



H.C. Wainwright Bioconnect Conference

January 2022

Disclaimer

This presentation by ANI Pharmaceuticals, Inc (“ANI” or the “Company”) contains forward-looking statements, including information about management's view of the Company's future expectations, plans and prospects, as well as other forward-looking statements, including the expected benefits from the recently completed acquisition of Novitium Pharma, LLC (“Novitium”), new drug applications and an abbreviated new drug applications , and the commercialization of Cortrophin Gel and its potential impact on the future prospects of the Company. Any statements made in this presentation other than those of historical fact, about an action, event or development, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different than those expressed or implied in such statements. Unknown or unpredictable factors also could have material adverse effects on the Company's future results. Information 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 Factors” section of the Company's Annual Report on Form 10-K and in the Company's other periodic reports and filings with the Securities and Exchange Commission (“SEC”). The forward-looking statements included in this presentation are made only as of the date hereof. The Company cannot guarantee future results, levels of activity, performance or achievements and you should not place undue reliance on these forward-looking statements.

ANI

Biopharmaceuticals
company poised for
strong & sustainable
growth



US-focused diversified biopharma with Rare Disease, Generics, Established Brands and CDMO businesses



Transformational opportunity with Cortrophin Gel

- ACTH market was \$770M in revenue in 2020
- FDA Approval on October 29, 2021; full scale commercial launch in early Q1 2022



**Strong CAGR
growth 2014 to 2020⁽¹⁾:**



30%
Revenues



26%
Gross Profit



Proven acquirer of branded and generic products

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



Strong GMP track record across sites – all in US / Canada

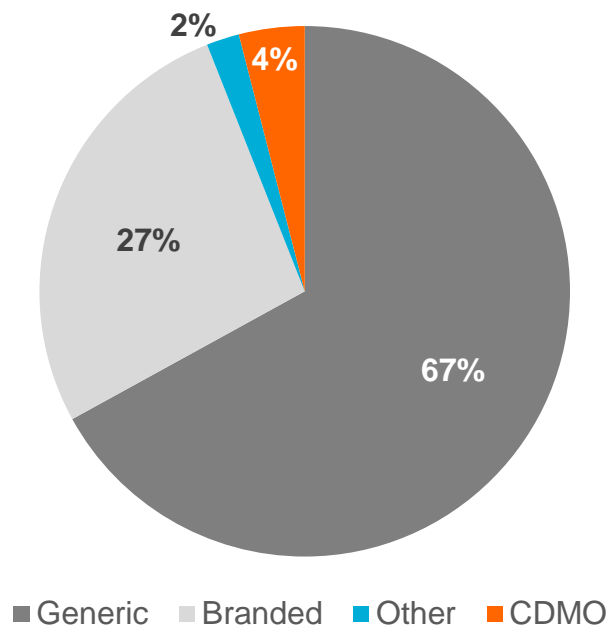


Maintains low net leverage: ~2.0x – 3.0x since 2016

⁽¹⁾ All 2020 numbers non-GAAP pro-forma assuming the April 2021 acquisition of NDAs and ANDA from Sandoz and the acquisition of Novitium had occurred as of January 1, 2020. For actual financial information regarding FY 2020, see our annual report on Form 10-K for the year ended December 31, 2020.

