



ANI Pharmaceuticals Reports Second Quarter 2022 Financial Results; Reports Record Net Revenues and Raises Full-Year 2022 Net Revenue Guidance for Purified Cortrophin® Gel

August 8, 2022

Second Quarter 2022 Results:

- Net revenues of \$73.9 million, net loss available to common shareholders of \$(15.3) million and diluted GAAP loss per share of \$(0.94) --
- Lead Rare Disease asset, Purified Cortrophin® Gel (Repository Corticotrophin Injection USP) 80 U/ml (Cortrophin) net sales of \$10.2 million --
- Adjusted non-GAAP EBITDA of \$9.9 million and adjusted non-GAAP diluted earnings per share of \$0.13 --
- Year-over-year net revenue growth of 52% --

Full-Year 2022 Guidance:

- Reiterates total Company net revenue guidance of \$295 million to \$315 million; adjusted non-GAAP EBITDA guidance of \$54 million to \$60 million; adjusted non-GAAP Earnings Per Share between \$1.34 and \$1.62 --
- Raises Cortrophin 2022 net revenue guidance to \$40 million to \$45 million --

Company Highlights:

- Strong launch trajectory for Cortrophin persists with ~500 cases initiated from more than 250 unique prescribers coupled with expanded market access leading to over 134 million lives on formulary --
- Generics business ranked sixth in number of ANDAs approved in last 12 months; launched several limited competition new products; acquired four ANDAs from Oakrum Pharmaceuticals --
- Announced consolidation of manufacturing network with expected closing of Oakville, Canada, plant by Q1 2023 --
- Appointed Meredith W. Cook as SVP, General Counsel and Corporate Secretary --

BAUDETTE, Minn.--(BUSINESS WIRE)--Aug. 8, 2022-- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced business highlights and financial results for the three and six months ended June 30, 2022.

"Second quarter net revenues of \$73.9 million represent a new quarterly record for the Company, driven by the first full quarter of Purified Cortrophin Gel sales and growth in generic pharmaceuticals revenues. We continue to see acceleration in the number of patients treated with Cortrophin. We are pleased to see over 250 prescribers, including both prescribers experienced with ACTH therapy and first-time prescribers. In addition, we have made meaningful progress on expanding access for Cortrophin to approximately 134 million lives, including a recent positive coverage decision by United Healthcare's commercial and managed Medicaid plans," said Nikhil Lalwani, President and CEO of ANI.

"Our generics business unit remains focused on bringing new products to patients and customers, and I'm proud to share that ANI is now ranked sixth among all companies in terms of number of ANDA approvals received in the past 12 months. In addition, we continued to drive cost competitiveness by consolidating our manufacturing network and realizing further operational efficiencies. Overall, we believe that ANI is well positioned for sustainable growth and continuing to serve patients in need," concluded Lalwani.

Second Quarter 2022 Financial Highlights:

- Net revenues were \$73.9 million compared to \$48.6 million in Q2 2021.
- GAAP net loss available to common shareholders was \$(15.3) million, and diluted GAAP loss per share was \$(0.94).
- Adjusted non-GAAP EBITDA was \$9.9 million compared to \$13.1 million in Q2 2021.
- Adjusted non-GAAP diluted earnings per share was \$0.13, compared to diluted earnings per share of \$0.67 in Q2 2021.
- Cash and cash equivalents were \$63.4 million, net accounts receivable was \$150.4 million, and face value of debt was \$298.5 million as of June 30, 2022.

Cortrophin Launch Update:

The Company raises its revenue guidance for Cortrophin to be in the range of \$40 million to \$45 million from its previous guidance of \$35 million to \$40 million.

Key highlights (as of August 5, 2022):

- **Launch Trajectory:** Since the Company's last earnings report, new patient cases initiated have doubled. As of August 5, approximately 500 new cases have been initiated. The Company is also seeing meaningful improvement across conversion rates from enrollment to fulfillment. The Company has continued to strengthen its infrastructure, including

expansion of its hub, patient support services and distribution network.

