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): November 15, 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 November 15, 2023, Nikhil Lalwani, President & CEO of ANI Pharmaceuticals, Inc., will present at the Jefferies 2023 London Healthcare Conference in London, UK. 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 November 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.

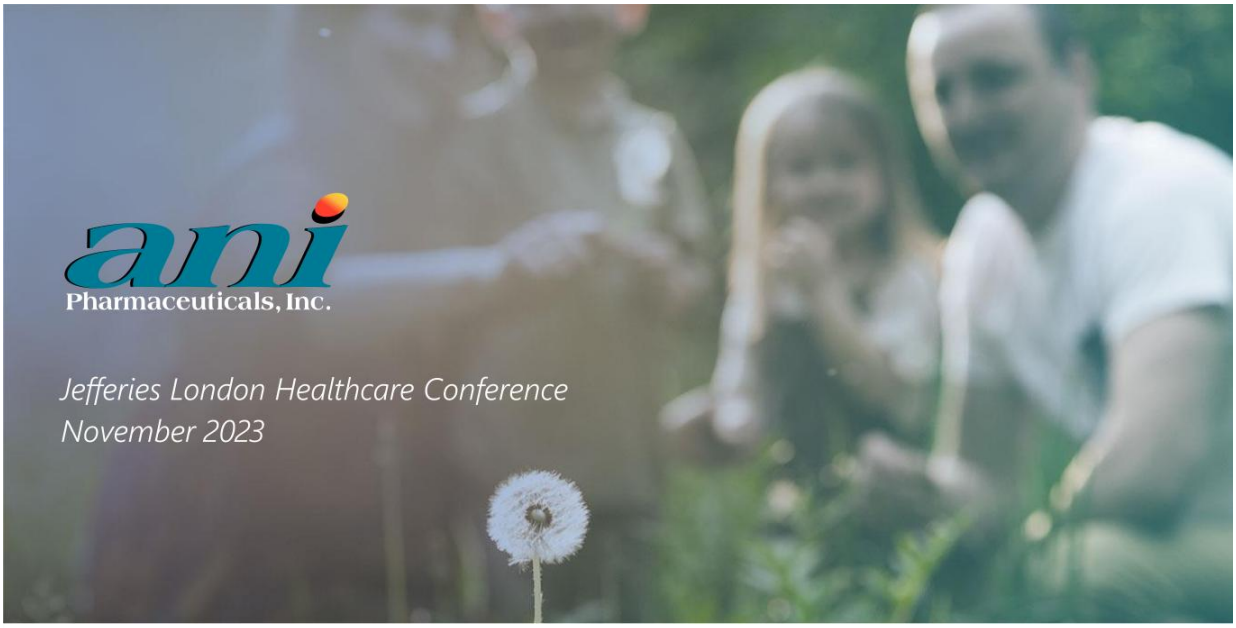
SIGNATURES

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: November 15, 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. Uncertainties and risks include, but are not limited to: risks that we may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason; delays or failure in obtaining and maintaining approvals by the FDA of the products we sell; changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls; the ability of our manufacturing partners to meet our product demands and timelines; our dependence on single source suppliers of ingredients due to the time and cost to validate a second source of supply; acceptance of our products at levels that will allow us to achieve profitability; our ability to develop, license or acquire, and commercialize new products; the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products; our ability to protect our intellectual property rights; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the impact of any litigation to which we are, or may become, a party; our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; our ability to maintain the services of our key executives and other personnel; whether we experience difficulties finding a buyer for the plant and property resulting from the closure of our Oakville, Ontario manufacturing plant; and general business and economic conditions, such as inflationary pressures, geopolitical conditions including but not limited to the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, and the effects and duration of outbreaks of public health emergencies, such as COVID-19, and other risks and uncertainties that are described in ANI's Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the Securities and Exchange Commission. Unknown or unpredictable factors also could have material adverse effects on the Company's future results. 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: Rare Disease, Generics and Established Brands businesses drive robust profitable growth

ani Pharmaceuticals, Inc.
Serving Patients Improving Lives

Key Growth Drivers

Rare Disease business with lead asset Purified Cortrophin Gel (PCG) and expansion through M&A