Strong and Growing U.S.-Focused Diversified BioPharma Company

Revenues (2020) ⁽¹⁾



ANI in Numbers ⁽¹⁾

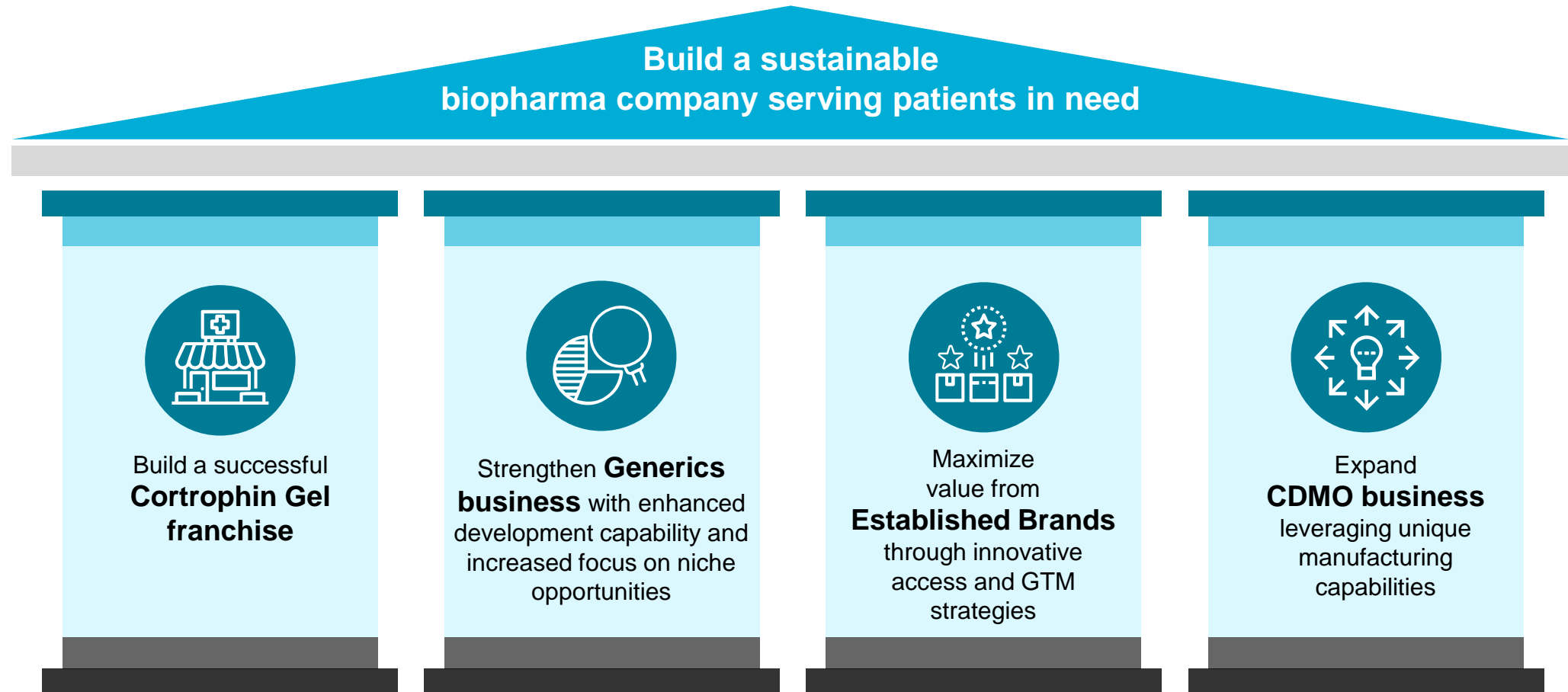
55 Generic Products	15 Branded Products	6.4% Largest Product's Percentage of Total Revenue in PF20
\$220MM / \$202MM PF 2020 / September YTD 2021 Revenue		\$76MM / \$67MM PF 2020 / September YTD 2021 Adjusted EBITDA ⁽²⁾
34% PF 2020 Adjusted EBITDA Margin		62% 2020PF Adjusted Gross Margin

Note: all figures pro-forma full year 2020 unless otherwise noted.

⁽¹⁾ All 2020 numbers non-GAAP pro-forma assuming the April 2021 acquisition of NDAs and ANDA from Sandoz had occurred as of January 1, 2020. For actual financial information regarding FY 2020, see our Annual Report on Form 10-K for the year ended December 31, 2020. All September year-to-date 2021 numbers non-GAAP pro-forma assuming the November 2021 acquisition of Novitium had occurred as of January 1, 2021. For actual information regarding the YTD 2021, see our Quarterly report of Form 10-Q for the nine-month period ended September 30, 2021.

⁽²⁾ Non-GAAP financial measure. See reconciliation to most directly comparable GAAP financial measure in Appendix A.

