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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



Launched Rare Disease Business Unit's lead asset, Purified Cortrophin® Gel¹

- Transformational opportunity in ~\$600MM ACTH market
- Launched early Q1 2022; 250 new patient cases initiated; 2022 revenue guidance \$35MM - 40MM



Strengthened Generics Business with enhanced R&D capability to fuel growth

- Completed acquisition of Novitium Pharma to bring complex, limited competition products to market
- Commercial team integrated; capturing synergies in Operations, Distribution, Procurement



Strong CAGR growth 2018 to 2022E:



12%
Revenues



10%
Gross Profit



Proven acquirer of branded and generic products to complement growth

- Closed 2-4 deals each year for last 8 years

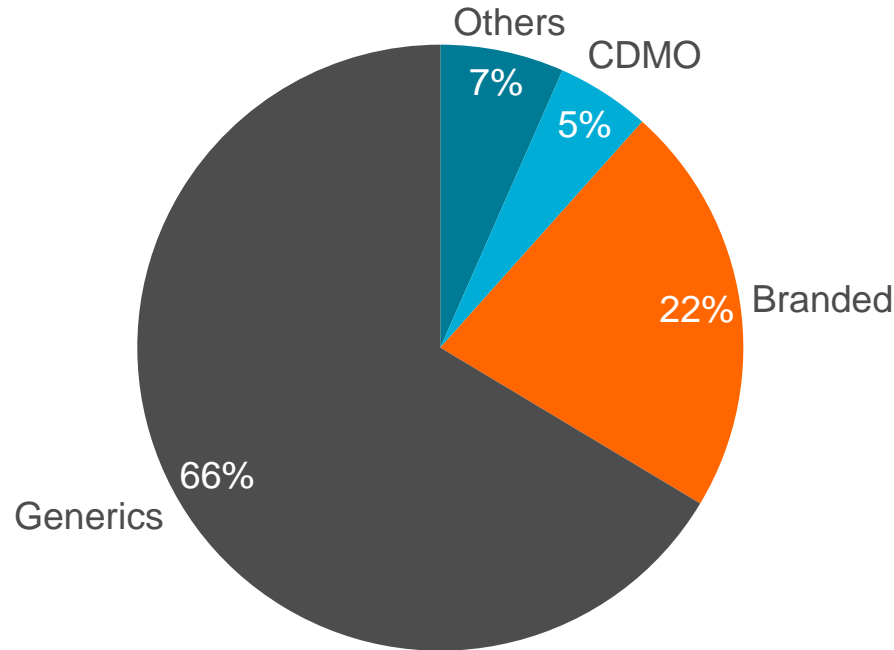


Strong GMP track record across sites – all in North America

⁽¹⁾Purified Cortrophin® Gel (Cortrophin)

Strong and Growing U.S.-Focused Biopharmaceuticals Company

Revenues (2021)



Purified 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

30%

2021 Adjusted EBITDA Margin

56-58%

2022E Adjusted Gross Margin

\$42MM - \$46MM

Investment in Cortrophin launch SG&A expenses in 2022

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

2021 / 2022E Adjusted EBITDA⁽¹⁾

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

~\$600M

ACTH market in 2021

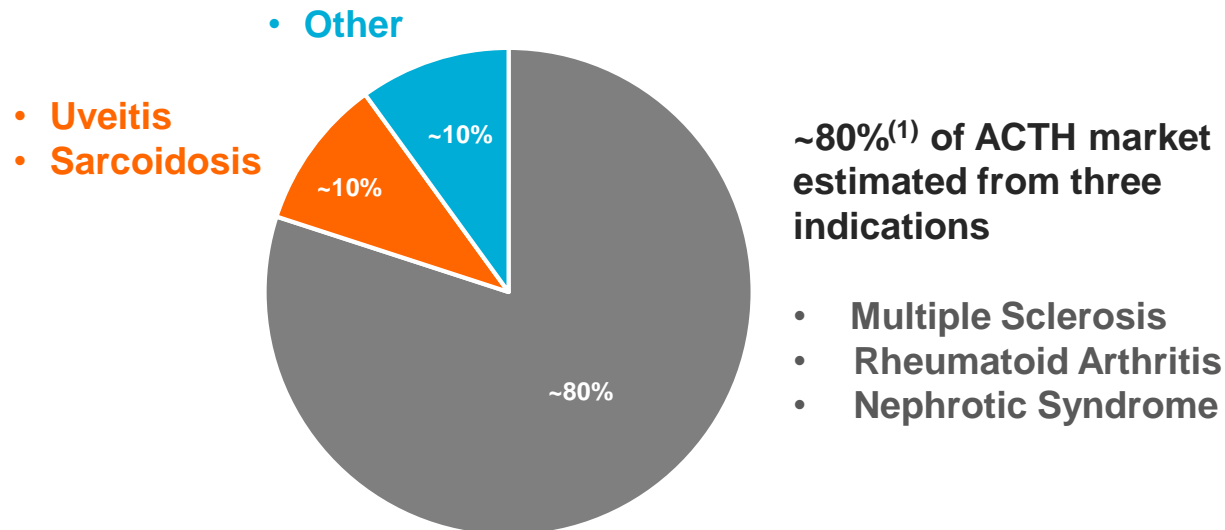
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Competitor in-class

