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): June 5, 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 June 5, 2024, Nikhil Lalwani, President & CEO of ANI Pharmaceuticals, Inc., will present at the 2024 Jefferies Global Healthcare Conference in New York City. A copy of the investor 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 June 5, 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: June 5, 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. Adjusted non-GAAP EBITDA is defined as net income (loss), excluding tax expense or benefit, interest expense, (net), other expense, (net), depreciation, amortization, non-cash stock-based compensation expense, Novitium transaction expenses, contingent consideration fair value adjustment, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, 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), non-cash stock-based compensation expense, Novitium transaction expenses, non-cash interest expense, depreciation and amortization expense, contingent consideration fair value adjustment, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, 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 2024 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 and in-licensing

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

Generics with enhanced R&D capabilities driving new product launches; operational excellence

Established brands with unique commercial capability, high margins and strong cash flow generation

Financial Strength[1]

$487M
2023 revenue

54%
year-over-year revenue growth

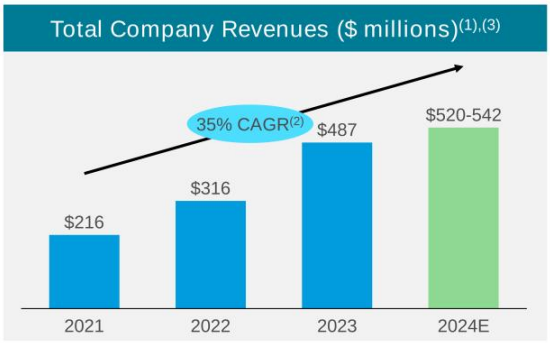
140%
Adjusted non-GAAP EBITDA growth

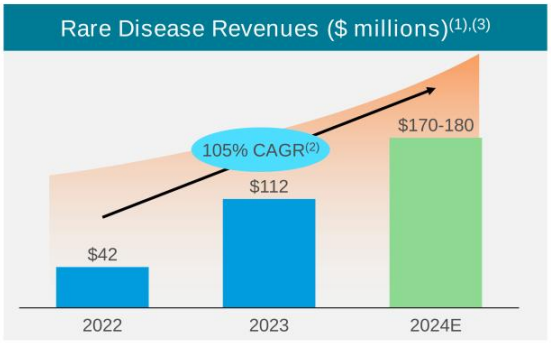
$229M
Cash[2]

$119M
Cash flow from operations

1. As of December 31, 2023.
2. As of March 31, 2024.

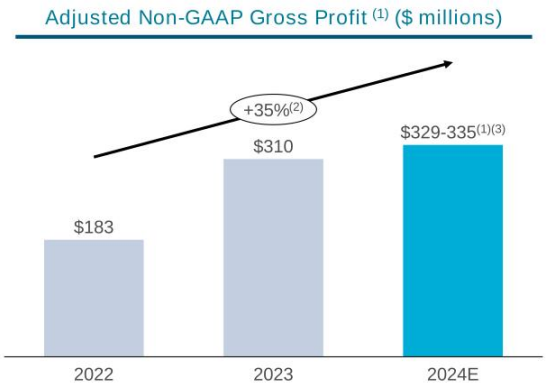
ANI has delivered high revenue growth consistently since 2021; Rare Disease expected to be largest driver of growth going forward

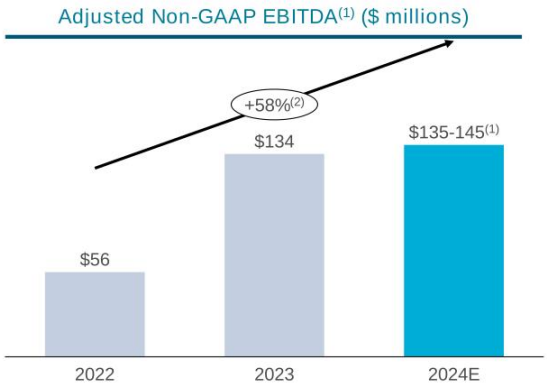




1. 2024 estimates reflect 2024 guidance, initially provided on February 29, 2024 and reiterated on May 10, 2024.
2. CAGRs are calculated based on the midpoints of the 2024 guidance ranges.
3. Total Company CAGR calculated using 2021-2024; Rare Disease CAGR calculated using 2022-2024 (Cortrophin Gel was launched in 2022).

