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ANI Pharmaceuticals

US-focused diversified biopharmaceuticals company with Rare Disease, Generics, Established Brands & CDMO businesses, poised for strong and sustainable growth



Strong trajectory for launch of lead Rare Disease asset Purified Cortrophin® Gel¹

- Transformational opportunity in ~\$600MM ACTH market
- Since Q1 2022 launch, 500 new patient cases initiated by 250+ unique prescribers
- Raised Cortrophin Gel 2022 net revenue guidance to \$40MM - 45MM at Q2 earnings call



Sustainable Generics growth engine established

- Sales of generics pharmaceuticals grew 46% year-over-year in the 2nd quarter
- Company ranked 6th across 100+ companies in number of ANDA approvals in last 12 months
- Consolidating manufacturing operations and driving operational efficiencies to improve cost-basis



Proven acquirer of branded and generic products to complement organic growth

- Closed ~2-4 deals each year for last 8 years
- Acquired four limited competition ANDAs from Oakrum Pharma in July 2022



Strong CAGR growth 2018 to 2022E:



11%
Revenues



7%
Gross Profit

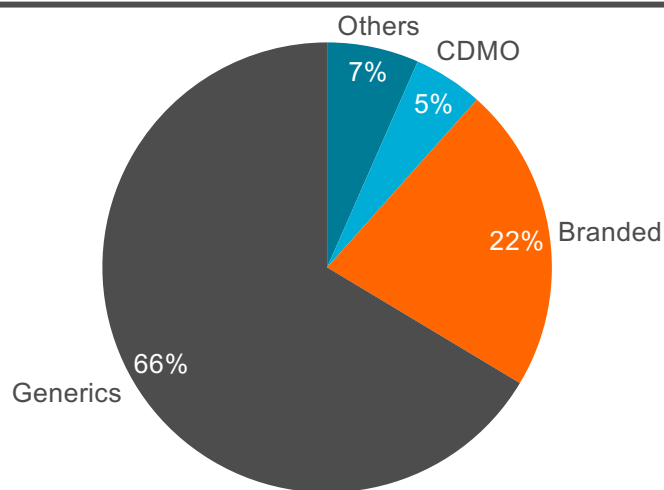


Strong GMP track record across sites – all in North America

⁽¹⁾Purified Cortrophin® Gel (Cortrophin)

Strong and Growing U.S.-Focused Biopharmaceuticals Company

Revenues (2021)



Cortrophin Gel launch will increase branded products share in 2022 revenues

ANI in Numbers

86

Generic Products

16

Branded Products

6%

Largest Product's
Percentage of Total Revenue in 2021

**\$216MM /
\$295MM - \$315MM**

2021 / 2022E Revenues

\$40MM - \$45MM

Cortrophin Gel 2022E Revenues

30%

2021 Adjusted
EBITDA Margin⁽¹⁾

56-58%

2022E Adjusted
Gross Margin⁽¹⁾

\$42MM - \$46MM

Investment in Cortrophin Gel launch
SG&A expenses in 2022

\$64.4MM / \$54MM - \$60MM

2021 / 2022E Adjusted EBITDA⁽¹⁾

⁽¹⁾ Non-GAAP financial measure

Cortrophin Gel is a transformational opportunity for ANI; potential significant growth driver with commercial longevity

~\$600M

ACTH market in 2021

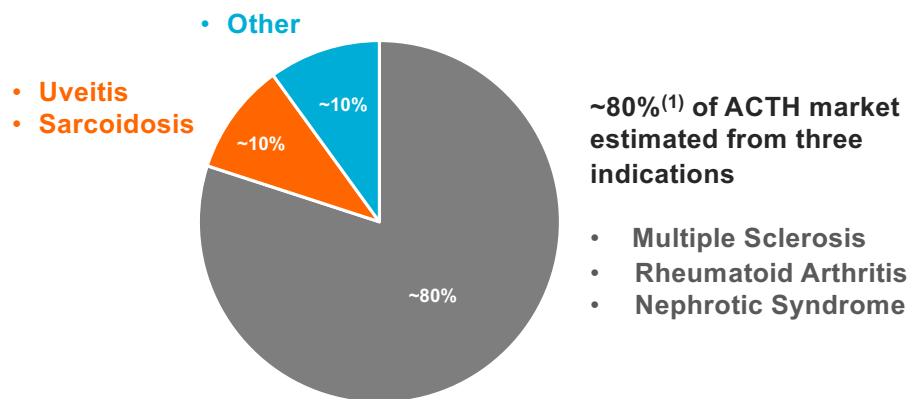
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Competitor in-class

Launched

January 24, 2022

















Cortrophin Gel is approved for all current ACTH indications, with the exception of infantile spasms



