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): November 8, 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 2.02 Results of Operations and Financial Condition

On November 8, 2024, ANI Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 8, 2024
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: November 8, 2024

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Name: Stephen P. Carey

Title: Senior Vice President Finance and Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

ANI Pharmaceuticals Reports Record Third Quarter 2024 Financial Results and Raises 2024 Guidance

- *Generated record quarterly net revenues of $148.3 million, representing year-over-year growth of 12.5%, and record Purified Cortrophin® Gel net revenues of $52.6 million, an increase of 76.8% year-over-year*
- *Net loss of $(24.2) million and adjusted non-GAAP EBITDA of $35.1 million*
- *Diluted GAAP loss per share of $(1.27) and adjusted non-GAAP diluted earnings per share of $1.34*
- *Completed the acquisition of Alimera Sciences, Inc. on September 16, 2024, adding two commercial assets ILUVIEN® and YUTIQ® with significant growth potential to its Rare Disease portfolio*
- *Implemented new capital structure that is expected to reduce interest expense by approximately $39.0 million on an annualized basis [(1)]*
- *Increased 2024 guidance with expected net revenues of $594 million to $602 million, adjusted non-GAAP EBITDA of $149 million to $153 million and adjusted non-GAAP earnings per share of $4.90 to $5.05*
- *Guidance includes Purified Cortrophin Gel net revenues of $196 million to $200 million, representing year-over-year growth of 75% to 78%, and ILUVIEN and YUTIQ net revenues of $30 million to $32 million*

BAUDETTE, Minn., November 8, 2024 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced financial results and business highlights for the three months ended September 30, 2024.

“I am very pleased to report our third quarter results as we continue to execute against our purpose of ‘Serving Patients, Improving Lives,’” said Nikhil Lalwani, President & CEO of ANI. “During the quarter, our team drove record performance for both our lead Rare Disease asset Cortrophin Gel and our Generics business. We also put a new, more efficient and effective capital structure in place and completed the acquisition of Alimera, which is highly synergistic to our Rare Disease business. We believe our proven commercial execution capabilities can further unlock the potential for ILUVIEN and YUTIQ, two growing and durable assets, as well as accelerate the growth of Cortrophin Gel in ophthalmology.”

“Based on our strong third quarter results, the continued momentum across the business, and the addition of ILUVIEN and YUTIQ, we are pleased to raise our full year 2024 guidance,” concluded Mr. Lalwani.

[(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.

Third Quarter and Recent Business Highlights:

Rare Disease Segment

Revenues for ANI's lead asset, Cortrophin Gel, totaled $52.6 million for the third quarter of 2024, an increase of 76.8% 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 unique prescribers since launch and achieved growth across all targeted specialties – ophthalmology, neurology, rheumatology nephrology and pulmonology. ANI continued taking steps to further strengthen the Cortrophin Gel franchise and completed development of a Pre-Filled Syringe for Cortrophin Gel and submitted a supplemental new drug application (sNDA) in October.

Generics Business

ANI's Generics business achieved 10.8% year-over-year growth in the third quarter of 2024, driven by strong R&D capabilities and operational excellence leveraging its U.S. based manufacturing footprint and robust FDA compliance track record. The Company launched five new products during the quarter, several into limited competition markets, and one additional product so far in the fourth quarter, bringing the year to date total to sixteen.

Closed Acquisition of Alimera Sciences

On September 16, 2024, the Company completed the acquisition of Alimera Sciences. The transaction significantly expands the scope and scale of ANI's Rare Disease business with the addition of two growing and durable ophthalmology products, ILUVIEN and YUTIQ. Integration is progressing as anticipated and the Company now has a 45-person ophthalmology sales force promoting ILUVIEN, YUTIQ and Cortrophin. In addition, the Company remains on track to capture approximately $10 million of identified cost synergies in 2025.

The acquisition contributed $3.9 million of revenues to ANI for the last two weeks of the quarter, and the Company expects revenue between $30.0 million and $32.0 million for the year (for the period of September 16, 2024 through December 31, 2024).

