the Company has reorganized the segment information that is regularly provided to the chief operating decision maker. Starting in the fourth quarter, the Company is now organized into two reportable segments as follows:

- **Rare Disease and Brands:** Consists of Rare Disease products Cortrophin Gel, ILUVIEN, and YUTIQ, and a portfolio of approximately 16 branded products that were previously included in Established Brands.
- **Generics and Other:** Consists of generic pharmaceutical products including those sold through traditional wholesale and retail sales channels, sales of contract manufactured products, royalties on contract manufactured products, and revenue from product development services.

Fourth Quarter and Recent Business Highlights:

Rare Disease and Brands

Revenues for ANI’s lead Rare Disease asset Cortrophin Gel totaled \$59.4 million for the fourth quarter of 2024, an increase of 42.3% over the same period in 2023, driven by increased volume from both overall ACTH market growth and share growth. During the quarter, the Company saw increasing demand with the highest number of quarterly new patient starts and new cases initiated since launch, and growth across all targeted specialties – ophthalmology, neurology, rheumatology nephrology and pulmonology. Momentum has continued in the first quarter of 2025 with the number of new cases initiated reaching a new high in February.

Cortrophin Gel remains on a strong multi-year growth trajectory with the overall ACTH category returning to growth in 2024 and the number of patients on ACTH therapy today still substantially lower than it was several years ago. Notably, approximately 40% of Cortrophin Gel prescribers were naïve to the ACTH category prior to prescribing Cortrophin Gel, and approximately 15% of Cortrophin Gel use is for acute gouty arthritis flares for which Cortrophin Gel is the only approved ACTH therapy.

Revenues for ILUVIEN and YUTIQ were \$27.6 million for the fourth quarter, which was the first full quarter of ownership following the acquisition of Alimera Sciences. The Company believes there is significant room for growth for both ILUVIEN and YUTIQ given the novel, long-acting nature of the products and size of the addressable markets, and is executing on commercial, clinical, and operational initiatives to capture these growth opportunities.

ANI has made substantial progress toward increasing supply security for the ILUVIEN and YUTIQ franchise. The Company has submitted a prior approval supplement (PAS) to the FDA seeking to add YUTIQ's indication of chronic non-infectious uveitis affecting the posterior segment of the eye (NIU-PS) to the ILUVIEN label. The Company expects FDA approval of the PAS in the second quarter of 2025 and plans to market ILUVIEN for chronic NIU-PS in addition to its current indication of diabetic macular edema (DME) in the U.S. For reference, ILUVIEN is already approved and marketed for DME and NIU-PS outside the U.S., including in 17 European countries and the Middle East. In order to support the transition to ILUVIEN, in July 2024, ANI extended its partnership with Siegfried, its long-term supplier for ILUVIEN, through 2029, and contracted with Siegfried to upgrade equipment on the existing manufacturing line and significantly expand capacity through the addition of a second manufacturing line. In conjunction with these initiatives, ANI and EyePoint have agreed to non-renewal of the current supply agreement for supply of YUTIQ by EyePoint to ANI effective May 31, 2025.

Revenues for Brands increased 58.9% to \$19.8 million, driven by increased demand for certain products, as has occurred periodically over the past two years. While this additional demand has persisted into the first quarter of 2025, the Company anticipates a normalized performance thereafter for the purpose of full year 2025 guidance.

Generics and Other

ANI's Generics revenues increased 9.4% to \$78.6 million during the quarter, driven by strong R&D capabilities and operational excellence leveraging its U.S.-based manufacturing footprint. The Company launched five new products during the quarter and 17 for the full year. ANI's strong R&D and commercial productivity continued into the first quarter of 2025 with the launch of Prucalopride Tablets with 180 days of exclusivity.

