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): **September 18, 2015**

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**	**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)

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(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On September 18, 2015, ANI Pharmaceuticals, Inc. (the "Company" or "ANI") and Merck Sharp & Dohme B.V. ("Merck") entered into an asset purchase agreement (the "Merck Agreement") pursuant to which the Company agreed to acquire Merck's right, title and interest in NDA #008975 for Cortrophin Gel Injection, 40 units/mL and 80 units/mL and NDA #009854 for Cortrophin-Zinc Injection, 40 units/mL (collectively, the "NDAs") and certain documentation and trademark rights relating to the products under the NDAs (the "Acquired Assets"). Under the Merck Agreement, the Company will also receive a non-exclusive, irrevocable, perpetual right and license (with the right to grant sublicenses) to certain manufacturing technology relating to the manufacture of the products under the NDAs.

In consideration for the purchase of the Acquired Assets, the Company will pay Merck (i) an aggregate purchase price of $75 million upon the closing of the acquisition and (ii) a percentage of future net sales of the products under the NDAs.

Upon closing of the acquisition, the Company will assume all liabilities and obligations for the Acquired Assets, except for any liabilities arising from the manufacture or sale of products under the NDAs prior to the closing of the acquisition. The closing of the acquisition is expected to occur in January 2016.

The Merck Agreement contains various customary representations, warranties, covenants and closing conditions, as well as customary provisions relating to insurance, indemnity, confidential information and confidentiality and other matters.

Item 7.01. Regulation FD Disclosure.

On September 21, 2015, the Company issued a press release to announce the anticipated acquisition of the Acquired Assets and posted to its website its September 2015 Acquisition of Corticotropin and Corticotropin-Zinc NDAs Presentation.

The press release and presentation are available on the Company's website, www.anipharmaceuticals.com, and are furnished with this Current Report on Form 8-K as Exhibits 99.1 and 99.2 and incorporated into this Item 7.01 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Press release, dated September 21, 2015
99.2	ANI Pharmaceuticals, Inc. Acquisition of Corticotropin and Corticotropin-Zinc NDAs Presentation, September 2015

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.

By: /s/ Charlotte C. Arnold
Charlotte C. Arnold
Vice President, Finance, and Chief Financial Officer

Dated: September 21, 2015

ANI Pharmaceuticals to Acquire Two NDAs from Merck for $75 Million

Transaction Highlights:

- Corticotropin, 40 units/mL and 80 units/mL, NDA #008975

- Corticotropin-zinc hydroxide, 40 units/mL, NDA #009854

- Assets will be acquired by foreign subsidiary to achieve more favorable tax treatment for ANI

- Acquisition significantly advances ANI's core strategy of re-commercializing previously approved products

Conference call to discuss transaction scheduled today at 10:00am ET

Dial in number: (855) 582-8078; conference ID: 43851450

BAUDETTE, Minn., Sept. 21, 2015 /PRNewswire/ -- ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today announced that it has agreed to acquire the NDAs for purified corticotropin gel and corticotropin-zinc hydroxide from Merck (known as MSD outside of the United States and Canada) for $75 million in cash and a percentage of future net sales. ANI estimates that the current annual U.S. market for the products it is acquiring is approximately one billion dollars as evidenced by sales of H.P. Acthar® gel marketed by Mallinckrodt Pharmaceuticals. The acquisition is being funded through cash on hand and is subject to certain customary closing conditions.

Corticotropin gel is a purified corticotropin (ACTH) in a sterile solution of gelatin for prolonged activity. Corticotropin-zinc hydroxide (sterile corticotropin zinc hydroxide suspension USP) is a sterile aqueous suspension of purified corticotropin (ACTH) with zinc hydroxide for repository action. The products are approved for various disease states including Multiple Sclerosis, Rheumatic disorders, Dermatologic diseases, and a variety of Collagen, Ophthalmic, Respiratory diseases as well as Allergic and Edematous states.

