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 2, 2021

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)	(IRS 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**

(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:

☐ 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)

☐ 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 5.07. Submission of Matters to a Vote of Security Holders.

On June 2, 2021, ANI Pharmaceuticals, Inc. (the "Company") held its 2021 annual meeting of stockholders (the "Annual Meeting"). The following sets forth the matters that were voted upon by the Company's stockholders at the Annual Meeting and the voting results for such matters. These matters are described in more detail in the Company's definitive proxy statement on Schedule 14A filed with the Securities and Exchange Commission on April 29, 2021 (the "Proxy Statement").

1. The Company's stockholders voted to elect the following directors, each to serve until his or her successor has been duly elected and qualified or until his or her earlier resignation or removal. The final voting results are as follows:

Nominee	For	Against	Abstentions	Broker Non-Votes
1. Robert E. Brown, Jr.	9,466,522	325,176	3,376	797,905
2. Thomas Haughey	9,534,467	257,199	3,408	797,905
3. Nikhil Lalwani	9,655,278	136,331	3,465	797,905
4. David B. Nash, M.D., M.B.A.	9,409,937	381,762	3,375	797,905
5. Antonia R. Pera	9,656,007	135,634	3,433	797,905
6. Jeanne A. Thoma	9,652,137	139,542	3,395	797,905
7. Patrick D. Walsh	9,392,837	398,827	3,410	797,905

2. The Company's stockholders approved, on a non-binding advisory basis, the compensation of the Company's named executive officers, as described in the Proxy Statement. The final voting results are as follows:

For	Against	Abstentions	Broker Non-Votes
9,417,485	328,111	49,478	797,905

3. The Company's stockholders ratified the appointment of EisnerAmper LLP as the Company's independent registered public accounting firm for the year ending December 31, 2021. The final voting results are as follows:

For	Against	Abstentions	Broker Non-Votes
10,546,523	42,147	4,309	--

4. The Company's stockholders approved in connection with the Company's pending acquisition of Novitium Pharma LLC ("Novitium"), the issuances of (a) 2,466,667 shares of common stock to certain members of Novitium and (b) 25,000 shares of Series A Convertible Preferred Stock to Ampersand 2020 Limited Partnership. The final voting results are as follows:

For	Against	Abstentions	Broker Non-Votes
9,727,248	57,285	10,541	797,905

Item 7.01. Regulation FD Disclosure.

On June 4, 2021, the Company posted an investor presentation to the Investor Relations section of its website at www.anipharmaceuticals.com in connection with a presentation by its executives at an investor conference. A copy of the investor presentation is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, are furnished and 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, as amended or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit	Description
99.1	Investor Presentation – June 2021.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

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 thereunto duly authorized.

ANI PHARMACEUTICALS, INC.

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

Dated: June 4, 2021

Disclaimer

Cautionary Note Regarding Forward-Looking Statements

This presentation contemplates the acquisition by ANI Pharmaceuticals, Inc ("ANI" or the "Company") of Novitium Pharma, LLC ("Novitium") and contains forward- looking statements, including information about management's view of ANI's and Novitium's future expectations, plans and prospectus, as well as other forward-looking statements, including the potential benefits from the acquisition of new drug applications and an abbreviated new drug application for Sandoz, Inc. and the timing for submission of the sNDA for Cortrophin Gel. 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.

No Offer or Solicitation

This presentation is for informational purposes only and is neither an offer to sell or purchase, nor a solicitation of an offer to sell, buy or subscribe for any securities, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended (the "Securities Act"), or an exemption therefrom.

Use of Projections

This presentation contains financial forecasts with respect to, among other things, income sources, revenue growth, and equity values. These unaudited financial projections should not be relied upon as being necessarily indicative of future results. The inclusion of the unaudited financial projections in this presentation is not an admission or representation that such information is material. The assumptions and estimates underlying the unaudited financial projections are inherently uncertain and are subject to a wide variety of significant business, economic and competitive risks and uncertainties that could cause actual results to differ materially from those contained in the unaudited financial projections. There can be no assurance that the prospective results are indicative of future performance or that actual results will not differ materially from those presented in the unaudited financial projections. Inclusion of the unaudited financial projections in this presentation should not be regarded as a representation by any person that the results contained in the unaudited financial projections will be achieved.

Industry and Market Data

The information contained here also includes information provided by third parties. None of ANI, Novitium, their respective affiliates and any third parties that provided information to ANI or Novitium provide guarantees of the accuracy, completeness and timeliness or availability of the information. None of ANI, Novitium and any of their respective affiliates nor any of the research providers are responsible for any errors or omissions or conclusions form the use of such content.

