



*May 2023*



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## Non-GAAP Financial Measures

This presentation includes certain non-GAAP financial measures, including Adjusted EBITDA, 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 EBITDA is a non-GAAP financial measure that represents prior to interest expense, net, other expense, net, income taxes, and depreciation and amortization, as adjusted to add back certain non-cash and non-recurring charge. Adjusted EBITDA 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 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.

## Other Information

The Company has filed a registration statement on Form S-3 (including a base prospectus, Registration No. 333-239771) with the SEC for the offering to which this presentation relates, which was declared effective on July 17, 2020. Before you invest, you should read the prospectus supplement, the accompanying prospectus and the information incorporated therein by reference, including the Risk Factors set forth in those materials. When available, you may obtain these documents for free by visiting EDGAR on the SEC website [www.sec.gov](http://www.sec.gov) or from Guggenheim Securities, LLC, Attention: Equity Syndicate Department, 330 Madison Avenue, 8<sup>th</sup> Floor, New York, NY 10017, by calling (212) 518-9544 or by e-mail at [GSEquityProspectusDelivery@guggenheimpartners.com](mailto:GSEquityProspectusDelivery@guggenheimpartners.com).

# ANI Pharmaceuticals Is Well Positioned to Drive Sustainable Profitable Growth

Building a sustainable  
Biopharma company serving patients in need



**Strengthen generics business with enhanced R&D capability** focused on niche opportunities, cost-competitiveness and supply reliability



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

**Scaling up Rare Disease** business with **Purified Cortrophin Gel (PCG)** launch momentum and adding assets that leverage our Rare Disease infrastructure

