ANI Pharmaceuticals Reports Fourth Quarter and Record Full-Year 2023 Financial Results and Provides 2024 Guidance

February 29, 2024

- *Generated quarterly net revenues of $131.7 million, representing year-over-year growth of 39.7%, net income to common shareholders of $0.7 million, GAAP diluted earnings per share of $0.04*
- *Delivered adjusted non-GAAP EBITDA of $30.2 million, and adjusted non-GAAP diluted earnings per share of $1.00*
- *Rare Disease business delivered Q4 net revenues of $41.7 million, representing quarter-over-quarter growth of 40.4% and year-over-year growth of 137.3%*
- *Generated $119.0 million in cash from operating activities during the year, ending Q4 with $221.1 million in cash*
- *2024 guidance issued with 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., Feb. 29, 2024 (GLOBE NEWSWIRE) -- 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, 2023.

Nikhil Lalwani, President and CEO of ANI stated, “The fourth quarter capped off a record year for ANI, as we delivered record growth in annual net revenue and adjusted non-GAAP EBITDA. For our lead Rare Disease asset, Cortrophin Gel, new patient starts accelerated in Q4, and we posted the strongest sequential growth in net revenue to date. The momentum continued for new cases initiated, new unique and repeat prescribers, and we made steady gains across all core indications while also tapping into new therapeutic areas.”

“In 2024, we will continue to use our highly capable R&D engine, operational excellence and U.S.-based manufacturing footprint to launch new products and address patient needs. We expect our Rare Disease business to remain the primary driver of growth, with our Cortrophin Gel franchise estimated to deliver more than a 50% year-on-year increase in revenues in 2024. We are still early in the trajectory for this franchise and believe we have plenty of headroom to drive market share in our core therapeutic areas while also addressing new indications and expanding the overall ACTH market. We believe our strong balance sheet gives us the flexibility to further increase the scope and scale of our Rare Disease business by adding an asset that will leverage our well-established platform. With a record 2023, we are excited about the path ahead, and the opportunity to continue ‘Serving Patients, Improving Lives’,” concluded Mr. Lalwani.

Fourth Quarter and Recent Business Highlights:

Rare Disease Business

Revenues for the Company’s lead asset, Cortrophin Gel, totaled $41.7 million for the fourth quarter of 2023, an increase of 137.3% over the same period in 2022, driven by increased volume. During the quarter, the Company achieved a record number of new cases initiated and new patient starts, and saw continued growth in the number of new unique and repeat prescribers. The overall ACTH category again experienced growth led by increased demand for Cortrophin Gel across the initially targeted specialties of neurology, rheumatology, and nephrology, while gaining momentum in the newer area of pulmonology.

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 its scope and scale.

Generics Business, Established Brands and Other

Revenues for generic pharmaceuticals products, established brands and other grew 17.3% year-over-year in the fourth quarter of 2023. ANI’s Generics business concluded a successful year with 11 new products launched, 20 new products filed and the number two ranking retained in Competitive Generic Therapy approvals.

Throughout 2023, ANI supplied patients with over 1.5 billion doses of therapeutics to patients in need and leveraged its operational excellence and U.S.-based manufacturing to further market share gains by providing customers a stable supply of products.

Fourth Quarter 2023 Financial Results

	Three Months Ended December 31,			
(in thousands)	2023	2022	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 71,826	$ 58,014	$ 13,812	23.8%
Established brand pharmaceutical products, royalties, and other pharmaceutical services	18,079	18,628	(549)	(2.9)%
Generics, established brands, and other segment total net revenues	$ 89,905	$ 76,642	$ 13,263	17.3%

Rare Disease Segment				
Rare disease pharmaceutical products	41,749	17,590	24,159	137.3%
Total net revenues	$ 131,654	$ 94,232	$ 37,422	39.7%

Net revenues for generic pharmaceutical products were $71.8 million, an increase of 23.8% year-over-year, driven by increased volumes in the base business and contribution from new products launched in 2022 and 2023.

Net revenues for established brand pharmaceutical products, royalties, and other pharmaceutical services were $18.1 million, a decrease of 2.9% year-over-year, driven by lower volume.

Net revenues for Rare Disease pharmaceutical products, which consist entirely of sales of Cortrophin Gel, were $41.7 million, an increase of 137.3% year-over-year driven by increased volume.

