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): September 7, 2023

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-31812**	**58-2301143**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

210 Main Street West **Baudette, Minnesota**	**56623**
(Address of principal executive offices)	(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which 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)

☐ Pre-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 ☐

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. ☐

Item 2.02 **Results of Operations and Financial Condition**

On September 7, 2023, members of ANI Pharmaceuticals, Inc.'s senior management team will make a virtual presentation to investors as part of a non-deal roadshow. A copy of the investor presentation is furnished herewith as Exhibit 99.1.*

Item 7.01 **Regulation FD Disclosure**

The information included 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

Exhibit No.	**Description**
99.1	Investor Presentation, dated September 2023
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

* The information in 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 shall it be deemed 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.

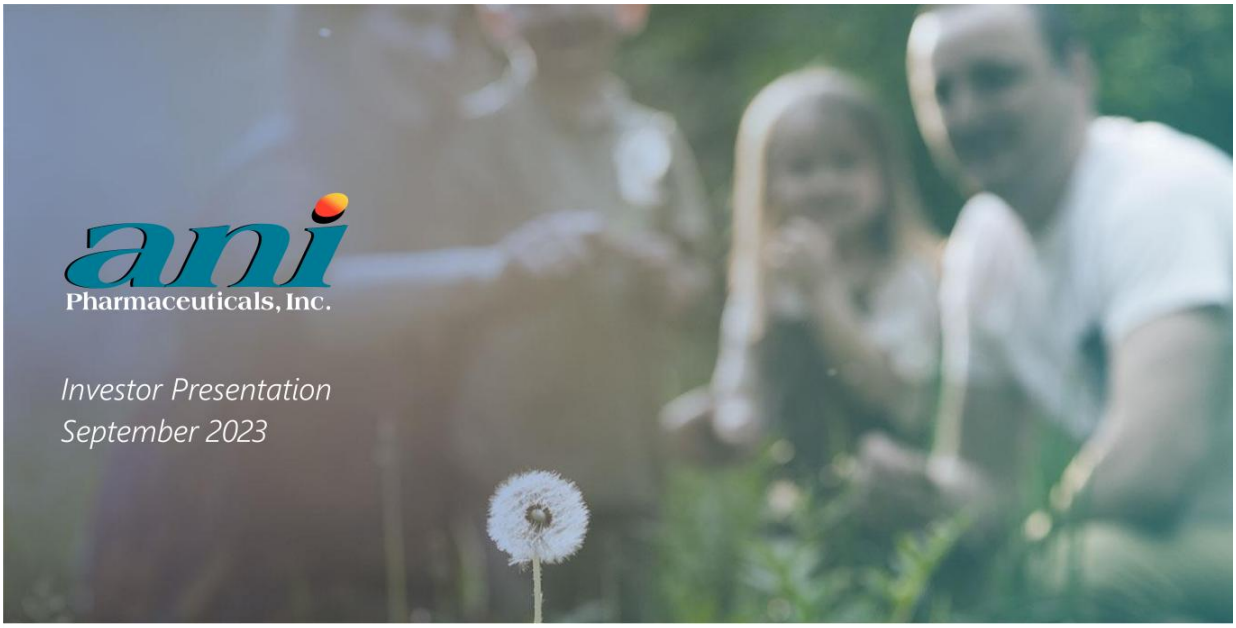
SIGNATURES

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: September 7, 2023

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey
Name: Stephen P. Carey
Title: Senior Vice President Finance and Chief Financial Officer



