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 19, 2017

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 Number)**

210 Main Street West **Baudette, Minnesota** **(Address of principal executive offices)**	**56623** **(Zip Code)**

Registrant's telephone number, including area code: (218) 634-3500

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 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 7.01 Regulation FD Disclosure.

On June 19, 2017, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its June 2017 Investor Presentation. We may use this presentation in our communications or at conferences. The presentation is available on our website, www.anipharmaceuticals.com, and is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be “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, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Forward-Looking Statements

Certain statements contained in the presentation slides furnished with this report contain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about future operations, products, financial position, operating results, prospects, pipeline or potential markets therefor, and other statements that are not historical in nature, particularly those that utilize terminology such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” other words of similar meaning, derivations of such words, and the use of future dates.

Uncertainties and risks may cause our actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that we may face with respect to importing raw materials, increased competition, acquisitions, contract manufacturing arrangements, delays or failure in obtaining product approval from the U.S. Food and Drug Administration ("FDA"), general business and economic conditions, market trends, product development, regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect our actual results are described in our filings with the Securities and Exchange Commission, including our most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as our proxy statement/prospectus, filed with the Securities and Exchange Commission on April 14, 2016. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit
99.1	ANI Pharmaceuticals, Inc. Investor Presentation, June 2017

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.

ANI PHARMACEUTICALS, INC.

Date: June 19, 2017

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

Exhibit 99.1

ani Pharmaceuticals, Inc.

A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Investor Presentation

June 20, 2017

Forward-Looking Statements

To the extent any statements made in this presentation deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about price increases, the Company's future operations, products financial position, operating results and prospects, the Company's pipeline or potential markets therefore, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this presentation speak only as of the date of this presentation and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

ani Pharmaceuticals, Inc.

Experienced Senior Management Team

		With ANI Since	Previous Affiliation
Arthur S Przybyl	President and CEO	2009	Akorn
Stephen Carey	VP, Finance and CFO	2016	Par Pharmaceutical
James Marken	SVP, Operations & Prod. Development	2007	Solvay
Robert Schrepfer	SVP, BD and Specialty Sales	2013	Healthcare Value Capital
David Sullivan	VP, Quality Operations	2014	Boston Scientific
Ellen Camos	VP, Regulatory Affairs	2012	Sandoz
Mark Ginski	VP, Corticotropin Development	2016	Mallinckrodt
Karen Quinn	VP, Corticotropin Regulatory Affairs	2017	Takeda

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Building a Stable Base with Diversified Growth

What we do:

- Acquire, develop, manufacture and commercialize GENERIC Rx products
- Acquire, manufacture and commercialize MATURE BRAND Rx products
- Provide high quality CONTRACT MANUFACTURING services to select clients

Our strategy:

- Assemble a portfolio of limited competition / high barrier product opportunities
- Acquire previously approved A/NDA products to minimize development risk
- Control quality and own the manufacturing process as possible

ANI Objective

Create long term shareholder value by building a sustainable and growing base business in Generic and Mature Brand Rx products while advancing a transformational opportunity to re-commercialize Cortrophin® Gel and Cortrophin-Zinc®

Three Platforms Form Strong Base Business

Generic Rx	• 22 commercial products • 1Q17 net revenues: $26.6M (+101% vs. 1Q16) • 74 Pipeline products – 43 previously approved and can be re-commercialized via CBE30 or Prior Approval Supplement • Addressable market of pipeline = $2.5B
Brand Rx	• 7 commercial products • 1Q17 net revenues: $8.0M (+44% vs. 1Q16) • 3 Pipeline products – Cortrophin Gel, Cortrophin-Zinc and Vancocin™ Oral Solution • Addressable market of pipeline = $1.3B
CMO	• 4 customers / 7 SKUs • 1Q17 net revenues: $1.8M (+30% vs. 1Q16)