Operating expenses were $124.9 million, an increase of 35.2% year-over-year, as a result of the following factors:

- Cost of sales increased 47.1% year-over-year to $53.4 million, primarily due to significant growth in sales volumes of generic and Rare Disease pharmaceutical products.
- Research and development expenses increased 89.0% year-over-year to $9.9 million, primarily due to a higher level of activity associated with ongoing and new projects.
- Selling, general, and administrative expenses increased 34.0% year-over-year to $44.5 million, primarily due to increased employment related costs, Rare Disease sales and marketing costs, legal expenses, and patient assistance program costs, as well as an overall increase in activities required to support growth.

Net income available to common shareholders for the fourth quarter of 2023 was $0.7 million as compared to net loss of $(4.7) million in the prior year period. Diluted earnings per share for the fourth quarter of 2023 was $0.04 compared to diluted GAAP loss per share of $(0.28) in the prior year period.

Adjusted non-GAAP diluted earnings per share was $1.00 in the fourth quarter of 2023 compared to $0.76 in the fourth quarter of 2022.

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, 2023, the Company had $221.1 million in unrestricted cash and cash equivalents, $162.1 million in net accounts receivable and $294.0 million (face value) in outstanding debt. The Company generated year-to-date cash flow from operations of $119.0 million.

Full Year 2024 Guidance:

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

ANI expects total company adjusted non-GAAP gross margin between 62% and 63%. In addition, the Company anticipates between 19.3 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 a U.S. GAAP effective tax rate of between approximately 20.0% to 22.0%. The Company will tax effect non-GAAP adjustments for computation of adjusted non-GAAP diluted earnings per share at a tax rate of 26.0%.

Conference Call

The Company's management will host a conference call today to discuss its fourth quarter and full-year 2023 results.

Date	Thursday, February 29, 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 800-839-8531 and entering access code 4470257.

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. Beginning in the fourth quarter of 2022, ANI no longer excludes expense for In-Process Research & Development or Cortrophin Gel pre-launch charges and sales and marketing expenses from its non-GAAP results. Historically, the Company excluded these charges. These changes have been made to align with views expressed by the U.S. Securities and Exchange Commission. Prior periods have been recast to reflect these changes.

Adjusted non-GAAP EBITDA is defined as net income (loss), excluding tax expense or benefit, interest expense, (net), other expense, (net), depreciation, amortization, the excess of fair value over cost of acquired inventory, non-cash stock-based compensation expense, Novitium transaction expenses, contingent consideration fair value adjustment, 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 (Loss)

ANI's management considers adjusted non-GAAP net income (loss) 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 excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, Novitium transaction expenses, contingent consideration fair value adjustment, and certain other items that vary in frequency and impact on ANI's results of operations. Management uses adjusted non-GAAP net income (loss) when analyzing Company performance. Beginning in the fourth quarter of 2022, ANI no longer excludes expense for In-Process Research & Development or Cortrophin Gel pre-launch charges and sales and marketing expenses from its non-GAAP results. Historically, the Company excluded these charges. These changes have been made to align with views expressed by the U.S. Securities and Exchange Commission. Prior periods have been recast to reflect these changes.

Adjusted non-GAAP net income (loss) is defined as net income (loss), plus the excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation expense, Novitium transaction expenses, non-cash interest expense, depreciation and amortization expense, contingent consideration fair value adjustment, 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 (loss) should be considered in addition to, but not in lieu of, net income (loss) reported under GAAP. A reconciliation of adjusted non-GAAP net income (loss) to the most directly comparable GAAP financial measure is provided below.

