

**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): May 11, 2023

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 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**

Not Applicable
(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 (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 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 8.01 Other Events

Underwritten Equity Offering

On May 11, 2023, ANI Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that it has commenced an underwritten public offering of its common stock. The Company intends to grant the underwriters of the offering a 30-day option to purchase up to an additional 15 percent of the number of shares of common stock sold in connection with the offering. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Neither the disclosures on this Current Report on Form 8-K nor the exhibits hereto shall constitute an offer to sell or the solicitation of an offer to buy the securities described herein and therein, nor shall there be any sale of such securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Recent Developments

We have submitted multiple binding bids totaling less than \$25 million in the aggregate to acquire certain abbreviated new drug approvals (ANDAs) and assume certain related contracts pursuant to an auction sale process under Section 363 of the Bankruptcy Code by George L. Miller, as the Chapter 7 trustee of Akorn Holding Company LLC, Akorn Intermediate Company LLC and Akorn Intermediate Company, as debtors under Chapter 7 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware jointly administered under Case No. 23-10253-KBO. The auction process is scheduled to conclude on or about May 12th, 2023. There can be no assurance that our bids will be successful, and we may have certain bids accepted but not others. If all or a portion of our bids are successful, then the funds to be used for such acquisition will come from the Company’s existing cash resources and not from any proceeds of this offering.

Risk Factor Update

The following risk factor is provided to update and supplement the risk factors of the Company previously disclosed under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 and the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.

“We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business.”

Many of our products are eligible for reimbursement under federal and state health care programs such as Medicaid, Medicare, TRICARE, and/or state pharmaceutical assistance programs, and as a result, certain U.S. federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights are, and will be, applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business.

The domestic and foreign laws that may affect our ability to operate include, but are not limited to: (i) the U.S. Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, as a means of inducing, or in exchange for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) U.S. federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other federal healthcare program payers that are false or fraudulent; (iii) new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; (iv) the U.S. Physician Payments Sunshine Act, which among other things, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually information related to certain "payments or other transfers of value" made to physicians, physician assistants, advanced practice nurses and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, and similar state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; (v) the government pricing rules applicable to the Medicare and Medicaid programs, the 340B Drug Pricing Program, the U.S. Department of Veterans Affairs program, the TRICARE program, and state price transparency reporting laws; and (vi) state and foreign law equivalents of each of the above U.S. laws, such as anti-kickback and false claims laws which may apply to items or services. Defense of litigation claims and government investigations can be costly, time-consuming, and distract management, and it is possible that we could incur judgments, settlements, deferred or non-prosecution agreements, or corporate integrity agreements that would require us to change the way we operate our business. We are committed to conducting the sales and marketing of our products in compliance with the healthcare fraud and abuse laws, but certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that govern our activities, such as federal and state anti-kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn and construed by the courts. While we manage our business activities to comply with these statutory provisions, due to their breadth, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the DOJ, the Office of Inspector General at the U.S. Department of Health and Human Services, and other agencies have increased their enforcement activities with respect to the manufacturing, sales, marketing, research and similar activities of pharmaceutical companies in recent years, and many pharmaceutical companies have been subject to government investigations related to these practices. A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacturing and/or distribution activities, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions.

Any of these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows."

We are subject to certain privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements, as well as any breach of unsecured identifiable personal information protected by law, could subject us to significant costs, fines, penalties (civil and criminal), and civil litigation which may have a material adverse effect on our business, financial condition or results of operations.

As regulatory focus on privacy issues continues to increase, and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. In addition, the interpretation and application of consumer, health-related, and data protection laws are often uncertain, contradictory, and in flux, which complicates compliance efforts.

Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the Company. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain such words as “estimate,” “project,” “intend,” “forecast,” “target,” “anticipate,” “plan,” “planning,” “expect,” “believe,” “will,” “should,” “could,” “would,” “may,” or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, but are not limited to, statements about the Company’s intent to grant the underwriters of the offering an option to purchase additional shares and discussions about the underwritten public offering. Actual events or results may differ materially from those described in this press release due to a number of important factors. Current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this Current Report on Form 8-K will prove to be accurate. Except to the extent required by applicable laws or rules, the Company does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause the Company’s actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in the Company’s filings with the U.S. Securities and Exchange Commission, including the Company’s most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

Item 9.01 Exhibits

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
<u>No.</u>	
99.1	Press Release of the Company, dated May 11, 2023
104	Cover Page Interactive Data File (embedded with 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 hereunto duly authorized.

Dated: May 11, 2023

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Name: Stephen P. Carey

Title: Senior Vice President Finance and Chief Financial Officer

ANI PHARMACEUTICALS ANNOUNCES PROPOSED PUBLIC OFFERING OF COMMON STOCK

BAUDETTE, Minn.-- (BUSINESS WIRE) – May 11, 2023 -- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (“ANI”) today announced that it intends to offer and sell shares of its common stock in an underwritten public offering. All of the shares to be sold in the offering will be offered by ANI. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering. In addition, ANI intends to grant the underwriters a 30-day option to purchase up to an additional 15% of shares of its common stock offered in the public offering.

Guggenheim Securities, LLC is acting as book-running manager.

ANI anticipates using the net proceeds from the offering to in-license, acquire or invest in additional businesses, technologies, products or assets, to fund its commercialization efforts, including, but not limited to, sales and marketing and consulting expenses related thereto, and for general corporate purposes. As part of its business, ANI actively monitors and considers various business development opportunities.

The securities described above are being offered by ANI pursuant to a shelf registration statement on Form S-3 (File No. 333-239771) which was initially filed by ANI with the Securities and Exchange Commission (the “SEC”) on July 9, 2020, and was declared effective by the SEC on July 17, 2020.

The securities will be offered only by means of a prospectus supplement and accompanying prospectus relating to the offering that form a part of the registration statement. A preliminary prospectus supplement and the accompanying prospectus relating to and describing the terms of the offering will be filed with the SEC and will be available on the SEC’s website at <http://www.sec.gov>. Copies of the final prospectus supplement, when available, and accompanying prospectus relating to the offering may be obtained from Guggenheim Securities, LLC, Attention: Equity Syndicate Department, 330 Madison Avenue, New York, NY 10017, by telephone at (212) 518-9544, or by email at GSEquityProspectusDelivery@guggenheimpartners.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any of the securities described herein, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by building a successful Purified Cortrophin® Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including without limitation statements regarding the offer and sale of shares, the terms of the offering and expected use of proceeds are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause ANI's actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties related to market conditions and satisfaction of customary closing conditions related to the offering, as well as the risks and uncertainties set forth in ANI's Annual Report on Form 10-K for the year ended December 31, 2022, the preliminary prospectus supplement related to the proposed public offering and subsequent filings with the SEC. Any of these risks and uncertainties could materially and adversely affect ANI's results of operations, which would, in turn, have a significant and adverse impact on ANI's stock price. Any forward-looking statements contained in this press release speak only as of the date hereof, and ANI specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor Relations:

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Source: ANI Pharmaceuticals, Inc.
