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): March 12, 2024

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 March 12, 2024, members of ANI Pharmaceuticals, Inc.'s (the "Company") senior management team met with investors at the Leerink Partners Global Biopharma Conference and provided an updated investor presentation. The Company will use the updated presentation in various meetings with investors from time to time. 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 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 March 2024
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: March 12, 2024

ANI PHARMACEUTICALS, INC.

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

Disclaimer

To the extent any statements made in this presentation deal with 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, those relating to the commercialization and potential sales of the product and any additional product launches from the Company's generic pipeline, 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: Cortrophin Gel is our first rare disease pharmaceutical product; to the extent we are not able to continue to achieve commercial success with this product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; our approved products, including Cortrophin Gel, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; acquisitions and other investments could disrupt our business and harm our financial position and operating results; the limited number of suppliers for our active pharmaceutical ingredients could result in lengthy delays in production if we need to change suppliers; delays or failure in obtaining or 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; acceptance of our products at levels that will allow us to achieve profitability; 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; 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; 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 closing a sale transaction with 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, or conflicts relating to attacks on cargo ships in the Red Sea, 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.

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 (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements in this presentation speak only as of the date of this presentation and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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 and Generics drive robust profitable growth; Established Brands adds strong cash flow

ani Pharmaceuticals, Inc.
Serving Patients Improving Lives

Key Growth Drivers

Rare Disease business with lead asset **Purified Cortrophin Gel** and expansion through M&A

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

Generics with enhanced R&D capabilities driving new product launches; supply reliability

Established Brands

Financial Strength

$487M
2023 Revenue

+54%
year-over-year revenue growth

140%
Adjusted non-GAAP EBITDA growth

$221M
cash(1)

$119M
Cash flow from operations

1. As of 12/31/2023

Q4 2023: Another strong quarter, capping off a record 2023

Highlights

- Continued momentum for lead Rare Disease asset, Cortrophin Gel, with record new patient starts and cases initiated
- Steady gains across our core therapeutic areas (rheumatology, neurology, nephrology) while moving into new areas of opportunity (pulmonology, ophthalmology, gout) in the ACTH market
- Cortrophin momentum drove overall ACTH market expansion (15% year-over-year growth in 2023)
- Continued to leverage exceptional new product launch execution, operational excellence, and US-based manufacturing footprint to reliably serve patients in Generics and Established Brands

Q4 Revenues
$132M
40% YoY

Q4 Adj. Non-GAAP EBITDA(1)
$30M
29% YoY

Q4 Diluted non-GAAP EPS(1)
$1.00
32% YoY

2023 Cash Flow from Operations
$119M

Q4 Cortrophin Revenues
$42M
137% YoY

Q4 Generic, Established Brands, and Other Revenues
$90M
17% 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