Adjusted non-GAAP Diluted Earnings (Loss) per Share

ANI's management considers adjusted non-GAAP diluted earnings (loss) 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 excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, Novitium transaction expenses, contingent consideration fair value adjustment, and certain other items that vary in frequency and impact on ANI's results of operations. Management uses adjusted non-GAAP diluted earnings (loss) per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings (loss) per share is defined as adjusted non-GAAP net income (loss), 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 (loss) per share should be considered in addition to, but not in lieu of, diluted earnings or loss per share reported under GAAP. A reconciliation of adjusted non-GAAP diluted earnings (loss) 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; whether we experience difficulties closing a sale transaction with a buyer for the plant and property resulting from the closure of our Oakville, Ontario manufacturing plant; 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, such as COVID-19, and other risks and uncertainties that are described in ANI's Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the Securities and Exchange Commission.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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SOURCE: ANI Pharmaceuticals, Inc.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Net Revenues	$ 131,654	$ 94,232	$ 486,816	$ 316,385
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	53,420	36,326	181,513	138,785
Research and development	9,867	5,222	34,286	22,318
Selling, general, and administrative	44,462	33,188	161,697	124,044
Depreciation and amortization	15,194	14,484	59,791	56,972
Contingent consideration fair value adjustment	1,985	1,624	1,426	3,758
Restructuring activities	-	1,568	1,132	5,679
Intangible asset impairment charge	-	-	-	112
Total Operating Expenses	124,928	92,412	439,845	351,668
Operating Income (Loss)	6,726	1,820	46,971	(35,283)
Other Expense, net				
Interest expense, net	(5,746)	(7,506)	(26,940)	(28,052)
Other (expense) income, net	(33)	(42)	(159)	670
Income (Loss) Before (Benefit) Expense for Income Taxes	947	(5,728)	19,872	(62,665)
Income tax (benefit) expense	(208)	(1,485)	1,093	(14,769)
Net Income (Loss)	$ 1,155	$ (4,243)	$ 18,779	$ (47,896)
Dividends on Series A Convertible Preferred Stock	(406)	(407)	$ (1,625)	(1,625)

Net Income (Loss) Available to Common Shareholders	$ 749	$ (4,650)	$ 17,154	$ (49,521)
Basic and Diluted Income (Loss) Per Share:				
Basic Income (Loss) Per Share	$ 0.04	$ (0.28)	$ 0.86	$ (3.05)
Diluted Income (Loss) Per Share	$ 0.04	$ (0.28)	$ 0.85	$ (3.05)
Basic Weighted-Average Shares Outstanding	19,003	16,325	18,001	16,260
Diluted Weighted-Average Shares Outstanding	19,219	16,325	18,194	16,260

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

	December 31, 2023	December 31, 2022
Current Assets		
Cash and cash equivalents	$ 221,121	$ 48,228
Current restricted cash	-	5,006
Accounts receivable, net	162,079	165,438
Inventories	111,196	105,355
Prepaid income taxes	-	3,827
Assets held for sale	8,020	8,020
Prepaid expenses and other current assets	17,400	8,387
Total Current Assets	519,816	344,261
Non-current Assets		
Property and equipment, net	44,593	43,246
Deferred tax assets, net of deferred tax liabilities and valuation allowance	90,711	81,363
Intangible assets, net	209,009	251,635
Goodwill	28,221	28,221
Derivatives and other non-current assets	12,072	11,361
Total Assets	$ 904,422	$ 760,087
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	36,683	29,305
Accrued royalties	16,276	9,307
Accrued compensation and related expenses	23,786	10,312
Accrued government rebates	12,168	10,872
Income taxes payable	8,164	-
Returned goods reserve	29,678	33,399
Current contingent consideration	12,266	-
Accrued expenses and other	5,606	5,394
Total Current Liabilities	145,477	99,439
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	284,819	285,669
Non-current contingent consideration, net of current	11,718	35,058
Other non-current liabilities	4,809	1,381
Total Liabilities	$ 446,823	$ 421,547
Mezzanine Equity		
Convertible Preferred Stock, Series A	24,850	24,850
Stockholders' Equity		
Common Stock	2	1
Class C Special Stock	-	-

Preferred Stock	-	-
Treasury stock	(10,081)	(5,094)
Additional paid-in capital	514,103	403,901
Accumulated deficit	(80,132)	(97,286)
Accumulated other comprehensive income, net of tax	8,857	12,168
Total Stockholders' Equity	432,749	313,690
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 904,422	$ 760,087

