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 9, 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 June 9, 2023, ANI Pharmaceuticals, Inc. (the "Company") provided an investor presentation at the Jefferies Healthcare Conference in New York, New York. 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 June 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: June 9, 2023

ANI PHARMACEUTICALS, INC.

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

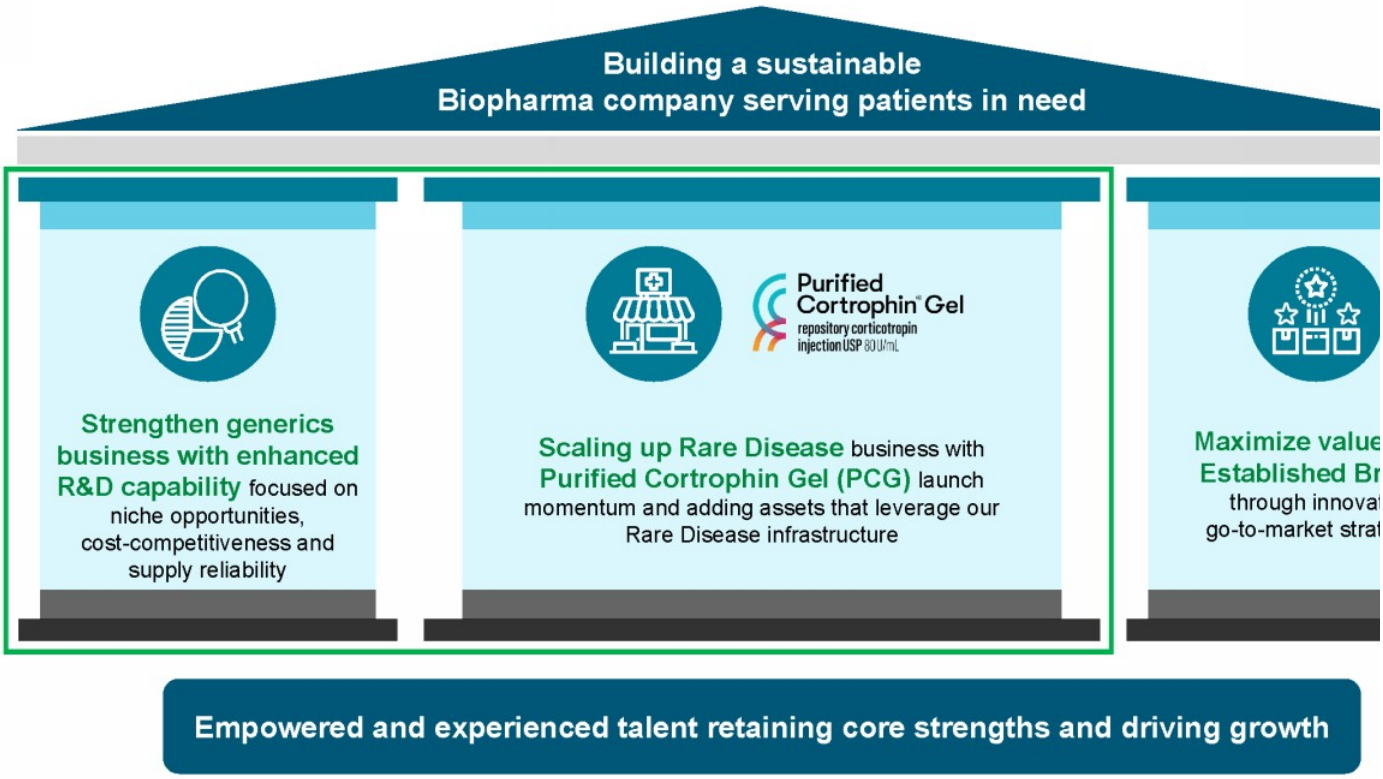
Disclaimer

This presentation by ANI Pharmaceuticals, Inc ("ANI" or the "Company") contains forward-looking statements, including information about management's view of the Co 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 ac development, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be different than those expressed or implied in such statements. Unknown or unpredictable factors also could have material adverse effects on the Company's future result concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the "Risk Fa the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in the Company's other periodic reports and filings with the Securities and Commission ("SEC"). The forward-looking statements included in this presentation are made only as of the date hereof. The Company cannot guarantee future results, le performance or achievements and you should not place undue reliance on these forward-looking statements. We undertake no obligation to update any forward-lookin 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, e by law.

