UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of Earliest Event Reported): February 8, 2024

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

001-31812

(Commission File Number)

58-2301143 (I.R.S. Employer Identification No.)

210 Main Street West Baudette, Minnesota

Delaware

(State or other jurisdiction of

incorporation)

(Address of principal executive offices)

56623 (Zip Code)

Registrant's telephone number, including area code: (218) 634-3500

Not Applicable

(Former name or former address, if changed since last report.)

Securities registered pursuant to Section 12(b) of the Act:

		Name of each exchange on which
Title of each class	Trading Symbol(s)	registered
Common Stock	ANIP	Nasdaq Stock Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company \Box

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 2.02 Results of Operations and Financial Condition

On February 8, 2024, Nikhil Lalwani, President & CEO, and other members of the senior leadership team of ANI Pharmaceuticals, Inc. will present at the Guggenheim Healthcare Talks 6th Annual Biotechnology Conference in New York City. A copy of the presentation is attached as Exhibit 99.1 hereto and incorporated herein by reference.*

Item 7.01	Regulation FD Disclosure
The information in	ncluded under Item 2.02 of this Current Report on Form 8-K is incorporated into this Item 7.01 by reference.*
Item 9.01	Exhibits
(d) Exhibits	
<u>Exhibit</u> <u>No.</u>	Description
99.1	Investor Presentation, dated February 2024
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)
	Item 2.02 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 8, 2024

ANI PHARMACEUTICALS, INC.

By: Name: Title: /s/ Stephen P. Carey Stephen P. Carey

Senior Vice President Finance and Chief Financial Officer



Disclaimer

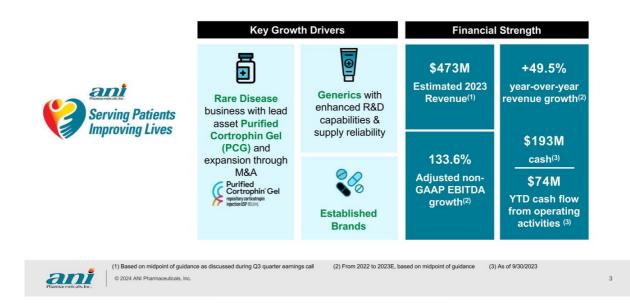
This presentation by ANI Pharmaceuticals, Inc ("ANI" or the "Company") contains forward-looking statements, including information about management's view of the Company's future expectations, plans and prospects, as well as other forward-looking statements. Any statements made in this presentation other than those of historical fact, about an action, event or development, are forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different than those expressed or implied in such statements. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different than those expressed or implied in such statements. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different than those expressed or implied in such statements. These statements is the other with the statements will be and ross include, but are not limited to: risks that we may face with respect to importing raw materials and delays in delivery or raw materials and delay competition single source suppliers on impedients due to the time and cost to validate a second source of supply acceptance of un products at levels that will allow us to achieve profitability, our ability to protect our intellectual property rights; the impact of legislative estimations and batechnology industries; our ability to matinitan the services of our key executives and other personnel, whether we experience difficu