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:							
				Net Revenues		**Cost of sales (excluding depreciation and amortization)**		**Selling, general, and administrative**		**Research and development**	
	Three Months Ended December 31,			**Three Months Ended December 31,**		**Three Months Ended December 31,**		**Three Months Ended December 31,**		**Three Months Ended December 31,**	
	2023	**2022**		**2023**	**2022**	**2023**	**2022**	**2023**	**2022**	**2023**	**2022**
Net Income (Loss)	$ 1,155	$ (4,243)	As reported:	$ 131,654	$ 94,232	$ 53,420	$ 36,326	$ 44,462	$ 33,188	$ 9,867	$ 5,222
Add/(Subtract):											
Interest expense, net	5,746	7,506									
Other expense, net	33	42									
Benefit for income taxes	(208)	(1,485)									
Depreciation and amortization	15,194	14,484									
Contingent consideration fair value adjustment	1,985	1,624									
Restructuring activities	—	1,568									
Impact of Canada operations (1)	283	79	Impact of Canada operations (1)	—	(1,227)	(51)	(474)	(232)	(776)	—	(56)
Stock-based compensation	5,621	3,737	Stock-based compensation	—	—	(185)	(104)	(5,196)	(3,444)	(240)	(189)
Excess of fair value over cost of acquired inventory	—	48	Excess of fair value over cost of acquired inventory	—	—	—	(48)	—	—	—	—
Novitium transaction expenses	391	(31)	Novitium transaction expenses	—	—	—	—	(391)	31	—	—
Adjusted non-GAAP EBITDA	$ 30,200	$ 23,329	As adjusted:	$ 131,654	$ 93,005	$ 53,184	$ 35,700	$ 38,643	$ 28,999	$ 9,627	$ 4,977

(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 (on-going as of December 31, 2023). 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:							
				Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative		Research and development	
	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,	
	2023	2022		2023	2022	2023	2022	2023	2022	2023	2022
Net Income (Loss)	$ 18,779	$(47,896)	As reported:	$ 486,816	$ 316,385	$ 181,513	$ 138,785	$ 161,697	$ 124,044	$ 34,286	$ 22,318
Add/(Subtract):											
Interest expense, net	26,940	28,052									
Other expense, net (1)	159	80									
Expense (benefit) for income taxes	1,093	(14,769)									
Depreciation and amortization	59,791	56,972									
Contingent consideration fair value adjustment	1,426	3,758									
Intangible asset impairment charge	—	112									
Restructuring activities	1,132	5,679									
Impact of Canada operations(2)	2,697	2,740	Impact of Canada operations(2)	(565)	(3,241)	(1,884)	(2,404)	(1,304)	(3,374)	(73)	(203)
Stock-based compensation	20,652	14,599	Stock-based compensation	—	—	(706)	(546)	(19,036)	(13,302)	(910)	(751)
Excess of fair value over cost of acquired inventory	—	5,294	Excess of fair value over cost of acquired inventory	—	—	—	(5,294)	—	—	—	—
Novitium transaction expenses	1,148	1,244	Novitium transaction expenses	—	—	—	—	(1,148)	(1,244)	—	—
Adjusted non-GAAP EBITDA	$ 133,817	$ 55,865	As adjusted:	$ 486,251	$ 313,144	$ 178,923	$ 130,541	$ 140,209	$ 106,124	$ 33,303	$ 21,364

(1) Adjustment to Other expense, net excludes $750 thousand of income related to the sale of an ANDA during the twelve months ended December 31, 2022.

(2) 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 (on-going as of December 31, 2023). 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 December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Net Income (Loss) Available to Common Shareholders	$ 749	$ (4,650)	$ 17,154	$ (49,521)
Add/(Subtract):				
Non-cash interest expense	804	982	3,335	3,865
Depreciation and amortization	15,194	14,484	59,791	56,972
Contingent consideration fair value adjustment	1,985	1,624	1,426	3,758
Restructuring activities	—	1,568	1,132	5,679
Intangible asset impairment charge	—	—	—	112
Impact of Canada operations (1)	283	79	2,697	2,740
Stock-based compensation	5,621	3,737	20,652	14,599
Excess of fair value over cost of acquired inventory	—	48	—	5,294
Novitium transaction expenses	391	(31)	1,148	1,244
Less:				
Estimated tax impact of adjustments (calc. at 24%)	(5,827)	(5,398)	(21,643)	(22,623)
Adjusted non-GAAP Net Income Available to Common Shareholders (2)	$ 19,200	$ 12,443	$ 85,692	$ 22,119
Diluted Weighted-Average Shares Outstanding	19,219	16,325	18,194	16,260
Adjusted Diluted Weighted-Average Shares Outstanding	19,219	16,357	18,194	16,282
Adjusted non-GAAP Diluted Earnings per Share	$ 1.00	$ 0.76	$ 4.71	$ 1.36

(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 (on-going as of December 31, 2023). 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 (Loss) Available to Common Shareholders excludes undistributed earnings to participating securities.