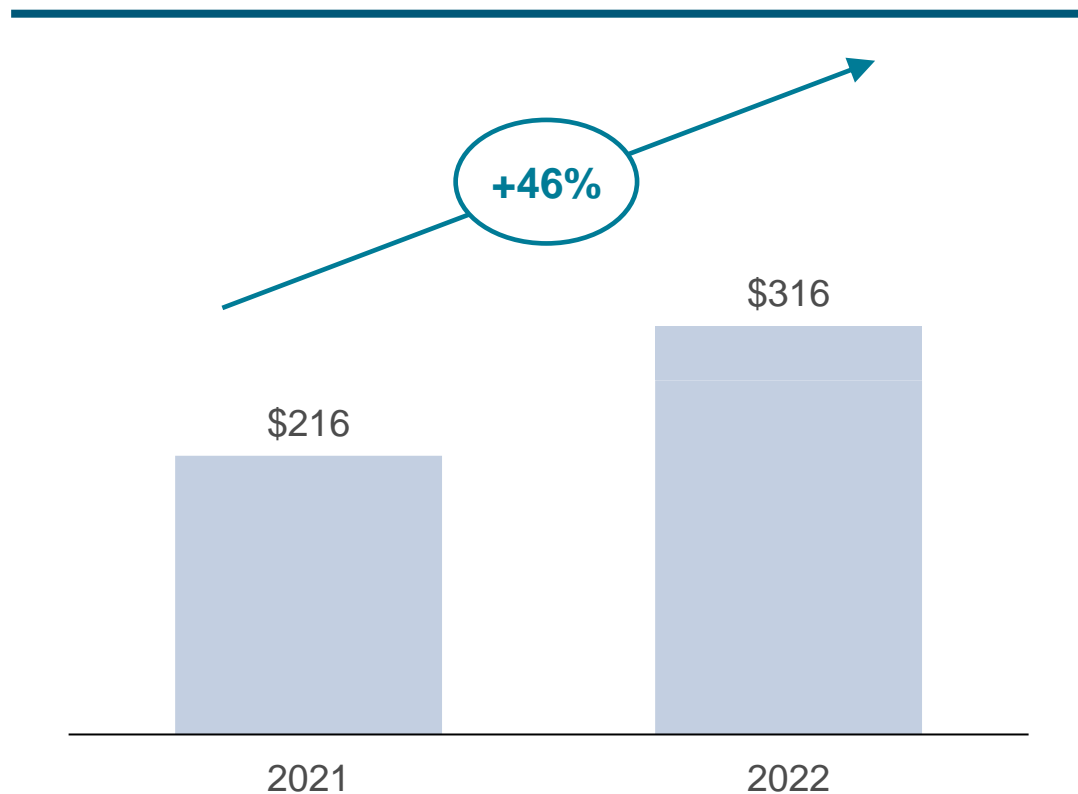


**Maximize value from Established Brands** through innovative go-to-market strategies

Empowered and experienced talent retaining core strengths and driving growth

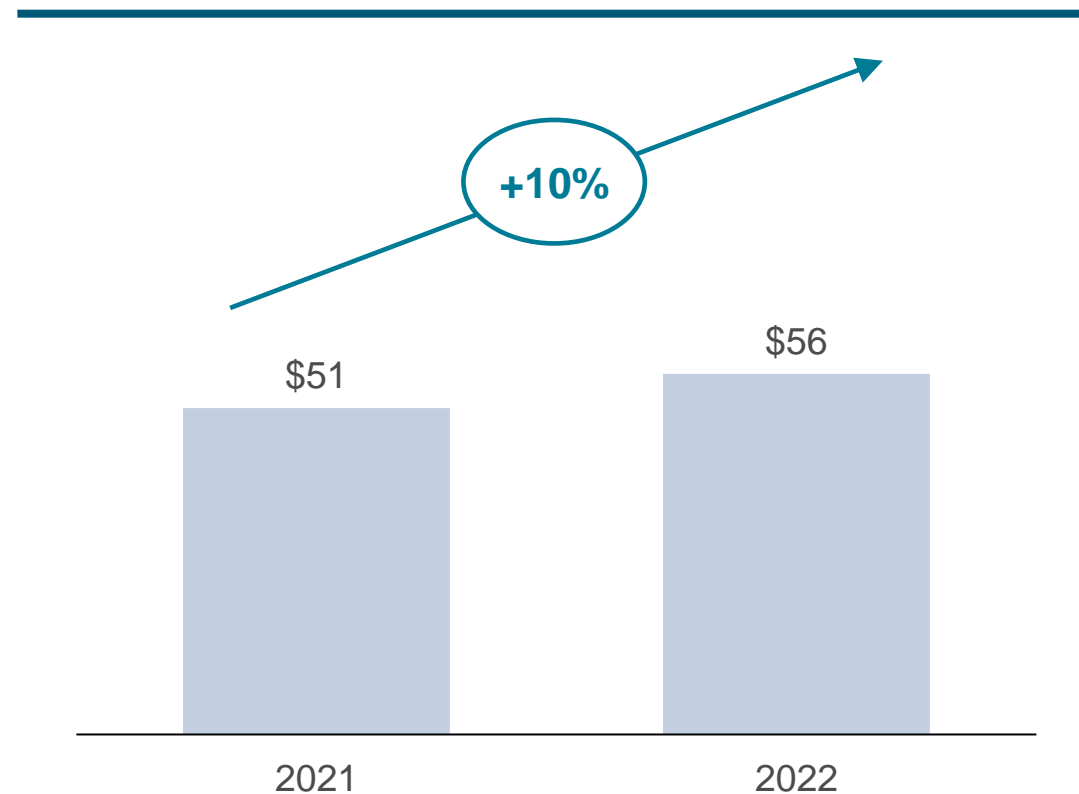
# 2022 was a Landmark Year for ANI, Which We Believe Creates Strong Growth Momentum for 2023 and Beyond

Revenues (\$ million)



Rare Disease segment expected to deliver significantly higher growth

Adjusted Non-GAAP EBITDA<sup>(1)</sup> (\$ million)