Non-GAAP Financial Measures

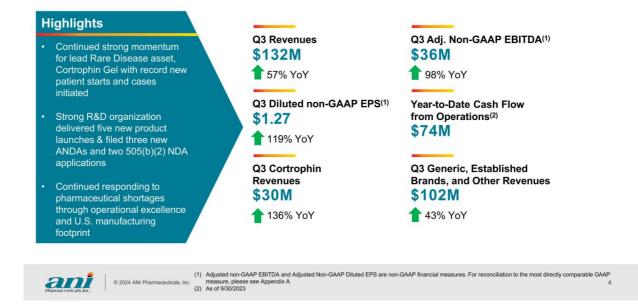
Non-GAP Financial Measures
This presentation includes certain non-GAP financial measures, including Adjusted EBITDA and Adjusted Earings Per Share (Adjusted EPS), that management reviews to evaluate its business, measure its
performance and make strategic decisions. Management believes that such non-GAP financial measures provide useful information to investors and others in understanding and evaluating its operating
results in the same maner as management. Beginning in the fourth quarter of 2022, ANI no longer excludes expense for In-Process Research & Development or Cortrophin Gel pre-launch charges and
agustend, and certain other items that vay in frequency and impact on ANI's results of operations. Adjusted non-GAP financial measures is idefined as net income (loss) is defined as net income (loss), bus the excess of fair value over
cost of acquired inventory sold, non-cash stock-based compenses, non-cash interest expense, (net), other expresse, for intraviation expenses, that van in frequency and impact on ANI's results of operations. Adjusted non-GAP elitotta is defined as an etinome (loss) is defined as net income (loss), bus the excess of fair value over
cost of acquired inventory sold, non-cash stock-based compenses in setults of operations. Adjusted PM enditive adjustement, and claulated using and exitain other items that vay in frequency and impact on ANI's results of operations. Resulted valued adjustement, and claulated using and exitain other setults for revence, net income (loss) divided by the diluted weighted average shares outstanding during the period. Adjusted EBITDA,
adjusted PS and any other operating performance measure calculated in accordance with GAP. Jusited 2012 Jusitement and clausification as the income incosa in the value interview of a value adjustement, and clausification are discussed to the excesse of the explored externing the formation to incrumation externing the distributory tax rate.
Adjusted PS and any other operating performance measure situ tell daluted Using the nature



ANI Pharmaceuticals: Rare Disease, Generics and Established Brands businesses drive robust profitable growth



Q3 2023: Achieved record financial results



Raised full year 2023 guidance for third quarter in a row

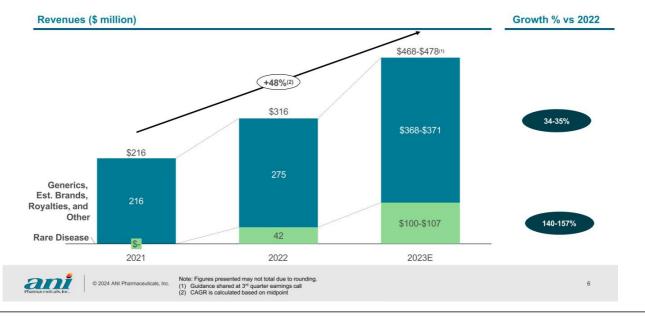
Metric (\$ millions except per share amounts)	Revised Full Year 2023 Guidance	Prior Full Year 2023 Guidance	Growth vs Prior Year Actuals
Net Revenue (total Company)	\$468 - \$478	\$425 - \$445	48% - 51%
Cortrophin Gel Net Revenue	\$100 - \$107	\$90 - \$100	140% - 157%
Adjusted Non-GAAP Gross Margin ⁽¹⁾	63% to 63.8%	63% to 64.8%	4.7 pts to 5.5 pts
Adjusted Non-GAAP EBITDA (1)	\$128 - \$133	\$115 - \$125	129% - 138%
Adjusted Non-GAAP Diluted EPS (1)	\$4.29 - \$4.57	\$3.62 - \$4.11	215% - 236%



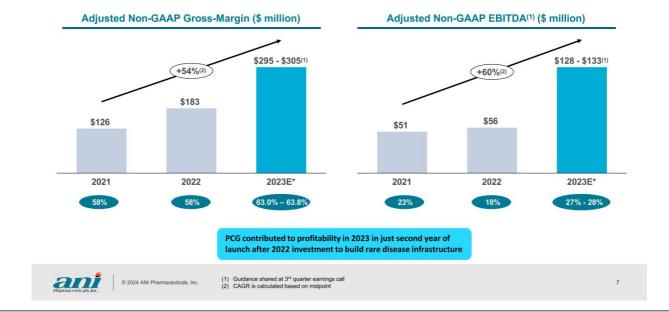
(1) Adjusted Non-GAAP Gross Margin, Adjusted non-GAAP EBITDA, and Adjusted Non-GAAP Diluted EPS are non-GAAP financial measures.