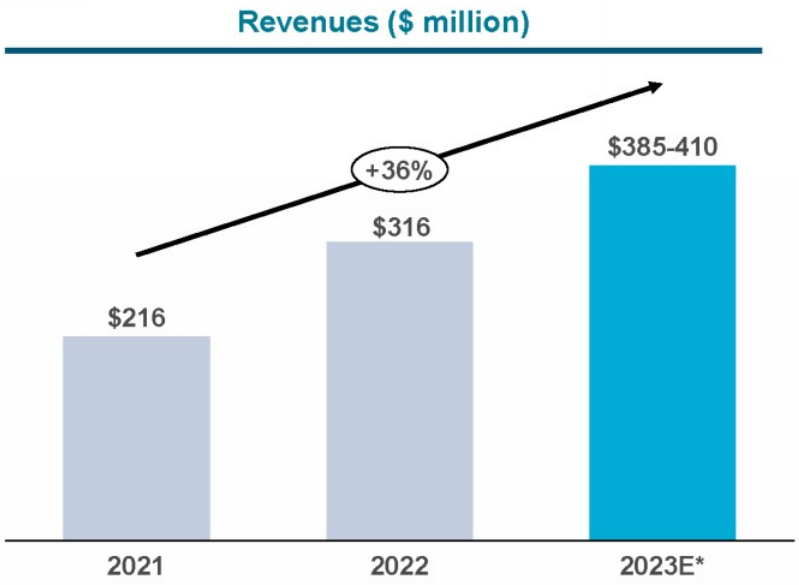
Non-GAAP Financial Measures

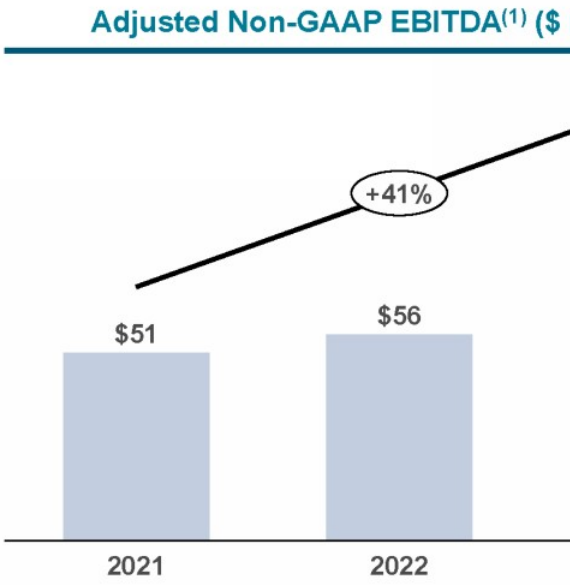
This presentation includes certain non-GAAP financial measures, including Adjusted EBITDA, that management reviews to evaluate its business, measure its performance strategic decisions. Management believes that such non-GAAP financial measures provide useful information to investors and others in understanding and evaluating its 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 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 m calculated in accordance with GAAP and should not be considered as substitutes for revenue, net income, operating profit, or any other operating performance measure accordance with GAAP. Using these non-GAAP financial measures to analyze the business would have material limitations because their calculations are based on the su determination of management regarding the nature and classification of events and circumstances that investors may find significant. In addition, although other compa may report measures titled Adjusted EBITDA or similar measures, such non-GAAP financial measures may be calculated differently from how management calculates its financial measures, which reduces their overall usefulness as comparative measures. Because of these limitations, you should consider Adjusted EBITDA alongside other performance measures, including net income and other financial results presented in accordance with GAAP. Please refer to the Appendix in this presentation for a reco non-GAAP financial measure to the most directly comparable GAAP measure.