Four Pillars to Drive Sustainable Growth



Empowered and experienced talent retaining core strengths and driving growth

Significant Progress Across Key Pillars Puts ANI at an Inflection Point



- ✓ Achieved sNDA approval on October 29, 2021, culminating 5+ year development effort
- ✓ ACTH market was \$770MM in revenue in 2020
- ✓ On-boarded energized & highly experienced *Rare Disease* leadership to drive successful launch
- ✓ Full-scale commercial launch in early Q1 2022



- ✓ Base Gx business delivering Q-o-Q growth with notable new product launches
- ✓ Enhance core capabilities in Sales, Marketing, Business Development and prudent fiscal management
- ✓ Acquisition of Novitium brings best-in-class R&D engine to accelerate new product launches

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

\$770M

ACTH market in 2020

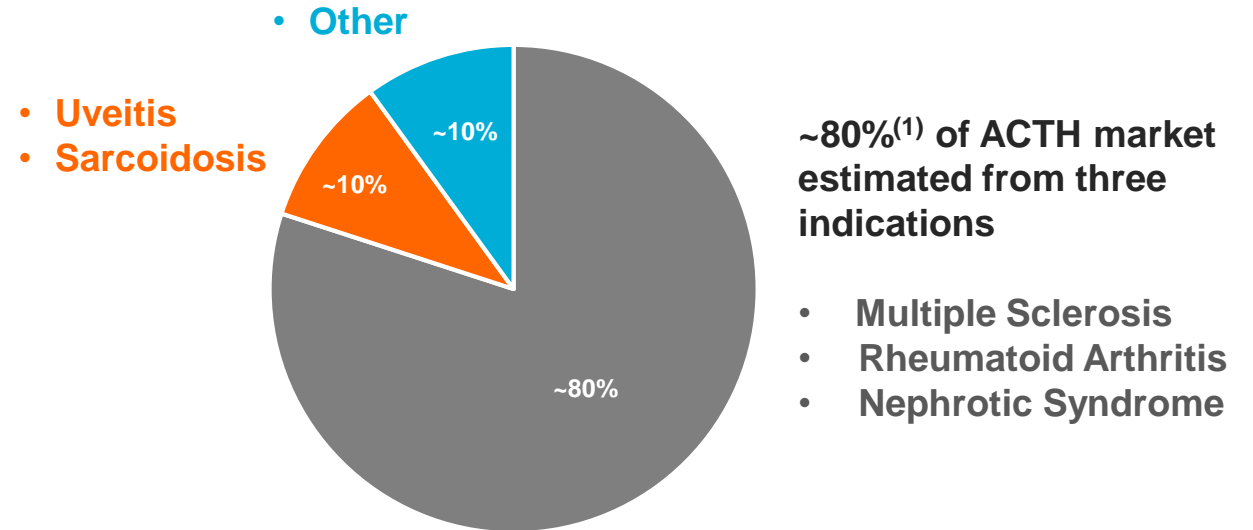
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Competitor in-class

Approved

October 29, 2021

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

Cortrophin Gel Is a Valuable Treatment Option With Decades of Clinical Efficacy Across Numerous Disease States



















“It is clear that the majority of patients are not responding optimally, if at all, to [current immune-modulatory drugs]”

Challenges, Progress, and Prospects of Developing Therapies to Treat Autoimmune Diseases; *Cell*; 2020.