Topline growth and Rare Disease operating leverage expected to drive continued strong EBITDA growth





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

Note: Figures presented may not total due to rounding.
1. 2024 estimates reflect 2024 guidance, initially provided on February 29, 2024, and reiterated on May 10, 2024.
2. CAGRs are calculated based on the midpoints of the 2024 guidance ranges.
3. Adj. Non-GAAP Gross-Profit 2024 estimates shown here aligned with the Adj. Non-GAAP Gross-Profit percentages provided on May 10, 2024.

Momentum continues in 2024 with ANI delivering record results in Q1

Highlights

- Steady gains in Q1 for lead Rare Disease asset Cortrophin Gel across core therapeutic areas (rheumatology, neurology, nephrology) and strong traction into new areas of opportunity (pulmonology and ophthalmology)
- Cortrophin Gel momentum has continued in Q2 with a record number of new patient starts in April followed by new record in May
- Continued to leverage exceptional new product launch execution (six new products launched in Q1), operational excellence, and U.S.-based manufacturing footprint to reliably serve patients in Generics and Established Brands

Q1 Revenues
$137M
29% YoY

Q1 Adj. non-GAAP EBITDA(1)
$38M
14% YoY

Q1 Diluted non-GAAP EPS(1)
$1.21
3% YoY

Q1 Adj. non-GAAP Net Income
$23M
21% YoY

Q1 Rare Disease Revenues
$37M
126% YoY

Q1 Generic, Established Brands, and Other Revenues
$100M
11% 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[2]	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 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.
2. 2024 guidance initially provided on February 29, 2024, and reiterated on May 10, 2024.

ANI Rare Disease: the story behind long-term sustainable lead asset Purified Cortrophin® Gel

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

Launched
January 2022

- Cortrophin Gel is purified corticotropin (ACTH), a treatment option for patients struggling with certain chronic autoimmune disorders
- Limited competition (only one other ACTH product on the market); long-term sustainability driven by high barriers to entry
- Estimated $600M ACTH market at launch in 2022; ~$1.2B category at peak in 2017; potential for significant future growth among both new and returning prescribers
- Approved for multiple indications; initially launched into therapeutic areas of neurology, nephrology and rheumatology; recently expanded into pulmonology and ophthalmology
- Re-introduced a much-needed patient and physician choice into the U.S. ACTH market (only one ACTH product had been available for multiple decades)

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

Growth in specialties targeted at launch[1]

- Continued prescription growth for original therapeutic areas of neurology, nephrology and rheumatology
- Prescribing momentum across existing and new prescribers
- Highest number of new patient starts in April followed by new record in May

Gaining traction in new therapeutic areas

- Given strong traction in pulmonology, added a second geographical region to pulmonology sales force in Q1 2024
- Highest number of new patient starts in pulmonology in Q1 2024
- Deployed a targeted ophthalmology sales force in Q1 2024
- Launched 1-mL vial size of Cortrophin Gel during Q4 2023, the only approved ACTH therapy indicated for the treatment of acute gouty arthritis flares

Expansion of market and Rare Disease platform

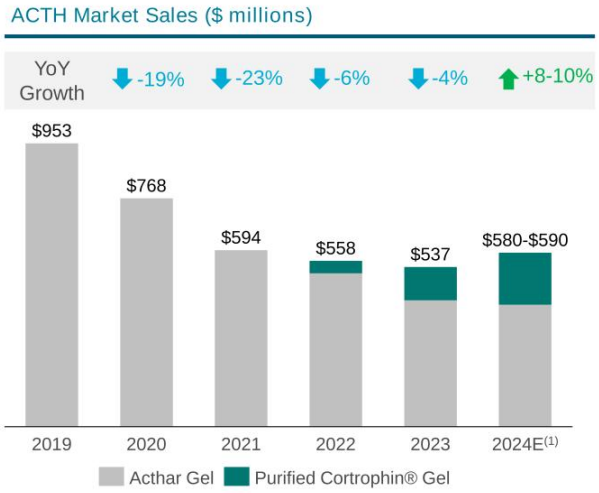
- Number of patients on ACTH therapy today is substantially lower than a few years ago, with room for significant growth
- Expanding the scope and scale of our Rare Disease business through M&A and in-licensing remains a high priority
- ANI has infrastructure and capabilities across medical affairs, patient support, specialty pharmacy distribution, and market access