New Capital Structure

During the quarter, ANI completed an offering of $316.25 million aggregate principal amount of 2.25% convertible senior notes due September 1, 2029, repaid its existing senior secured term loan facility ($292.5 million that carried an interest rate of SOFR+6.0%), and entered into a new senior secured credit agreement consisting of a $325.0 million delayed draw term loan facility (initial interest rate SOFR+2.75%) and $75.0 million revolving credit facility. The Company expects these capital structure changes to reduce interest expense by approximately $39.0 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.

Third Quarter 2024 Financial Results

(in thousands)	Three Months Ended September 30, 2024	2023	Change	% Change
Rare Disease Segment				
Cortrophin Gel	$ 52,555	$ 29,734	$ 22,821	76.8 %
ILUVIEN and YUTIQ	3,871	—	3,871	100.0 %
Rare Disease segment total net revenues	$ 56,426	$ 29,734	$ 26,692	89.8 %
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 78,223	$ 70,593	$ 7,630	10.8 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	13,683	31,502	(17,819)	(56.6)%
Generics, established brands, and other segment total net revenues	$ 91,906	$ 102,095	$ (10,189)	(10.0)%
Total net revenues	$ 148,332	$ 131,829	$ 16,503	12.5 %

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

Net revenues for Rare Disease pharmaceutical products, which include Cortrophin Gel and a partial quarter of contribution from ILUVIEN and YUTIQ, increased 89.8% to $56.4 million. Cortrophin Gel net revenues increased 76.8% to $52.6 million driven by increased volume.

Net revenues for generic pharmaceutical products increased 10.8% to $78.2 million, driven by increased volumes in the base business and contribution from new product launches.

Net revenues for established brand pharmaceutical products, royalties, and other pharmaceutical services decreased 56.6% to $13.7 million, in line with Company expectations.

On a GAAP basis, gross margin decreased from 63.5% to 57.5%, primarily due to an unfavorable mix resulting from decreased revenues from established brand pharmaceutical products, as well as significant growth of royalty bearing products. On a non-GAAP basis, gross margin decreased from 63.7% to 59.9%.

On a GAAP basis, research and development expenses decreased 8.9% to $10.1 million. On a non-GAAP basis, research and development expenses decreased 20.4% to $8.7 million.

On a GAAP basis, selling, general, and administrative expenses increased 88.2% to $79.1 million, primarily due to increased employment-related costs, investment in Rare Disease sales and marketing infrastructure and activities, legal expenses, expenses related to the acquisition of Alimera, and an overall increase in activities to support revenue growth. On a non-GAAP basis, selling, general, and administrative expenses increased 22.8% to $45.0 million.

On a GAAP basis, the Company reported a net loss attributable to common shareholders of $(24.6) million, or $(1.27) per share, for the third quarter of 2024 compared to net income of $9.5 million, or $0.46 per share, in the prior year period. On a non-GAAP basis, the Company reported diluted earnings per share of $1.34 for the third quarter of 2024 compared to $1.27 in the prior year period.

The Company reported a net loss of $(24.2) million, alongside, adjusted non-GAAP EBITDA for the third quarter of 2024 was $35.1 million, a decrease of 3.8% over the third quarter of 2023.

For reconciliations of adjusted non-GAAP EBITDA, non-GAAP research and development expenses, non-GAAP selling, general, and administrative expenses, 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 September 30, 2024, the Company had $145.0 million in unrestricted cash and cash equivalents, $196.4 million in net accounts receivable and $641.3 million in principal value of outstanding debt (inclusive of our senior convertible notes). The Company generated year-to-date cash flow from operations of $48.2 million.

Revised Full Year 2024 Guidance:

The Company is updating its full year 2024 guidance for the combined organization, which includes the anticipated results of Alimera from September 16, 2024.