Cortrophin Gel is the only ACTH-based therapy approved for the treatment of gouty arthritis

(1) Source: EvaluatePharma 2021; claims analysis

Experienced Rare Disease Leadership Team to Deliver a Successful Launch

Team Member		Position	Prior Experience	
	Chris Mutz	CCO Head of Rare Disease	<ul style="list-style-type: none"> 25+ years industry experience Commercial leadership at Alexion & Merck 7 rare disease launches 	 
	Mary Pao Seideman, MD/PhD	Chief Medical Officer	<ul style="list-style-type: none"> Hematologist / Oncologist Global and NA Medical Affairs leadership at GSK and Genentech 10 years launch consulting experience in rare disease, autoimmune disease, and oncology 	 
	Holly Zickler	VP Sales	<ul style="list-style-type: none"> 10+ years sales leadership experience Rare disease expertise and ACTH insight 	 
	Sherry Korczynski	VP Marketing Advocacy Patient Services	<ul style="list-style-type: none"> 25+ years industry experience 15 years with Lilly Led EpiPen marketing 	 
	Bill Mrocza, JD	VP Market Access Trade & Distribution	<ul style="list-style-type: none"> 25+ years industry experience Multiple rare disease launches 	 
	Mike Riffard	VP Operations	<ul style="list-style-type: none"> 25+ years industry experience Led commercial ops function at Sunovion 	 
	Elizabeth Powell	Chief Compliance Officer and Head of Legal	<ul style="list-style-type: none"> 25+ years industry experience Managing counsel, regulatory and commercial legal 	  <small>COUNSELORS AT LAW</small>

Cortrophin Gel Launch

First 6 Months ⁽¹⁾



Raised 2022 Cortrophin Gel revenue guidance to \$40MM to \$45MM from \$35MM to \$40MM



Over 250 unique prescribers have initiated 500+ new patient cases

- Approximately one third of unique prescribers have enrolled more than one patient
- Since Q1 earnings report, new patient cases and unique prescribers have doubled



Prescriptions distributed across nearly all label indications with a promotional focus on Rheumatology, Neurology and Nephrology



Continued strengthening of infrastructure, including expansion hub, patient support services, and distribution network



Average time from new case initiation to patient dispense has significantly improved since launch



Formulary coverage for 134 million+ lives

- On July 1, Cortrophin Gel was added to the formulary of United Health's Commercial & Managed Medicaid plans

⁽¹⁾ As of August 5, 2022

Strong Business Development Engine Fueled Growth of Established Brands & Generics Business Units Over The Years

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 Noven	Vancocin Lithobid
2011	Meda	Reglan

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	Bretylum
	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

Novitium acquisition: Added best-in-class R&D engine with Generics and 505(b)(2) capabilities

#6

Post-acquisition, ANI ranked number 6 in number of ANDA approvals in past 12 months

#1

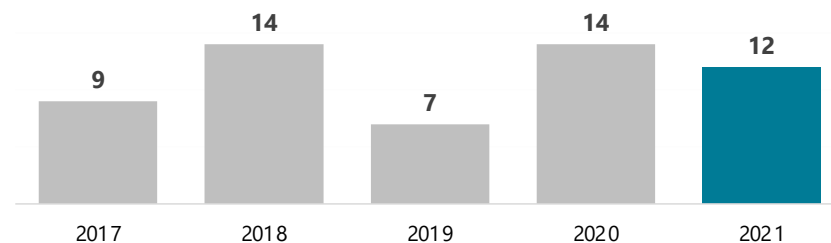
Retained position as leader in Competitive Generic Therapy (CGT) approvals

3

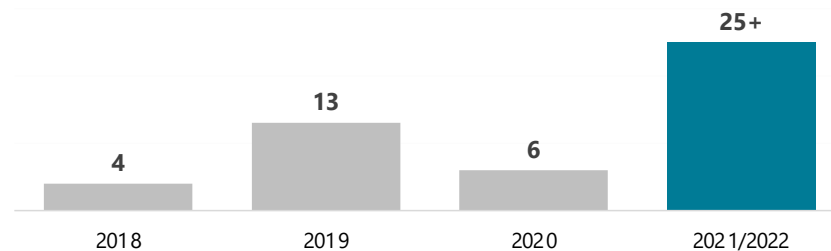
505(b)(2) candidates in oncology and hypertension

Actual Expected

Annual ANDA Filings by Novitium



Annual Product Launches by Novitium



Significant Progress Made on Key Integration Priorities with Novitium

- Successfully launched several products with approximately \$600mm in annualized sales during 2022, per IQVIA
- Filed 8 new ANDAs in 2022 to help strengthen product pipeline
- Increased scale and therefore impact of new products added to pipeline