Fourth Quarter 2024 Financial Results

(in thousands)	Three Months Ended December 31,			
	2024	2023	Change	% Change
Rare Disease and Brands				
Cortrophin Gel	\$ 59,400	\$ 41,749	\$ 17,651	42.3 %
ILUVIEN and YUTIQ	27,643	—	27,643	100.0 %
Rare Disease total net revenues	\$ 87,043	\$ 41,749	\$ 45,294	108.5 %
Brands	19,842	12,488	7,354	58.9 %
Rare Disease and Brands total net revenues	\$ 106,885	\$ 54,237	\$ 52,648	97.1 %
Generics and Other				
Generic pharmaceutical products	\$ 78,600	\$ 71,826	\$ 6,774	9.4 %
Royalties and other pharmaceutical services	5,089	5,591	(502)	(9.0)%
Generics and Other total net revenues	\$ 83,689	\$ 77,417	\$ 6,272	8.1 %
Total net revenues	\$ 190,574	\$ 131,654	\$ 58,920	44.8 %

All comparisons are made versus the same period in 2023 unless otherwise stated.

Total net revenues for the fourth quarter of 2024 were \$190.6 million, an increase of 44.8% over the prior year period. On an organic basis, excluding the acquisition of Alimera, total net revenues grew 23.8% year-over-year.

Net revenues for Rare Disease, which includes Cortrophin Gel, ILUVIEN and YUTIQ, increased 108.5% to \$87.0 million. Cortrophin Gel net revenues increased 42.3% to \$59.4 million driven by increased volume. ILUVIEN and YUTIQ generated net revenues of \$27.6 million in the first full quarter following the acquisition of Alimera.

Net revenues for Brands increased 58.9% to \$19.8 million driven by increased demand.

Net revenues for Generic pharmaceutical products increased 9.4% to \$78.6 million driven by increased volumes in the base business and contribution from new products launches.

On a GAAP basis, gross margin decreased from 59.4% to 57.9%, primarily due to significant growth of royalty bearing products, including Cortrophin Gel, and amortization of the inventory fair value step up recognized in conjunction with the acquisition of Alimera. On a non-GAAP basis, gross margin increased from 59.6% to 63.5%, primarily driven by favorable product mix due to higher revenues from Cortrophin Gel and Brands and a full quarter of ILUVIEN and YUTIQ sales.

On a GAAP basis, research and development expenses increased 68.7% to \$16.6 million due to expenses related to the NEW DAY and SYNCHRONICITY clinical trials, development of a Cortrophin Gel pre-filled syringe, and ongoing investment in generic R&D programs. On a non-GAAP basis, research and development expenses increased 68.1% to \$16.2 million.

On a GAAP basis, selling, general, and administrative expenses increased 56.8% to \$69.7 million, resulting from a full quarter of expense associated with the ANI and Alimera combined ophthalmology sales force, continued investment in Rare Disease sales and marketing activities, increased employment-related costs, including incentive-based compensation tied to record 2024 financial performance, and an overall increase in activities required to support the growth of our business. On a non-GAAP basis, selling, general, and administrative expenses increased 41.8% to \$54.8 million.

On a GAAP basis, the Company reported a net loss attributable to common shareholders of \$10.7 million, or \$0.55 per share, for the fourth quarter of 2024 compared to net income of \$0.7 million, or \$0.04 per share, in the prior year period. On a non-GAAP basis, the Company reported diluted earnings per share of \$1.63 for the fourth quarter of 2024 compared to \$1.00 in the prior year period.

Adjusted non-GAAP EBITDA for the fourth quarter of 2024 was \$50.0 million, an increase of 65.7% from the fourth quarter of 2023.

For reconciliations of adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 3 and Table 4 below, respectively.

Liquidity

As of December 31, 2024, the Company had \$144.9 million in unrestricted cash and cash equivalents, \$221.7 million in net accounts receivable and \$639.2 million in principal value of outstanding debt (inclusive of our senior convertible notes). The Company generated year-to-date cash flow from operations of \$64.0 million.