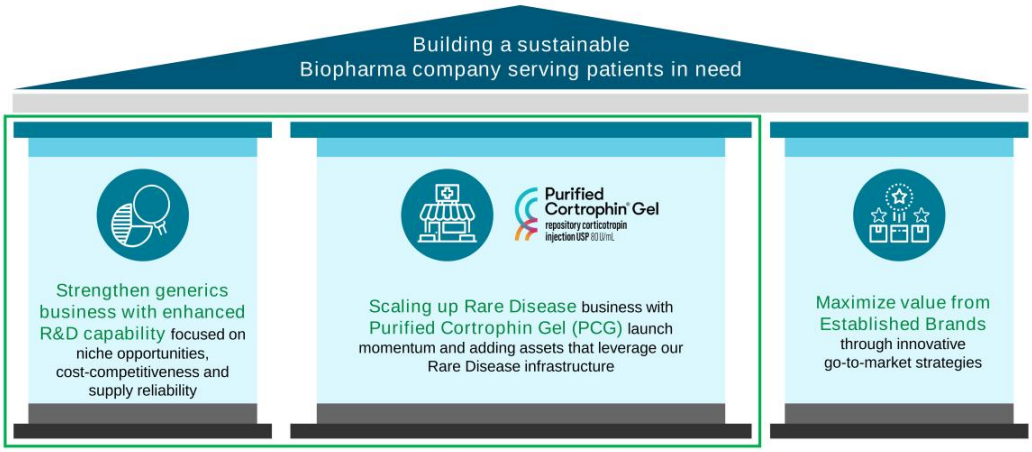
Disclaimer

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. 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. Unknown or unpredictable factors also could have material adverse effects on the Company's future results. Information concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in the Company's other periodic reports and filings with the Securities and Exchange Commission ("SEC"). The forward-looking statements included in this presentation are made only as of the date hereof. The Company cannot guarantee future results, levels of activity, performance or achievements and you should not place undue reliance on these forward-looking statements. We undertake no obligation to update any forward-looking statements made in this presentation to reflect events or circumstances after the date of this presentation or to reflect new information or the occurrence of unanticipated events, except as required by law.

Non-GAAP Financial Measures

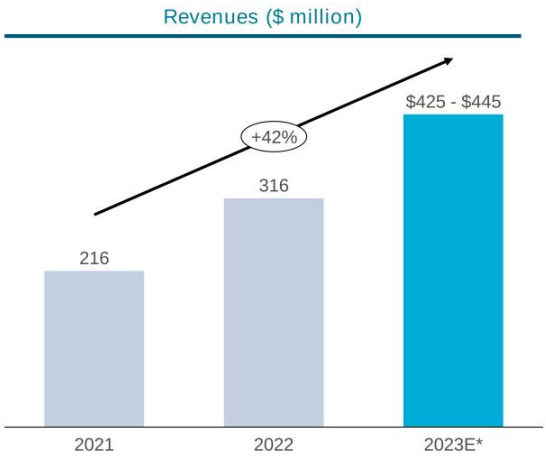
This presentation includes certain non-GAAP financial measures, including Adjusted EBITDA and Adjusted Earnings Per Share (Adjusted EPS), that management reviews to evaluate its business, measure its performance and make strategic decisions. Management believes that such non-GAAP financial measures provide useful information to investors and others in understanding and evaluating its operating results in the same manner 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 sales and marketing expenses from its non-GAAP results. 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 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. Adjusted non-GAAP diluted (loss)/earnings per share is defined as adjusted non-GAAP net income (loss) divided by the diluted weighted average shares outstanding during the period. Adjusted EBITDA, Adjusted EPS and any other ratio or metrics derived therefrom are financial measures not calculated in accordance with GAAP and should not be considered as substitutes for revenue, net income, operating profit, or any other operating performance measure calculated in accordance with GAAP. Using these non-GAAP financial measures to analyze the business would have material limitations because their calculations are based on the subjective determination of management regarding the nature and classification of events and circumstances that investors may find significant. In addition, although other companies in its industry may report measures titled Adjusted EBITDA or similar measures, such non-GAAP financial measures may be calculated differently from how management calculates its non-GAAP financial measures, which reduces their overall usefulness as comparative measures. Because of these limitations, you should consider Adjusted EBITDA and Adjusted EPS alongside other financial performance measures, including net income and other financial results presented in accordance with GAAP. Please refer to the Appendix in this presentation for a reconciliation of the non-GAAP financial measure to the most directly comparable GAAP measure. ANI is not providing a reconciliation for the forward-looking full year 2023 adjusted non-GAAP measures 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.

