ANI Pharmaceuticals Reports Record First Quarter 2024 Financial Results and Reiterates 2024 Guidance

May 10, 2024

- *Generated record quarterly net revenues of $137.4 million, representing year-over-year growth of 28.7%, net income to common shareholders of $17.8 million, and GAAP diluted earnings per share of $0.82*
- *Delivered record adjusted non-GAAP EBITDA of $37.6 million, and adjusted non-GAAP diluted earnings per share of $1.21*
- *Rare Disease business delivered Q1 net revenues of $36.9 million, representing year-over-year growth of 126.2%*
- *Reiterated 2024 guidance of net revenues of $520 million to $542 million, adjusted non-GAAP EBITDA of $135 million to $145 million and adjusted non-GAAP earnings per share of $4.26 to $4.67*
- *Guidance includes Purified Cortrophin® Gel (Repository Corticotrophin Injection USP) 80 U/ml (Cortrophin Gel) net revenues of $170 million to $180 million, representing year-over-year growth of 52% to 61%*

BAUDETTE, Minn., May 10, 2024 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced financial results and business highlights for the three months ended March 31, 2024.

Nikhil Lalwani, President and CEO of ANI stated, “Our record first quarter results demonstrate strength across all of our business segments. Our lead Rare Disease asset Cortrophin Gel experienced another quarter of robust year-over-year growth as prescription demand increased across our core specialties and our recent investments to expand awareness and utilization in new specialties began to yield results. We continue to believe that Cortrophin Gel has a long runway of growth driven by increasing market penetration and expansion of the overall ACTH market. This was further evidenced in April by achieving the highest number of new patient starts since launch.”

“Our Generics, Established Brands and Other segment also delivered strong performance in the first quarter. We are proud to report another quarter of double-digit increase in Generics revenue supported by strong new launch execution and operational excellence. We are energized by our first quarter results and look forward to building momentum throughout 2024 as we remain committed to our purpose of ‘Serving Patients, Improving Lives’,” concluded Mr. Lalwani.

First Quarter and Recent Business Highlights:

Rare Disease Segment

Revenues for the Company’s lead asset, Cortrophin Gel, totaled $36.9 million for the first quarter of 2024, an increase of 126.2% over the same period in 2023, driven by increased volume. During the quarter, the Company saw continued prescription growth across its core specialties of neurology, rheumatology, and nephrology, as well as traction in its newer specialties of pulmonology and ophthalmology. The Company continues to believe that its Rare Disease business remains ANI’s largest future growth driver and is actively exploring opportunities to acquire assets and/or establish partnerships to increase the scope and scale of the business.

Generics, Established Brands and Other Segment

Revenues for generic pharmaceuticals products, established brands and other grew 11.1% year-over-year in the first quarter of 2024. ANI’s Generics business launched six new products during the quarter, including a Competitive Generic Therapy (CGT) product with 180-day exclusivity. The Company retained its number two ranking for CGT approvals and top 15 ranking for overall generic approvals.

First Quarter 2024 Financial Results

	Three Months Ended March 31,			
(in thousands)	2024	2023	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 70,217	$ 63,713	$ 6,504	10.2%
Established brand pharmaceutical products, royalties, and other pharmaceutical services	30,276	26,743	3,533	13.2%
Generics, established brands, and other segment total net revenues	$ 100,493	$ 90,456	$ 10,037	11.1%
Rare Disease Segment				
Rare disease pharmaceutical products	36,937	16,330	20,607	126.2%
Total net revenues	$ 137,430	$ 106,786	$ 30,644	28.7%

Net revenues for generic pharmaceutical products were $70.2 million, an increase of 10.2% year-over-year, driven by increased volumes in the base business and contribution from new products launched in 2023 and the first quarter 2024.

Net revenues for established brand pharmaceutical products, royalties, and other pharmaceutical services were $30.3 million, an increase of 13.2%

year-over-year, driven by increased volume.

Net revenues for Rare Disease pharmaceutical products, which consist entirely of sales of Cortrophin Gel, were $36.9 million, an increase of 126.2% year-over-year driven by increased volume.

Operating expenses were $117.1 million, an increase of 20.9% year-over-year, as a result of the following factors:

- Cost of sales increased 30.4% year-over-year to $49.2 million, primarily due to significant growth in sales volumes of pharmaceutical products across all segments.
- Research and development expenses increased 77.4% year-over-year to $10.5 million, primarily due to a higher level of activity associated with ongoing and new projects.
- Selling, general, and administrative expenses increased 31.7% year-over-year to $48.0 million, primarily due to increased employment-related costs, investment in our Rare Disease sales and marketing infrastructure and activities, legal expenses, as well as an overall increase in activities to support revenue growth.