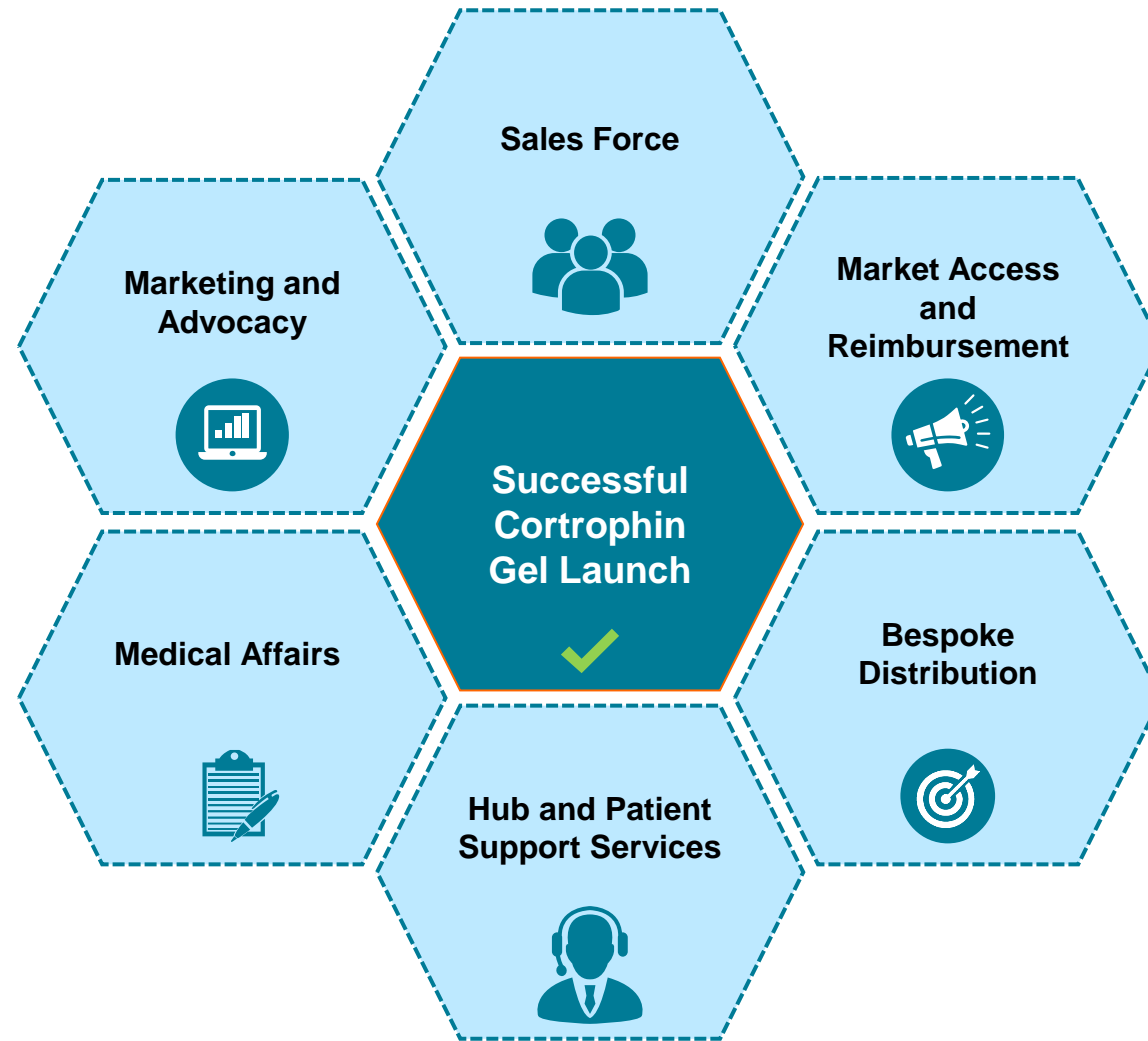
“The ACTH-drug class continues to provide hope for patients with chronic, difficult-to-treat illnesses”

Internationally recognized nephrologist; clinical director at top academic center; ACTH prescriber
October 2021

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 11 Years with Merck 8+ Years with Alexion 7 Rare Disease launches 	 
 Mary Pao Seidman, 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 	 
 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 	 
 Holly Zickler	VP Sales	<ul style="list-style-type: none"> 10+ Years Sales Leadership Experience Rare Disease Expertise and ACTH Insight 	 

Significant Ongoing Investment in People and Commercial Infrastructure to Support a Successful Launch in Early Q1 2022



Significant Progress Across Key Pillars Puts ANI At An Inflection Point



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- ✓ Enhance core capabilities in Sales, Marketing, Business Development and prudent fiscal management
- ✓ Acquisition of Novitium brings best-in-class R&D engine to accelerate new product launches

Strong Business Development Engine Fueled ANI's Growth 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 Significantly Strengthens ANI's Generics Business

