ANI Pharmaceuticals Reports Third Quarter 2021 Results

November 1, 2021

-- Third quarter 2021 net revenues of $52.1 million; net loss of $4.4 million and diluted loss per share of ($0.37) --

-- Third quarter adjusted non-GAAP EBITDA of $16.6 million and adjusted non-GAAP diluted earnings per share of $1.01 --

-- FDA approves supplemental new drug application for Purified Cortrophin ™Gel for the treatment of certain chronic autoimmune disorders; full-scale launch planned for early Q1 2022 --

-- Acquisition of Novitium Pharma LLC is expected to close in November 2021 --

-- Launched Nebivolol Tablets simultaneously from two manufacturing sites --

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. (ANI or the Company) (NASDAQ: ANIP) today announced business highlights and financial results for the three months ended September 30, 2021.

Third Quarter and Recent Business Highlights :

- The U.S. Food and Drug Administration (FDA) approved the Company's supplemental new drug application (sNDA) for Purified Cortrophin™ Gel (Repository Corticotropin Injection USP) (Cortrophin Gel) for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis and rheumatoid arthritis, in addition to excess urinary protein due to nephrotic syndrome.
- The Company plans full-scale Cortrophin Gel launch in the first quarter of 2022.
- The acquisition of Novitium Pharma LLC is expected to close in November 2021; and
- Launched Nebivolol Tablets simultaneously from two manufacturing sites. Nebivolol is the generic version of the reference listed drug (RLD) Bystolic®.

Third Quarter 2021 Financial Highlights :

- Net revenues were $52.1 million compared to $53.0 million in Q3 2020.
- GAAP net loss was $4.4 million and diluted GAAP loss per share was ($0.37).
- Adjusted non-GAAP EBITDA was $16.6 million.
- Adjusted non-GAAP diluted earnings per share was $1.01.
- Cash and cash equivalents were $15.3 million, net accounts receivable was $106.7 million, and face value of debt was $202.9 million as of September 30, 2021.

"The approval of Cortrophin Gel marks a critical milestone for ANI. During the past five years, we have made a significant investment in establishing and updating manufacturing processes and ensuring a sustainable, U.S.-based supply chain for this important product. Physicians now have a much-needed treatment option for patients with acute exacerbations of multiple sclerosis and rheumatoid arthritis, as well as nephrotic syndrome, who can benefit from a repository corticotropin. We have built an experienced rare disease leadership team to drive a full-scale commercial launch early in the first quarter of 2022," said Nikhil Lalwani, President and CEO of ANI.

"ANI is at an inflection point, having achieved critical milestones against key strategic pillars which we believe will deliver sustainable growth. Approval of the Cortrophin Gel sNDA enables ANI to serve patients in need and build new capabilities. In addition, we have delivered a strong third quarter in our base business, and the Novitium acquisition investment thesis is well on track, achieving ten new product approvals since March of 2021," concluded Lalwani.

Third Quarter 2021 Financial Results

Net Revenues (in thousands)	**Three Months Ended September 30,**	
	2021	**2020**
Generic pharmaceutical products	$ 35,140	$ 37,712
Branded pharmaceutical products	14,313	12,411
Contract manufacturing	2,382	2,152
Royalty and other income	226	704
Total net revenues	$ 52,061	$ 52,979

Net revenues for generic pharmaceutical products were $35.1 million during the three months ended September 30, 2021, a decrease of 6.8% compared to $37.7 million for the same period in 2020. From a product perspective, the net decrease was due to declines in sales of Erythromycin

Ethylsuccinate (EES), Methazolamide, Penicillamine and Vancomycin. These decreases were partially offset by the second quarter 2021 launch of Nicardipine and the third quarter 2021 launch of Nebivolol. The decrease in net generic revenues was due in part to a decrease in average selling prices tempered by increased volumes among generic products.

Net revenues for branded pharmaceutical products were $14.3 million during the three months ended September 30, 2021, an increase of 15.3% compared to $12.4 million for the same period in 2020. The increase primarily reflects the April 2021 launch of the products acquired in the Sandoz, Inc. asset acquisition. These increases were tempered by decreased unit sales of InnoPran XL. The increase in net brand revenues was due in part to higher volumes tempered by a shift in mix towards brand products with lower average selling prices.

Contract manufacturing revenues were $2.4 million during the three months ended September 30, 2021, an increase of 10.7% compared to $2.2 million for the same period in 2020, due to a current year shift in mix towards customers with higher average selling prices, mostly offset by a decrease in the volume of orders.