During the first quarter of 2024, ANI completed the sale of its Oakville, Ontario, Canada manufacturing facility for $14.2 million and recognized a gain of $5.3 million on the sale. The Company also recognized a gain of $9.7 million on its investment in CG Oncology, which completed an initial public offering in January 2024.

Net income available to common shareholders for the first quarter of 2024 was $17.8 million as compared to net income of $1.0 million in the prior year period. Diluted GAAP earnings per share for the first quarter of 2024 was $0.82 compared to $0.06 in the prior year period.

Adjusted non-GAAP EBITDA for the first quarter of 2024 was $37.6 million, an increase of 14.0% over the first quarter of 2023.

Adjusted non-GAAP diluted earnings per share was $1.21 in the first quarter of 2024 compared to $1.17 in the prior year period.

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 March 31, 2024, the Company had $228.6 million in unrestricted cash and cash equivalents, $172.4 million in net accounts receivable and $293.3 million (face value) in outstanding debt. The Company generated cash flow from operations of $18.3 million in the first quarter of 2024.

Full Year 2024 Guidance:

	2024 Guidance	2023 Actual	Growth
Net Revenue (Total Company)	$520 million - $542 million	$486.8 million	7% - 11%
Cortrophin Gel Net Revenue	$170 million - $180 million	$112.1 million	52% - 61%
Adjusted Non-GAAP EBITDA	$135 million - $145 million	$133.8 million	1% - 8%
Adjusted Non-GAAP Diluted EPS	$4.26- $4.67	$4.71	(10)% - (1)%

ANI continues to expect total company adjusted non-GAAP gross margin between 62% and 63% and 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%.

The Company now anticipates between 19.4 million and 19.7 million shares outstanding (reflective of a full year of shares outstanding resulting from the May 2023 equity raise) for the purpose of calculating diluted EPS and now expects its U.S. GAAP effective tax rate to be between 22.0% to 25.0% as compared to 20.0% to 22.0%.

Conference Call

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

Date	Friday, May 10, 2024
Time	8:30 a.m. ET
Toll free (U.S.)	800-274-8461

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 800-938-2239 and entering access code 4555224.

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 income, excluding tax provision or benefit, interest expense, (net), other expense, (net), depreciation and amortization expense, non-cash stock-based compensation expense, Novitium transaction 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, 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, Novitium transaction 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, 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 income, plus the non-cash stock-based compensation expense, Novitium transaction expenses, non-cash interest expense, depreciation and amortization expense, 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, 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, Novitium transaction 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, 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 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.

About ANI

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. Our team is focused on delivering sustainable growth by scaling up our Rare Disease business through the successful launch of our lead asset, Purified Cortrophin® Gel, strengthening our generics business with enhanced research and development capability, innovation in established brands and leveraging our U.S. based manufacturing capabilities. For more information, please visit our website 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, 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: Cortrophin Gel is our first rare disease pharmaceutical product; to the extent we are not able to continue to achieve commercial success with this product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; our approved products, including Cortrophin Gel, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; acquisitions and other investments could disrupt our business and harm our financial position and operating results; the limited number of suppliers for our active pharmaceutical ingredients could result in lengthy delays in production if we need to change suppliers; delays or failure in obtaining or maintaining approvals by the FDA of the products we sell; changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls; acceptance of our products at

levels that will allow us to achieve profitability; 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; our dependence on single source suppliers of ingredients due to the time and cost to validate a second source of supply; 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 between Israel and Gaza, or conflicts relating to 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 Statement of Operations
(unaudited, in thousands, except per share amounts)

	Three Months Ended March 31,	
	2024	**2023**
Net Revenues	$ 137,430	$ 106,786
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	49,157	37,708
Research and development	10,511	5,924
Selling, general, and administrative	48,021	36,468
Depreciation and amortization	14,686	14,700
Contingent consideration fair value adjustment	90	961
Restructuring activities	—	1,130
Gain on sale of building	(5,347)	—
Total Operating Expenses, net	117,118	96,891
Operating Income	20,312	9,895
Other Income (Expense), net		
Unrealized gain on investment in equity securities	9,655	—
Interest expense, net	(4,600)	(7,696)
Other expense, net	(32)	(34)
Income Before Income Tax Expense	25,335	2,165
Income tax expense	7,128	726
Net Income	$ 18,207	$ 1,439
Dividends on Series A Convertible Preferred Stock	(406)	(406)
Net Income Available to Common Shareholders	$ 17,801	$ 1,033

Basic and Diluted Income Per Share:

Basic Income Per Share	$ 0.84	$ 0.06
Diluted Income Per Share	$ 0.82	$ 0.06
Basic Weighted-Average Shares Outstanding	19,099	16,392
Diluted Weighted-Average Shares Outstanding	19,422	16,531