Novitium in Numbers

\$53MM / \$47MM

2020 / September YTD 2021 Revenue

\$13MM / \$18MM

2020 / September YTD 2021 Adjusted EBITDA⁽¹⁾

24

Generic Products

25%

2020 Adjusted EBITDA Margin

25+ ANDAs filed in 2020 and 2021

~20 launches planned in 2022

Transaction Overview

- Transaction closed on November 19, 2021
- Consideration paid to Novitium incentivizes key personnel to continue delivering
 - \$89.5M of cash upon closing
 - Approx. 2.5M shares of ANI common stock
 - Up to \$46.5M of potential earnouts and royalties
- Concurrent debt refinancing
 - Closed \$300M Term Loan B and \$40M revolver (un-drawn)
 - Retired pre-existing Term Loan A
 - Closed \$25M PIPE investment from Ampersand

Note all figures 2020 unless otherwise noted.

⁽¹⁾ Non-GAAP financial measure.

Novitium acquisition:

Added Best-in-class R&D engine with Generics and 505(b)(2) capabilities

- ~13 months

Average filing to approval time
- ~20

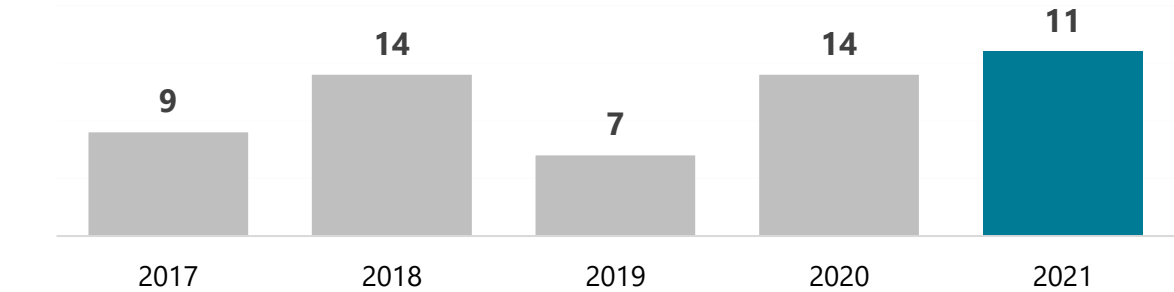
Gx launches planned in 2022
- 3

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

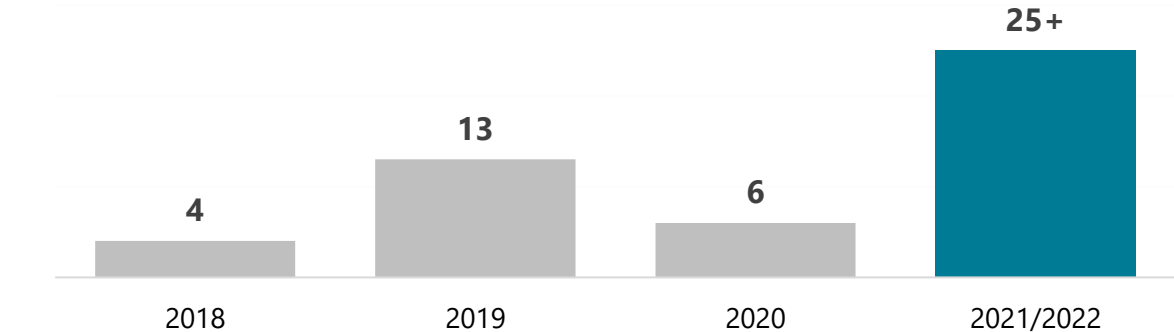
Novitium management has developed and commercialized over 100 ANDAs across specialty dosage forms in the U.S.