	Revised Full Year 2024 Guidance	Prior Full Year 2024 Guidance	2023 Actual	Growth
Net Revenue (Total Company)	$594 million - $602 million	$540 million - $560 million	$486.8 million	22% - 24%
Cortrophin Gel Net Revenue	$196 million - $200 million	$185 million - $195 million	$112.1 million	75% - 78%
ILUVIEN and YUTIQ Net Revenue	$30 million - $32 million	NA	NA	NA
Adjusted Non-GAAP EBITDA	$149 million - $153 million	$140 million - $150 million	$133.8 million	11% - 14%
Adjusted Non-GAAP Diluted EPS	$4.90 - $5.05	$4.38 - $4.82	$4.71	4% - 7%

ANI now expects total company adjusted non-GAAP gross margin to be at the high end of our previously communicated range of 61% to 62%. The Company will continue to tax effect non-GAAP adjustments for computation of adjusted non-GAAP diluted earnings per share at a tax rate of 26.0%, unless the item being adjusted is not tax deductible in whole or in part.

The Company now anticipates approximately 19.7 million and 19.9 million shares outstanding for the purpose of calculating adjusted non-GAAP diluted EPS for full year 2024 and fourth quarter 2024, respectively. The Company now expects its annual U.S. GAAP effective tax rate to be in the mid-single digits as compared to our previous expectation of between 22% and 25%, driven by the non-deductible nature of certain expenses incurred in conjunction with the acquisition of Alimera (against an annual forecasted GAAP pre-tax loss).

Upcoming Events

ANI plans to participate in the following investor events:

Guggenheim's Inaugural Healthcare Innovation Conference
November 13, 2024
Boston, MA

Jefferies London Healthcare Conference
November 20, 2024
London, UK

Conference Call

The Company's management will host a conference call today to discuss its third quarter 2024 results.

Date Friday, November 8, 2024
Time 8:00 a.m. ET
Toll free (U.S.) 800-445-7795
Conference ID 4757982
This conference call will also be webcast and can be accessed from the "Investors" section of ANI's website at www.anipharmaceuticals.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 800-839-8389 and entering access code 4757982.

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 2024 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 2024 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 Established 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, 2024 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: our ability to continue to achieve commercial success with Cortrophin Gel, our first rare disease pharmaceutical product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; the ability of our approved products, including Cortrophin Gel, and products acquired in the acquisition of Alimera, 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 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 in production, 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; our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel and products acquired in the acquisition of Alimera; 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, 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; 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Net Revenues	$ 148,332	$ 131,829	$ 423,802	$ 355,162
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	63,075	48,101	169,930	128,093
Research and development	10,128	11,121	27,935	24,419
Selling, general, and administrative	79,075	42,007	179,917	117,235
Depreciation and amortization	15,748	15,207	45,131	44,597
Contingent consideration fair value adjustment	825	(2,555)	1,274	(559)
Restructuring activities	—	—	—	1,132
Gain on sale of building	—	—	(5,347)	—
Total Operating Expenses, net	168,851	113,881	418,840	314,917
Operating (loss) income	(20,519)	17,948	4,962	40,245
Other (Expense) Income, net				
Unrealized gain on investment in equity securities	1,355	—	8,298	—
Interest expense, net	(2,331)	(6,398)	(11,587)	(21,194)
Other expense, net	(2,535)	(39)	(2,655)	(126)
Loss on extinguishment of debt	(7,468)	—	(7,468)	—
(Loss) Income Before Income Tax (Benefit) Expense	(31,498)	11,511	(8,450)	18,925
Income tax (benefit) expense	(7,332)	1,571	(204)	1,301
Net (Loss) Income	$ (24,166)	$ 9,940	$ (8,246)	$ 17,624
Dividends on Series A Convertible Preferred Stock	(406)	(406)	(1,219)	(1,219)
Net (Loss) Income Available to Common Shareholders	$ (24,572)	$ 9,534	$ (9,465)	$ 16,405
Basic and Diluted (Loss) Income Per Share:				
Basic (Loss) Income Per Share	$ (1.27)	$ 0.46	$ (0.49)	$ 0.84
Diluted (Loss) Income Per Share	$ (1.27)	$ 0.45	$ (0.49)	$ 0.83
Basic Weighted-Average Shares Outstanding	19,404	18,883	19,275	17,663
Diluted Weighted-Average Shares Outstanding	19,404	19,125	19,275	17,823