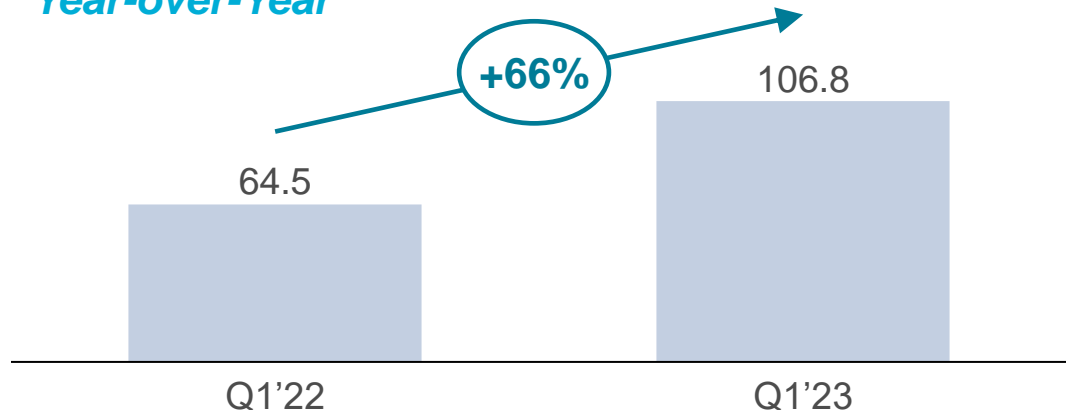


Investment in Rare Disease infrastructure

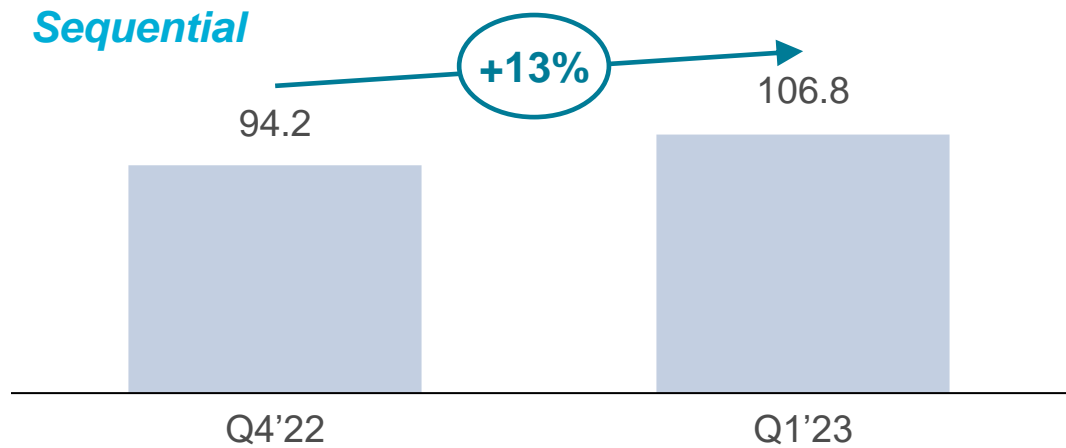
# ANI Achieved Record Quarterly Revenues and Adjusted Non-GAAP EBITDA in First Quarter of 2023