Revised Full Year 2025 Guidance:

	Full Year 2025 Guidance	Previous Full Year 2025 Guidance	2024 Actual	Growth
Net Revenue (Total Company)	\$756 million - \$776 million	\$739 million - \$759 million	\$614 million	23% - 26%
Cortrophin Gel Net Revenue	\$265 million - \$274 million	n/p	\$198 million	34% - 38%
ILUVIEN and YUTIQ Net Revenue	\$97 million - \$103 million	n/p	\$32 million	n/m
Adjusted Non-GAAP EBITDA	\$190 million - \$200 million	\$182 million - \$192 million	\$156 million	22% - 28%
Adjusted Non-GAAP Diluted EPS	\$6.12 - \$6.49	n/p	\$5.20	18% - 25%

n/p - not provided in January 13, 2025 preliminary guidance.

n/m - not meaningful percentage due to comparison of only a partial year of ILUVIEN and YUTIQ Net Revenue in 2024.

ANI expects total company adjusted non-GAAP gross margin between 63% and 64%. The Company will continue to tax effect non-GAAP adjustments for computation of adjusted non-GAAP diluted earnings per share as a tax rate of 26%, unless the item being adjusted is not tax deductible in whole or in part.

The Company anticipates approximately 20.1 million and 20.4 million shares outstanding for the purpose of calculating adjusted non-GAAP diluted EPS and expects its annual U.S. GAAP effective tax rate to be approximately 25%.

Upcoming Events

ANI plans to participate in the following investor events:

Raymond James Annual Institutional Investors Conference
March 4, 2025
Orlando, FL

Leerink Partners Global Healthcare Conference
March 11, 2025
Miami Beach, FL

Conference Call

The Company's management will host a conference call today to discuss its fourth quarter and full-year 2024 results.

Date Friday, February 28, 2025
Time 8:00 a.m. ET
Toll free (U.S.) 800-579-2543
Conference ID 4860276

This conference call will also be webcast and can be accessed from the "Investors" section of ANI's website at www.anipharma.com. The webcast replay of the call will be available at the same site approximately one hour after the end of the call.

A replay of the conference call will also be available within two hours of the call's completion and will remain accessible for two weeks by dialing 800-756-0554 and entering access code 4860276.

Non-GAAP Financial Measures

Adjusted non-GAAP EBITDA

ANI's management considers adjusted non-GAAP EBITDA to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by non-cash stock-based compensation and differences in capital structures, tax structures, capital investment cycles, ages of related assets, and compensation structures among otherwise comparable companies. Management uses adjusted non-GAAP EBITDA when analyzing Company performance.

Adjusted non-GAAP EBITDA is defined as net (loss) income, excluding tax provision or benefit, interest expense, net, other expense, net, loss on extinguishment of debt, depreciation and amortization expense, non-cash stock-based compensation expense, M&A transaction and integration expenses, contingent consideration fair value adjustments, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, amortization of certain purchase price adjustments, severance expense, and certain other items that vary in frequency and impact on ANI's results of operations. Adjusted non-GAAP EBITDA should be considered in addition to, but not in lieu of, net income or loss reported under GAAP. A reconciliation of adjusted non-GAAP EBITDA to the most directly comparable GAAP financial measure is provided below.

ANI is not providing a reconciliation for the forward-looking full year 2025 adjusted EBITDA guidance because it does not currently have sufficient information to accurately estimate all of the variables and individual adjustments for such reconciliation, including "with" and "without" tax provision information. As such, ANI's management cannot estimate on a forward-looking basis without unreasonable effort the impact these variables and individual adjustments will have on its reported results.

Adjusted non-GAAP Net Income

ANI's management considers adjusted non-GAAP net income to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by the non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, M&A transaction and integration expenses, contingent consideration fair value adjustment, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, loss on extinguishment of debt, amortization of certain purchase price adjustments, severance expense, and certain other items that vary in frequency and impact on ANI's results of operations. Management uses adjusted non-GAAP net income when analyzing Company performance.

Adjusted non-GAAP net income is defined as net (loss) income, plus the non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, M&A transaction and integration expenses, contingent consideration fair value adjustment, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, loss on extinguishment of debt, amortization of certain purchase price adjustments, severance expense, and certain other items that vary in frequency and impact on ANI's results of operations, less the tax impact of these adjustments calculated using an estimated statutory tax rate. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI's results. Adjusted non-GAAP net income should be considered in addition to, but not in lieu of, net income reported under GAAP. A reconciliation of adjusted non-GAAP net income to the most directly comparable GAAP financial measure is provided below.