Launched

January 24, 2022



















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



Cortrophin 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	
 <p>Chris Mutz</p>	CCO Head of Rare Disease	<ul style="list-style-type: none"> • 25+ Years industry experience • 11 Years with Merck • 8+ Years with Alexion • 7 Rare Disease launches 	 
 <p>Mary Pao Seideman, MD/PhD</p>	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 	 
 <p>Holly Zickler</p>	VP Sales	<ul style="list-style-type: none"> • 10+ Years Sales Leadership Experience • Rare Disease Expertise and ACTH Insight 	 
 <p>Sherry Korczynski</p>	VP Marketing Advocacy Patient Services	<ul style="list-style-type: none"> • 25+ Years industry experience • 15 Years with Lilly • Led EpiPen Marketing 	 
 <p>Bill Mrocza, JD</p>	VP Market Access Trade & Distribution	<ul style="list-style-type: none"> • 25+ Years industry experience • Multiple Rare Disease Launches 	 
 <p>Mike Riffard</p>	VP Operations	<ul style="list-style-type: none"> • 25+ Years industry experience • Led Commercial Ops Function at Sunovion 	 

Cortrophin Launch

First 15 Weeks ⁽¹⁾



Built experienced ~50-person Rare Disease salesforce

- Reached 50% of targeted prescribers



Over 125 unique prescribers have initiated 250+ new patient cases

- ~ 25% of unique prescribers have enrolled more than one patient



Initial enrollments distributed across target specialties of rheumatology, neurology, nephrology



Steady growth in number of new patient cases/week



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



Formulary coverage for 100 million+ lives

⁽¹⁾ As of May 10th, 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	Vancocin
	Noven	Lithobid
2011	Meda	Reglan

Generics		
Class	Seller	Products
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

~13
months

Average filing to approval time

#1

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

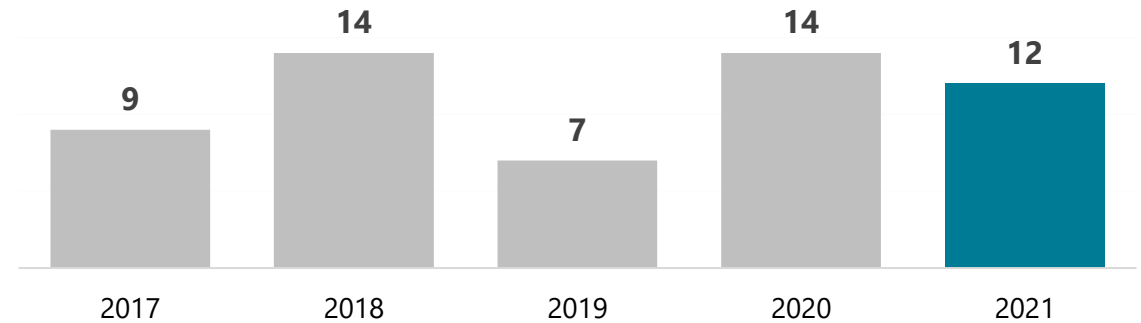
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505(b)(2) candidates in oncology and hypertension