- **Physician Interest:** The prescriber base has also doubled to more than 250 unique prescribers as of August 5. Approximately one third of the prescribers have written multiple prescriptions. Prescriptions continue to be distributed across our targeted specialties.
- **Patient Access:** Our consistent efforts to bring savings to the healthcare system have resulted in expanded market access with over 134 million lives on formulary. Notably, on July 1, Cortrophin was added to the formulary for United Healthcare's commercial and managed Medicaid plans.

Generics Growth Engine Update:

Sales of generic pharmaceutical products grew 46% year-over-year in the second quarter. The Company remains focused on growing its new product pipeline and driving cost competitiveness.

- **Focus on R&D Excellence:** During the first six months of 2022, ANI has filed 8 ANDAs, and in the second quarter successfully launched multiple limited competition products. ANI is now ranked sixth in terms of ANDA approvals received in the past 12 months.
- **Operational Synergies:** During the quarter, the Company announced its intention to consolidate manufacturing operations and cease operations at the Oakville, Ontario, Canada manufacturing. With the additional manufacturing capacity gained as part of the Novitium acquisition, ANI can support future growth and continue serving customers through its remaining facilities. Once fully executed, this operational efficiency is expected to improve profitability and cash flow by \$7 million to \$8 million on an annualized basis. The Company currently expects one-time cash charges of approximately \$3.1 million and non-cash charges of \$4.5 million in conjunction with this action.
- **Business Development:** The Company continues to be active on the business development front and acquired four limited competition ANDAs from Oakrum Pharma in July. The Company expects to launch these products and see the value unlock in 2023.

Second Quarter 2022 Financial Results

Products and Services	Three Months Ended	
	June 30,	June 30,
(in thousands)	2022	2021
Sales of generic pharmaceutical products	\$ 49,863	\$ 34,199
Sales of established brand pharmaceutical products	8,463	11,038
Sales of rare disease pharmaceutical products	10,202	—
Sales of contract manufactured products	4,389	2,322
Royalties from licensing agreements	194	—
Product development services	531	97
Other	213	969
Total net revenues	\$ 73,855	\$ 48,625

Net revenues for generic pharmaceutical products were \$49.9 million during the three months ended June 30, 2022, an increase of 46% compared to \$34.2 million for the same period in 2021. The net increase was primarily driven by revenues from commercial generic products acquired in our acquisition of Novitium and increased revenues of Nebivolol, which ANI launched in September 2021, partially offset by a decrease in revenues from sales of several legacy ANI generic products.

Net revenues for branded pharmaceutical products were \$8.5 million during the three months ended June 30, 2022, a decrease of 23% compared to \$11.0 million for the same period in 2021. The net decrease was principally due to a decrease in sales of InnoPran XL[®] and Inderal[®] XL.

Contract manufacturing revenues were \$4.4 million during the three months ended June 30, 2022, an increase of 89% compared to \$2.3 million for the same period in 2021, due to an increase in the volume of orders, primarily related to the addition of Novitium contract manufacturing revenues.

Net revenues of rare disease pharmaceutical products were \$10.2 million for the quarter, consisting entirely of sales of Cortrophin Gel. There were no sales of rare disease pharmaceutical products during the comparable prior year period.

Operating expenses increased by 35% to \$86.8 million for the three months ended June 30, 2022, from \$64.2 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by \$13.0 million to \$35.3 million in the second quarter of 2022 compared to \$22.3 million in the prior year period, driven primarily by \$7.9 million in costs related to Novitium and \$2.0 million related to an increase in the sales of products subject to profit sharing arrangements.

Research and development expenses were \$4.2 million in the second quarter of 2022, an increase of \$1.4 million from the prior year period due primarily to Novitium-related activities, partially offset by a decrease in expense associated with the completion of our Cortrophin development efforts.