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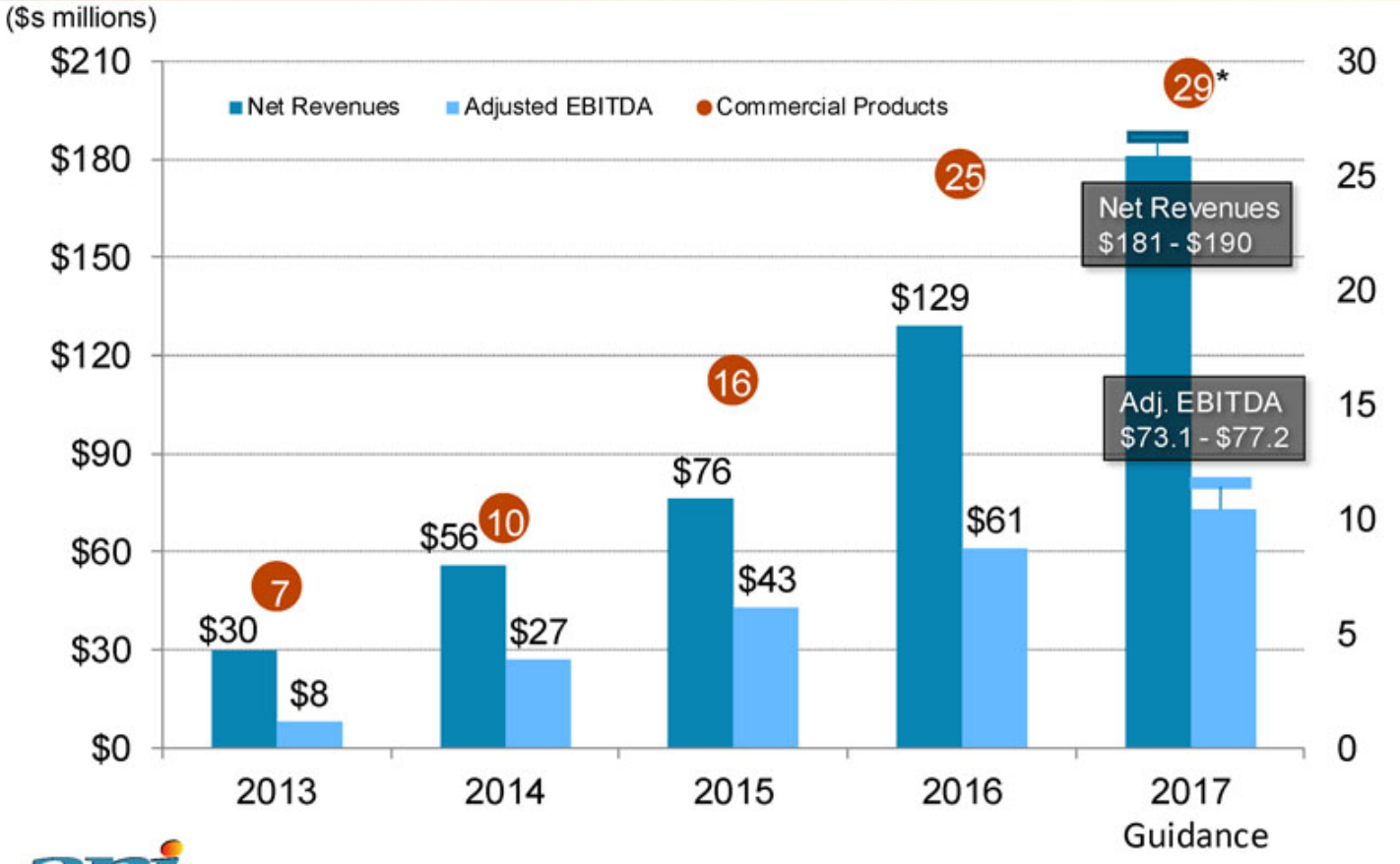
Company estimates, IMS Health - March 2017

Growth Led by New Product Introductions



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* 29 Commercial Products as of May 31, 2017

Transformational Acquisition: Cortrophin Assets

Jan. 2016 - ANI Acquires Two NDAs from Merck for $75 Million + % Net Sales

- NDA #008975 Purified Cortrophin Gel, 40 units/mL and 80 units/mL
- NDA #009854 Cortrophin-Zinc, 40 units/mL
- Drug Master File 4181 for corticotropin *(withdrawn)*
- API Process "know-how"