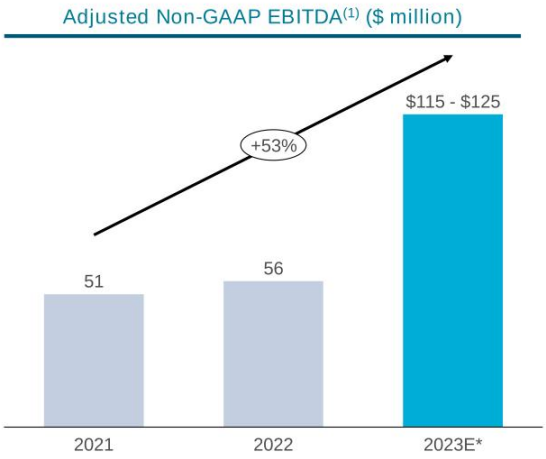
ANI Pharmaceuticals is Well Positioned to Drive Sustainable Profitable Growth



Empowered and experienced talent retaining core strengths and driving growth

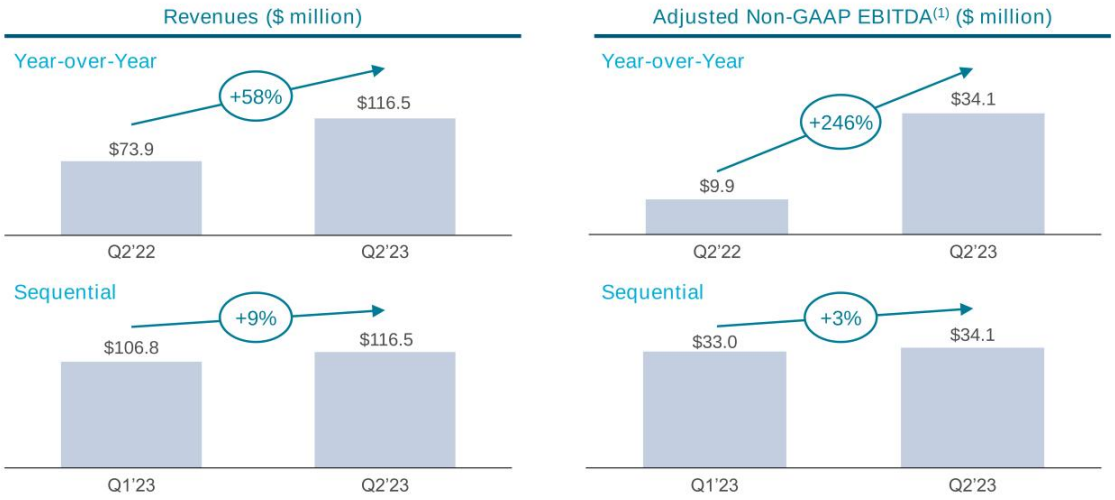
2022 Was a Year of Strong Growth for ANI and the Momentum has Continued During the First Half of 2023





(1) Adjusted non-GAAP EBITDA is a non-GAAP financial measure. For reconciliation of Adjusted Non-GAAP EBITDA to the most directly comparable GAAP measure, please see Appendix A.
* CAGR is calculated based on midpoint.

ANI Achieved Record Quarterly Revenues and Adjusted Non-GAAP EBITDA in Q1 2023 and Again in Q2 2023



(1) Adjusted non-GAAP EBITDA is a non-GAAP financial measure. For reconciliation of Adjusted Non-GAAP EBITDA to the most directly comparable GAAP measure, please see Appendix A.

Raised Full Year 2023 Guidance for Second 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)	$425 - $445	$385 - $410	34% - 41%
Cortrophin Gel Net Revenue	$90 - $100	$80 - $90	116% - 140%
Adjusted Non-GAAP Gross Margin	63% to 64.8%	60% to 62.5%	4.7 pts to 6.5 pts
Adjusted Non-GAAP EBITDA (1)	$115 - $125	$97 - $107	106% - 124%
Adjusted Non-GAAP Diluted EPS (1)	$3.62 - $4.11	$2.99 - $3.45	166% - 202%

(1) Adjusted non-GAAP EBITDA and Adjusted Non-GAAP Diluted EPS are non-GAAP financial measures. For reconciliation to the most directly comparable GAAP measure, please see Appendix A.