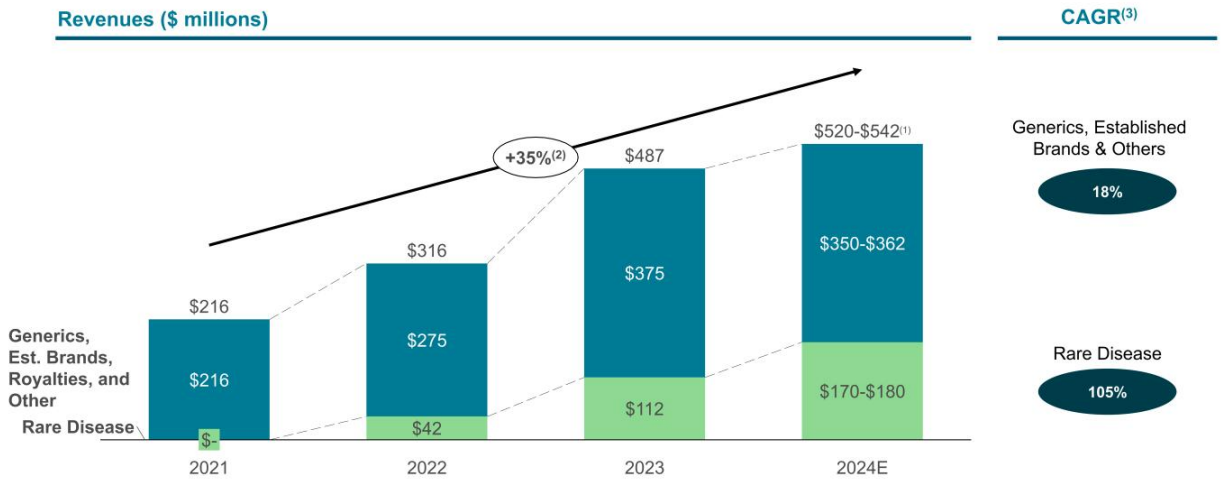
2024 Guidance

Metric ($ millions except per share amounts)	Full Year 2024 Guidance	2023 Actuals	Growth vs Prior Year Actuals
Net Revenue (Total Company)	$520 - $542	$487	7 - 11%
Cortrophin Gel Net Revenue	$170 - $180	$112	52 - 61%
Adjusted Non-GAAP EBITDA (1)	$135 - $145	$134	1 - 8%
Adjusted Non-GAAP Diluted EPS (1)	$4.26 - $4.67	$4.71	(10) - (1)%

Adjusted Non-GAAP Diluted EPS guidance reflects a full year of shares outstanding from our May 2023 secondary equity raise.

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

ANI has consistently delivered high-growth since 2021; strong momentum across all business segments



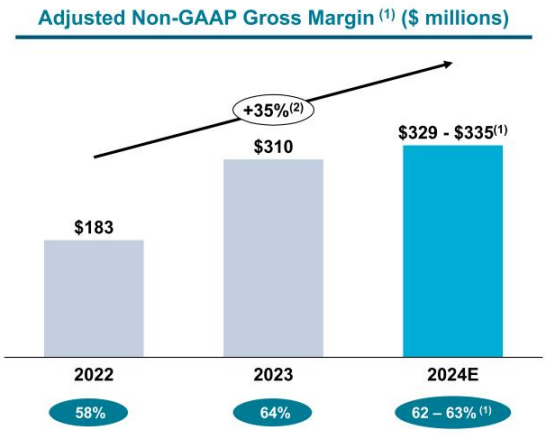
Note: Figures presented may not total due to rounding.
1. 2024 Guidance shared on fourth quarter earnings call (February 29, 2024)
2. CAGR is calculated based on midpoint
3. Generics, Established Brands, Royalties and Others CAGR calculated 2021-2024; Rare Disease CAGR calculated using years 2022-2024

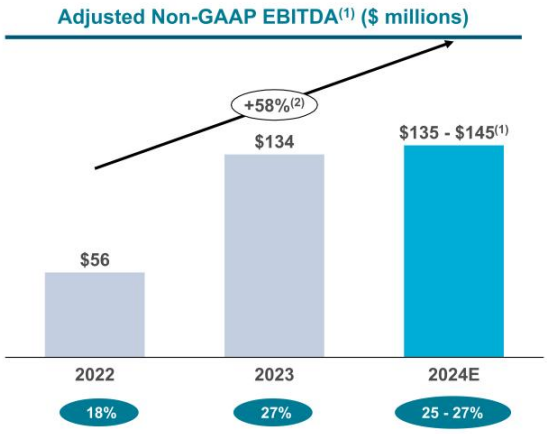
Revenue growth in 2024 driven by momentum across key growth drivers: Rare Disease and Generics

Business Segment	2023 Actuals ($ millions)	Full Year 2024 Guidance ($ millions)	Notes
Rare Disease	**$112**	**$170 - $180**	52% - 61% YoY growth
Generics	$269		High single-digit/low double-digit YoY organic growth
Established Brands, Royalties & Other	$106		2023 had full-year benefits from supply tailwinds; 2024 guidance includes only tailwinds already seen in Q1
Total Generics, Established Brands, Royalties & Other	**$375**	**$350 - $362**	
Total Company	**$487**	**$520 - $542**	7% - 11% YoY growth

Note: Figures presented may not total due to rounding.

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





Rare Disease contributed to profitability in 2023 in just second year of launch after 2022 investment to build Rare Disease infrastructure

Note: Figures presented may not total due to rounding.
1. 2024 Guidance shared on fourth quarter earnings call (February 29, 2024)
2. CAGR is calculated based on midpoint of 2024 guidance range

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

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

Continued momentum within specialties initially targeted at launch[1]
- Record number of new patient starts and new cases initiated in Q4'23
- New patient starts accelerated in Q4, and ANI posted the strongest sequential growth in net revenue to date
- Strong growth across the 3 specialties targeted at launch: neurology, nephrology and rheumatology