Actual Expected

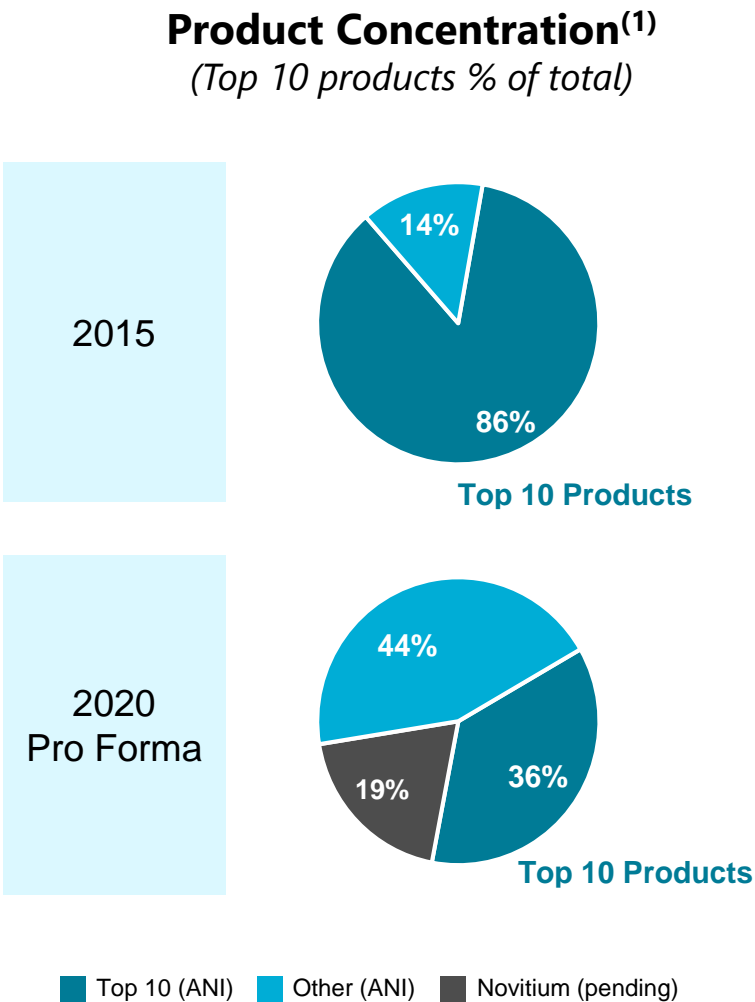
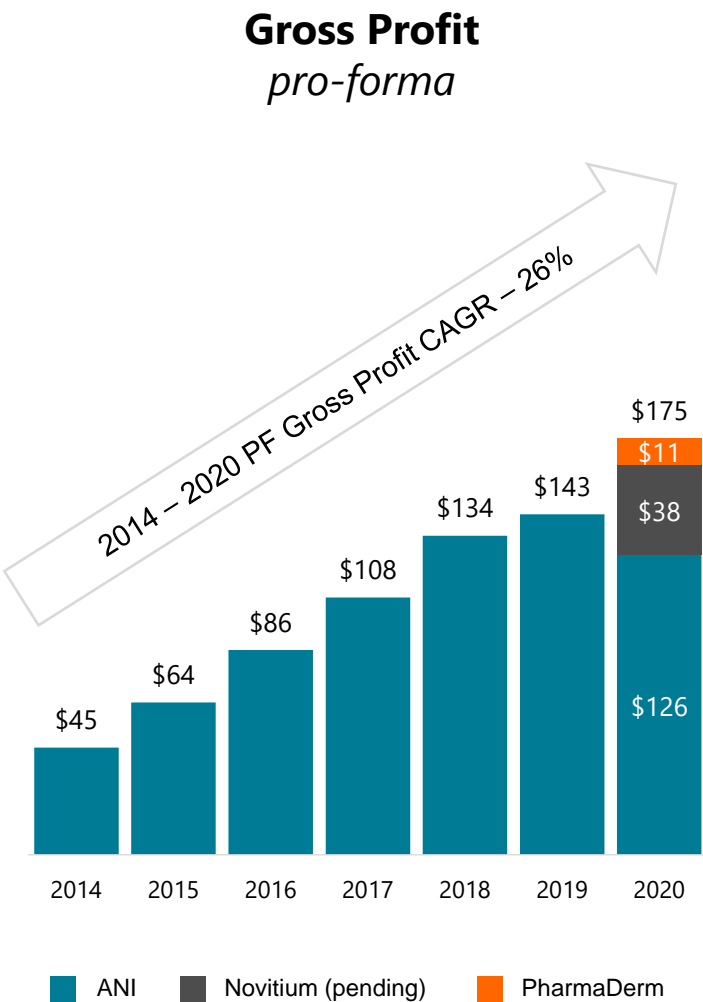
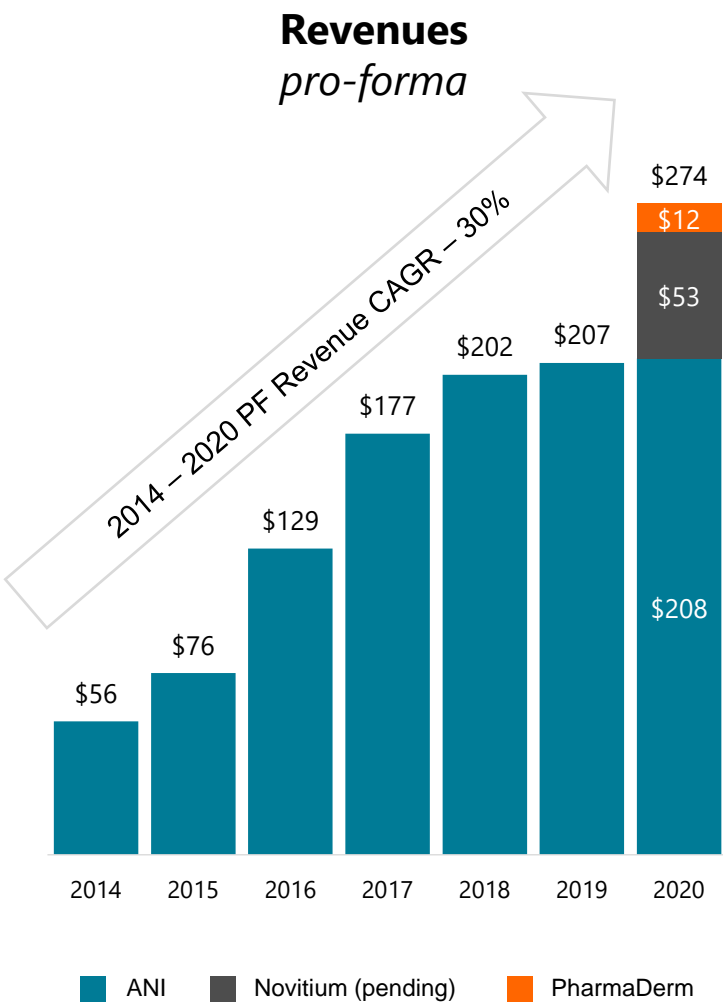
Annual ANDA Filings by Novitium