Selling, general and administrative expenses increased to \$32.0 million in the second quarter of 2022, or 70%, compared to \$18.8 million in the prior year quarter, reflecting a \$12.5 million increase in sales and marketing expenses related to our launch of Cortrophin and increased expenses related to the addition of Novitium headcount and activities, partially offset by a \$1.6 million decrease in transaction expenses related to the Novitium acquisition.

Depreciation and amortization increased by 22% in the second quarter of 2022 to \$13.8 million from \$11.3 million in the comparable quarter in 2021,

primarily due to amortization of intangible assets acquired in the Novitium acquisition.

Net loss available to common shareholders for the second quarter of 2022 was \$(15.3) million as compared to net loss of \$(14.1) million in the prior year period. Diluted loss per share for the three months ended June 30, 2022 was \$(0.94) compared to diluted loss per share of \$(1.17) in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$0.13 in the second quarter of 2022 compared to \$0.67 in the second quarter of 2021.

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, respectively.

Liquidity

As of June 30, 2022, the Company had \$63.4 million in unrestricted cash and cash equivalents plus \$150.4 million in net accounts receivable. The Company had \$298.5 million (face value) in outstanding debt as of June 30, 2022.

2022 GUIDANCE

The following summarizes 2022 guidance:

Total Company measures:

- Net Revenue between \$295 million and \$315.0 million, representing approximately 36% to 46% growth as compared to \$216.1 million recognized in 2021
- Research and Development expense between \$16.0 and \$18.0 million
- Adjusted non-GAAP EBITDA between \$54.0 million and \$60.0 million
- Adjusted non-GAAP Diluted Earnings per Share between \$1.34 and \$1.62

Purified Cortrophin Gel specific measures:

- Revised Net Revenue between \$40.0 million and \$45.0 million as compared to previous guidance of \$35.0 million and \$40.0 million
- Direct Selling, General and Administrative expenses between \$42.0 and \$46.0 million

In addition, we currently anticipate between 16.9 and 17.0 million shares outstanding and an effective tax rate of approximately 24% prior to any federal tax reform.

Conference Call

As previously announced, ANI management will host its second quarter 2022 conference call as follows:

Date	August 8, 2022
Time	8:00 a.m. ET
Toll free (U.S.)	800-225-9448
Global	203-518-9708

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 800-753-6121 and entering access code 7163806.

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 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, Cortrophin pre-launch charges, 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 2022 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 (Loss)/Income

ANI's management considers adjusted non-GAAP net (loss)/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, 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 (loss)/income when analyzing Company performance.

Adjusted non-GAAP net (loss)/income is defined as net (loss)/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, Cortrophin pre-launch charges, 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 (loss)/income should be considered in addition to, but not in lieu of, net (loss)/income reported under GAAP. A reconciliation of adjusted non-GAAP net (loss)/income to the most directly comparable GAAP financial measure is provided below.

Adjusted non-GAAP Diluted (Loss)/Earnings per Share

ANI's management considers adjusted non-GAAP diluted (loss)/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, 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 (loss)/earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted (loss)/earnings per share is defined as adjusted non-GAAP net (loss)/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 (loss)/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 (loss)/earnings per share to the most directly comparable GAAP financial measure is provided below.