ANI Rationale

The market opportunity and durability of the corticotropin products, together with the approved regulatory status, creates a compelling and potentially transformational asset unique to the pharmaceutical marketplace

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Cortrophin - A Compelling Strategic Opportunity

Regulatory and Development Considerations

- Approved NDAs/Discontinued Marketing: Clear and abbreviated pathway to re-commercialization
- Acquired: NDAs, DMF* and other documentation (e.g. batch records, historical data)

Commercial Considerations

- $1B+ U.S. market opportunity today and growing
- Provides patients, prescribers and payors with valuable therapeutic alternative
- Broad label / concentrated prescriber base
- Durable assets: high barrier to generic entry, ANI's products represent the last of the dormant corticotropin filings that were not withdrawn via Federal Register

Value Creation

- Provides Patients, Payors and Physicians with valuable therapeutic option
- Potential to generate substantial revenues and cash flow
- High risk-adjusted ROI and NPV

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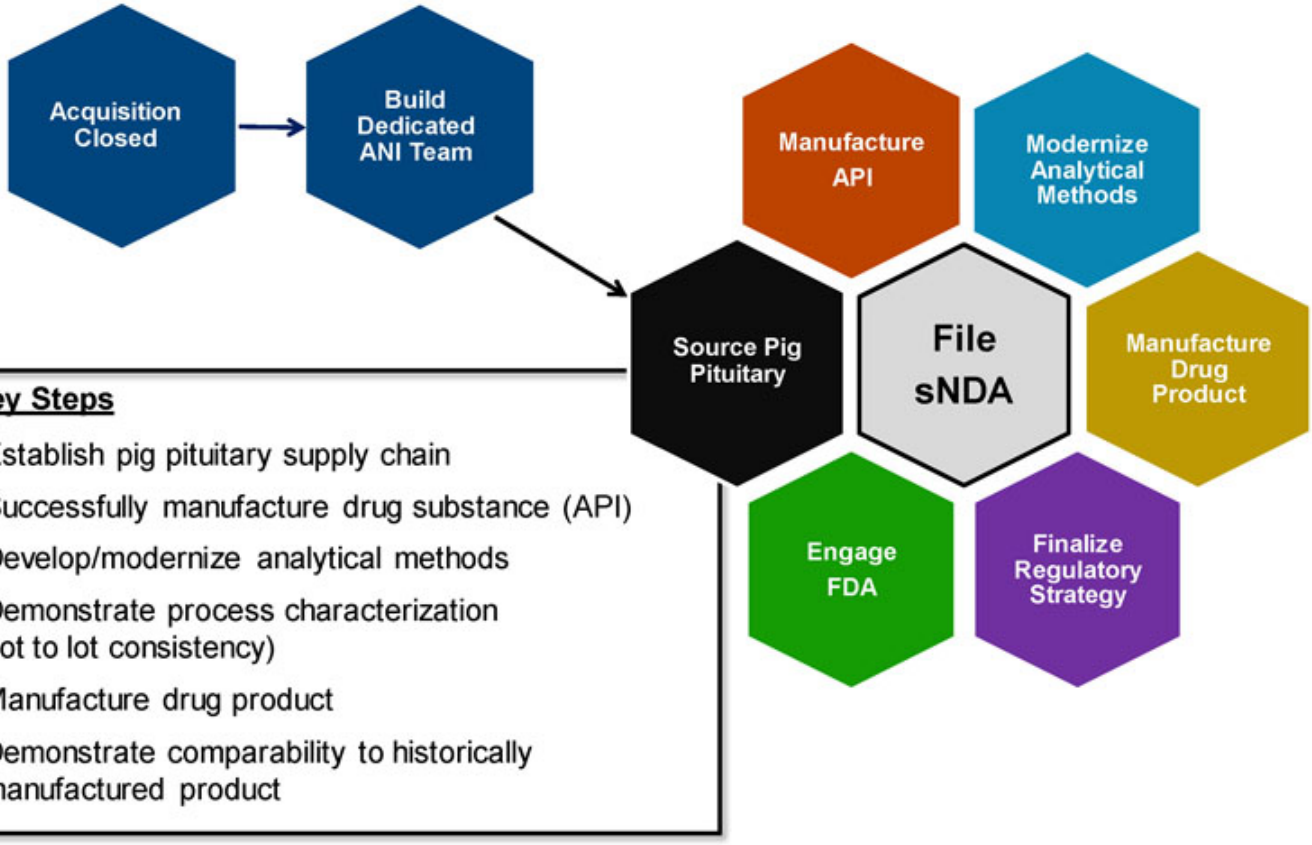
* DMF = drug master file