Strong Launch Momentum for Foundational Rare Disease Asset, Purified Cortrophin Gel

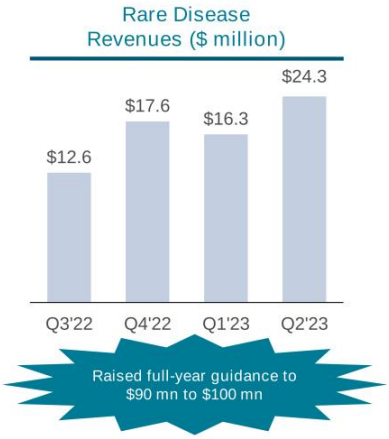
Purified Cortrophin® Gel
repository corticotropin injection USP 80 U/mL

Accelerating momentum with record number of new patient starts, new cases **initiated and new unique prescribers in Q2'23**
- Continued growth in repeat prescribers
- ACTH market continues to show year-over-year growth for thirteen consecutive months*

Continued growth across all targeted specialties of neurology, nephrology and rheumatology; pulmonology** sales team gaining momentum

Built strong Rare Disease platform with medical affairs, patient support, specialty pharmacy distribution, market access, and experienced sales force

Rare Disease expected to be the largest strategic driver of ANI's growth
- Well positioned to build upon the strength of our Rare Disease platform
- Actively pursuing M&A and in-licensing opportunities

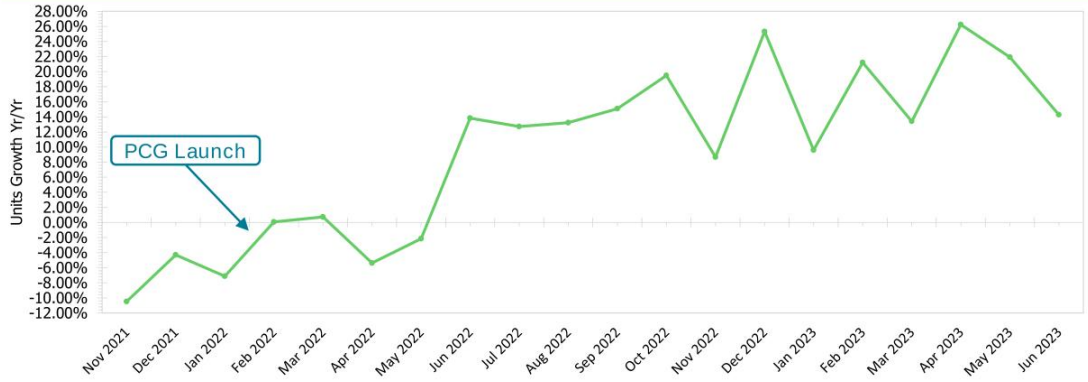


* According to IQVIA data ** Initiated in 2023

ACTH Class has Shown Year-over-Year Monthly Unit Growth For Thirteen consecutive months

Purified Cortrophin® Gel repository corticotropin injection USP 80 U/mL

ACTH Units – Year-over-Year Change



From June 2022 to June 2023, the ACTH category has demonstrated thirteen months of consecutive growth year-over-year

Source: IQVIA

Strong R&D Capabilities, Operational Excellence and U.S.-based Manufacturing Footprint Helped Capture New Business Opportunities and Drive Growth in Generics

Superior pipeline and new product launch execution

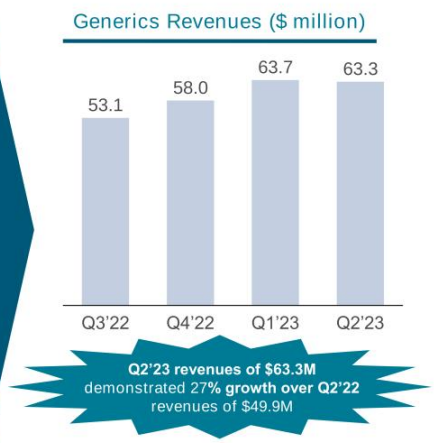
- Increased R&D investment with focus on niche opportunities
- Filed 5 new ANDAs in 2023, including ANI's first two Para IV submissions
- Retained top 12 ranking in number of ANDA approvals*
- 2023 launches include Colestipol, Nitrofurantoin suspension & Estradiol Gel

Driving cost-excellence

- Significant focus on savings in procurement of raw materials and finished goods through innovative strategies
- Lean and entrepreneurial mentality towards all spend
- Augmented our analytical and development facility in Chennai, India with over 60 skilled colleagues

Ensuring reliability of supply

- Strong compliance and audit history enhanced further by successful recent FDA audits across sites
- Maintaining healthy inventory levels for finished goods and raw materials
- U.S.-based manufacturing sites (New Jersey & Minnesota)