## Revenues (\$ million)

*Year-over-Year*

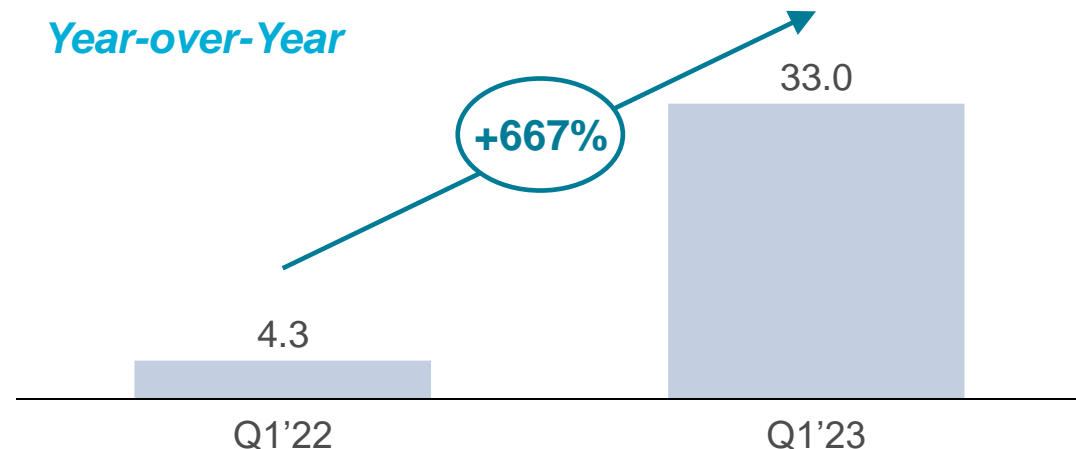


*Sequential*

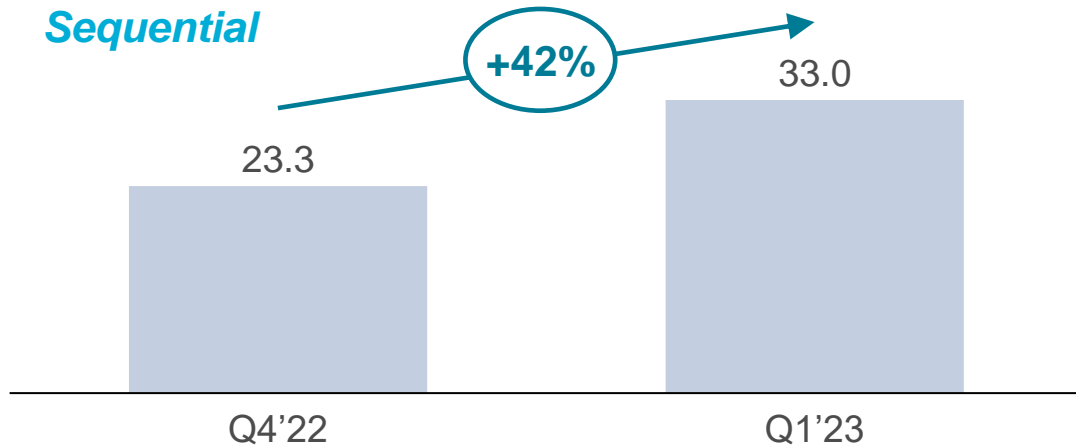


## Adjusted Non-GAAP EBITDA<sup>(1)</sup> (\$ million)

*Year-over-Year*



*Sequential*



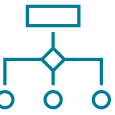
(1) Adjusted non-GAAP EBITDA is a non-GAAP financial measure. For reconciliation of Adjusted Non-GAAP EBITDA to the most directly comparable GAAP measure, please see Appendix A.

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



## Accelerating momentum with record quarterly number of new cases initiated in Q1'23 & record monthly new patient starts and cases initiated in April'23

- As of March 8, 2023, over 510 unique prescribers had initiated 1,120 new patient cases
- Continued growth in number of new unique prescribers and repeat prescribers
- Many prescribers who had previously slowed or discontinued use of the ACTH class have re-started their use of ACTH therapy after the launch of Purified Cortrophin Gel



## Prescriptions distributed across nearly all label indications with a promotional focus on rheumatology, neurology, nephrology, and pulmonology\*

- Ramped-up peer-to-peer education programs across three target specialties to further increase awareness of Cortrophin Gel
- Recruitment and onboarding of modest dedicated pulmonology sales team completed