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Revenue growth driven by momentum across Rare Disease, Generics and Established Brands



Profitability driven by gross profit pull through and leveraging of Rare Disease infrastructure



Rare Disease: ANI's primary growth engine accelerating with lead asset Purified Cortrophin Gel (PCG) as foundation



\$24.3



* Initiated in Q2, 2023 ** According to IQVIA data © 2024 ANI Pharmaceuticals, Inc.

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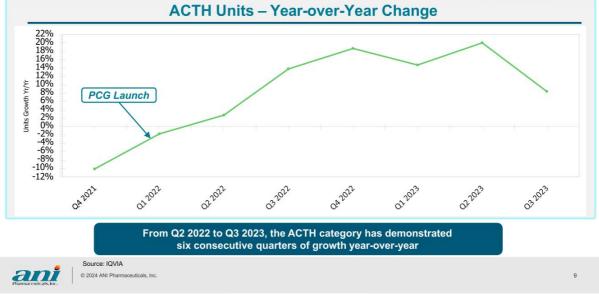


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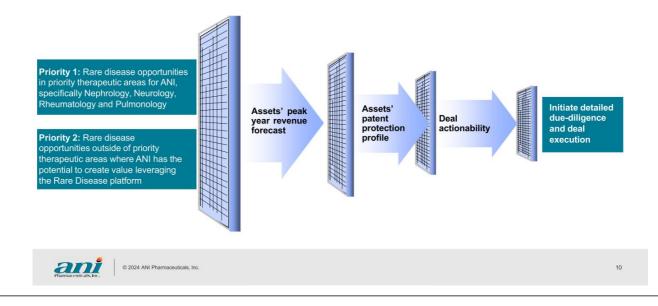
\$29.7

ACTH Class has shown year-over-year quarterly unit growth for six consecutive quarters since Cortrophin launch

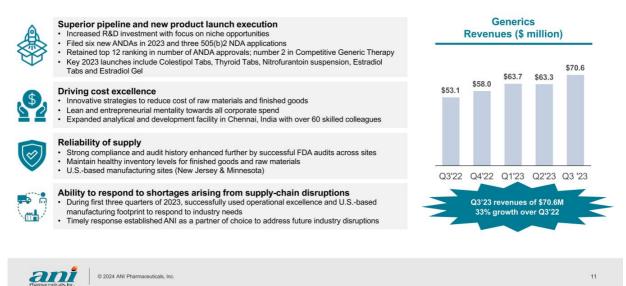




Focused efforts ongoing to increase scope and scale of Rare Disease business through M&A



Superior R&D capabilities and operational excellence driving growth in Generics



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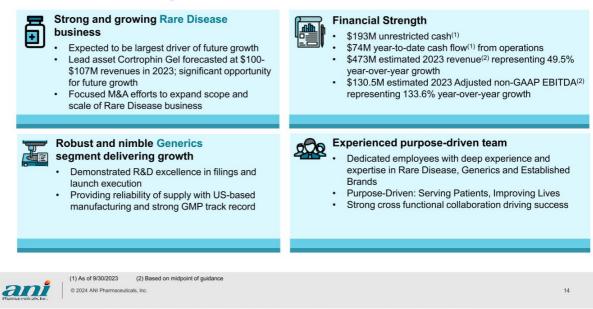
U.S.-based manufacturing footprint; strong GMP track record, including successful FDA audits at all three sites