* Based on recent 6 months FDA approval activity; Source – FDA Website, Internal Analysis

U.S. Based Manufacturing Footprint; Strong GMP Track Record, Including Successful Recent 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	• 100K ft^2 of manufacturing, packaging, lab, warehouse, and administrative space • Undergoing 20K ft^2 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
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

Executive Leadership Team with Proven Track Records and Broad Industry Expertise

Nikhil Lalwani
President & Chief Executive Officer
Cipla · McKinsey & Company

- 20+ years leadership experience in pharmaceuticals and healthcare
- Proven track record of developing and executing multi-year strategic growth plans

Chris Mutz
Head of Rare Diseases / Cortrophin
MERCK · ALEXION

- 25+ years commercialization experience
- Responsible for building / leading launch of Soliris for gMG and NMOSD in the US

Meredith Cook
SVP, Legal & General Counsel
amneal · ML

- 20+ years of legal and leadership experience in specialty and generics pharmaceuticals
- Served as Vice President and Associate GC for Amneal Pharmaceuticals
- Previously with Morgan Lewis & Bockius, LLP

Samy Shanmugam
COO, New Jersey Operations & Head of Global R&D
PAR PHARMACEUTICAL · NOVEL

- Former Head of R&D and Operations for Par Pharmaceuticals
- Founded Edict Pharmaceuticals, Nuray chemicals and Ethics BioLab
- Developed over 100 specialty dosage forms and ANDAs in the US

Chad Gassert
SVP, Corporate Development & Strategy
PAR PHARMACEUTICAL · SANDOZ

- Former SVP of Business Development, M&A, Partnerships and Licensing for Par Pharmaceuticals
- Formulation development scientist for Sandoz

Stephen Carey
SVP, Finance & Chief Financial Officer
PAR PHARMACEUTICAL · Schering-Plough

- 30+ years financial executive experience
- Former SVP, Controller and Principal Accounting Officer for Par Pharmaceuticals

Krista Davis
SVP, Human Resources & CHRO
NOVARTIS

- 20+ years of leadership experience in HR, talent management, and organizational development across industries and cultures
- Former Global Head, People & Organization for Novartis Technical Operations

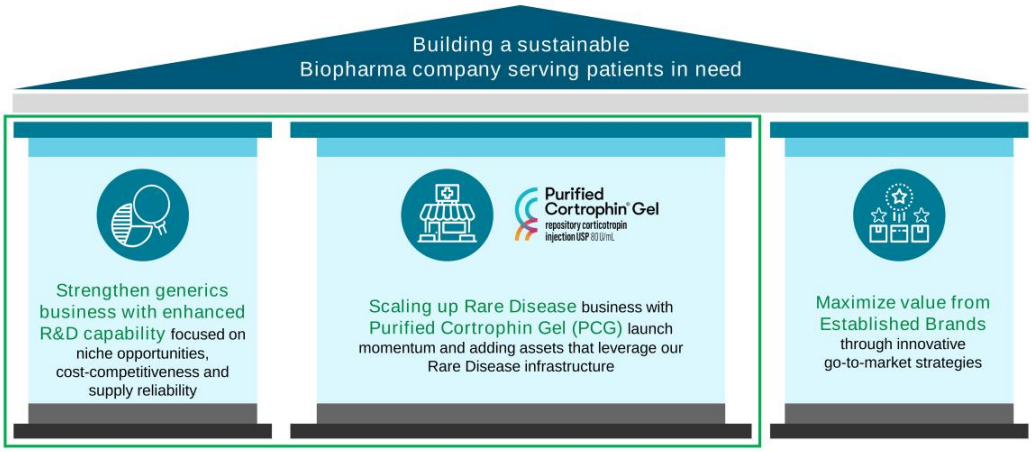
Ori Gutwerg
SVP, Generics
Perrigo · TARO

- 17+ years pharmaceutical experience across generic and branded products
- Proven track record of business development and accelerating growth