Annual Product Launches by Novitium



Strong Growth Trajectory and Attractive Financial Profile



⁽¹⁾ All 2020 numbers non-GAAP pro-forma assuming the April 2021 acquisition of NDAs and ANDA from Sandoz had occurred as of January 1, 2020. For actual financial information regarding FY 2020, see our Annual Report on Form 10-K for the year ended December 31, 2020.

Significant North American Manufacturing Footprint

with ample capacity and strong GMP track record

Facility Overview and Capabilities

Annual Capacity

GMP



Baudette, MN
130k sf

- 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



Baudette, MN
Containment Facility - 47k sf

- 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



Oakville, ON Canada –
101k sf

- Manufacturing, packaging, lab, warehouse, administrative
- US FDA and Health Canada inspected
- Controlled drugs and substance license
- Solutions, suspensions, topicals, tablets, and capsules
- Serialization-ready



East Windsor, NJ
100k sf

- 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

- 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 ~1BN doses
- Capsules ~150MM doses
- Liquids ~3MM bottles
- Topicals ~2MM tubes

- Tablets & Capsules ~3.0BN doses
- Packaged Units ~20MM units
- Liquids ~10MM bottles
- Powder ~ 2MM bottles

Four FDA inspections since 2013
Latest inspection – April 2019;
Results: No 483

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

Four FDA and five Health Canada inspections since 2014; Five Health Canada inspections **Latest inspections - January 2021;**
Results: “Compliant” Rating

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



APPENDIX

Executive Leadership Team with Proven Track Records & 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