Cortrophin - Path to Re-Commercialization



Key Steps

- Establish pig pituitary supply chain
- Successfully manufacture drug substance (API)
- Develop/modernize analytical methods
- Demonstrate process characterization (lot to lot consistency)
- Manufacture drug product
- Demonstrate comparability to historically manufactured product

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Uniquely Experienced Team Assembled

Build Dedicated ANI Team

Mark Ginski, PhD – VP Corticotropin Product Development (Project Team Leader)

- Joined ANI in 2016 from Mallinckrodt
- Previously responsible for modernizing the CMC package of discontinued peptide-based products and preparing them for re-commercialization

Cortrophin Analytics Team

- Director of Cortrophin Analytics – 25 years experience in large molecule analytics, biochemistry and bioinformatics
- Direct experience developing and modernizing analytical methods for API and drug products derived from porcine tissue
- Team of five scientists includes one scientist working on-site at ANI's API contract manufacturer

Cortrophin API Manufacturing Team

- Two former managers from Diosynth, historical API manufacturer
- Provide valuable hands-on historical experience with manufacturing and testing the most recent commercial lots of API
- Instrumental in the successful completion of manufacturing the initial batch of corticotropin API

Karen Quinn, PhD – VP Corticotropin Regulatory Affairs

- Joined ANI in 2017 from Takeda, led global biologics regulatory CMC group
- Previously led regulatory package update for successful FDA approval of Creon® a drug product whose API is derived from porcine animal tissue

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Partner Secured for Pituitary Source

Supply

- Secured commercial scale quantities of pig pituitary glands from a leading pork producer in the U.S.
- Supplier has multiple U.S.- based sites that can meet ANI's requirements
- Supplier is currently harvesting porcine glands for other FDA approved drug products
- Currently building inventory to support API needs for next 12 months

Quality

- Quality audits scheduled for all slaughter houses supplying pituitary glands
- Quality processes in place to ensure all raw material processing is compliant with applicable FDA/USDA/PQA guidelines

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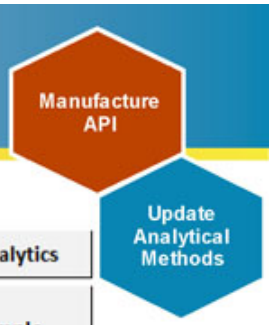
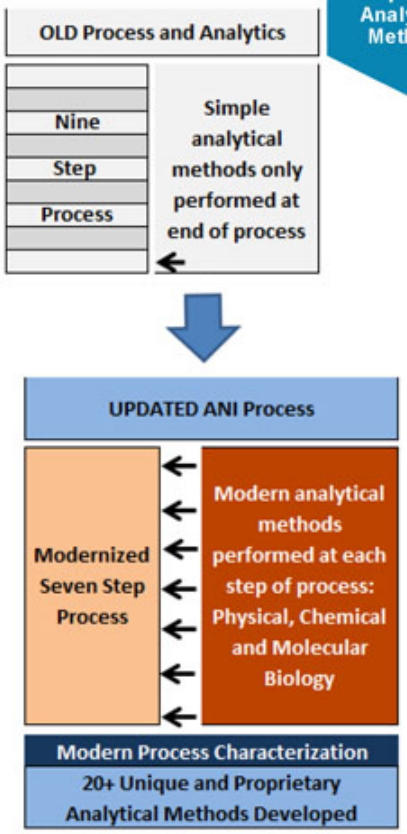
Modernize API Manufacturing Process & Analytics