Expansion into new areas
- Launched new 1-mL vial size of Cortrophin Gel during Q4'23, the only approved ACTH therapy indicated for the treatment of acute gouty arthritis flares; received specific J-Code
- Recently established pulmonology-focused sales team already driving Cortrophin Gel use; further expanding the pulmonology sales team in 2024
- Expanding into ophthalmology in early 2024

Improved ACTH awareness and helped drive total market growth
- ACTH market posted seven consecutive quarters of year-over-year growth[2]
- Overall ACTH market grew 15%[2] in 2023, but number of patients on ACTH therapy today remains substantially lower than a few years ago, leaving room for significant added growth

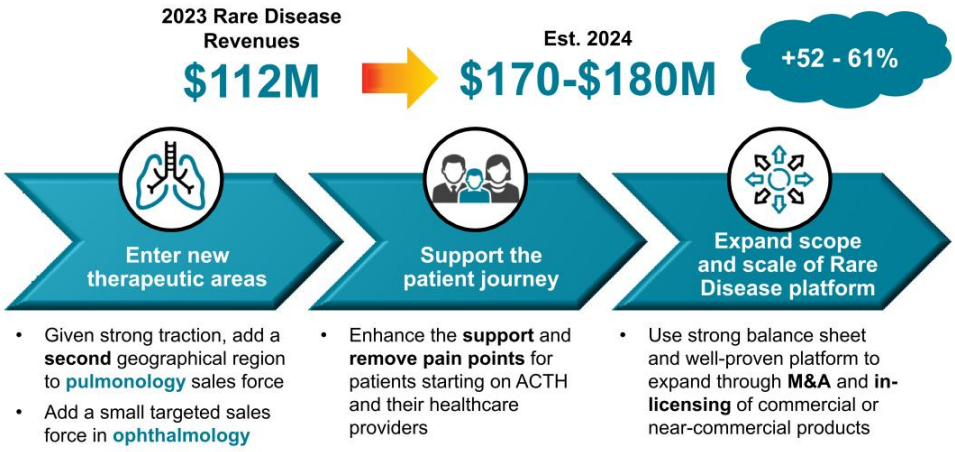
Ability to leverage an established and proven Rare Disease platform
- Experienced leadership team and sales force with a proven track record
- Infrastructure and capabilities across medical affairs, patient support, specialty pharmacy distribution, and market access

Rare Disease Revenues ($ millions)

Full year 2024 guidance of $170 - $180 million

1. Purified Cortophin Gel was launched in January 2022
2. According to IQVIA data

Investing in the Cortrophin Gel franchise to drive growth in 2024 and beyond

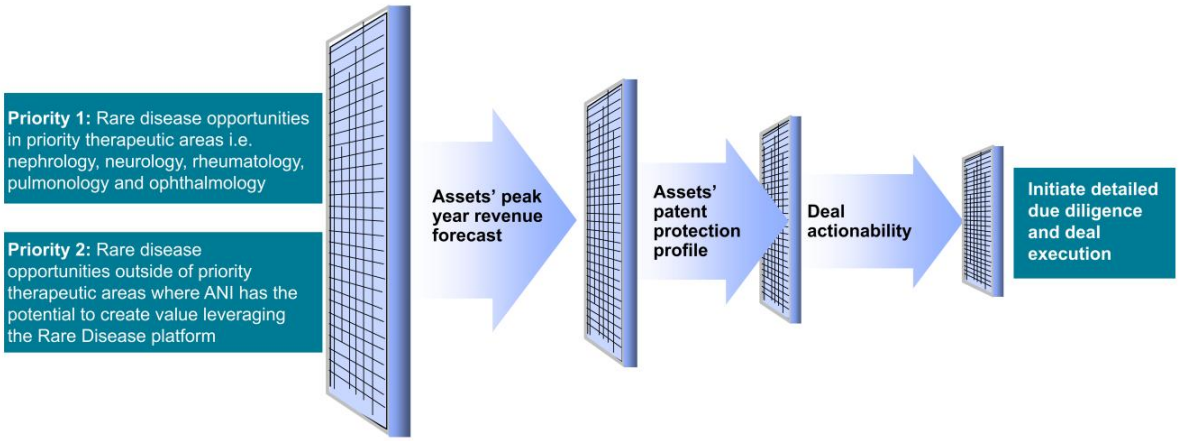


- Given strong traction, add a **second** geographical region to **pulmonology** sales force
- Add a small targeted sales force in **ophthalmology**

- Enhance the **support** and **remove pain points** for patients starting on ACTH and their healthcare providers