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

	September 30, 2024	December 31, 2023
Current Assets		
Cash and cash equivalents	$ 144,982	$ 221,121
Restricted Cash	35	—
Accounts receivable, net	196,361	162,079
Inventories	148,042	111,196
Prepaid income taxes	6,104	—
Assets held for sale	—	8,020
Prepaid expenses and other current assets	17,475	17,400
Investment in equity securities	8,298	—
Total Current Assets	521,297	519,816
Non-current Assets		
Property and equipment, net	56,704	44,593
Deferred tax assets, net of deferred tax liabilities and valuation allowance	67,661	90,711
Intangible assets, net	569,825	209,009
Goodwill	60,426	28,221
Derivatives and other non-current assets	11,464	12,072
Total Assets	$ 1,287,377	$ 904,422
Current Liabilities		
Current debt, net of deferred financing costs	$ 7,152	$ 850
Accounts payable	60,890	36,683
Accrued royalties	23,447	16,276
Accrued compensation and related expenses	29,777	23,786
Accrued government rebates	10,693	12,168
Income taxes payable	—	8,164
Returned goods reserve	37,068	29,678
Current contingent consideration	1,283	12,266
Accrued licensor payment	1,809	—
Accrued expenses and other	17,814	5,606
Total Current Liabilities	189,933	145,477
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	312,918	284,819
Non-current convertible notes, net of deferred financing costs	305,293	—
Non-current contingent consideration	20,175	11,718
Accrued licensor payment, net of current	21,316	—
Other non-current liabilities	6,944	4,809
Total Liabilities	$ 856,579	$ 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	(20,722)	(10,081)
Additional paid-in capital	510,899	514,103
Accumulated deficit	(89,597)	(80,132)
Accumulated other comprehensive income, net of tax	5,366	8,857
Total Stockholders' Equity	405,948	432,749
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 1,287,377	$ 904,422

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

	Three Months Ended September 30,			Reconciliation of certain adjusted non-GAAP accounts:							
				Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative		Research and development	
				Three Months Ended September 30,		Three Months Ended September 30,		Three Months Ended September 30,		Three Months Ended September 30,	
	2024	2023		2024	2023	2024	2023	2024	2023	2024	2023
Net (Loss) Income	$ (24,166)	$ 9,940	As reported:	$ 148,332	$ 131,829	$ 63,075	$ 48,101	$ 79,075	$ 42,007	$ 10,128	$ 11,121
Add/(Subtract):											
Interest expense, net	2,331	6,398									
Other expense, net	2,535	39									
Loss on extinguishment of debt	7,468	—									
(Benefit) provision for income taxes	(7,332)	1,571									
Depreciation and amortization	15,748	15,207									
Contingent consideration fair value adjustment	825	(2,555)									
Unrealized gain on investment in equity securities	(1,355)	—									
Impact of Canada operations (1)	—	275	Impact of Canada operations (1)	—	—	—	(128)	—	(147)	—	—
Stock-based compensation	7,484	5,444	Stock-based compensation	—	—	(318)	(182)	(6,723)	(5,023)	(443)	(239)
M&A transaction and integration expenses	9,945	165	M&A transaction and integration expenses	—	—	—	—	(9,945)	(165)	—	—
Litigation expenses	2,899	—	Litigation expenses	—	—	—	—	(2,899)	—	—	—
Inventory step-up amortization	3,224	—	Inventory step-up amortization	—	—	(3,224)	—	—	—	—	—
Severance	5,308	—	Severance	—	—	—	—	(5,308)	—	—	—
Equity payout	10,190	—	Equity payout	—	—	—	—	(9,171)	—	(1,019)	—
Adjusted non-GAAP EBITDA	$ 35,104	$ 36,484	As adjusted:	$ 148,332	$ 131,829	$ 59,533	$ 47,791	$ 45,029	$ 36,672	$ 8,666	$ 10,882

(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.