As part of its acquisition strategy, ANI has determined to pursue the formation of one or more foreign subsidiaries to effect its acquisitions, manufacture products and/or provide other ancillary services. It is expected that this acquisition from Merck will be effected through one of such subsidiaries. It is anticipated that this will enable ANI to achieve a lower over-all tax rate for its operations.

ANI will host a conference call to discuss the transaction at 10:00am eastern time today. The call will be open to the public and can be accessed through a conference line by dialing (855) 582-8078. The conference ID is 43851450. A recording of the conference call will be available within two hours of the completion of the call and will remain accessible for a period of seven days following the call. To access the replay, dial (855) 859-2056. The access code for the replay is 43851450. This press release and a slide presentation have been posted to the Investor Relations section of the Company's website, www.anipharmaceuticals.com.

Arthur S. Przybyl, President and CEO of ANI Pharmaceuticals stated, "This acquisition is intended to enable us to compete in a one billion dollar branded market alongside H.P. Acthar® gel. We are confident in our ability to re-commercialize these products."

Robert W. Schrepfer, VP Business Development of ANI Pharmaceuticals, commented, "This represents a transformational opportunity for ANI that remains consistent with our strategy of acquiring and re-commercializing previously approved products. We have added a unique and substantial opportunity to our expanding product pipeline and by establishing a new foreign platform we feel that ANI has set the stage for long term growth both organically and through future acquisitions."

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release 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; 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 news release speak only as of the date of this news release 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.

For more information about ANI, please contact:
Investor Relations
IR@anipharmaceuticals.com

Exhibit 99.2

A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Acquisition of Corticotropin and Corticotropin-Zinc NDAs

September 2015

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.

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ani Pharmaceuticals, Inc.

ANI Mission

ANI Pharmaceuticals is an integrated specialty pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals.

We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations.

Acquisition Overview

- **Assets**
  - NDA 008975 Corticotropin 40 units/mL and 80 units/mL
  - NDA 009854 Corticotropin-zinc hydroxide 40 units/mL
- **Terms**
  - $75 million in cash
  - A percentage of future net sales
- **Structure**
  - ANI to acquire and commercialize assets via foreign subsidiary
- **Timing**
  - Expected close in January 2016
  - Subject to customary closing conditions

ani Pharmaceuticals, Inc.

Compelling Strategic Opportunity

- **Provides patients, physicians and payors with valuable therapeutic option**

- **Large and growing U.S. market with concentrated prescriber base**
  - H.P. Acthar® gel - $1 billion in annual sales with double digit script growth*
  - Broad label with minimal penetration
    - Use focused in Neurology, Rheumatology, Nephrology and Pulmonology
    - Large potential U.S. patient population ~ 4,000,000*
    - Small current patient user base ~ 10,000*
- **Approved status shortens development period**

- **Durable assets**
  - High barrier to generic entry
  - Lifecycle strategy in place

ani Pharmaceuticals, Inc.