Adjusted non-GAAP Diluted Earnings per Share

ANI's management considers adjusted non-GAAP diluted earnings per share to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by the non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, M&A transaction and integration expenses, contingent consideration fair value adjustment, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, loss on extinguishment of debt, amortization of certain purchase price adjustments, severance expense, and certain other items that vary in frequency and impact on ANI's results of operations. Management uses adjusted non-GAAP diluted earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings per share is defined as adjusted non-GAAP net income, as defined above, divided by the diluted weighted average shares outstanding during the period. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI's results. Adjusted non-GAAP diluted earnings per share should be considered in addition to, but not in lieu of, diluted earnings (loss) per share reported under GAAP. A reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure is provided below.

ANI is not providing a reconciliation for the forward-looking full year 2025 adjusted diluted earnings per share guidance because it does not currently have sufficient information to accurately estimate all of the variables and individual adjustments for such reconciliation, including "with" and "without" tax provision information. As such, ANI's management cannot estimate on a forward-looking basis without unreasonable effort the impact these variables and individual adjustments will have on its reported results.

Other non-GAAP metrics

ANI's management considers non-GAAP research and development expenses and non-GAAP selling, general, and administrative expenses to be financial indicators of ANI's operating performance, providing investors and analysts with useful measures of operating results unaffected by non-cash stock-based compensation expense, M&A transaction and integration expenses, contingent consideration fair value adjustments, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, amortization of certain purchase price adjustments, severance expense, and certain other items that vary in frequency and impact on ANI's results of operations.

Management uses adjusted non-GAAP research and development expenses and non-GAAP selling, general, and administrative expenses when analyzing Company performance.

Non-GAAP research and development expenses is defined as research and development expenses, excluding non-cash stock-based compensation expense, M&A transaction and integration expenses, and certain other items that vary in frequency and impact on ANI's results of operations.

Non-GAAP selling, general, and administrative expenses is defined as selling, general, and administrative expenses, excluding impact of Canada operations, non-cash stock-based compensation expense, M&A transaction and integration expenses, litigation expenses related to certain matters, severance expense, and certain other items that vary in frequency and impact on ANI's results of operations.

Each of adjusted non-GAAP research and development expenses and non-GAAP selling, general, and administrative expenses should be considered in addition to, but not in lieu of, research and development expenses, and selling, general, and administrative expenses reported under GAAP, respectively.

A reconciliation of each of non-GAAP research and development expenses and non-GAAP selling, general and administrative expenses to the most directly comparable GAAP financial measure is provided below.

ANI's management also considers non-GAAP gross margin to be a financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by unaffected by non-cash stock-based compensation expense, M&A transaction and integration expenses, contingent consideration fair value adjustments, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, amortization of certain purchase price adjustments, severance expense, and certain other items that vary in frequency and impact on ANI's results of operations. Management uses non-GAAP gross margin when analyzing Company performance.

Non-GAAP gross margin is defined as adjusted non-GAAP net revenues less non-GAAP cost of sales (excluding depreciation and amortization) divided by non-GAAP net revenues. Non-GAAP gross margin should be considered in addition to, but not in lieu of, gross margin reported under GAAP.

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.anipharma.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.

Investor Contact Lisa M. Wilson, In-Site Communications, Inc.

212-452-2793

lwilson@insitecony.com

SOURCE: ANI Pharmaceuticals, Inc.