ANI Pharmaceuticals Is Well Positioned to Drive Sustainable Profitable



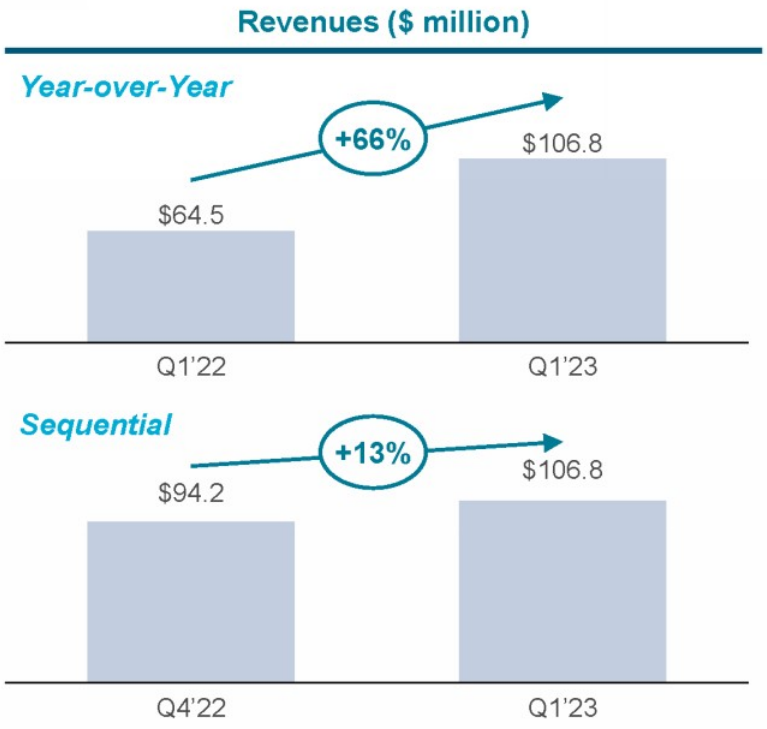
2022 Was a Landmark Year for ANI, Which We Believe Creates Strong
Momentum for 2023 and Beyond

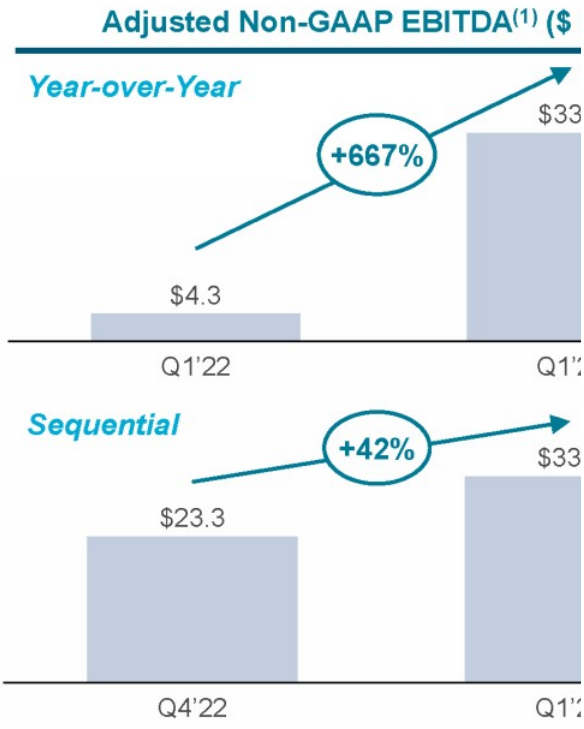




(1) Adjusted non-GAAP EBITDA is a non-GAAP financial measure. For reconciliation of Adjusted Non-GAAP EBITDA to the most directly comparable GAAP measure,
* CAGR is calculated based on midpoint.