* Per publically available information disclosed by Mallinckrodt Pharmaceuticals

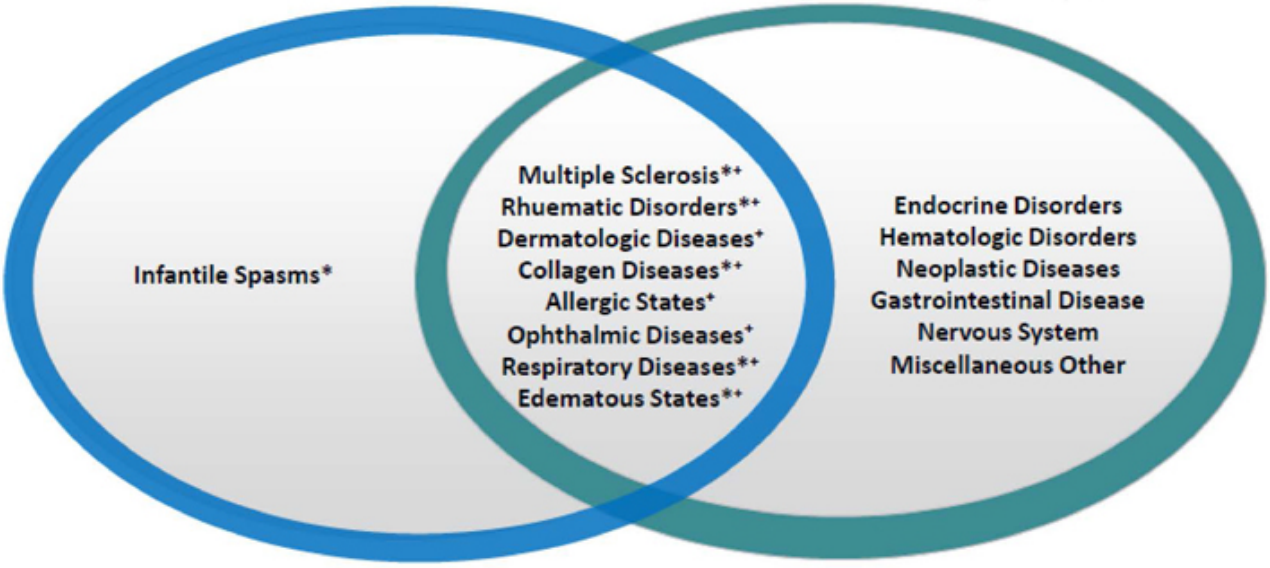
Current Corticotropin Label(s) Similar to H.P. Acthar®

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)

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



* 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

ani Pharmaceuticals, Inc.

Steps to Re-Commercialization

- **Regulatory**
  - Meet with FDA to initiate re-activation of NDA(s)
  - CMC – provide documentation to justify any changes to site, suppliers, DMF
  - Drug substance/drug product – demonstrate similarity to product manufactured under approved NDA
  - Label – match H.P. Acthar® gel indications, excluding Infantile Spasm
  - Filing type – sNDA as prior approval supplement
- **Quality**
  - Utilize modern methods to characterize active pharmaceutical ingredient (API)
- **Supply chain**
  - Secure partner for API and sterile manufacture

ani Pharmaceuticals, Inc.

Products Aligned with ANI Acquisition Strategy

		LIMITED COMPETITION	POTENT / CONTROLLED SUBSTANCE	COMPLEX FORMULATIONS	LIMITED or EXCLUSIVE API	ANI MANUFACTURE	PREVIOUSLY APPROVED
Brands	CORTICOTROPIN (corticotropin injection) 40 Units / mL and 80 Units / mL	✓	✓	✓	✓		✓
	CORTICOTROPIN-ZINC (corticotropin-zinc injection) 40 Units / mL	✓	✓	✓	✓		✓
	TESTOSTERONE GEL (testosterone gel satchets)	✓	✓		✓		✓
	VANCOCIN (vancomycin hydrochloride capsules)			✓			✓
	REGLAN (metoclopramide tablets)					✓	✓
	LITHOBID (lithium carbonate tablets)					✓	✓
Generics	ETODOLAC (etodolac capsules)	✓				✓	✓
	METHAZOLAMIDE (methazolamide tablets)	✓			✓	✓	✓
	PROPAFENONE (propafenone tablets)	✓				✓	✓
	FLECAINIDE (flecainide tablets)	✓				✓	✓
	TEVA ANDA BASKET 1 (31 previously approved ANDAs)	✓	✓	✓	✓	✓	✓
	TEVA ANDA BASKET 2 (22 previously approved ANDAs)	✓	✓	✓	✓	✓	✓

ani Pharmaceuticals, Inc.

Summary - Unique Opportunity / Long Term Value

- **Approved NDAs**
  - Corticotropin: 40 units/mL and 80 units/mL
  - Corticotropin-zinc hydroxide: 40 units/mL
- **$1 billion market currently dominated by a single product**
- **Adds significant long-term value driver to ANI platform**
- **Tax advantaged structure**

ani Pharmaceuticals, Inc.

Conclusion