James Marken
SVP, Operations & Product Development
SOLVAY

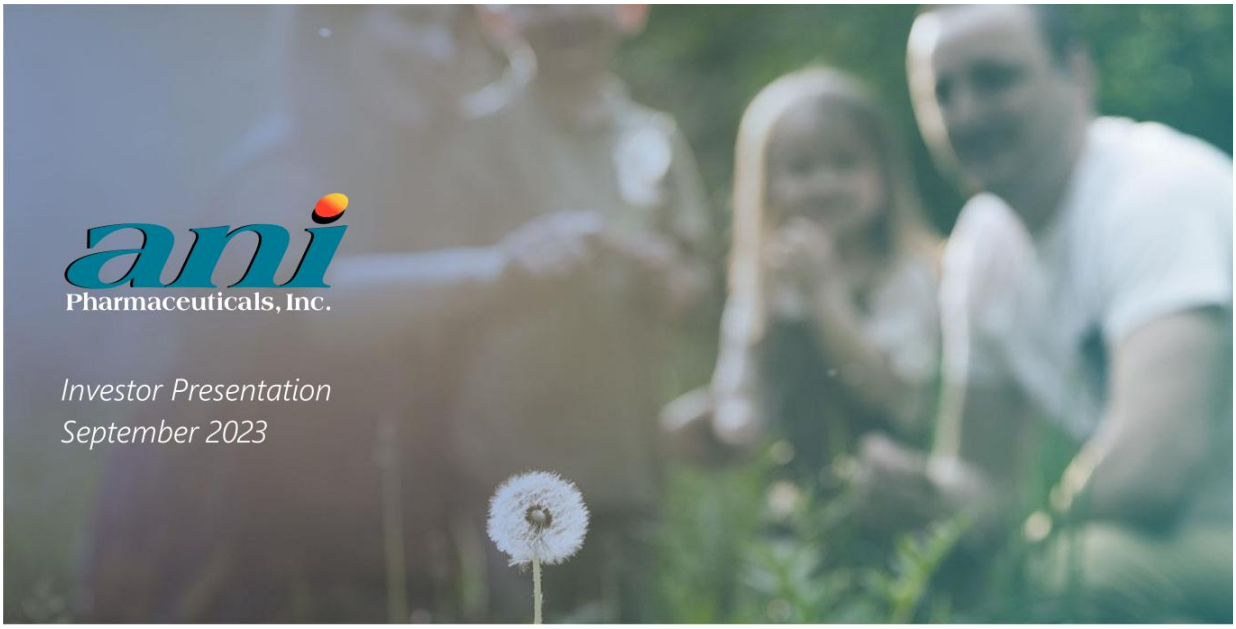
- 30+ years of pharmaceuticals experience, overseeing production and logistical functions for company facilities
- Expertise in quality control, validation and manufacturing

ANI Pharmaceuticals Is Well Positioned to Drive Sustainable Profitable Growth



Empowered and experienced talent retaining core strengths and driving growth

ANI Recently Celebrated a Decade Since Listing on the NASDAQ



Adjusted Non-GAAP EBITDA Calculation – 2Q 2023 and 2022

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

	Three Months Ended June 30,	
	2023	2022
Net Income (Loss)	$ 6,245	$ (14,923)
Add/(Subtract):		
Interest expense, net	7,100	6,669
Other expense (income), net (1)	53	(14)
Income tax benefit	(996)	(3,895)
Depreciation and amortization	14,690	13,764
Contingent consideration fair value adjustment	1,035	(1,095)
Intangible asset impairment charge	—	112
Restructuring activities	2	2,570
Impact of Canada operations (2)	492	1,820
Stock-based compensation	5,249	3,756
Excess of fair value over cost of acquired inventory	—	973
Novitium transaction expenses	249	124
Adjusted non-GAAP EBITDA	$ 34,119	$ 9,861

(1) Adjustment to Other expense (income), 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 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, which was completed as of 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.

Adjusted Non-GAAP EBITDA Calculation – Full Year 2022 and 2021

Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation
(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]	$ 55,865	$ 50,611

(1) 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.

(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, 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.

(3) 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.

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

- For the twelve-month period ended December 31, 2022, non-GAAP financial measures have been recast to include $1.2 million of incremental R&D expense and a corresponding reduction in full year Adjusted non-GAAP EBITDA 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 $780K of additional Purified Cortrophin Gel pre-launch charges and $13.4 million of Cortrophin related SG&A expense, and a corresponding reduction in full year Adjusted non-GAAP EBITDA of $14.2 million.