	Nine Months Ended September 30,			Reconciliation of certain adjusted non-GAAP accounts:							
				Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative		Research and development	
				Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023		2024	2023	2024	2023	2024	2023	2024	2023
Net (Loss) Income	$ (8,246)	$ 17,624	As reported:	$ 423,802	$ 355,162	$ 169,930	$ 128,093	$ 179,917	$ 117,235	$ 27,935	$ 24,419
Add/(Subtract):											
Interest expense, net	11,587	21,194									
Other expense, net	2,655	126									
Loss on extinguishment of debt	7,468	—									
(Benefit) provision for income taxes	(204)	1,301									
Depreciation and amortization	45,131	44,597									
Contingent consideration fair value adjustment	1,274	(559)									
Restructuring activities	—	1,132									
Gain on sale of building	(5,347)	—									
Unrealized gain on investment in equity securities	(8,298)	—									
Impact of Canada operations (1)	—	2,414	Impact of Canada operations (1)	—	(565)	—	(1,833)	—	(1,073)	—	(73)
Stock-based compensation	22,283	15,031	Stock-based compensation	—	—	(911)	(521)	(20,300)	(13,839)	(1,072)	(671)
M&A transaction and integration expenses	14,198	757	M&A transaction and integration expenses	—	—	—	—	(14,198)	(757)	—	—
Litigation expenses	4,738	—	Litigation expenses	—	—	—	—	(4,738)	—	—	—
Inventory step-up amortization	3,224	—	Inventory step-up amortization	—	—	(3,224)	—	—	—	—	—
Severance	5,308	—	Severance	—	—	—	—	(5,308)	—	—	—
Equity payout	10,190	—	Equity payout	—	—	—	—	(9,171)	—	(1,019)	—
Adjusted non-GAAP EBITDA	$ 105,961	$ 103,617	As adjusted:	$ 423,802	$ 354,597	$ 165,795	$ 125,739	$ 126,202	$ 101,566	$ 25,844	$ 23,675

(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.

ANI Pharmaceuticals, Inc. and Subsidiaries
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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net (Loss) Income Available to Common Shareholders	$ (24,572)	$ 9,534	$ (9,465)	$ 16,405
Add/(Subtract):				
Non-cash interest (income) expense	(18)	856	(82)	2,530
Depreciation and amortization	15,748	15,207	45,131	44,597
Contingent consideration fair value adjustment	825	(2,555)	1,274	(559)
Loss on extinguishment of debt	7,468	—	7,468	—
Restructuring activities	—	—	—	1,132
Gain on sale of building	—	—	(5,347)	—
Unrealized gain on investment in equity securities	(1,355)	—	(8,298)	—
Impact of Canada operations (1)	—	275	—	2,414
Stock-based compensation	7,484	5,444	22,283	15,031
M&A transaction and integration expenses	9,945	165	14,198	757
Litigation expenses	2,899	—	4,738	—
Inventory step-up amortization	3,224	—	3,224	—
Severance	5,308	—	5,308	—
Equity payout	10,190	—	10,190	—
Other expense	2,493	—	2,536	—
Less:				
Estimated tax impact of adjustments	(13,147)	(4,654)	(23,134)	(15,816)
Adjusted non-GAAP Net Income Available to Common Shareholders (2)	$ 26,492	$ 24,272	$ 70,024	$ 66,491
Diluted Weighted-Average				
Shares Outstanding	19,404	19,125	19,275	17,823
Adjusted Diluted Weighted-Average				
Shares Outstanding	19,766	19,125	19,629	17,823
Adjusted non-GAAP				
Diluted Earnings per Share	$ 1.34	$ 1.27	$ 3.57	$ 3.73

(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.