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

	March 31, 2024	December 31, 2023
Current Assets		
Cash and cash equivalents	$ 228,597	$ 221,121
Accounts receivable, net	172,418	162,079
Inventories	113,837	111,196
Assets held for sale	—	8,020
Prepaid expenses and other current assets	16,050	17,400
Investment in equity securities	9,655	—
Total Current Assets	540,557	519,816
Non-current Assets		
Property and equipment, net	48,526	44,593
Deferred tax assets, net of deferred tax liabilities and valuation allowance	87,607	90,711
Intangible assets, net	196,044	209,009
Goodwill	28,221	28,221
Derivatives and other non-current assets	13,569	12,072
Total Assets	$ 914,524	$ 904,422
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	49,430	36,683
Accrued royalties	15,475	16,276
Accrued compensation and related expenses	9,526	23,786
Accrued government rebates	9,509	12,168
Income taxes payable	11,402	8,164
Returned goods reserve	32,853	29,678
Current contingent consideration	414	12,266
Accrued expenses and other	7,430	5,606
Total Current Liabilities	136,889	145,477
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	284,607	284,819
Non-current contingent consideration	11,160	11,718
Other non-current liabilities	5,055	4,809
Total Liabilities	$ 437,711	$ 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	(18,742)	(10,081)
Additional paid-in capital	523,628	514,103
Accumulated deficit	(62,331)	(80,132)
Accumulated other comprehensive income, net of tax	9,406	8,857
Total Stockholders' Equity	451,963	432,749

Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 914,524	$ 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 March 31,			Reconciliation of certain adjusted non-GAAP accounts:							
				Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
				Three Months Ended March 31,		Three Months Ended March 31,		Three Months Ended March 31,		Three Months Ended March 31,	
	2024	2023		2024	2023	2024	2023	2024	2023	2024	2023
Net Income	$18,207	$ 1,439	As reported:	$137,430	$106,786	$49,157	$37,708	$48,021	$36,468	$10,511	$ 5,924
Add/(Subtract):											
Interest expense, net	4,600	7,696									
Other expense, net	32	34									
Provision for income taxes	7,128	726									
Depreciation and amortization	14,686	14,700									
Contingent consideration fair value adjustment	90	961									
Restructuring activities	—	1,130									
Gain on sale of building	(5,347)	—									
Unrealized gain on investment in equity securities	(9,655)	—									
Impact of Canada operations [1]	—	1,647	Impact of Canada operations [1]	—	(565)	—	(1,416)	—	(732) [2]	—	(64)
Stock-based compensation	6,934	4,338	Stock-based compensation	—	—	(280)	(151)	(6,371)	(3,980)	(283)	(207)
Novitium transaction expenses	713	342	Novitium transaction expenses	—	—	—	—	(713)	(342)	—	—
Litigation expenses	245	—	Litigation expenses	—	—	—	—	(245)	—	—	—
Adjusted non-GAAP EBITDA	$37,633	$33,013	As adjusted:	$137,430	$106,221	$48,877	$36,141	$40,692	$31,414 [2]	$10,228	$ 5,653

[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] The Company corrected the Impact of Canada Operations in the Selling, general, and administrative expenses column for the three months ended March 31, 2023. The Company determined that the correction is not material to the previously issued US GAAP to Non-GAAP Reconciliation. Adjusted non-GAAP EBITDA for the three months ended March 31, 2023 did not change from the original Press Release and Form 8-K filed on May 8, 2023 as a result of this correction.

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 March 31,	
	2024	**2023**
Net Income Available to Common Shareholders	$ 17,801	$ 1,033
Add/(Subtract):		
Non-cash interest (income) expense	(10)	987
Depreciation and amortization	14,686	14,700
Contingent consideration fair value adjustment	90	961
Restructuring activities	—	1,130
Gain on sale of building	(5,347)	—
Unrealized gain on investment in equity securities	(9,655)	—
Impact of Canada operations (1)	—	1,647
Stock-based compensation	6,934	4,338
Novitium transaction expenses	713	342
Litigation expenses	245	—
Less:		
Estimated tax impact of adjustments (calc. at 26% and 24% for the three months ended March 31, 2024 and 2023, respectively)	(1,991)	(5,785)
Adjusted non-GAAP Net Income Available to Common Shareholders (2)	$ 23,466	$ 19,353
Diluted Weighted-Average		
Shares Outstanding	19,422	16,531
Adjusted Diluted Weighted-Average		
Shares Outstanding	19,422	16,531
Adjusted non-GAAP		
Diluted Earnings per Share	$ 1.21	$ 1.17

(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.