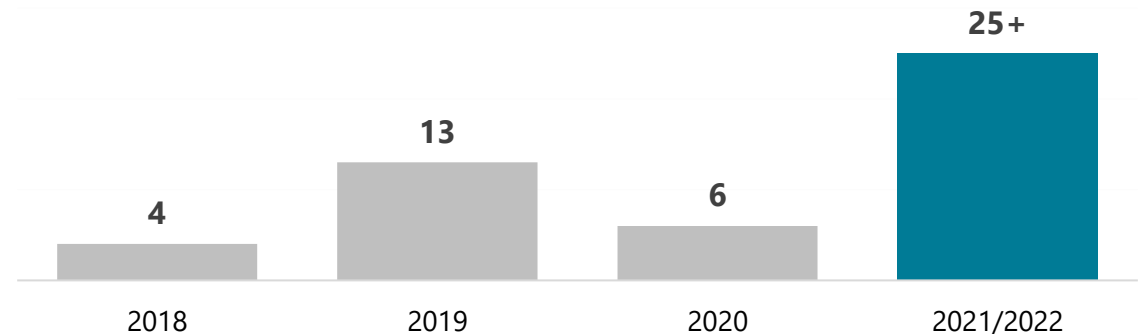
Novitium management has developed and commercialized over 100 ANDAs across specialty dosage forms in the U.S.

Actual Expected

Annual ANDA Filings by Novitium



Annual Product Launches by Novitium



Significant progress made against our key integration priorities with Novitium

- Successfully launched several products with approximately \$240mm in annualized sales in Q1 2022, per IQVIA
- Filed 6 new ANDAs in 2022 to help strengthen our 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