FINANCIAL TABLES FOLLOW

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 1: US GAAP Statements of Operations
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Net Revenues	\$ 190,574	\$ 131,654	\$ 614,376	\$ 486,816
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	80,280	53,420	250,210	181,513
Research and development	16,646	9,867	44,581	34,286
Selling, general, and administrative	69,719	44,462	249,636	161,697
Depreciation and amortization	22,600	15,194	67,731	59,791
Contingent consideration fair value adjustment	(1,893)	1,985	(619)	1,426
Gain on sale of building	—	—	(5,347)	—
Restructuring activities	—	—	—	1,132
Intangible asset impairment charge	7,600	—	7,600	—
Total Operating Expenses, net	194,952	124,928	613,792	439,845
Operating (Loss) Income	(4,378)	6,726	584	46,971
Other Expense, net				
Unrealized (loss) gain on investment in equity securities	(1,991)	—	6,307	—
Interest expense, net	(6,015)	(5,746)	(17,602)	(26,940)
Other expense, net	(1,378)	(33)	(4,033)	(159)
Loss on extinguishment of debt	—	—	(7,468)	—
Income (Loss) Before (Benefit) Expense for Income Taxes	(13,762)	947	(22,212)	19,872
Income tax (benefit) expense	(3,486)	(208)	(3,690)	1,093
Net (Loss) Income	\$ (10,276)	\$ 1,155	\$ (18,522)	\$ 18,779
Dividends on Series A Convertible Preferred Stock	(406)	(406)	(1,625)	(1,625)
Net (Loss) Income Available to Common Shareholders	\$ (10,682)	\$ 749	\$ (20,147)	\$ 17,154
Basic and Diluted (Loss) Income Per Share:				
Basic (Loss) Income Per Share	\$ (0.55)	\$ 0.04	\$ (1.04)	\$ 0.86
Diluted (Loss) Income Per Share	\$ (0.55)	\$ 0.04	\$ (1.04)	\$ 0.85
Basic Weighted-Average Shares Outstanding	19,445	19,003	19,318	18,001
Diluted Weighted-Average Shares Outstanding	19,445	19,219	19,318	18,194

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 2: US GAAP Balance Sheets
(unaudited, in thousands)

	December 31, 2024	December 31, 2023
Current Assets		
Cash and cash equivalents	\$ 144,861	\$ 221,121
Restricted cash	33	—
Accounts receivable, net	221,726	162,079
Inventories	136,782	111,196
Assets held for sale	—	8,020
Prepaid expenses and other current assets	17,975	17,400
Investment in equity securities	6,307	—
Total Current Assets	527,684	519,816
Non-current Assets		
Property and equipment, net	56,863	44,593
Deferred tax assets, net of deferred tax liabilities and valuation allowance	85,106	90,711
Intangible assets, net	541,834	209,009
Goodwill	59,990	28,221
Derivatives and other non-current assets	12,220	12,072
Total Assets	\$ 1,283,697	\$ 904,422
Current Liabilities		
Current debt, net of deferred financing costs	\$ 9,172	\$ 850
Accounts payable	45,656	36,683
Accrued royalties	22,626	16,276
Accrued compensation and related expenses	37,725	23,786
Accrued government rebates	18,714	12,168
Income taxes payable	6,749	8,164
Returned goods reserve	39,274	29,678
Current contingent consideration	29	12,266
Accrued expenses and other	13,735	5,606
Total Current Liabilities	193,680	145,477
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	309,108	284,819
Non-current convertible notes, net of deferred financing costs	305,812	—
Non-current contingent consideration, net of current	19,825	11,718
Accrued licensor payments due	20,961	—
Other non-current liabilities	5,781	4,809
Total Liabilities	\$ 855,167	\$ 446,823
Mezzanine Equity		
Convertible Preferred Stock, Series A	24,850	24,850
Stockholders' Equity		
Common Stock	2	2
Class C Special Stock	—	—
Preferred Stock	—	—
Treasury stock	(21,040)	(10,081)
Additional paid-in capital	519,653	514,103
Accumulated deficit	(100,279)	(80,132)
Accumulated other comprehensive income, net of tax	5,344	8,857
Total Stockholders' Equity	403,680	432,749
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	\$ 1,283,697	\$ 904,422

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation
(unaudited, in thousands)