Non-GAAP Financial Measures

This presentation includes certain non-GAAP financial measures, including Adjusted EBITDA and Adjusted Gross Margin, 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 net income 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 Appendix A in this presentation for a reconciliation of the non-GAAP financial measure to the most directly comparable GAAP measure.

Company Snapshot

Poised for sustainable growth

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

Transformational opportunity with Cortrophin Gel
- Only competitor in same class delivered ~$780mm in revenues in 2020
- sNDA submission on track for June 2021

Strong CAGR growth 2014 to 2020*:

30% Revenues

26% Gross Profit

Proven acquirer of branded and generic products
- Closed 2-4 deals each year for last 8 years

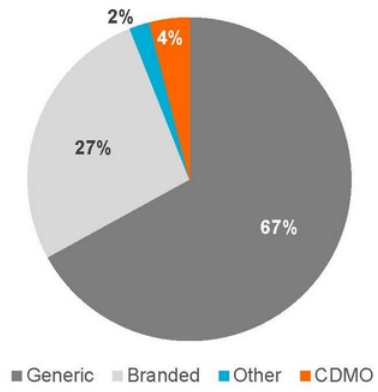
Strong GMP track record across sites

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

*Pro-forma for pending acquisition of Novitium and April 2021 acquisition of NDAs and ANDA from San

Strong and Growing U.S.-Focused and 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

$220.4MM PF 2020 Revenue

$75.6MM PF 2020 Adjusted EBITDA[2]

34.3% PF 2020 Adjusted EBITDA Margin

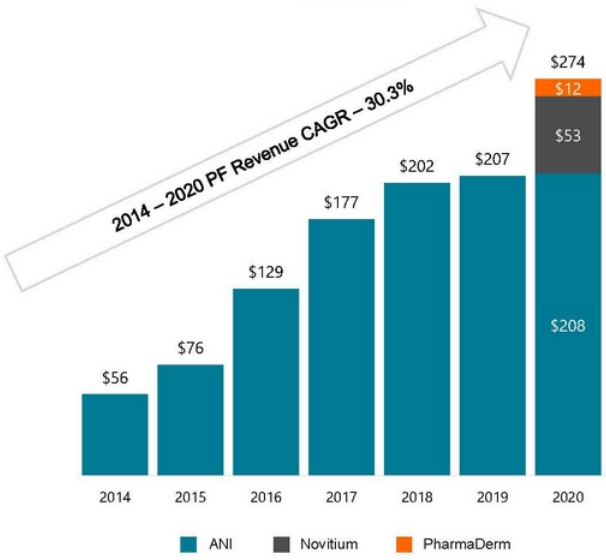
25.7% 2014 – 2020PF Revenue CAGR

62.2% 2020PF Adjusted Gross Margin

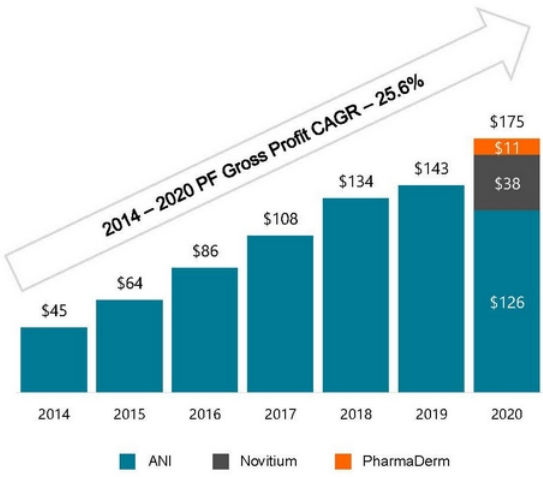
[1] Pro-forma for April 2021 acquisition of NDAs and ANDA from San
[2] Non-GAAP financial measure. See reconciliation to most directly comparable GAAP financial measure in Appendi