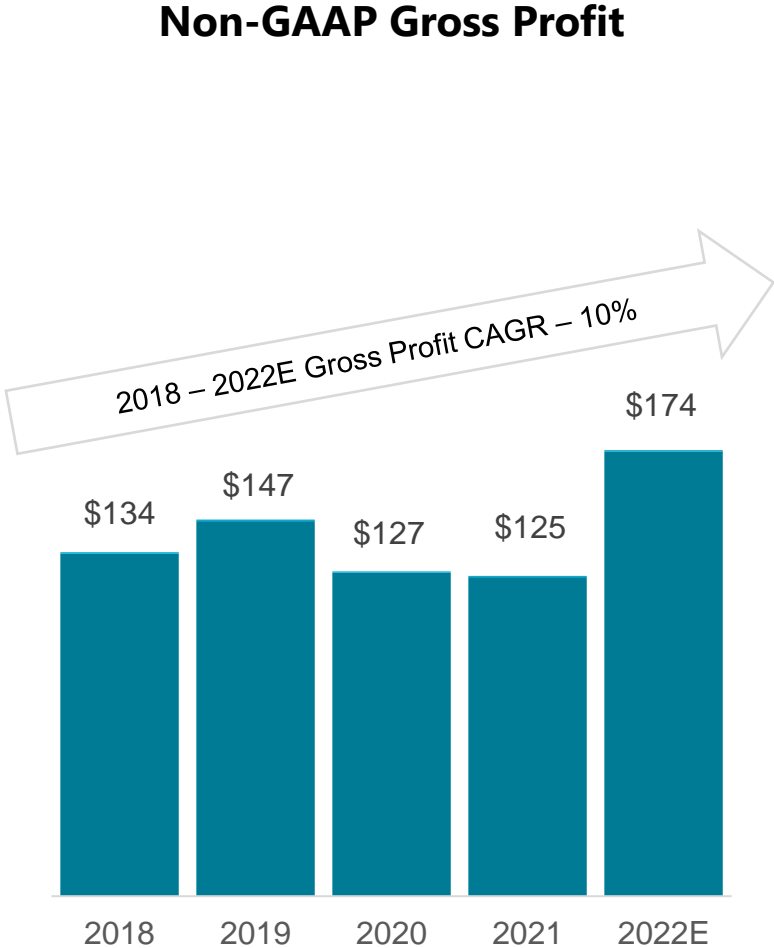
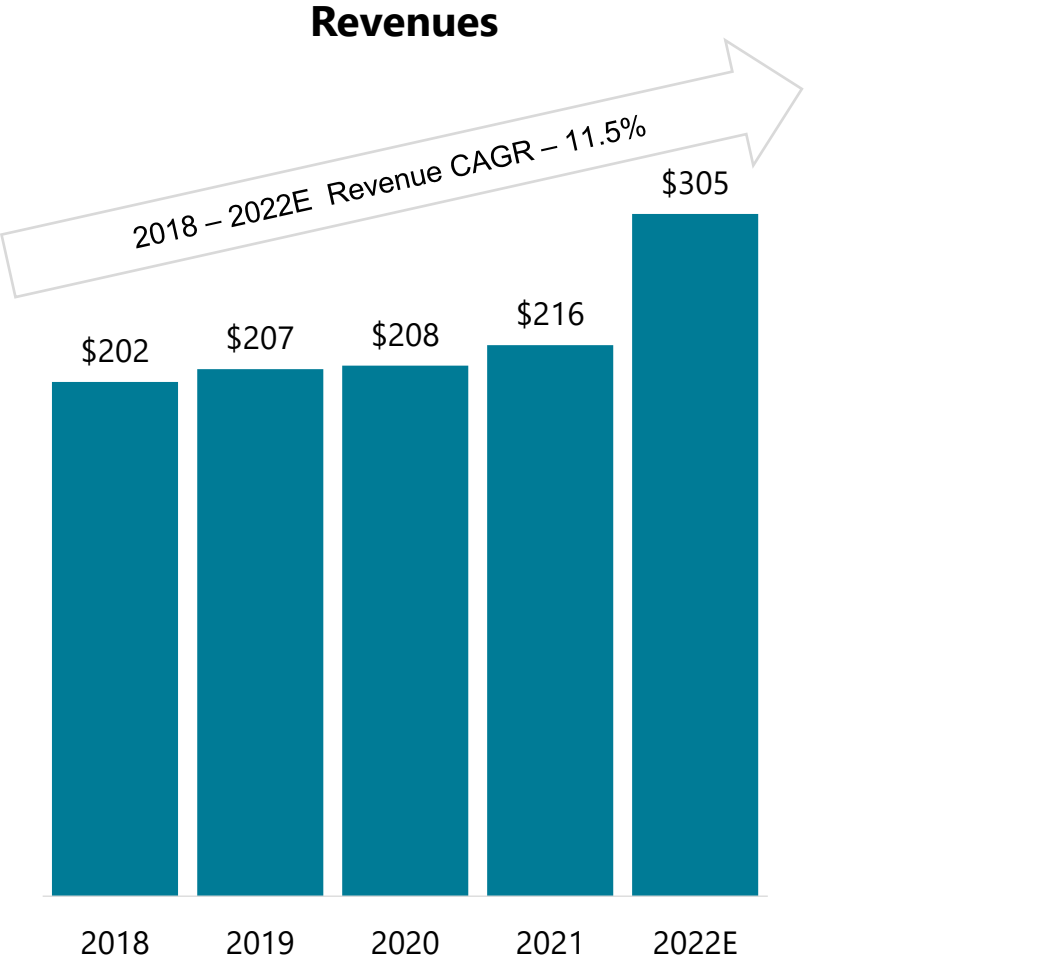
GMP

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

Poised for Return to Strong Financial Growth





APPENDIX



EBITDA Reconciliation

ANI Pharmaceuticals, Inc. and Subsidiaries		
Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation		
<i>(unaudited, in thousands)</i>		
	Year Ended December 31, 2021	Three Months Ended March 31, 2022
Net Loss	\$ (42,603)	\$ (20,130)
Add/(Subtract):		
Interest expense, net	11,922	6,613
Other expense, net	6,243	89
Benefit for income taxes	(13,455)	(5,767)
Depreciation and amortization	47,252	14,557
Legal settlement expense	8,750	-
Contingent consideration fair value adjustment	500	753
Cortrophin pre-launch charges and sales & marketing expenses ⁽¹⁾	14,228	-
Stock-based compensation	10,489	3,237
Asset impairments ⁽²⁾	2,737	-
Excess of fair value over cost of acquired inventory	7,460	3,829
Novitium transaction expenses	9,382	1,092
Royalty settlement	1,934	-
Adjusted non-GAAP EBITDA	\$ 64,839	\$ 4,273

(1) Beginning in 2022, we no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP EBITDA.

(2) 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.