	Reconciliation of certain adjusted non-GAAP accounts:										
	Three Months Ended December 31,			Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
				Three Months Ended December 31,		Three Months Ended December 31,		Three Months Ended December 31,		Three Months Ended December 31,	
	2024	2023		2024	2023	2024	2023	2024	2023	2024	2023
Net (Loss) Income	\$(10,276)	\$ 1,155	As reported:	\$ 190,574	\$ 131,654	\$ 80,280	\$ 53,420	\$ 69,719	\$ 44,462	\$ 16,646	\$ 9,867
Add/Subtract:											
Interest expense, net	6,015	5,746									
Other expense, net	1,378	33									
(Benefit) provision for income taxes	(3,486)	(208)									
Depreciation and amortization	22,600	15,194									
Contingent consideration fair value adjustment	(1,893)	1,985									
Unrealized loss on investment in equity securities	1,991	—									
Intangible asset impairment charge	7,600	—									
Impact of Canada operations (1)	—	283	Impact of Canada operations (1)	—	—	—	(51)	—	(232)	—	—
Stock-based compensation	7,061	5,621	Stock-based compensation	—	—	(367)	(185)	(6,233)	(5,196)	(461)	(240)
M&A transaction and integration expenses	5,965	391	M&A transaction and integration expenses	—	—	—	—	(5,965)	(391)	—	—
Litigation expenses	1,657	—	Litigation expenses	—	—	—	—	(1,657)	—	—	—
Inventory step-up amortization	10,375	—	Inventory step-up amortization	—	—	(10,375)	—	—	—	—	—
Severance	1,057	—	Severance	—	—	—	—	(1,057)	—	—	—
Adjusted non-GAAP EBITDA	<u>\$ 50,044</u>	<u>\$ 30,200</u>	As adjusted:	<u>\$ 190,574</u>	<u>\$ 131,654</u>	<u>\$ 69,538</u>	<u>\$ 53,184</u>	<u>\$ 54,807</u>	<u>\$ 38,643</u>	<u>\$ 16,185</u>	<u>\$ 9,627</u>

⁽¹⁾ Impact of Canada operations includes CDMO revenues, cost of sales relating to CDMO revenues, all selling, general, and administrative expenses, and all research and development expenses recorded in Canada in the period presented, exclusive of restructuring activities, stock-based compensation, and depreciation and amortization, which are included within their respective line items above. The adjustment of Canada operations represents revenues, cost of sales and expense that will not recur after the completion of the closure of our Canada operations (complete as of March 31, 2023) and the sale of the facility (complete as of March 31, 2024). The adjustment of Canada operations does not adjust for revenues, cost of sales, and expense that will recur at our other manufacturing facilities after the transfer of certain manufacturing activities is complete.

Reconciliation of certain adjusted non-GAAP accounts:

	Twelve Months Ended December 31,		As reported:	Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
	2024	2023		Twelve Months Ended December 31,	Twelve Months Ended December 31,	Twelve Months Ended December 31,	Twelve Months Ended December 31,	Twelve Months Ended December 31,	Twelve Months Ended December 31,		
	2024	2023		2024	2023	2024	2023	2024	2023	2024	2023
Net (Loss) Income	\$ (18,522)	\$ 18,779	As reported:	\$ 614,376	\$ 486,816	\$ 250,210	\$ 181,513	\$ 249,636	\$ 161,697	\$ 44,581	\$ 34,286
Add/(Subtract):											
Interest expense, net	17,602	26,940									
Other expense, net	4,033	159									
Loss on extinguishment of debt	7,468	—									
(Benefit) provision for income taxes	(3,690)	1,093									
Depreciation and amortization	67,731	59,791									
Contingent consideration fair value adjustment	(619)	1,426									
Unrealized gain on investment in equity securities	(6,307)	—									
Intangible asset impairment charge	7,600	—									
Gain on sale of building	(5,347)	—									
Restructuring activities	—	1,132									
Impact of Canada operations(1)	—	2,697	Impact of Canada operations(1)	—	(565)	—	(1,884)	—	(1,304)	—	(73)
Stock-based compensation	29,344	20,652	Stock-based compensation	—	—	(1,277)	(706)	(26,533)	(19,036)	(1,534)	(910)
M&A transaction and integration expenses	20,163	1,148	M&A transaction and integration expenses	—	—	—	—	(20,163)	(1,148)	—	—
Litigation expenses	6,395	—	Litigation expenses	—	—	—	—	(6,395)	—	—	—
Inventory step-up amortization	13,599	—	Inventory step-up amortization	—	—	(13,599)	—	—	—	—	—
Severance	6,365	—	Severance	—	—	—	—	(6,365)	—	—	—
Equity Payout	10,190	—	Equity Payout	—	—	—	—	(9,171)	—	(1,019)	—
Adjusted non-GAAP EBITDA	<u>\$ 156,005</u>	<u>\$ 133,817</u>	As adjusted:	<u>\$ 614,376</u>	<u>\$ 486,251</u>	<u>\$ 235,334</u>	<u>\$ 178,923</u>	<u>\$ 181,009</u>	<u>\$ 140,209</u>	<u>\$ 42,028</u>	<u>\$ 33,303</u>