Proven Strong Growth Profile

Revenues



Gross Profit



Strong Business Development Engine to Fuel Growth

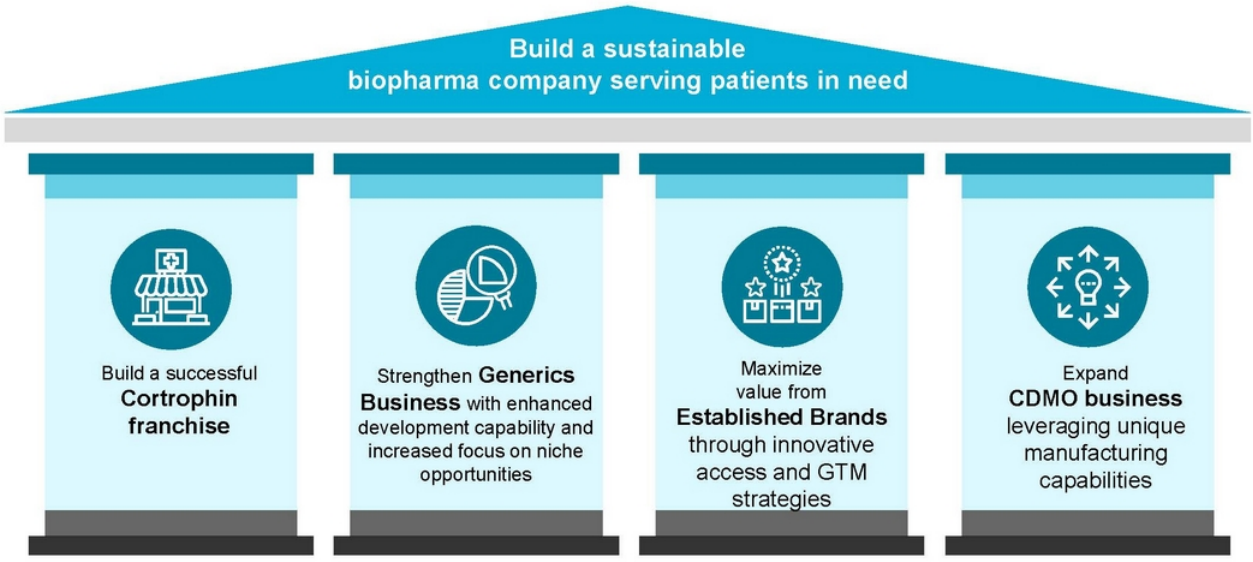
Brands – 9 Deals

Class	Seller	Products
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 assests
	Noven	Lithobid
2011	Meda	Reglan

Generics – 17 Deals

Class	Seller	Products
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

Four Pillars to Drive Sustainable Growth

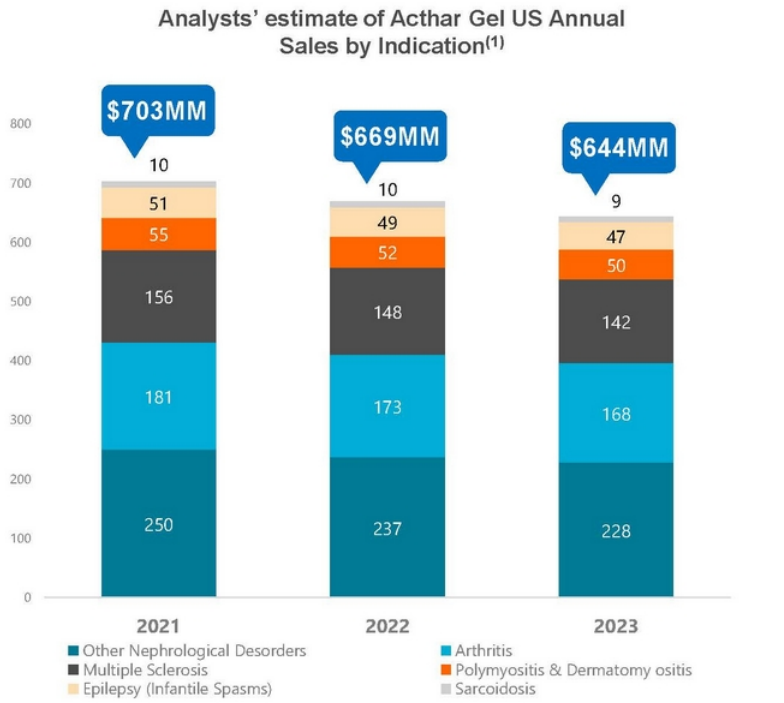


Empowered best-in-class experienced talent retaining core strengths and driving growth

CORTROPHIN GEL:
Transformational opportunity

sNDA filing on track for June 2021 submission to FDA

Only repository corticotropin (Acthar Gel) available on the market estimated to have sales of approximately **$640 - $700 million** in next three years