Operating expenses increased by 10.9% to $55.6 million for the three months ended September 30, 2021, from $50.2 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by $4.3 million to $24.4 million in the third quarter of 2021 from the prior year period, primarily as a result of $2.2 million in cost of sales representing the excess of fair value over cost of inventory acquired in the Sandoz, Inc. asset acquisition and subsequently sold during the period and increased volumes in the current year period. The increase was tempered by a $1.1 million decrease related to a decrease in sales of products subject to profit-sharing arrangements.

Research and development expenses decreased from $2.9 million to $2.5 million, a decrease of 16.4%, primarily due to a decrease in expense related to Cortrophin.

Selling, general and administrative expenses increased by $1.5 million in the third quarter of 2021 to $17.2 million compared to $15.7 million in the comparable quarter in 2020. The increase primarily reflects the $0.5 million of transaction expenses related to the pending Novitium acquisition and $2.1 million in sales and marketing expenses related to Cortrophin pre-launch activities incurred during the three months ended September 30, 2021. Depreciation and amortization expense was $11.3 million for the three months ended September 30, 2021, essentially unchanged compared to $11.4 million for the same period in 2020.

Net loss for the third quarter of 2021 was $4.4 million as compared to net income of $0.4 million in the prior year period. Diluted loss per share for the three months ended September 30, 2021 was ($0.37), compared to diluted earnings per share of $0.04 in the prior year period.

Adjusted non-GAAP diluted earnings per share was $1.01 in the third quarter of 2021 compared to $0.97 in the third quarter of 2020.

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

Liquidity

As of September 30, 2021, the Company had $15.3 million in unrestricted cash and cash equivalents plus $106.7 million in net accounts receivable. The Company had $202.9 million (face value) in outstanding debt as of September 30, 2021.

Conference Call

As previously announced, ANI Pharmaceuticals management will host its third quarter 2021 conference call as follows:

Date	Monday, November 1, 2021
Time	8:30 a.m. ET
Toll free (U.S.)	(877) 876-9173

Webcast (live and replay) www.anipharmaceuticals.com, under the “Investors” section

A replay of the conference call will be available within two hours of the call’s completion and will remain accessible for one week by dialing 800-938-2243 and entering access code 6513021.

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 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, expense from acquired in-process research and development, Novitium transaction expenses, Cortrophin pre-launch charges, asset impairments, legal settlement expense, credit facility ticking fee 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.

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 excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, acquired in-process research

and development (“IPR&D”) expense, Novitium transaction expenses, asset impairments, legal settlement expense, credit facility ticking fee 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 income, 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, expense from acquired in-process research and development, Cortrophin pre-launch charges, asset impairments, legal settlement expense, credit facility ticking fee 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 excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, acquired IPR&D expense, Novitium transaction expenses, asset impairments, legal settlement expense, credit facility ticking fee 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 or 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.

About ANI

ANI Pharmaceuticals is a diversified bio-pharmaceutical 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. For more information, please visit www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release relate to 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, statements about the Company’s corporate strategy, the pending acquisition of Novitium and expected closing, the planned commercial launch of Cortrophin Gel in the first quarter of 2022 which will be the first rare disease pharmaceutical product to be sold by the Company, future operations, products, financial position, operating results and prospects, including plans for sustainable growth, and 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, any delays in the currently expected timeline for approval of the Novitium acquisition by the U.S. Federal Trade Commission (FTC), which is required for the closing of the acquisition, or the risk that such approval is not obtained; the Company’s failure to satisfy other closing conditions to complete the Novitium acquisition and the related equity and debt financing transactions contemplated to close concurrently with the acquisition; the inability of the Company to develop and sales and marketing platform for Cortrophin Gel, or delays or higher than anticipated costs to do so; the ability of the Company to successfully maintain manufacturing capabilities and adequate commercial quantities of Cortrophin Gel at acceptable costs and quality levels; broad acceptance of Cortrophin Gel by physicians, patents and the healthcare community; the acceptance of pricing and placement of Cortrophin Gel on payers’ formularies; risks the Company may face with respect to importing raw materials; the use of single source suppliers and the time it may take to validate and qualify another supplier, if necessary; increased competition and strategies employed by competitors; the ability to realize benefits anticipated from acquisitions; costs and regulatory requirements relating to contract manufacturing arrangements; delays or failure in obtaining product approvals from the U.S. Food and Drug Administration; general business and economic conditions, including the ongoing impact of the COVID-19 pandemic; market trends for our products; regulatory environment and changes; and regulatory and other approvals relating to product development and manufacturing.