(1) Impact of Canada operations includes CDMO revenues, cost of sales relating to CDMO revenues, all selling, general, and administrative expenses, and all research and development expenses recorded in Canada in the period presented, exclusive of restructuring activities, stock-based compensation, and depreciation and amortization, which are included within their respective line items above. The adjustment of Canada operations represents revenues, cost of sales and expense that will not recur after the completion of the closure of our Canada operations (complete as of March 31, 2023) and the sale of the facility (complete as of March 31, 2024). The adjustment of Canada operations does not adjust for revenues, cost of sales, and expense that will recur at our other manufacturing facilities after the transfer of certain manufacturing activities is complete.

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Table 4: Adjusted non-GAAP Net Income and Adjusted non-GAAP Diluted Earnings per Share Reconciliation
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Net (Loss) Income Available to Common Shareholders	\$ (10,682)	\$ 749	\$ (20,147)	\$ 17,154
Add/(Subtract):				
Non-cash interest expense	232	804	149	3,335
Depreciation and amortization	22,600	15,194	67,731	59,791
Contingent consideration fair value adjustment	(1,893)	1,985	(619)	1,426
Restructuring activities	—	—	—	1,132
Gain on sale of building	—	—	(5,347)	—
Unrealized loss (gain) on investment in equity securities	1,991	—	(6,307)	—
Intangible asset impairment charge	7,600	—	7,600	—
Impact of Canada operations (1)	—	283	—	2,697
Stock-based compensation	7,061	5,621	29,344	20,652
M&A transaction and integration expenses	5,965	391	20,163	1,148
Litigation expenses	1,657	—	6,395	—
Inventory step-up amortization	10,375	—	13,599	—
Severance	1,057	—	6,365	—
Equity payout	—	—	10,190	—
Loss on extinguishment of debt	—	—	7,468	—
Other expense	1,335	—	3,869	—
Less:				
Estimated tax impact of adjustments	(15,021)	(5,827)	(38,154)	(21,643)
Adjusted non-GAAP Net Income Available to Common Shareholders (2)	\$ 32,277	\$ 19,200	\$ 102,299	\$ 85,692
Diluted Weighted-Average				
Shares Outstanding	19,445	19,219	19,318	18,194
Adjusted Diluted Weighted-Average				
Shares Outstanding	19,785	19,219	19,668	18,194
Adjusted non-GAAP				
Diluted Earnings per Share	\$ 1.63	\$ 1.00	\$ 5.20	\$ 4.71

⁽¹⁾ Impact of Canada operations includes CDMO revenues, cost of sales relating to CDMO revenues, all selling, general, and administrative expenses, and all research and development expenses recorded in Canada in the period presented, exclusive of restructuring activities, stock-based compensation, and depreciation and amortization, which are included within their respective line items above. The adjustment of Canada operations represents revenues, cost of sales and expense that will not recur after the completion of the closure of our Canada operations (complete as of March 31, 2023) and the sale of the facility (complete as of March 31, 2024). The adjustment of Canada operations does not adjust for revenues, cost of sales, and expense that will recur at our other manufacturing facilities after the transfer of certain manufacturing activities is complete.

⁽²⁾ Adjusted non-GAAP Net Income Available to Common Shareholders excludes undistributed earnings to participating securities.