ANI Achieved Record Quarterly Revenues and Adjusted Non-GAAP EBI First Quarter of 2023





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

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

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

- 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

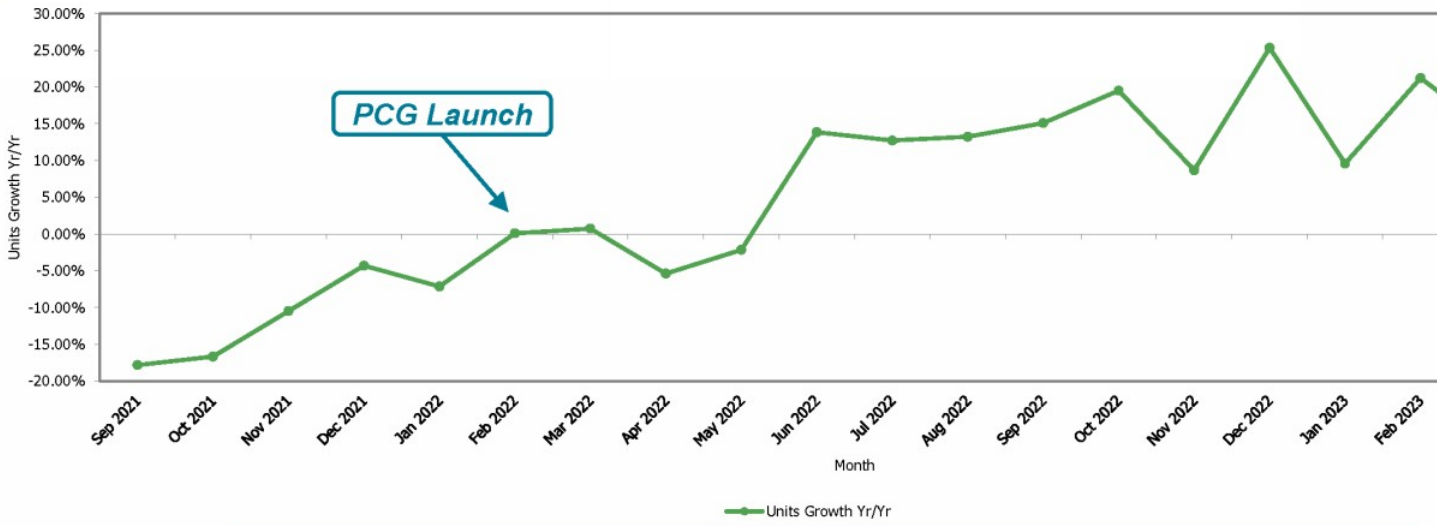
2022 Rare D
Revenues ($

Q1'23 revenues of
with expectations
delivering full-year

* Initiated in 2023.

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 April 2023, the ACTH category has demonstrated eleven months of consecutive year-over-year growth

Source: IQVIA

Focused Efforts to Strengthen Generics Business, Enhancing Growth M

Superior pipeline and new product launch execution

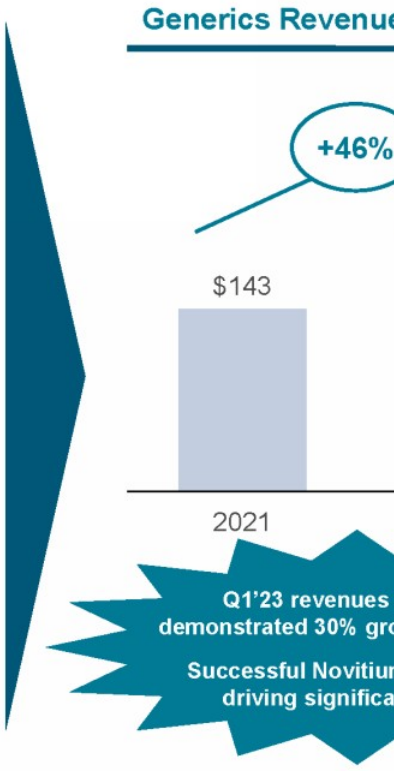
- Increased R&D investment with focus on niche opportunities
- Filed 12 new ANDAs in 2022 and retained top 10 ranking in number of ANDA approvals
- With the recent approvals, ANI **shares the leadership position on Competitive Generic Therapy (CGT) approvals**