About ANI

ANI Pharmaceuticals 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 building a successful Purified Cortrophin® Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. 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 regarding 2022 Financial Guidance, statements about the Company's corporate strategy, future operations, product development and launches, financial performance, financial position, operating results and prospects, including plans for sustainable growth, the successful commercialization of products, 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, the costs involved in commercializing Cortrophin, the ability to maintain regulatory approval of the product and maintain sufficiency of the product, the ability to obtain reimbursement from third-party payors for this product, evolving government legislation, the opinions and views of key opinion leaders and physicians who treat patients with chronic diseases and who may prescribe Cortrophin, ANI's ability to generate projected net product revenue and gain market share on the timeline expected, actions taken by competitors in response to a new market entrant; the ability of the Company to successfully maintain manufacturing capabilities and adequate commercial quantities of Cortrophin at acceptable costs and quality levels; broad acceptance of Cortrophin by physicians, patients and the healthcare community; the acceptance of pricing and placement of Cortrophin 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; manufacturing difficulties or delays, ANI's reliance on third parties over which it may not always have full control, increased competition and strategies employed by competitors; the ability to realize benefits anticipated from acquisitions, including but not limited to, post-close integration activities related to the Novitium acquisition; disruptions to our operations resulting from the anticipated closure of our Oakville, Ontario, manufacturing plant; 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 and uncertainties regarding the COVID-19 pandemic and inflationary pressures; market trends for our products; regulatory environment and changes; and regulatory and other approvals relating to product development and manufacturing, 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, 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.

For more details, visit www.cortrophin.com.

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

Three Months Ended June 30, Six Months Ended June 30,

	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Net Revenues	\$ 73,855	\$ 48,625	\$ 138,332	\$ 103,146
Operating Expenses:				
Cost of sales (excl. depreciation and amortization)	35,294	22,314	69,565	42,299
Research and development	4,165	2,805	9,439	5,773
Selling, general, and administrative	31,958	18,820	60,775	36,407
Depreciation and amortization	13,764	11,324	28,321	22,222
Contingent consideration fair value adjustment	(1,095)	-	(342)	-
Legal settlement expense	-	8,400	-	8,400
Purified Cortrophin Gel pre-launch charges	-	515	-	553
Restructuring activities	2,570	-	2,570	-
Intangible asset impairment charge	112	-	112	-
Total Operating Expenses	<u>86,768</u>	<u>64,178</u>	<u>170,440</u>	<u>115,654</u>
Operating Loss	(12,913)	(15,553)	(32,108)	(12,508)
Other Expense, Net				
Interest expense, net	(6,669)	(2,531)	(13,282)	(4,985)
Other income/(expense), net	764	(67)	675	(582)
Loss Before Benefit for Income Taxes	(18,818)	(18,151)	(44,715)	(18,075)
Benefit for income taxes	3,895	4,045	9,662	4,055
Net Loss	<u>\$ (14,923)</u>	<u>\$ (14,106)</u>	<u>\$ (35,053)</u>	<u>\$ (14,020)</u>
Dividends on Series A Convertible Preferred Stock	(407)	-	(812)	-
Net Loss Available to Common Shareholders	<u>\$ (15,330)</u>	<u>\$ (14,106)</u>	<u>\$ (35,865)</u>	<u>\$ (14,020)</u>
Basic and Diluted Loss Per Share:				
Basic Loss Per Share	\$ (0.94)	\$ (1.17)	\$ (2.21)	\$ (1.16)
Diluted Loss Per Share	\$ (0.94)	\$ (1.17)	\$ (2.21)	\$ (1.16)
Basic Weighted-Average Shares Outstanding	16,272	12,085	16,205	12,045
Diluted Weighted-Average Shares Outstanding	<u>16,272</u>	<u>12,085</u>	<u>16,205</u>	<u>12,045</u>

ANI Pharmaceuticals, Inc. and Subsidiaries

Table 2: US GAAP Balance Sheets

(unaudited, in thousands)

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Current Assets		
Cash and cash equivalents	\$ 63,385	\$ 100,300
Accounts receivable, net	150,410	128,526
Inventories, net	92,545	81,693
Prepaid income taxes	2,013	3,667
Assets held for sale	8,020	-
Prepaid expenses and other current assets	6,026	7,589
Total Current Assets	<u>322,399</u>	<u>321,775</u>
Non-current Assets		
Property and equipment	71,042	75,627
Accumulated depreciation	(27,271)	(22,956)
Property and equipment, net	43,771	52,671
Restricted cash	5,001	5,001
Deferred tax assets, net of deferred tax liabilities and valuation allowance	76,587	67,936
Intangible assets, net	269,593	294,122