Ensured **business continuity** & **minimized disruption** on day 1



Accelerated capture of **high-value synergies**



Preserved **nimble decision making** with clear decision rights and process discipline



Energized, empowered, and retained key talent

Consolidation of Manufacturing Network to Capture Operational Synergies of \$7-\$8 million

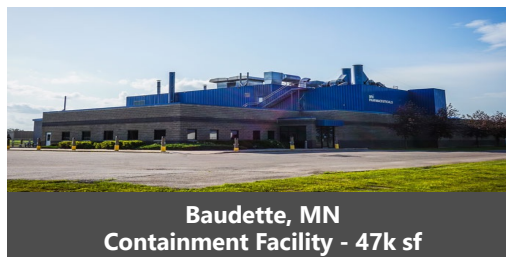
- Proactive step to drive **cost competitiveness** and **sustainability of generics** business
- Manufacturing network well positioned to ensure **new product launches** and **supply continuity** for patients and customers
- Operations at Oakville, Canada plant expected to end by **Q1 2023**
- Majority of products will be **transitioned to 1 of 3 sites** in the U.S.
- ANI will **seek buyer** for facility
- Estimated **\$7-\$8 million** annual benefit to profitability and cash flow

Significant North American Manufacturing Footprint

with ample capacity and strong GMP track record



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 ft² of manufacturing, packaging, lab, warehouse, and administrative space
- Undergoing 20K ft² 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 – April 2019;
Results: No 483

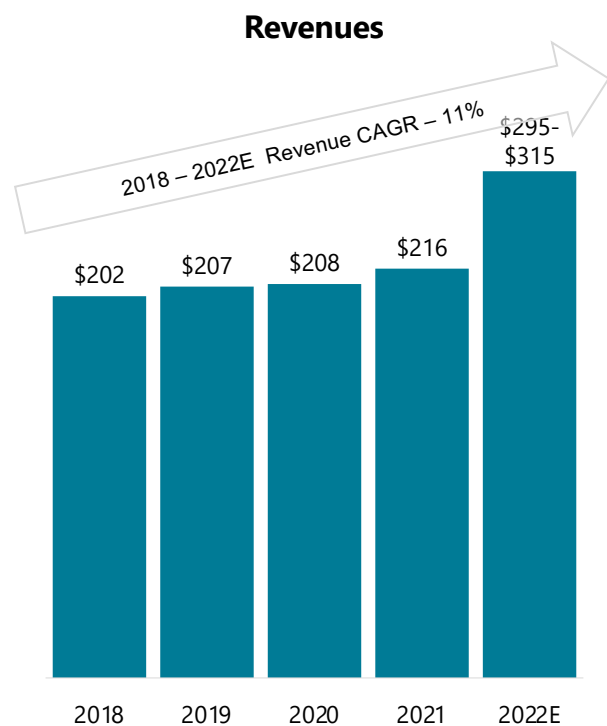
Six DEA inspections since 2013
Latest inspection – April 2021;
Results: No findings

Five FDA inspections since 2017
Latest inspection – July 2021;
Results: VAI status



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Poised for Return to Strong Financial Growth





APPENDIX



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EBITDA Reconciliation

Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation		
(unaudited, in thousands)		
	Year Ended December 31, 2021	Six Months Ended June 30, 2022
Net Loss	\$ (42,603)	\$ (35,053)
Add/(Subtract):		
Interest expense, net	11,922	13,282
Other expense, net ⁽¹⁾	6,243	75
Benefit for income taxes	(13,455)	(9,662)
Depreciation and amortization	47,252	28,321
Legal settlement expense	8,750	-
Contingent consideration fair value adjustment	500	(342)
Cortrophin Gel pre-launch charges and sales & marketing expenses ⁽²⁾	14,228	-
Stock-based compensation	10,489	6,992
Asset impairments ⁽³⁾	2,737	112
Restructuring activities	-	2,570
Impact of Canada operations ⁽⁴⁾	-	1,820
Excess of fair value over cost of acquired inventory	7,460	4,802
Novitium transaction expenses	9,382	1,217
Royalty settlement	1,934	-
Adjusted non-GAAP EBITDA	\$ 64,839	\$ 14,134

- (1) Adjustment to Other (income)/expense, net excludes \$750 thousand of income related to the sale of an ANDA during the three months ended June 30, 2022.
- (2) Beginning in 2022, we no longer adjust for "Cortrophin Gel pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP EBITDA.
- (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) Impact of Canada operations includes revenues and operating expenses, exclusive of restructuring activities, stock-based compensation and depreciation and amortization, which are included within their respective line items above.