

**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): April 6, 2021**

**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**  
(IRS Employer Identification No.)

**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)

Securities registered pursuant to Section 12(b) of the Act:

**Title of each class:**  
Common Stock

**Trading Symbol(s):**  
ANIP

**Name of each exchange on which registered:**  
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 7.01. Regulation FD Disclosure.**

On April 6, 2021, ANI Pharmaceuticals, Inc. issued a press release announcing its acquisition of the new drug applications for OXISTAT<sup>®</sup> Lotion, VEREGEN<sup>®</sup> Ointment, Pandel<sup>®</sup> Cream and the abbreviated new drug application for ApexiCon<sup>®</sup> E Cream from Sandoz Inc., a global leader in generic pharmaceuticals. The press release announcing the acquisition is furnished as Exhibit 99.1 and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

**Item 9.01 Financial Statements and Exhibits.**

<u>Exhibit</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release dated April 6, 2021.</a>
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

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**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: April 6, 2021

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**FOR IMMEDIATE RELEASE**

**ANI Pharmaceuticals Expands Branded Products Portfolio Through Acquisition of Sandoz Inc. NDAs**

-- Accretive transaction in line with growth strategy laid out for Branded Products business --

**Baudette, Minnesota (April 6, 2021)** – ANI Pharmaceuticals, Inc. (“ANI”) (NASDAQ:ANIP) today announced that it has acquired the new drug applications (“NDAs”) for OXISTAT<sup>®</sup> Lotion, VEREGEN<sup>®</sup> Ointment, and Pandel<sup>®</sup> Cream and the abbreviated new drug application (“ANDA”) for ApexiCon<sup>®</sup> E Cream from Sandoz Inc. Pandel<sup>®</sup> Cream will be transitioned later upon receiving the requisite approvals. Collectively, these products generated net revenues of \$13.2 million in 2020. The acquisition was funded through borrowings under the Company’s pre-existing revolver credit facility.

In conjunction with the acquisition, ANI and Sandoz have entered into a multi-year manufacturing and supply agreement for OXISTAT<sup>®</sup> Lotion, Pandel<sup>®</sup> Cream and Apexicon<sup>®</sup> E Cream. ANI intends to transfer the manufacture and packaging of these three products to its own manufacturing sites in the future.

“This acquisition is in line with our strategy to expand our established brands business through accretive deals. Importantly, ANI will ensure that patients in need continue to receive these high-quality dermatology products. The acquisition leverages our innovative brand commercialization infrastructure and our North American manufacturing footprint,” stated Nikhil Lalwani, President and CEO.

The Company previously shared the four pillars of its strategy for delivering sustainable future growth:

- Build a successful Cortrophin franchise;
- Strengthen the Generics business by enhancing development capabilities and increased focus on niche opportunities;
- Maximize the value from established brands through programmatic business development and innovative access and go-to-market strategies; and
- Expand CDMO business leveraging unique North American-based manufacturing capabilities.

**About OXISTAT<sup>®</sup> (oxiconazole nitrate) Lotion 1%**

OXISTAT Lotion is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, or *Epidermophyton floccosum*.

**About Pandel<sup>®</sup> (hydrocortisone probutate) Cream 0.1%**

Pandel is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age or older.

**About VEREGEN<sup>®</sup> (sinecatechins) Ointment 15%**

VEREGEN is a topical ointment indicated for the treatment of external genital and perianal warts (*Condylomata acuminata*) in immunocompetent patients 18 years and older.

**About ApexiCon® E Cream (diflorasone diacetate cream USP 0.05% [emollient])**

ApexiCon E Cream is a topical corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

For more information, including the complete list of indications and usages, please see the Full Prescribing Information.

**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](http://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 the Company’s strategy, the Company’s future operations, products financial position, operating results and prospects, the Company’s 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 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 transitioning these products; 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 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.

**Contact**

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*SOURCE: ANI Pharmaceuticals, Inc.*

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