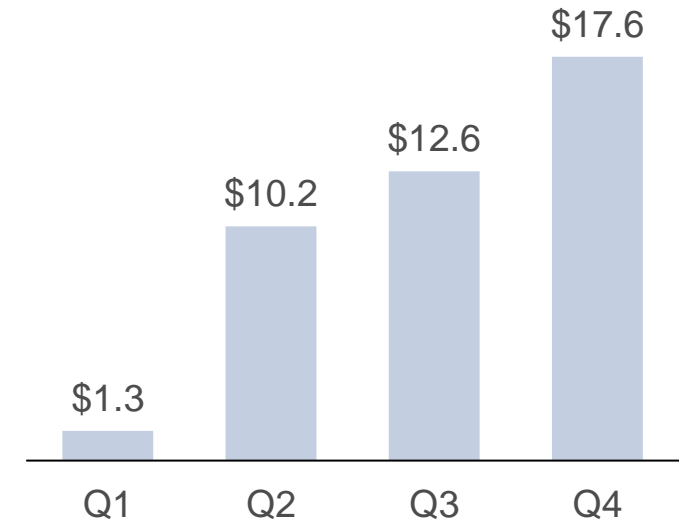


## Increased market access significantly for ACTH class for appropriate patients in need



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

## 2022 Rare Disease Revenues (\$ million)

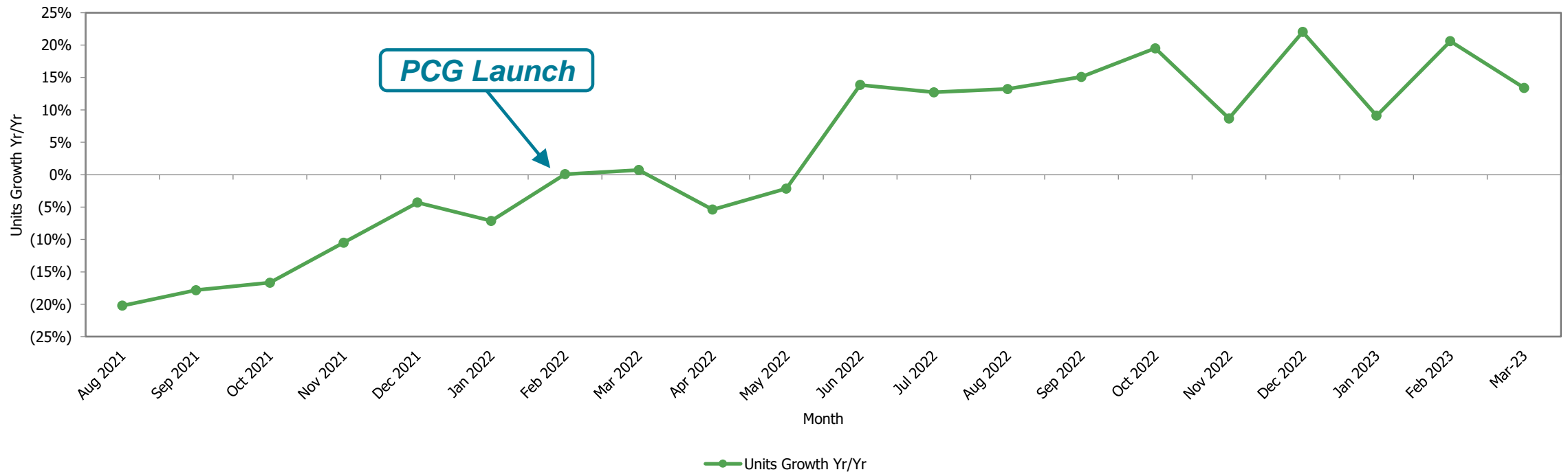


Q1'23 revenues of \$16.3 mn in line with expectations and on track for delivering full-year guidance

# Importantly, ACTH Class has Shown Year-Over-Year Unit Growth Since PCG Launch and for the First Time Since 2019



## ACTH Units – Year-over-Year Change



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

# Focused Efforts to Strengthen Generics Business, Enhancing Growth Momentum

## Superior pipeline and new product launch execution

- Increased R&D investment with focus on niche opportunities
- Filed 12 new ANDAs in 2022 and retained top 10 ranking in number of ANDA approvals
- Retained number two ranking in Competitive Generic Therapy approvals in 2022

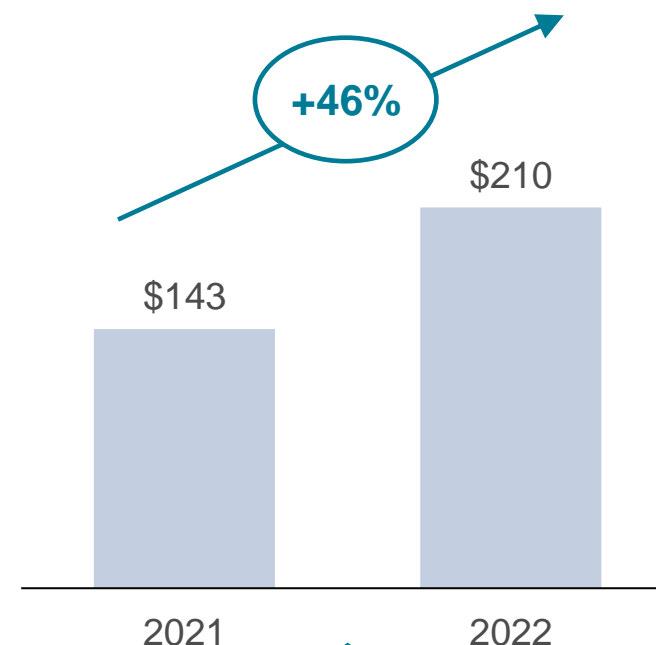
## Driving cost-excellence

- Consolidation of manufacturing network is on track with rationalization of manufacturing operations in Oakville
- Augmented our analytical and development facility in Chennai, India with over 60 skilled colleagues