Impact of Canada operations ⁽²⁾	1,820	-	Impact of Canada operations ⁽²⁾	(1,045)	(1,249)	(1,545)	(71)				
Cortrophin pre-launch charges and sales & marketing expenses ⁽³⁾	-	3,044	Cortrophin pre-launch charges and sales & marketing expenses ⁽³⁾		-	-	(2,490)	-	-		
Stock-based compensation	6,992	4,713	Stock-based compensation		(288)	(10)	(6,338)	(4,429)	(366) (274)		
Excess of fair value over cost of acquired inventory	4,802	1,492	Excess of fair value over cost of acquired inventory		(4,802)	(1,492)	-	-	-		
Novitium transaction expenses	1,217	4,633	Novitium transaction expenses		-	-	(1,217)	(4,633)	-		
Adjusted non-GAAP EBITDA	<u>\$ 14,134</u>	<u>\$ 31,996</u>	As adjusted:	<u>\$ 137,287</u>	<u>\$ 103,146</u>	<u>\$ 63,226</u>	<u>\$ 40,797</u>	<u>\$ 51,675</u>	<u>\$ 24,855</u>	<u>\$ 9,002</u>	<u>\$ 5,499</u>

(1) Adjustment to Other (income)/expense, net excludes \$750 thousand of income related to the sale of an ANDA during the three months ended June 30, 2022.

(2) Impact of Canada operations includes revenues and operating expenses, exclusive of restructuring activities, stock-based compensation and depreciation and amortization, which are included within their respective line items above.

(3) Beginning in 2022, we no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP EBITDA.

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net Loss Available to Common Shareholders	\$ (15,330)	\$ (14,106)	\$ (35,865)	\$ (14,020)
Add/(Subtract):				
Non-cash interest expense	967	539	1,920	1,085
Depreciation and amortization expense	13,764	11,324	28,321	22,222
Contingent consideration fair value adjustment	(1,095)	-	(342)	-
Restructuring activities	2,570	-	2,570	-
Legal settlement expense	-	8,400	-	8,400
Intangible asset impairment charge	112	-	112	-
Impact of Canada operations ⁽¹⁾	1,820	-	1,820	-
Cortrophin pre-launch charges and sales & marketing expenses ⁽²⁾	-	2,902	-	3,044
Stock-based compensation	3,756	2,844	6,992	4,713
Excess of fair value over cost of acquired inventory	973	1,492	4,802	1,492
Novitium transaction expenses	124	1,690	1,217	4,633
Less:				
Estimated tax impact of adjustments (calc. at 24%)	(5,518)	(7,006)	(11,379)	(10,941)
Adjusted non-GAAP Net Income Available to Common Shareholders	<u>\$ 2,143</u>	<u>\$ 8,080</u>	<u>\$ 168</u>	<u>\$ 20,627</u>
Diluted Weighted-Average Shares Outstanding	16,272	12,085	16,205	12,045
Adjusted Diluted Weighted-Average Shares Outstanding	16,282	12,100	16,218	12,059
Adjusted non-GAAP Diluted Earnings per Share	<u>\$ 0.13</u>	<u>\$ 0.67</u>	<u>\$ 0.01</u>	<u>\$ 1.71</u>

(1) Impact of Canada operations includes revenues and operating expenses, exclusive of restructuring activities, stock-based compensation and depreciation and amortization, which are included within their respective line items above.

(2) Beginning in 2022, we no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP Net Loss.

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Investor Contact

Lisa M. Wilson
In-Site Communications, Inc.
212-452-2793
lwilson@insitecony.com

Media Contact

Faith Pomeroy-Ward
ANI Pharmaceuticals, Inc.
817-807-8044
Faith.pomeroyward@anipharmaceuticals.com

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