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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

**Current Report  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): **September 19, 2013**

**ANI PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-31812**  
(Commission File Number)

**58-2301143**  
(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**

(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))
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**Item 7.01 Regulation FD Disclosure.**

On September 19, 2013, ANI Pharmaceuticals, Inc. (the “Company”) posted to its website its September 2013 Corporate Presentation. The presentation is available on the Company’s website, [www.anipharmaceuticals.com](http://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 under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the Company’s plans, objectives, expectations and intentions with respect to future operations and products, the anticipated financial position, operating results and growth prospects of the Company 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. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. 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 the risk that Company estimates regarding product development may not be realized; the Company may in the future fail to meet NASDAQ listing requirements; general business and economic conditions; the Company’s need for and ability to obtain additional financing; the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; and the marketing success of the Company’s licensees or sublicensees. 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 report on Form 10-Q, as well as its proxy statement/prospectus, filed with the Securities and Exchange Commission on May 8, 2013. All forward-looking statements in this quarterly report speak only as of the date made and are based on the Company’s current beliefs 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.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>No.</u>	<u>Description</u>
99.1	ANI Pharmaceuticals, Inc. Corporate Presentation September 2013

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**SIGNATURE**

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 and Chief Financial Officer*

Dated: September 19, 2013

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**A Specialty Pharmaceutical Company**

**NASDAQ: ANIP**

HIGH POTENCY DRUGS – NARCOTIC DRUGS – RX LIQUIDS AND TABLETS – CONTRACT MANUFACTURING

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# Corporate Presentation

September 2013

## Cautionary Statement Concerning Forward-Looking Statements

This presentation and certain information incorporated herein by reference contain forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the Company's plans, objectives, expectations and intentions with respect to future operations and products, the anticipated financial position, operating results and growth prospects of the Company 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. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. 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 the risk that Company estimates regarding product development may not be realized; the Company may in the future fail to meet NASDAQ listing requirements; general business and economic conditions; the Company's need for and ability to obtain additional financing; the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; and the marketing success of the Company's licensees or sublicensees. 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 report on Form 10-Q, as well as its proxy statement/prospectus, filed with the Securities and Exchange Commission on May 8, 2013. All forward-looking statements in this quarterly report speak only as of the date made and are based on the Company's current beliefs 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.

# Mission Statement

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ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) is an integrated specialty pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals.

ANI’s mission is to utilize its manufacturing assets to develop and market niche generic pharmaceuticals, focusing on opportunities in pain management (narcotics), anti-cancer (oncolytics), women’s health (hormones and steroids), as well as complex formulations including extended release and combination products.



# Company Overview – Poised for Growth

## ● ANI Today

- Core competencies: marketing and manufacturing
- Experienced management team
- Existing business + potential future royalty stream
  - For the interim six-month period ended June 30, 2013<sup>(1)</sup>:
    - ❖ \$7.5 million Rx product revenues
    - ❖ \$4.2 million contract manufacturing and services revenues
    - ❖ Annual organic growth 17% year/year
  - Potential future royalty stream: Teva's Bio-T-Gel™
  - 12 products in development: total current market \$850 million<sup>(2)</sup>
- Two manufacturing facilities: narcotics and potent compounds
- Well-capitalized balance sheet: +\$12 million cash / no debt



(1) Unaudited

(2) Based on Company estimates, and recent IMS and NSP Audit data



# Leadership – Deep Industry Experience

## Senior Management

Arthur S. Przybyl, President and CEO  
Charlotte C. Arnold, VP and CFO  
Robert J. Jamnick, VP Quality and PD  
James G. Marken, VP Operations  
Robert W. Schrepfer, VP BD

## ANI Since

2009  
2009  
2007  
2007  
2013

## Previous Affiliation

Akorn (NASDAQ: AKRX)  
MVP Capital Partners  
Solvay  
Solvay  
Healthcare Value Capital

## Board of Directors

Robert E. Brown, Jr. Chairman  
Arthur S. Przybyl, President and CEO  
Fred Holubow  
Ross Mangano  
Tracy Marshbanks  
Thomas A. Penn  
Daniel Raynor

## Member Since

2009  
2009  
2013  
2013  
2006  
2009  
2013





# History and Highlights

- 2004 Company founded with acquisition of over-the-counter pharmaceutical manufacturing plant in Gulfport, Mississippi
- 2007 ANI acquires two manufacturing plants located in Baudette, Minnesota from Solvay Pharmaceuticals
- 2009 New management team brought in by investors; Art Przybyl, CEO and Charlotte Arnold, CFO
- 2010 New strategy: ANI to focus on Rx products and contract manufacturing (Gulfport operation divested)
- 2011 ANI expands marketed Rx portfolio to seven products
- 2013 ANI completes reverse merger with BioSante Pharmaceuticals and obtains NASDAQ Global Market listing (NASDAQ: ANIP)