Reproduce/Modernize Historical API Manufacturing Process

- Manufacturing Process
  - Reduce process from "paper" to practice with minimal process changes
  - Modernize process / equipment for compliance and quality
  - Comprehensive understanding from tissue extraction through purification
  - Establish in-process controls / critical process parameters
- U.S. API Contract Manufacturer Secured
  - Extensive experience manufacturing animal-derived APIs for FDA approved commercial drug products
  - Quality audit successfully completed
  - Able to support full commercial scale needs
  - ANI employees on-site full time to oversee manufacturing and analytical operations



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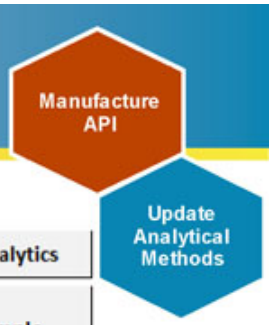
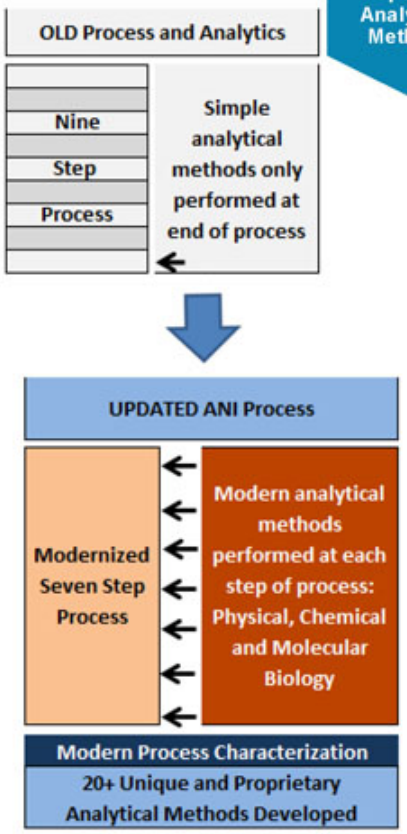
Modernize API Manufacturing Process & Analytics



Reproduce/Modernize Historical API Manufacturing Process

- First Small-scale API Successfully Manufactured
  - Objective: familiarize with each step of the API manufacturing process
  - Weight yield assessed after completion of each process step and compared to historical results
  - Additional chemical analysis performed on in-process samples after completion of each major process step
  - Small-scale batch successful on first attempt
- Intermediate-scale API Manufacturing Ongoing
  - Increase scale of API manufacturing process 5-fold
  - Objective: demonstrate lot to lot consistency
  - Support changes to process via comparability studies
  - Validate analytical methods



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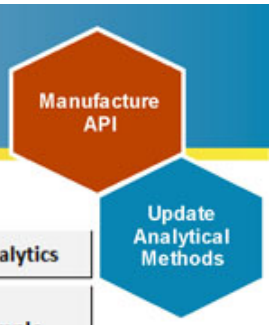
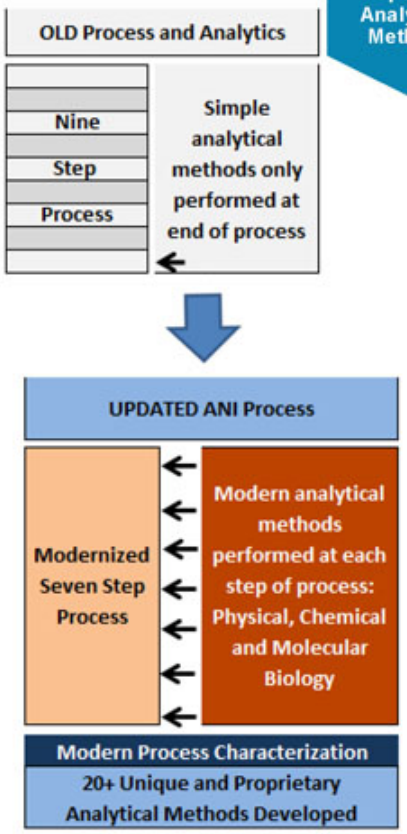
Modernize API Manufacturing Process & Analytics