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, including its most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q. 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. Except as required by law, the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020

Net Revenues	$ 52,061	$ 52,979	$ 155,207	$ 151,223
Operating Expenses:				
Cost of sales (excl. depreciation and amortization)	24,413	20,118	66,712	62,617
Research and development	2,456	2,939	8,229	12,318
Selling, general, and administrative	17,181	15,725	53,588	50,621
Depreciation and amortization	11,346	11,358	33,568	33,739
Legal settlement expense	-	-	8,400	-
Cortrophin pre-launch charges	227	37	780	8,275
Total Operating Expenses	55,623	50,177	171,277	167,570
Operating (Loss)/Income	(3,562)	2,802	(16,070)	(16,347)
Other Expense, net				
Interest expense, net	(2,497)	(2,510)	(7,482)	(6,898)
Other expense, net	(1,071)	(229)	(1,653)	(335)
(Loss)/Income Before Benefit for Income Taxes	(7,130)	63	(25,205)	(23,580)
Benefit for income taxes	2,683	371	6,738	4,667
Net (Loss)/Income	$ (4,447)	$ 434	$ (18,467)	$ (18,913)
(Loss)/Earnings Per Share				
Basic (Loss)/Earnings Per Share	$ (0.37)	$ 0.04	$ (1.53)	$ (1.58)
Diluted (Loss)/Earnings Per Share	$ (0.37)	$ 0.04	$ (1.53)	$ (1.58)
Basic Weighted-Average Shares Outstanding	12,107	11,991	12,066	11,953
Diluted Weighted-Average Shares Outstanding	12,107	12,003	12,066	11,953

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

	September 30, 2021	December 31, 2020
Current Assets		
Cash and cash equivalents	$ 15,254	$ 7,864
Accounts receivable, net	106,714	95,793
Inventories, net	61,684	60,803
Prepaid income taxes	3,030	-
Prepaid expenses and other current assets	4,702	5,861
Total Current Assets	191,384	170,321
Property and equipment	60,816	58,797
Accumulated depreciation	(21,290)	(17,528)
Property and equipment, net	39,526	41,269
Restricted cash	5,001	5,003
Deferred tax assets, net of deferred tax liabilities and valuation allowance	60,196	51,704
Intangible assets, net	170,141	188,511
Goodwill	3,580	3,580
Other non-current assets	626	802
Total Assets	$ 470,454	$ 461,190
Current Liabilities		
Current debt, net of deferred financing costs	$ 15,927	$ 13,243
Accounts payable	11,513	11,261
Accrued royalties	3,996	6,407
Accrued compensation and related expenses	4,539	6,231

Current income taxes payable, net	-	3,906
Accrued government rebates	11,713	7,826
Returned goods reserve	32,229	27,155
Deferred revenue	62	80
Accrued expenses and other	4,893	2,456
Total Current Liabilities	84,872	78,565
Non-current debt, net of deferred financing costs and current component	186,063	172,443
Derivatives and other non-current liabilities	8,116	14,482
Total Liabilities	279,051	265,490
Stockholders' Equity		
Common stock	1	1
Treasury stock	(3,135)	(2,246)
Additional paid-in capital	222,211	214,354
Accumulated deficit	(23,439)	(4,972)
Accumulated other comprehensive loss, net of tax	(4,235)	(11,437)
Total Stockholders' Equity	191,403	195,700
Total Liabilities and Stockholders' Equity	$ 470,454	$ 461,190

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, 2021	2020
Net (Loss)/Income	$ (4,447)	$ 434
Add/(Subtract):		
Interest expense, net	2,497	2,510
Other expense, net	2,271	229
Benefit for income taxes	(2,683)	(371)
Depreciation and amortization	11,346	11,358
Cortrophin pre-launch charges and sales & marketing expenses	2,192	37
Stock-based compensation	2,807	2,383
CEO transition items[(2)]	-	204
Asset impairments[(3)]	-	92
Excess of fair value over cost of acquired inventory	2,225	111
Novitium transaction expenses	431	-
Adjusted non-GAAP EBITDA	$ 16,639	$ 16,987

	Nine Months Ended September 30, 2021	2020
Net Loss	$ (18,467)	$ (18,913)
Add/(Subtract):		
Interest expense, net	7,482	6,898
Other expense, net	2,853	335
Benefit for income taxes	(6,738)	(4,667)
Depreciation and amortization	33,568	33,739
Legal settlement expense	8,400	-
Cortrophin pre-launch charges and sales & marketing expenses	5,236	8,275
Stock-based compensation[(1)]	7,520	7,078

CEO transition items[2]	-	7,349
Cortrophin team restructuring	-	401
Acquired IPR&D expense	-	3,784
Asset impairments[3]	-	884
Excess of fair value over cost of acquired inventory	3,717	4,183
Charges related to market exits	-	567
Novitium transaction expenses	5,064	-
Adjusted non-GAAP EBITDA	$ 48,635	$ 49,913

Reconciliation of certain adjusted non-GAAP accounts:

	Cost of sales (excl. depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
	Three Months Ended September 30,		Three Months Ended September 30,		Three Months Ended September 30,	
	2021	2020	2021	2020	2021	2020
As reported:	$ 24,413	$ 20,118	$ 17,181	$ 15,725	$ 2,456	$ 2,939
Cortrophin pre-launch charges and sales & marketing expenses			(1,965)			
Stock-based compensation	(5)	(37)	(2,653)	(2,223)	(149)	(123)
CEO transition items[2]				(204)		
Asset impairments[3]						(92)
Excess of fair value over cost of acquired inventory	(2,225)	(111)				
Novitium transaction expenses			(431)			
As adjusted:	$ 22,183	$ 19,970	$ 12,132	$ 13,298	$ 2,307	$ 2,724

Reconciliation of certain adjusted non-GAAP accounts:

	Cost of sales (excl. depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
	Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020	2021	2020
As reported:	$ 66,712	$ 62,617	$ 53,588	$ 50,621	$ 8,229	$ 12,318
Cortrophin pre-launch charges and sales & marketing expenses			(4,456)			
Stock-based compensation[1]	(15)	(107)	(7,082)	(6,496)	(423)	(475)
CEO transition items[2]				(7,349)		
Cortrophin team restructuring				(47)		(354)
Acquired IPR&D expense						(3,784)
Asset impairments[3]		(740)		(52)		(92)
Excess of fair value over cost of acquired inventory	(3,717)	(4,183)				
Charges related to market exits		(267)				(300)
Novitium transaction expenses			(5,064)			
As adjusted:	$ 62,980	$ 57,320	$ 36,986	$ 36,677	$ 7,806	$ 7,313

(1) For the nine months ended September 30, 2020, Stock-based compensation excludes $3.4 million of stock-based compensation expense associated with the departure of a former President and CEO. This amount is included in this table as part of CEO transition items.

(2) CEO transition items for the nine months ended September 30, 2020 is comprised of $3.4 million of stock-based compensation expense and $3.1 million of expense for salary continuation, bonus and other fringe benefits associated with the departure of our former President and CEO, as well as certain legal and recruiting costs related to the search for a permanent replacement.

(3) For the nine months ended September 30, 2020, Asset impairments is comprised of finished goods inventory reserves for Bretylium and accounts receivable reserves due to customer bankruptcy, tempered by a modest recovery of previously reserved inventory related to market exits.

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,	
	2021	2020	2021	2020
Net (Loss)/Income	$ (4,447)	$ 434	$ (18,467)	$ (18,913)
Add/(Subtract):				
Non-cash interest expense	559	565	1,644	1,222
Depreciation and amortization expense	11,346	11,358	33,568	33,739
Cortrophin pre-launch charges and sales & marketing expenses	2,192	37	5,236	8,275
Legal settlement expense	-	-	8,400	-
Acquired IPR&D expense	-	-	-	3,784
Stock-based compensation(1)	2,807	2,383	7,520	7,078
CEO transition items(2)	-	204	-	7,349
Cortrophin team restructuring	-	-	-	401
Asset impairments(3)	-	92	-	884
Excess of fair value over cost of acquired inventory	2,225	111	3,717	4,183
Charges related to market exits	-	-	-	567
Credit facility ticking fee expense	2,434	-	2,434	-
Novitium transaction expenses	431	-	5,064	-
Less:				
Estimated tax impact of adjustments (calc. at 24%)	(5,279)	(3,540)	(16,220)	(16,196)
Adjusted non-GAAP Net Income	$ 12,269	$ 11,644	$ 32,896	$ 32,373
Diluted Weighted-Average Shares Outstanding	12,107	12,003	12,066	11,953
Adjusted Diluted Weighted-Average Shares Outstanding	12,119	12,003	12,080	11,977
Adjusted non-GAAP Diluted Earnings per Share	$ 1.01	$ 0.97	$ 2.72	$ 2.70

(1) For the nine months ended September 30, 2020, Stock-based compensation excludes $3.4 million of stock-based compensation expense associated with the departure of a former President and CEO. This amount is included in this table as part of CEO transition items.

(2) CEO transition items for the nine months ended September 30, 2020 is comprised of $3.4 million of stock-based compensation expense and $3.1 million of expense for salary continuation, bonus and other fringe benefits associated with the departure of our former President and CEO, as well as certain legal and recruiting costs related to the search for a permanent replacement.

(3) For the nine months ended September 30, 2020, Asset impairments is comprised of finished goods inventory reserves for Bretylium and accounts receivable reserves due to customer bankruptcy, tempered by a modest recovery of previously reserved inventory related to market exits.

Investor Relations:
Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Source: ANI Pharmaceuticals, Inc.