	Baudette, MN 130k sf	Baudette, MN Containment Facility - 47k sf	East Windsor, NJ 200k sf
Facility Overview and Capabilities	 Manufacturing, packaging, warehouse Schedule CII vault & CIII cage space Lab space - R&D/analytical testing Solutions, suspensions, topicals, tablets, capsules, and powder for suspension DEA-licensed for Schedule II controlled substances 	 Manufacturing, packaging, warehouse Low-humidity suite for moisture-sensitive compounds Fully-contained high potency facility for hormone, steroid, and oncolytic products DEA Schedule III capability 	 200K ft² of manufacturing, packaging, lab, warehouse, and administrative space Undergoing 20K ft² expansion that adds 17 new manufacturing suites Solid oral tablets and capsules, liquid suspensions and solutions, powder for oral suspension, controlled substances as well as containment & nano-milling API development & low volume production
Annual Capacity	 Solid Dose ~2.5BN doses Liquid Unit ~23MM doses Liquids ~20MM bottles Powder ~4MM bottles 	 Tablets ~2.5BN doses Capsules ~150MM doses Blisters ~ 45MM doses 	Tablets & Capsules ~3.0BN doses Packaged Units ~20MM units Liquids ~10MM bottles Powder ~ 2MM bottles Semi-solid – 6MM units
GMP	Four FDA inspections since 2013 Latest inspection – November 2022 Results: VAI status	Six DEA inspections since 2013 Latest inspection – November 2022 Results: VAI status	Six FDA inspections since 2017 Latest inspection – March 2023 Results: NAI status (Zero 483s)
Pharmaceuticals, Inc.	© 2024 ANI Pharmaceuticals, Inc.		12

Executive Leadership Team with proven track records and broad industry expertise



Investment summary



ANI recently celebrated a decade since listing on the NASDAQ









Adjusted non-GAAP EBITDA calculation – 3Q 2023 and 2022

	Three Months Ended September 30,			
(unaudited, in thousands)	2023		2022	
Net Income (Loss)	\$	9,940	\$	(8,600)
Add/(Subtract): Interest expense, net		6.398		7.264
Other expense (income), net		39		(37)
Income tax expense (benefit)		1,571		(3,622)
Depreciation and amortization		15,207		14,167
Contingent consideration fair value adjustment		(2,555)		2,476
Restructuring activities		-		1,541
Impact of Canada operations (1)		275		840
Stock-based compensation		5,444		3,869
Excess of fair value over cost of acquired inventory		_		443
Novitium transaction expenses		165		59
Adjusted non-GAAP EBITDA	s	36,484	\$	18,400

(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 amorization, 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 September 30, 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.

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Adjusted non-GAAP EBITDA calculation - full year 2022 and 2021

Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reco (unaudited, in thousands)

	Twelve Months Ended December 31,		
	-	2022	2021
Net Loss	\$	(47,896)	\$ (42,603)
Add/(Subtract):			
Interest expense, net		28,052	11,922
Other expense, net ⁽¹⁾		80	6,243
Benefit for income taxes		(14,769)	(13,455)
Depreciation and amortization		56,972	47,252
Contingent consideration fair value adjustment		3,758	500
Legal settlement expense		(-)	8,750
Intangible asset impairment charge		112	-
Restructuring activities		5,679	-
Impact of Canada operations ⁽²⁾		2,740	-
Stock-based compensation		14,599	10,489
Asset impairments ⁽³⁾			2,737
Excess of fair value over cost of acquired inventory		5,294	7,460
Novitium transaction expenses		1,244	9,382
Royalty settlement	_	-	1.934
Adjusted non-GAAP EBITDA ⁽⁴⁾	S	55.865	\$ 50.611

- Adjustment to other expense, net excludes \$750K of income related to the sale of an ANDA during the three months ended December 31, 2021, and excludes \$750K and \$1,9 million of income related to the sale of an ANDA during the twelve months ended December 31, 2022 and 2021, respectively.
 Ilmpact 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 amorization, 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, expected to be complete by March 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.
 For the three and twelve months ended December 31, 2021, Asset impairments is comprised of an ANDA intangible asset impairment and related inventory reserve charge.
 Beginning in the fourth quarter of 2022, ANI will no longer exclude expenses for In-Process Research & Development or Corrophin pre-launch charges and sales and marketing expenses from its non-GAAP results. Historically, the company excluded these charges.
 For the twelve-month period ended December 31, 2021, non-GAAP Fantal measures have been recast to include 512 million of incremental RAD expense and a corresponding reduction in full year Adjusted non-GAAP FBITDA as compared to the amount reported in our third quarter 2022 earnings release and associated Form 8-K.
 For the twelve-month period ended December 31, 2021, non-GAAP results have been recast to include 5780K of additional Purified Co

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