Reproduce/Modernize Historical API Manufacturing Process

- Commercial-scale Corticotropin API Manufacturing
  - Objective: increase scale of API manufacturing process by ~ 5x from intermediate-scale
  - Manufacture batch to demonstrate API process is well-controlled
  - Establish in-process controls
  - Assemble characterization package
  - Complete viral clearance validation
  - Complete API manufacturing process validation
  - Manufacture registration batches with sufficient ICH stability for sNDA filing



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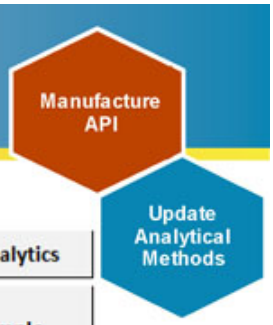
Modernize API Manufacturing Process & Analytics

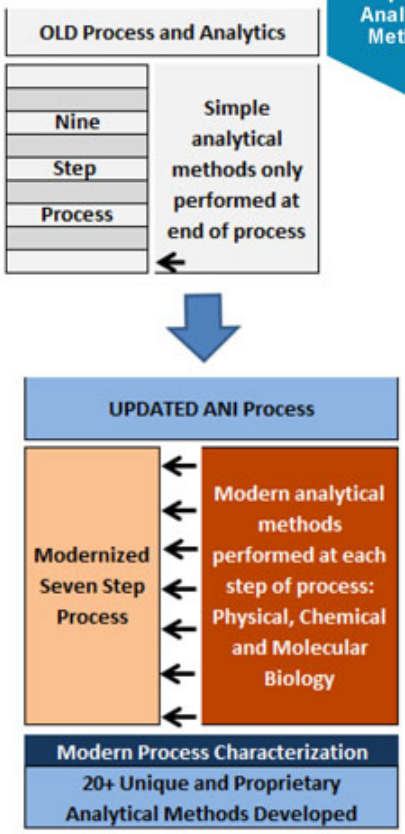


Modernize Analytics

- Historical Analytical Methods:
  - Out-dated and not compliant with current FDA standards
  - Only employed at end of API manufacturing process

Objectives:

- Update/Modernize existing analytical methods
  - Analytical package to include modern physical, chemical and molecular biology methods
- Develop new methods to supplement API characterization
  - ANI has developed unique and proprietary HPLC methods for intermediate products created after completion of each step of the modern process
- Introduce in-process methods
  - ANI is tracking over a dozen different peptides known to be secreted by porcine pituitary glands



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Secure Drug Product Manufacturer

Ideal Contract Manufacturer

- RFP issued to select U.S. based drug product CMOs
- Strong history manufacturing sterile injectable products & FDA compliance
- Experience manufacturing API from animal tissues
- Appropriate scale to manufacture projected ANI volumes

Key Items

- Target CMO selection and finalize supply agreement in 2017

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Regulatory Strategy for Re-commercialization

- Comparability protocol
  - Goal: Demonstrate comparability to previously marketed product
  - Retrospective comparison to historical data package including in-process, characterization, release and stability data
- Fully modernize product
  - Manufacturing process (drug substance and drug product)
  - Analytical technology
  - Demonstrate consistency and stability
- Engage FDA
  - Type C FDA meeting planned for 2nd half of 2017 prior to sNDA submission
  - Objective: Outline product, review changes, updated labeling, discuss comparability approach and modernization activities