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



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 Windsc** *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^2 of manufacturing, warehouse, and administra • Undergoing 20K ft^2 expans manufacturing suites • Solid oral tablets and capsu and solutions, powder for o controlled substances as w nano-milling • API development & low vol
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 • Packaged Units ~20MM un • 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 20* **Latest inspection – March 2** **Results: NAI status & Zero**

Executive Leadership Team with Proven Track Records and Broad Indust

Nikhil Lalwani
President & Chief Executive Officer

Cipla · McKinsey & Company

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

Chris Mutz
Head of Rare Diseases / Cortrophin

MERCK · ALEXION

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

Meredith Cook
SVP, Legal & General Counsel

amneal · ML

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

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

PAR PHARMACEUTICAL · NOVEL

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

Chad Gassert
SVP, Corporate Development & Strategy

PAR PHARMACEUTICAL · SANDOZ

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

Stephen Carey
SVP, Finance & Chief Financial Officer

- 30+ years financial executive experience
- Former SVP. Controller and Principal Accounting Offi Pharmaceuticals

Krista Davis
SVP, Human Resources & CHRO

- 20 years of leadership experience in HR, talent mana organizational development across industries and cul
- Former Global Head, People & Organization for Nova

Ori Gutwerg
SVP, Generics

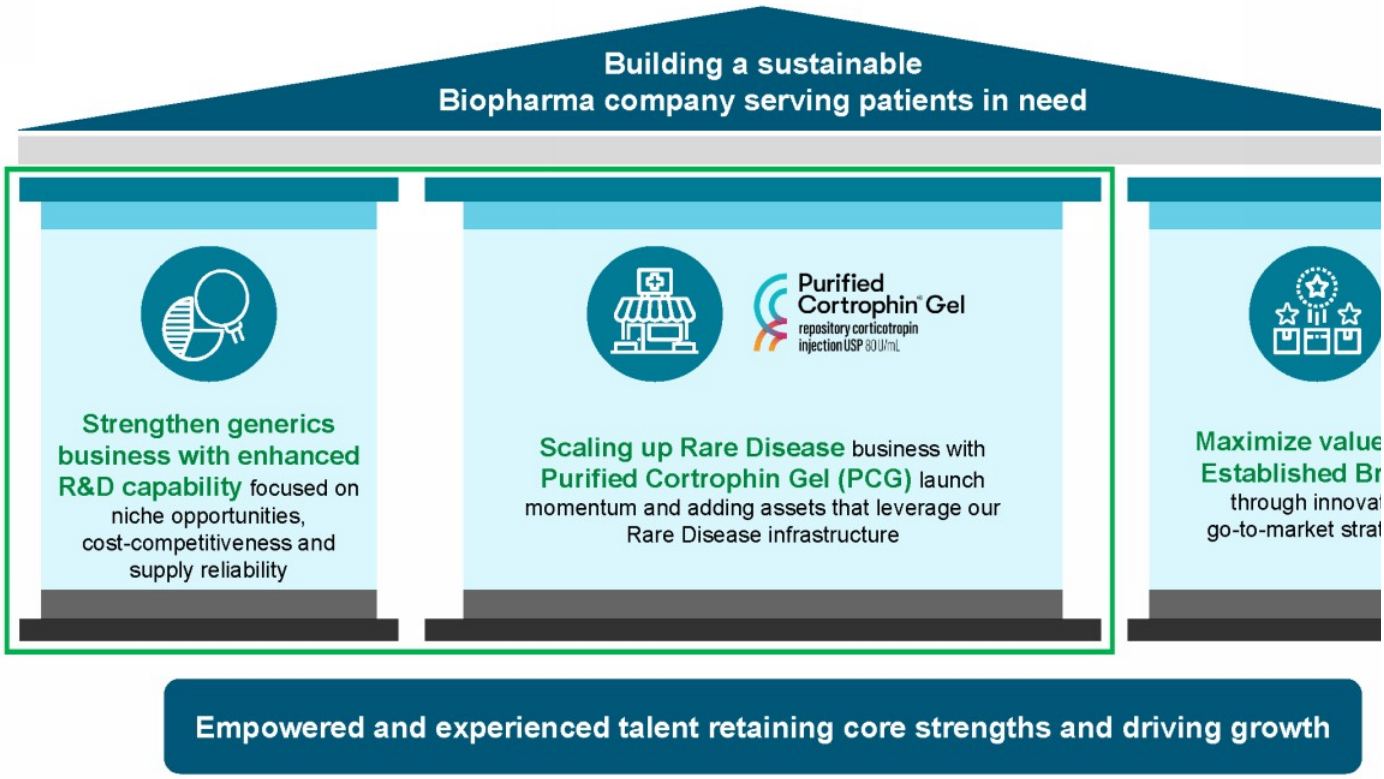
- 17+ years pharmaceutical experience across generic and b
- Proven track record of business development and accelera