## Ensuring reliability of supply

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

## Generics Revenues (\$ million)



Q1'23 revenues of \$63.7M demonstrated 30% growth over Q1'22

Successful Novitium acquisition driving significant growth



# Entirely 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**  
100k 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<sup>2</sup> of manufacturing, packaging, lab, warehouse, and administrative space
- Undergoing 20K ft<sup>2</sup> 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



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



**Stephen Carey**  
SVP, Finance & Chief Financial Officer



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



**Chris Mutz**  
Head of Rare Diseases / Cortrophin



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



**Krista Davis**  
SVP, Human Resources & CHRO



- 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



- 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



**Ori Gutwerg**  
SVP, Generics



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



**Samy Shanmugam**  
COO, New Jersey Operations & Head of Global R&D



- 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



**James Marken**  
SVP, Operations & Product Development



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



**Chad Gassert**  
SVP, Corporate Development & Strategy



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

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# EBITDA Reconciliation – 1Q 2023 and 2022

## Adjusted non-GAAP EBITDA Calculation and US GAAP to non-GAAP Reconciliation

(unaudited, in thousands)

	Three Months Ended	
	March 31,	
	2023	2022
<b>Net Loss</b>	<b>\$ 1,439</b>	<b>\$ (20,130)</b>
Add/(Subtract):		
Interest expense, net	7,696	6,613
Other expense, net	34	89
Income tax provision (benefit)	726	(5,767)
Depreciation and amortization	14,700	14,557
Contingent consideration fair value adjustment	961	753
Restructuring activities	1,130	-
Impact of Canada operations <sup>(1)</sup>	1,645	-
Stock-based compensation	4,337	3,237
Excess of fair value over cost of acquired inventory	-	3,829
Novitium transaction expenses	342	1,092
<b>Adjusted non-GAAP EBITDA</b>	<b>\$ 33,010</b>	<b>\$ 4,273</b>

<sup>(1)</sup> 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 is complete 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.

# EBITDA Reconciliation – 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	December 31, 2021
<b>Net Loss</b>	<b>\$ (47,896)</b>	<b>\$ (42,603)</b>
Add/(Subtract):		
Interest expense, net	28,052	11,922
Other expense, net <sup>(1)</sup>	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 <sup>(2)</sup>	2,740	-
Stock-based compensation	14,599	10,489
Asset impairments <sup>(3)</sup>	-	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
<b>Adjusted non-GAAP EBITDA<sup>(4)</sup></b>	<b>\$ 55,865</b>	<b>\$ 50,611</b>

- (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.

# ANI's Strong Business Development Engine Fueled Growth in Earlier Years

Generics		
Class	Seller	Products
2022	Oakrum Pharma	4 limited competition ANDAs
2020	Harris	Fluconazole
	Ricon	Clobetasol cream
	Amerigen	23 Gx Products
2019	Coceptis	7 Gx Products
	Cambrex	Lidocaine
	Pii	Bretylium
	Teva	31 ANDAs
2018	Appco	Ranitidine + Chlorzoxazone
	Impax	7 Gx Products
	IDT	23 ANDAs
2016	Aspen	Brethine
	H2	Lipofen AG + HC Rectal Cream
2015	Teva	Basket #2 – 22 ANDAs
	Teva	Flecainide
2013	Teva	Basket #1 – 31 ANDAs
	Sofgen	Nimodipine + Omega

Brands		
Class	Seller	Products
2021	Sandoz	Veregen Oxistat Apexicon Pandel
2018	AZ	Atacand & Atacand HCT
		Casodex & Arimidex
2017	Cranford	Inderal XL
		Innopran XL
2016	Akrimax	Inderal LA/Prop ER
2016	Merck	Cortrophin
2014	Shire	Vancocin
	Noven	Lithobid
2011	Meda	Reglan