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

Generics with enhanced R&D capabilities & supply reliability

Established Brands

Financial Strength

$473M
Estimated 2023 Revenue(1)

+49.5%
year-over-year revenue growth(2)

133.6%
Adjusted non-GAAP EBITDA growth(2)

$193M
cash(3)

$74M
YTD cash flow from operating activities (3)

(1) Based on midpoint of guidance as discussed during Q3 quarter earnings call (2) From 2022 to 2023E, based on midpoint of guidance (3) As of 9/30/2023

Q3 2023: Achieved record financial results

Highlights

- Continued strong momentum for lead Rare Disease asset, Cortrophin Gel with record new patient starts and cases initiated
- Strong R&D organization delivered five new product launches & filed three new ANDAs and two 505(b)(2) NDA applications
- Continued responding to pharmaceutical shortages through operational excellence and U.S. manufacturing footprint

Q3 Revenues
$132M
57% YoY

Q3 Adj. Non-GAAP EBITDA(1)
$36M
98% YoY

Q3 Diluted non-GAAP EPS(1)
$1.27
119% YoY

Year-to-Date Cash Flow from Operations(2)
$74M

Q3 Cortrophin Revenues
$30M
136% YoY

Q3 Generic, Established Brands, and Other Revenues
$102M
43% YoY

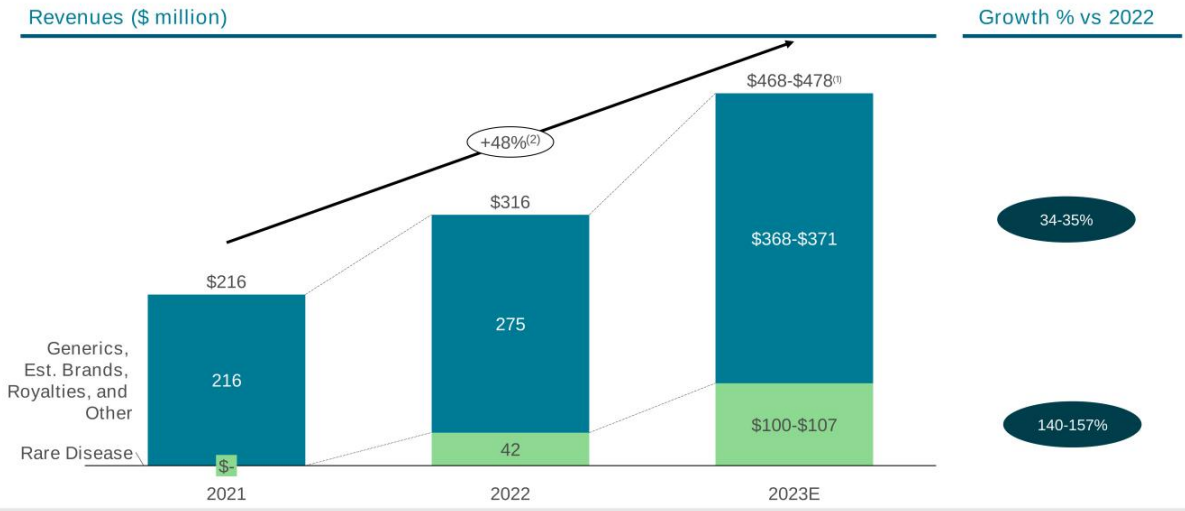
(1) Adjusted non-GAAP EBITDA and Adjusted Non-GAAP Diluted EPS are non-GAAP financial measures. For reconciliation to the most directly comparable GAAP measure, please see Appendix A
(2) As of 9/30/2023

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.