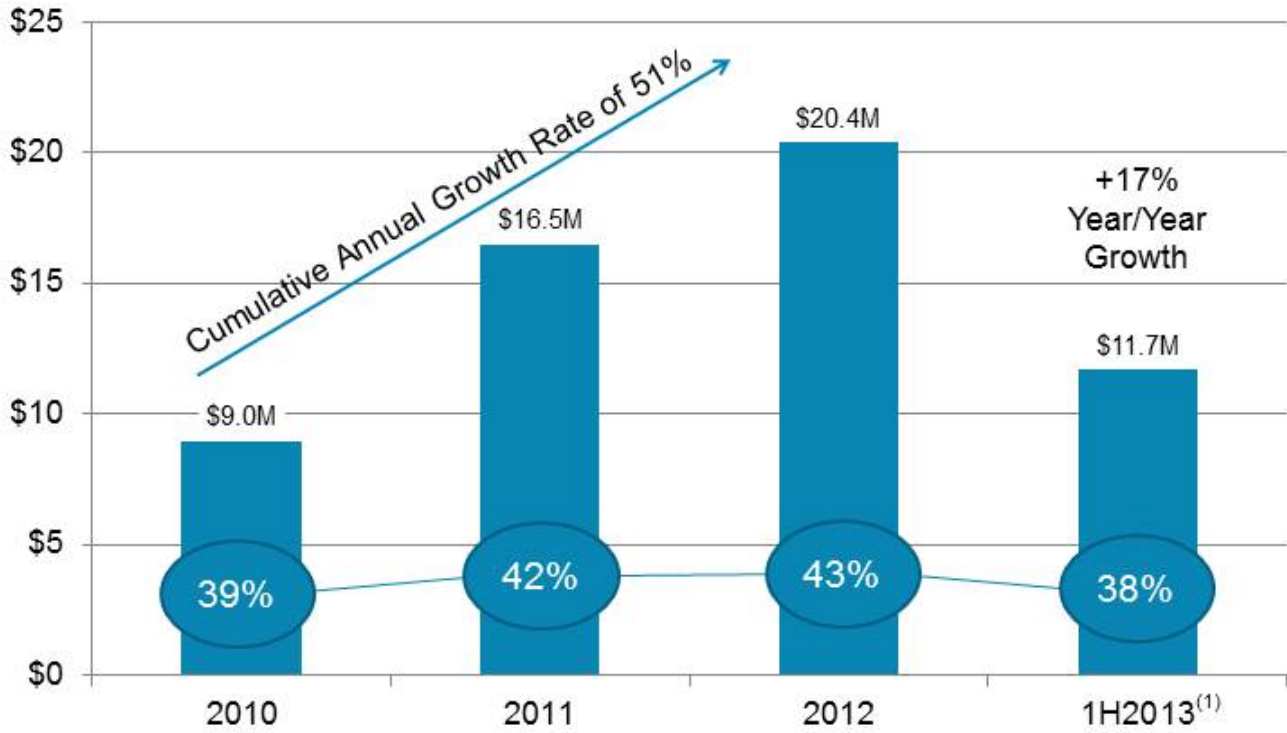


# Sales and Marketing Overview



# Historical Revenue Growth

\$s in millions



● Cost of sales as a percentage of net revenues, excluding depreciation and amortization

(1) Unaudited



# Current Rx Product Portfolio

<u>Generic Products</u>	<u>Position</u>	<u>Market Share<sup>(1)</sup></u>
Fluvoxamine Tablets	#1	54%
HC Enema	#1	85%
Opium Tincture	#1	64%
EE/MT Tablets	#2	42%
Metoclopramide Solution	#2	31%

## Branded Products

Cortenema™

Reglan Tablets™



(1) Based on Company estimates, and recent IMS and NSP Audit data

# Contract Manufacturing and Royalties

## ● Current Business

- \$4.2 million in contract manufacturing and services revenues during the six-month period ended June 30, 2013<sup>(1)</sup>
- Five customers
  - Eleven products and fourteen SKUs

## ● Future Opportunities

- Three customers in development
  - Three products and seven SKUs
- Potential future royalty: Teva's Bio-T-Gel™

# Product Development / Business Development Overview



# Product Development Highlights

- 12 products in development
  - Five filed ANDAs
  - Seven ANDAs in progress
    - Development partners: Ricon and Sofgen
  - Total combined current market: \$850 million<sup>(1)</sup>

Therapeutic Category	Filed	In Development	Market Size <sup>(1)</sup> (\$ in millions)
Oncolytics and Narcotics	3	2	\$97 million
Other (e.g. Extended Release, Combination Products)	2	5	\$753 million



(1) Based on Company estimates, and recent IMS and NSP Audit data



# Business Development Highlights

- Acquired undisclosed ANDA, March 2010
- Acquired Reglan™ tablets, June 2011
- Product development partnership with Ricon, June 2011
- Acquired Bio-T-Gel™ royalty arrangement with Teva, June 2013
- Product development partnership with Sofgen, August 2013

# Manufacturing Overview



# Manufacturing – Main Street Facility

- Location: Baudette, Minnesota

- 52,000 square feet of manufacturing, packaging, and warehouse facilities
- Rx solutions, suspensions, topicals, tablets, and capsules
- DEA-licensed for Schedule II controlled substances
- 17,000 square feet of laboratory space for product development and analytical testing



# Manufacturing – IDC Road Facility

- Location: Baudette, Minnesota

- Fully-contained high potency facility with capabilities to manufacture hormone, steroid, and oncolytic products
- 47,000 square feet of manufacturing and packaging, and warehouse facilities
- 100 nano-gram per eight-hour weighted average maximum exposure limit to ensure employee safety
- DEA Schedule IIIN capability



# Capitalization and Shareholders



# Capitalization and Shareholders

- Market capitalization (as of September 18<sup>th</sup>, 2013) of approximately \$85 million
- 9.5 million shares outstanding
- Major shareholders

	Ownership
Officers and Directors	3.7%
Meridian Venture Partners	29.6%
First Analysis Corporation	8.5%
Argentum Capital Partners II	5.9%
Healthcare Value Capital LLC	3.9%

## Poised for Growth