Rare Disease Revenues ($ millions)[2]

Full year 2024 guidance of $170 - $180 million[3]

1. Purified Cortrophin® Gel was launched in January 2022.
2. Revenues declined from Q4 to Q1 in each year due to insurance resets and channel dynamics that are typical for Rare Disease products.
3. 2024 guidance initially provided on February 29, 2024 and reiterated at 2nd quarter earnings on May 10, 2024.

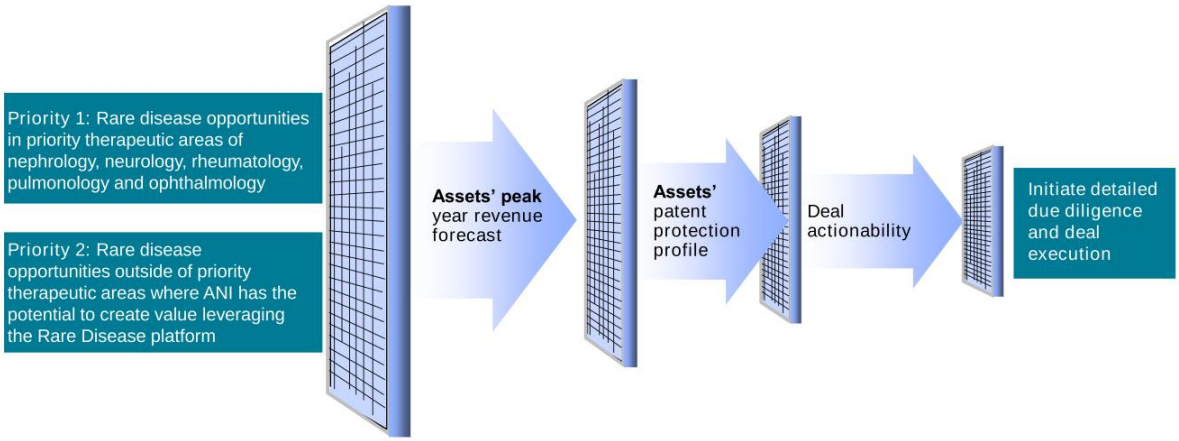
ACTH market is expected to return to growth in 2024 and we believe Cortrophin Gel remains on a strong multi-year growth trajectory



- Since the launch of Cortrophin Gel in 2022, the ACTH class has stabilized on a dollar basis after years of declines
- In 2024, the ACTH category is expected to grow ~8-10%+ on dollar basis
- Number of patients on ACTH therapy today is substantially lower than a few years ago, with room for significant growth

1. Cortrophin Gel 2024 guidance initially provided on February 29, 2024, and reiterated on May 10, 2024. MNK expects a low single-digit sales decline for Acthar Gel in 2024 per its first quarter 2024 earnings release (May 9, 2024). ACTH market sales of $580-590 million for 2024E is based on Cortrophin Gel guidance + Acthar Gel sales assuming a 3-4% YoY decline.

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



Strong balance sheet to support Rare Disease business development

	2022	2023	Q1'2024[2]
Cash & Cash Equivalents	$48M	$221M	$229M
Net Debt/EBITDA	4.4x	0.5x	0.5x
Gross Debt	$297M	$294M	$293M
Net Debt	$249M	$73M	$64M
Adjusted Non-GAAP EBITDA [1]	$56M	$134M	$138M

Note: Items may not foot due to rounding.
1. Adjusted Non-GAAP EBITDA is a Non-GAAP financial measure.
2. Balance sheet metrics as on March 31, 2024; Adjusted Non-GAAP EBTIDA represents trailing twelve-month period.