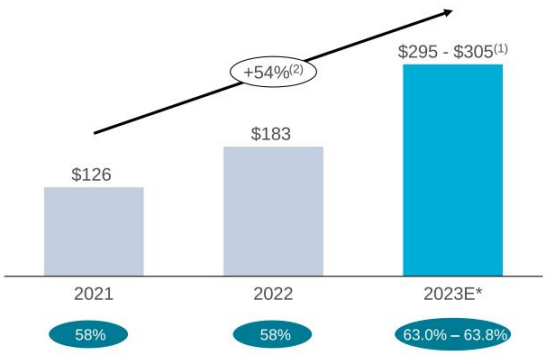
Revenue growth driven by momentum across Rare Disease, Generics and Established Brands



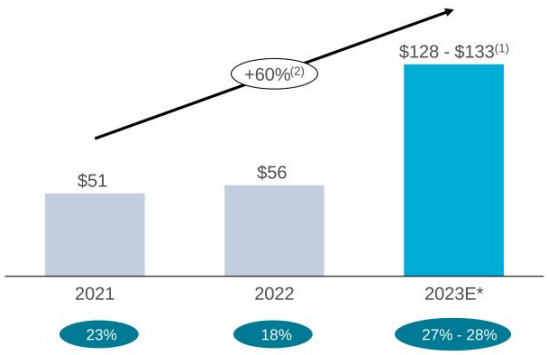
Note: Figures presented may not total due to rounding.
(1) Guidance shared at 3rd quarter earnings call
(2) CAGR is calculated based on midpoint

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

Adjusted Non-GAAP Gross-Margin ($ million)



Adjusted Non-GAAP EBITDA(1) ($ million)



PCG contributed to profitability in 2023 in just second year of launch after 2022 investment to build rare disease infrastructure

(1) Guidance shared at 3rd quarter earnings call
(2) CAGR is calculated based on midpoint

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

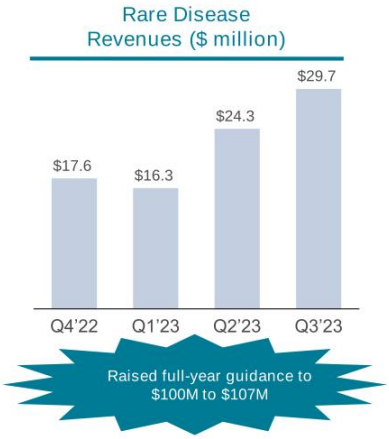
Purified Cortrophin® Gel
repository corticotropin injection USP 80 U/mL

Continued strong momentum with record number of new patient starts and new **cases initiated in Q3'23**
- Grew all targeted specialties of neurology, nephrology and rheumatology; pulmonology* sales team gaining momentum
- Continued growth in new unique prescribers and repeat prescribers, including prescribers who are naive to ACTH therapy

ACTH market posted six consecutive quarters of year-over-year growth**
- Company efforts to improve awareness of ACTH therapy for appropriate patients
- Number of patients on therapy today remains significantly lower than patients on ACTH therapy few years ago, providing opportunity for ANI to serve patients in need

Announced FDA approval and commercial availability of new 1-mL vial size of Cortrophin Gel
- Only approved purified corticotrophin indicated for the treatment of acute gouty arthritis flares
- Received specific J-Code to support physician administration of 1 ml vial

Established and proven Rare Disease Platform
- Experienced leadership team and sales force with a proven track record
- Infrastructure and capabilities across medical affairs, patient support, specialty pharmacy distribution, and market access