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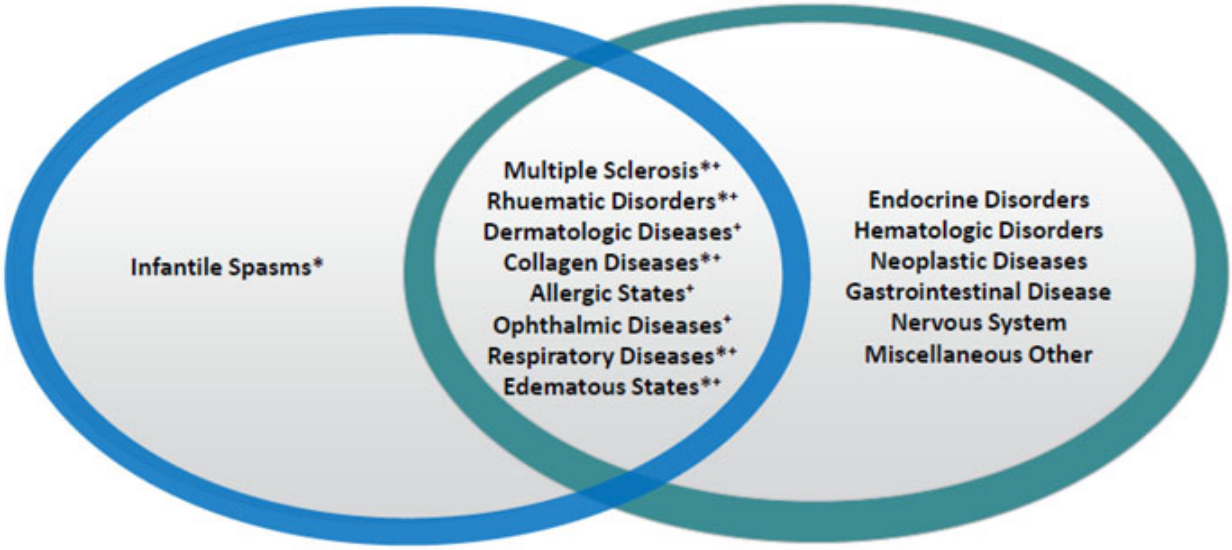
Final Corticotropin Label Subject to FDA Discussions

H.P. Acthar® Label

- **H.P. Acthar® Gel** is a highly purified sterile preparation of the adrenocorticotropic hormone in 16% gelatin to provide a prolonged release after intramuscular or subcutaneous injection

Corticotropin Label(s)

- **Cortrophin Gel** is a purified corticotropin (ACTH) in a sterile solution of gelatin for prolonged activity
- **Cortrophin-Zinc** (sterile corticotropin zinc hydroxide suspension USP) is a sterile aqueous suspension of purified corticotrophin (ACTH) with zinc hydroxide for repository action



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* Currently marketed indication by Mallinckrodt

\+ H.P. Acthar® label was limited to these indications as of 2008 when Questcor sought approval to add Infantile Spasm to the label

Key Re-commercialization Milestones

	Duration	Status	Additional Details
Manufacture small-scale batch of corticotropin API	4 mos.	Complete	• Initial batch yields equivalent to historical yields • Analytical method development and testing ongoing • Initiate stability testing
Select drug product CMO	6 mos.	Ongoing	• RFP issued in 1Q17
Manufacture intermediate-scale batches of corticotropin API	2-3 mos. per batch	Ongoing	• Demonstrate lot to lot consistency • Further refine/modernize analytical methods and process • Establish API specifications
Type C meeting with FDA		Target 2H2017	• Present re-commercialization plan • Preliminary batch characterization and comparability data • Updated analytical methods
Manufacture demo batches of Cortrophin Gel	TBD	Target 2H2017	• Initiate formulation / fill / finish of drug product
Manufacture commercial-scale batches of corticotropin API	2-3 mos. per batch	Not started	• Process validation • Registration / Commercial batches • Initiate registration-enabling ICH stability studies
Manufacture registration batches of Cortrophin Gel	TBD	Not started	• Process validation • Registration / Commercial batches • Initiate registration-enabling ICH stability studies
Initiate registration stability for sNDA	6 mos.	Not started	• Six months of accelerated stability from drug substance and drug product batches at time of submission
sNDA submission	TBD	TBD	• PAS filing - PDUFA four month review time

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Cortrophin - Substantial Commercial Opportunity

Commercial Strategy

- Provide patients with drug pricing relief
- Deploy targeted specialty sales force
- Support growth of Cortrophin use through Patient, Prescriber and Payor education
- Engage and support key constituents
  - Patient advocacy groups
  - Prescribers and Payors

Commercial Opportunity

- Subject to finalization of:
  - Product label
  - ANI pricing strategy
  - Sales and marketing plan
- Illustrative example^:

Current corticotropin market	$1,220M
Target market share	50%
Annual ANI Operating Income (net of royalties)	$200M+

^ for illustrative purposes only, not company guidance

ani Pharmaceuticals, Inc.