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

Robust pipeline and new product launch execution
- Launched six new products during Q1 2024, including a Competitive Generic Therapy (CGT) product with 180-day exclusivity
- Number two ranking in CGT approvals and top 15 manufacturer in number of product approvals
- Increasing 2024 R&D spend to 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 all sites
- Q1 2024 capacity expansion at New Jersey site
- 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
- Operational excellence and U.S.-based manufacturing footprint enables our ability to quickly respond to patient and customer needs
- Reliability, track record and nimbleness have established ANI as a partner of choice

Generics Revenues
($ millions)

2024 guidance of high single-digit/low double-digit growth[1]

1. Guidance initially provided on February 29, 2024, and reiterated on May 10, 2024.

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
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 • 20K ft^2 expansion added 17 new manufacturing suites and new QC lab • 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 DEA 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 driver of growth

- Largest expected driver of future growth
- Lead asset Cortrophin Gel forecasted at $170-$180M revenues in 2024[1] (+52% - 61%) with significant multi-year future growth opportunity
- 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 in the high single-digit to low double-digit range
- Demonstrated R&D excellence in filings and launch execution
- Providing reliability of supply with US-based manufacturing and strong GMP track record

Financial Strength

- $229M unrestricted cash[2]
- $119M cash flow from operations in 2023
- $520M - $542M estimated 2024 revenue[1] representing 7% - 11% year-over-year growth
- $135M-$145M estimated 2024 adjusted non-GAAP EBITDA
- $4.26-$4.67 estimated 2024 adjusted non-GAAP EPS

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. 2024 guidance initially provided on February 29, 2024, and reiterated on May 10, 2024.
2. As of March 31, 2024.

Adjusted non-GAAP EBITDA calculation – 1Q 2024 and 2023

	Three Months Ended March 31, 2024	2023
Net Income	$ 18,207	$ 1,439
Add/(Subtract):		
Interest expense, net	4,600	7,696
Other expense, net	32	34
Provision for income taxes	7,128	726
Depreciation and amortization	14,686	14,700
Contingent consideration fair value adjustment	90	961
Restructuring activities	—	1,130
Gain on sale of building	(5,347)	—
Unrealized gain on investment in equity securities	(9,655)	—
Impact of Canada operations (1)	—	1,647
Stock-based compensation	6,934	4,338
Novitium transaction expenses	713	342
Litigation expenses	245	—
Adjusted non-GAAP EBITDA	$ 37,633	$ 33,013

(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 (complete as of March 31, 2024). 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 EPS calculation – 1Q 2024 and 2023

	Three Months Ended March 31, 2024	2023
Net Income Available to Common Shareholders	$ 17,801	$ 1,033
Add/(Subtract):		
Non-cash interest (income) expense	(10)	987
Depreciation and amortization	14,686	14,700
Contingent consideration fair value adjustment	90	961
Restructuring activities	—	1,130
Gain on sale of building	(5,347)	—
Unrealized gain on investment in equity securities	(9,655)	—
Impact of Canada operations (1)	—	1,647
Stock-based compensation	6,934	4,338
Novitium transaction expenses	713	342
Litigation expenses	245	—
Less:		
Estimated tax impact of adjustments (calc. at 26% and 24% for the three months ended March 31, 2024 and 2023, respectively)	(1,991)	(5,785)
Adjusted non-GAAP Net Income Available to Common Shareholders (2)	$ 23,466	$ 19,353
Diluted Weighted-Average Shares Outstanding	19,422	16,531
Adjusted Diluted Weighted-Average Shares Outstanding	19,422	16,531
Adjusted non-GAAP Diluted Earnings per Share	$ 1.21	$ 1.17

(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 (complete as of March 31, 2024). 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.

(2) Adjusted non-GAAP Net Income Available to Common Shareholders excludes undistributed earnings to participating securities.