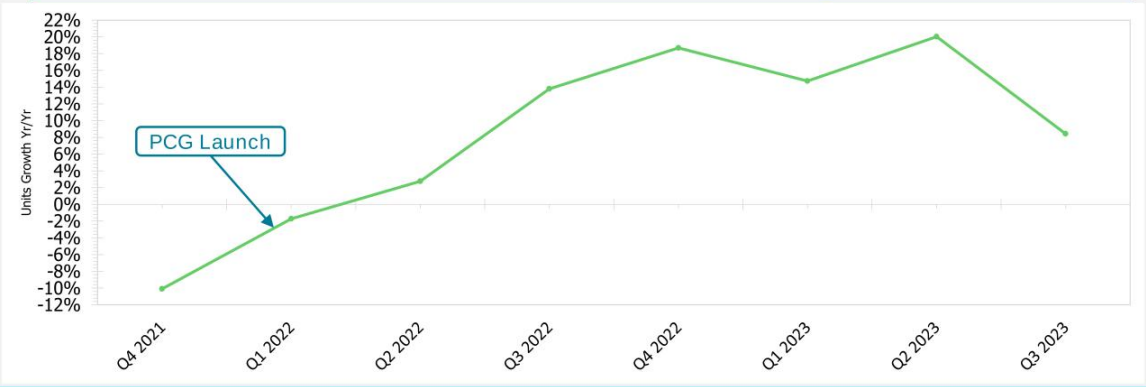


* Initiated in Q2, 2023 ** According to IQVIA data

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

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

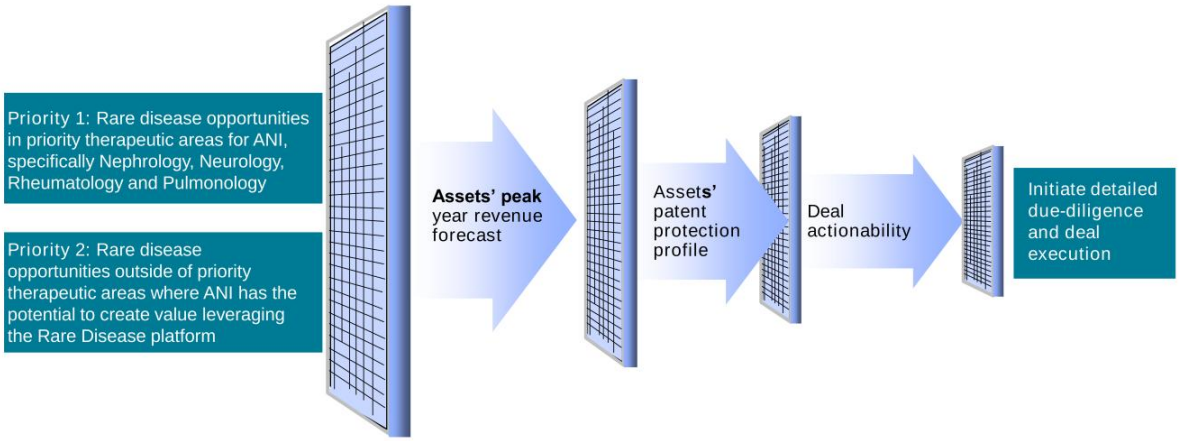
ACTH Units – Year-over-Year Change



From Q2 2022 to Q3 2023, the ACTH category has demonstrated six consecutive quarters of growth year-over-year

Source: IQVIA

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



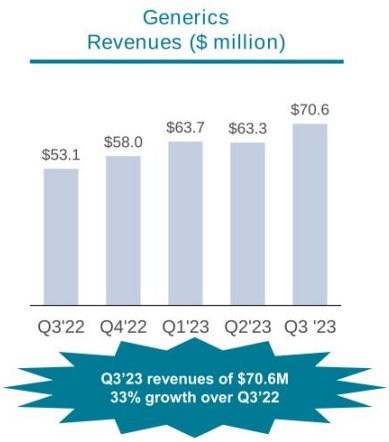
Superior R&D capabilities and operational excellence driving growth in Generics

Superior pipeline and new product launch execution
- Increased R&D investment with focus on niche opportunities
- Filed six new ANDAs in 2023 and three 505(b)2 NDA applications
- Retained top 12 ranking in number of ANDA approvals; number 2 in Competitive Generic Therapy
- Key 2023 launches include Colestipol Tabs, Thyroid Tabs, Nitrofurantoin suspension, Estradiol Tabs and Estradiol Gel

Driving cost excellence
- Innovative strategies to reduce cost of raw materials and finished goods
- Lean and entrepreneurial mentality towards all corporate spend
- Expanded analytical and development facility in Chennai, India with over 60 skilled colleagues

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

Ability to respond to shortages arising from supply-chain disruptions
- During first three quarters of 2023, successfully used operational excellence and U.S.-based manufacturing footprint to respond to industry needs
- Timely response established ANI as a partner of choice to address future industry disruptions



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 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 • 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)

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 | 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 | 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 | 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