Cipla

McKinsey
& Company



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

SOLVAY
pharmaceuticals



Samy Shanmugam⁽¹⁾

Novitium President & Co-Founder

- 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

PAR
PHARMACEUTICAL

NOVEL
LABORATORIES



Ori Gutwerg

SVP, Generics

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

TARO

Perrigo



Stephen Carey

SVP, Finance & Chief Financial Officer

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

Schering-Plough

PAR
PHARMACEUTICALS



Chris Mutz

Head of Rare Diseases/Cortrophin

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

MERCK

ALEXION



Chad Gassert⁽¹⁾

Novitium Chief Executive Officer, Co-Founder

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

PAR
PHARMACEUTICAL

SANDOZ



Ellen Connolly

Vice President of Regulatory Affairs

- ~20 years experience in Regulatory across organizations
- Leading Regulatory Affairs at ANI for over 5 years
- Prior to ANI, various roles in Regulatory at Sandoz and Eon

SANDOZ

⁽¹⁾ Joining ANI team upon close of Novitium transaction.

FY2020 EBITDA Reconciliation

ANI Pharmaceuticals, Inc. and Subsidiaries

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

(unaudited, in thousands)

	Year Ended December 31, 2020
Net (Loss)/Income	\$ (22,548)
Add/(Subtract):	
Interest expense, net	9,452
Other expense, net	494
Provision/(Benefit) for income taxes	(3,414)
Depreciation and amortization	44,638
Cortrophin pre-launch charges	11,263
Expensed FDA approval milestone payment	-
Stock-based compensation ⁽¹⁾	9,470
CEO transition items ⁽²⁾	7,386
Cortrophin team restructuring	401
Acquired IPR&D expense	3,784
Excess of fair value over cost of acquired inventory	4,296
Asset impairments ⁽³⁾	1,330
Charges related to market exits	567
Transaction and integration expenses	-
Adjusted non-GAAP EBITDA	\$ 67,119
Proforma Adjustment for April 2021 acquisition:	
EBITDA contribution from acquired products	8,500
Proforma 2020 Adjusted EBITDA	\$ 75,619

⁽¹⁾ For the year ended December 31, 2020, Stock-based compensation excludes \$3.4 million of stock-based compensation expense associated with the departure of our former President and CEO. This amount is included in this table as part of CEO transition items.

⁽²⁾ CEO transition items for the year ended December 31, 2020 is comprised of \$3.4 million of stock-based compensation expense and \$3.1 million of expense for salary continuation, bonus and other fringe benefits associated with the departure of our former President and CEO, as well as certain legal and recruiting costs related to the search for a permanent replacement.

⁽³⁾ For the year ended December 31, 2020, Asset impairments is comprised of finished goods inventory reserves for Bretylium, accounts receivable reserves due to customer bankruptcy, and the impairment of the marketing and distribution right intangible asset, tempered by a modest recovery of previously reserved inventory related to market exits. For the three and twelve month period ended December 2019, Asset impairments was comprised of the impairment of a product right intangible asset.

September YTD 2021 EBITDA Reconciliation

ANI Pharmaceuticals, Inc. and Subsidiaries
Adjusted non-GAAP EBITDA Calculation and GAAP to non-GAAP Reconciliation
(unaudited in thousands)

	Nine Months Ended September 30, 2021		
	<u>ANI</u>	<u>Novitium</u>	<u>Proforma</u>
Net (Loss) / Income	\$ (18,467)	\$ 15,533	\$ (2,934)
Add / Subtract:			
Interest Expense, net	7,482	(4)	7,478
Other Expense, net	2,853	(14)	2,839
Benefit for income taxes	(6,738)	-	(6,738)
Depreciation and amortization	33,568	2,367	35,935
Legal settlement expense	8,400	-	8,400
Cortrophin pre-launch charges and Sales & marketing expenses	5,236	-	5,236
Stock-based compensation	7,520	-	7,520
Excess of fair value over cost of acquired inventory	3,717	-	3,717
Novitium transaction expenses	5,064	1,386	6,450
PPE Loan Forgiveness	-	(1,316)	(1,316)
Adjusted non-GAAP EBITDA	\$ 48,635	\$ 17,952	\$ 66,587