James Marken
SVP, Operations & Product Development

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

ani Pharmaceuticals, Inc.

ANI Pharmaceuticals Is Well Positioned to Drive Sustainable Profitable



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
Net Loss	**$ 1,439**	**$ (20,130)**
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 [(1)]	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
Adjusted non-GAAP EBITDA	**$ 33,010**	**$ 4,273**

[(1)] Impact of Canada operations includes CDMO revenues, co revenues, all selling, general, and administrative expenses, an expenses recorded in Canada in the period presented, exclusi stock-based compensation, and depreciation and amortizatior respective line items above. The adjustment of Canada operat of sales and expense that will not recur after the completion o operations, which is complete as of March 31, 2023. The adju does not adjust for revenues, cost of sales, and expense that manufacturing facilities after the transfer of certain manufactu

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	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 inc
ANDA during the three months ended December 31, 20
$1.9 million of income related to the sale of an ANDA d
December 31, 2022 and 2021, respectively.

(2) Impact of Canada operations includes CDMO revenues
revenues, all selling, general and administrative expens
development expenses recorded in Canada in the perio
restructuring activities, stock-based compensation, and
which are included within their respective line items abo
operations represents revenues, cost of sales and expe
completion of the closure of our Canada operations, ex
31, 2023. The adjustment of Canada operations does
sales, and expense that will recur at our other manufact
of certain manufacturing activities is complete.

(3) For the three and twelve months ended December 31,
comprised of an ANDA intangible asset impairment and
charge.

(4) Beginning in the fourth quarter of 2022, ANI will no long
Process Research & Development or Cortrophin pre-la
marketing expenses from its non-GAAP results. Historic
these charges. These changes are being made to align
U.S. Securities and Exchange Commission. Prior perio
these changes.

- For the twelve month period ended December 31,
measures have been recast to include $1.2 million
and a corresponding reduction in full year Adjusted
compared to the amount reported in our third quart
associated Form 8-K.
- For the twelve month period ended December 31,
been recast to include $780K of additional Purified
charges and $13.4 million of Cortrophin related SG
corresponding reduction in full year Adjusted non-G

ANI's Strong Business Development Engine Fueled Growth in Earlier

Generics		
Class	**Seller**	**Products**
2022	Oakrum Pharma	4 limited competition ANDAs
2020	Harris	Fluconazole
	Ricon	Clobetasol cream
	Amerigen	23 Gx Products
2019	Coeptis	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