Investment summary

Strong and growing Rare Disease business

- Expected to be largest driver of future growth
- Lead asset Cortrophin Gel forecasted at $100-$107M revenues in 2023; significant opportunity for future growth
- Focused M&A efforts to expand scope and scale of Rare Disease business

Financial Strength

- $193M unrestricted cash(1)
- $74M year-to-date cash flow(1) from operations
- $473M estimated 2023 revenue(2) representing 49.5% year-over-year growth
- $130.5M estimated 2023 Adjusted non-GAAP EBITDA(2) representing 133.6% year-over-year growth

Robust and nimble Generics segment delivering growth

- Demonstrated R&D excellence in filings and launch execution
- Providing reliability of supply with US-based manufacturing and strong GMP track record

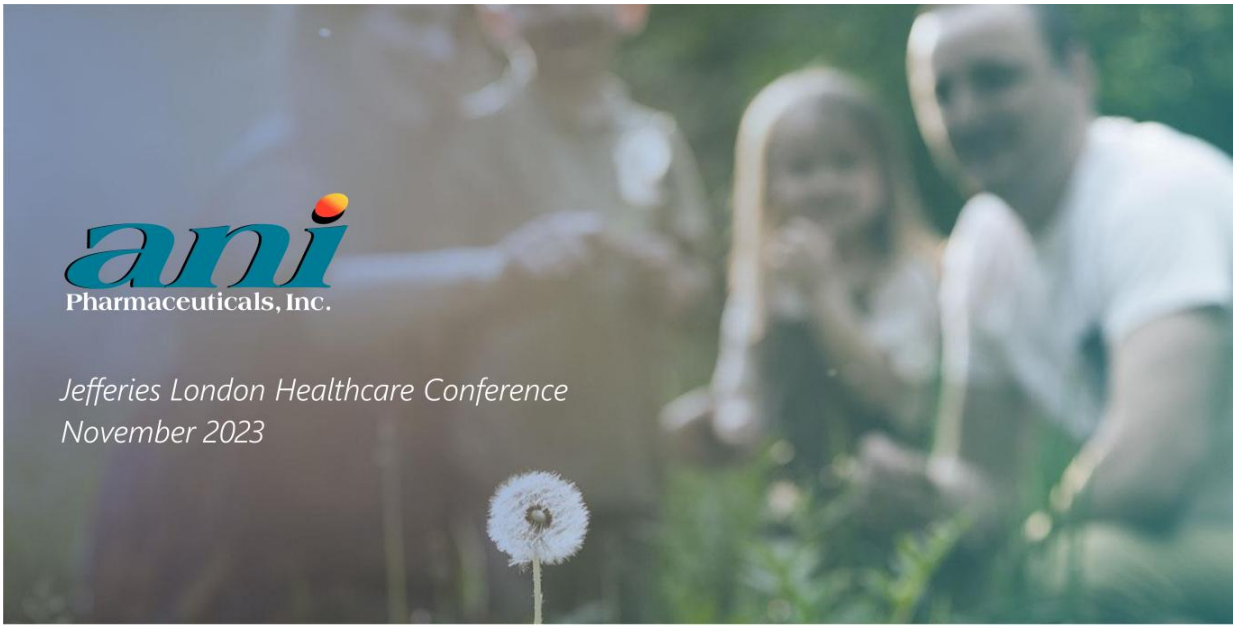
Experienced purpose-driven team

- Dedicated employees with deep experience and expertise in Rare Disease, Generics and Established Brands
- Purpose-Driven: Serving Patients, Improving Lives
- Strong cross functional collaboration driving success

(1) As of 9/30/2023 (2) Based on midpoint of guidance

ANI recently celebrated a decade since listing on the NASDAQ

ani Pharmaceuticals, Inc.
Serving Patients
Improving Lives



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

(unaudited, in thousands)	Three Months Ended September 30, 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	$ 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 amortization, which are included within their respective line items above. The adjustment of Canada operations represents revenues, cost of sales and expense that will not recur after the completion of the closure of our Canada operations (complete as of March 31, 2023) and the sale of the facility (on-going as of 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.

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.