(1) Based on Wall Street Equity Analyst Projecti

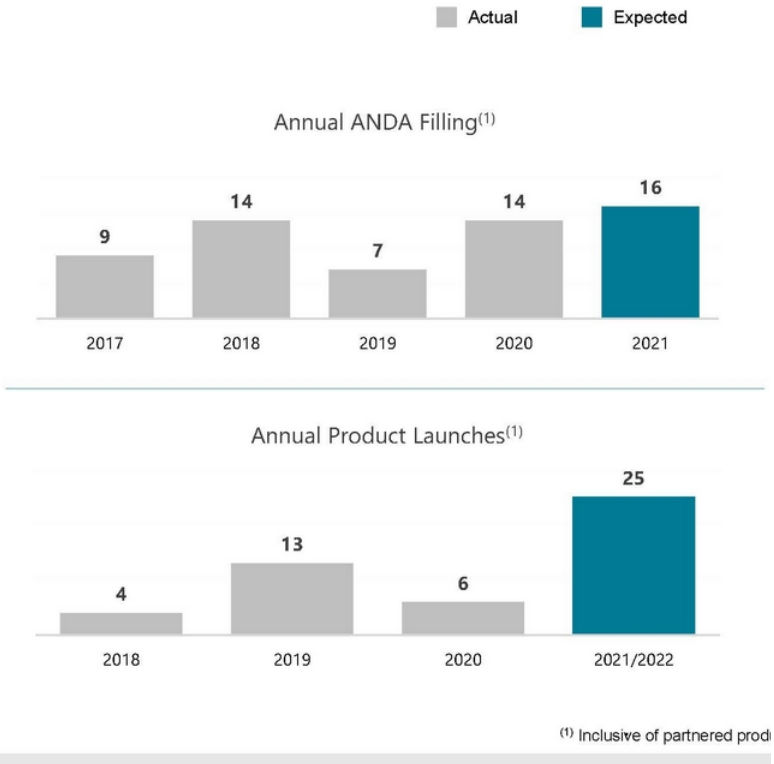
Novitium acquisition: adds best-in-class R&D engine with Generics and 505(b)(2) capabilities

~13 months — Average filing to approval time

~10 days — Average approval to launch time

95% — Products launched within seven days of approval

Management have developed and commercialized over 100 specialty dosage forms and ANDAs in the US



(1) Inclusive of partnered prod

Expanding Established Brands Portfolio Products: Derm Acquisition

Acquired Products

VERGEN® (sinecatechins) Ointment, 15%

OXISTAT® (oxiconazole nitrate) LOTION, 1%

PharmaDerm® Pandel® (hydrocortisone probutate) Cream, 0.1%

ApexiCon® E Cream (diflorosone diacetate cream USP 0.05% [emollient])

Key Deal Characteristics

- Favorable gross margin profile
- Purchase includes up to three years of inventory
- Transfer manufacturing in house
- Ability to leverage existing go-to-market strategies within sales and marketing

Product Summary

Product	Indication	Active Ingredient
Vergen	Genital Warts	Sinecatechins
Oxistat	Ringworm, Athlete's foot, Jock Itch	Oxiconazole nitrate
ApexiconE	Psoriasis, Eczema	Diflorosone diacetate
Pandel	Psoriasis, Eczema	Hydrocortisone probutate

Highly Efficient Execution Timeline

ANI executed the Derm acquisition within a seamless ~90-day process

*Acquisition was effective April 1, 2021

Significant North American Manufacturing Footprint

with ample capacity and excellent GMP track record

	Baudette, MN 130k sf	Baudette, MN Containment Facility - 47k sf	Oakville, ON – Canada 101k 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	• Manufacturing, packaging, lab, warehouse, administrative • US FDA and Health Canada inspected • Controlled drugs and substance license • Solutions, suspensions, topicals, tablets, and capsules • Serialization-ready
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 ~1BN doses • Capsules ~150MM doses • Liquids ~3MM bottles • Topicals ~2MM tubes
GMP	Four FDA inspections since 2013 **Latest inspection – September 2019; Results: No 483 (NAI)**	Five DEA inspections since 2013 **Latest inspection – September 2018; Results: No findings**	Four FDA and five Health Canada inspections since 2014; Five Health Canada inspections **Latest inspections - January 2021; Results: 9 observations, "Compliant" Rating**

Executive Leadership Team with 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

Samy Shanmugam*
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 | Novel

Ori Gutwerg
SVP, Generics
- 17+ years pharmaceutical experience across generic and branded products
- Proven track record of business development and accelerating growth

Taro | Bromed

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

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*
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 | Sandoz

*Joining ANI team upon close of Novitium transac

Thank You!

Appendix

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.