- Use strong balance sheet and well-proven platform to expand through **M&A** and **in-licensing** of commercial or near-commercial products

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



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

Robust pipeline and new product launch execution
- Delivered 11 new product launches and filed 20 new products with the FDA in 2023
- Retained top 12 ranking in number of ANDA approvals; number 2 in Competitive Generic Therapies
- Increased R&D spend in 2024 to consistently deliver new launches fueling high single-digit/low double-digit growth

Strong operational backbone and U.S.-based manufacturing footprint
- During 2023, supplied over 1.5 billion doses of therapeutics to patients in need
- Excellent compliance track record with successful FDA audits across sites
- Capacity expansion at New Jersey site on track; operational in Q1 2024
- Recently, New Jersey site successfully completed both a pre-approval and a pharmacovigilance inspection with the FDA with zero observations

Focus on cost excellence
- Systematic and relentless approach to reducing raw materials and finished goods costs
- Lean and entrepreneurial mentality towards all corporate spend

Ability to respond to tailwinds arising from drug-shortages in the market
- ANI successfully uses operational excellence and its U.S.-based manufacturing footprint to respond to patient and customer needs
- Timely response established ANI as a partner of choice

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

	 **Baudette, MN** *130k sf*	 **Baudette, MN** *Containment Facility - 47k sf*	 **East Windsor, NJ** *120k 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 ; Semi Solids
GMP	*Four FDA inspections since 2013* **Latest FDA inspection – November 2022** **Results: VAI status**	*Seven DEA inspections since 2013* **Latest FDA inspection – August 2023** **Results: VAI status**	*Seven FDA inspections since 2017, Four DEA inspections since 2016* **Latest FDA inspection – January 2024** **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

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

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

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

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

Ori Gutwerg
SVP, Generics
Perrigo | TARO

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

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

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

- Largest expected driver of future growth
- Lead asset Cortrophin Gel forecasted at $170-$180M revenues in 2024 (+52 - 61%) with significant opportunity for future growth
- Focused M&A efforts to expand scope and scale of Rare Disease business

Robust and nimble Generics segment delivering growth

- Key driver with targeted growth of high single-digit to low double-digit growth
- Demonstrated R&D excellence in filings and launch execution
- Providing reliability of supply with US-based manufacturing and strong GMP track record

Financial Strength

- $221M unrestricted cash(1)
- $119M cash flow from operations in 2023
- $531M estimated 2024 revenue(2) representing 9% year-over-year growth
- $140M estimated 2024 adjusted non-GAAP EBITDA(2)
- $4.47 estimated 2024 adjusted non-GAAP EPS(2)

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 12/31/2023 2. Based on midpoint of 2024 guidance range

Adjusted non-GAAP EBITDA calculation – 4Q 2023 and 2022

	Three Months Ended December 31,	
	2023	2022
Net Income (Loss)	$ 1,155	$ (4,243)
Add/(Subtract):		
Interest expense, net	5,746	7,506
Other expense, net	33	42
Benefit for income taxes	(208)	(1,485)
Depreciation and amortization	15,194	14,484
Contingent consideration fair value adjustment	1,985	1,624
Restructuring activities	—	1,568
Impact of Canada operations (1)	283	79
Stock-based compensation	5,621	3,737
Excess of fair value over cost of acquired inventory	—	48
Novitium transaction expenses	391	(31)
Adjusted non-GAAP EBITDA	$ 30,200	$ 23,329

(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 December 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 2023 and 2022

	Twelve Months Ended December 31,	
	2023	2022
Net Income (Loss)	$ 18,779	$ (47,896)
Add/(Subtract):		
Interest expense, net	26,940	28,052
Other expense, net (1)	159	80
Expense (benefit) for income taxes	1,093	(14,769)
Depreciation and amortization	59,791	56,972
Contingent consideration fair value adjustment	1,426	3,758
Intangible asset impairment charge	—	112
Restructuring activities	1,132	5,679
Impact of Canada operations (2)	2,697	2,740
Stock-based compensation	20,652	14,599
Excess of fair value over cost of acquired inventory	—	5,294
Novitium transaction expenses	1,148	1,244
Adjusted non-GAAP EBITDA	$ 133,817	$ 55,865

(1) Adjustment to Other expense, net excludes $750 thousand of income related to the sale of an ANDA during the twelve months ended December 31, 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 (complete as of March 31, 2023) and the sale of the facility (on-going as of December 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.