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 21, 2019

ADAMIS PHARMACEUTICALS CORPORATION
(Exact Name of Registrant as Specified in Charter)

Delaware	**0-26372**	**82-0429727**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

11682 El Camino Real, Suite 300 **San Diego, CA** (Address of Principal Executive Offices)	**92130** (Zip Code)

Registrant's telephone number, including area code: **(858) 997-2400**

(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 (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. ☐

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	ADMP	NASDAQ Capital Market

Item 8.01 Other Events

On May 21, 2019, Adamis Pharmaceuticals Corporation (the "Company") issued a press release announcing that on May 20, 2019, the Company received notice that it had been named and served as a defendant in a lawsuit filed by kaléo Inc. in the United States District Court for the District of Delaware regarding the Company's higher dose naloxone injection product candidate for the treatment of opioid overdose, for which the Company has previously submitted a New Drug Application to the U.S. Food and Drug Administration and which is being reviewed by the agency. The complaint alleges, among other things, that the Company's product candidate infringes patents purportedly held by kaléo relating to its naloxone auto-injector product. Although the ultimate outcome of this matter cannot be determined with certainty, Adamis believes that its naloxone injection product, which combines a generic formulation of naloxone with Adamis' proprietary injection device, does not infringe any valid and enforceable patent held by kaléo and that kaléo's complaint is without merit. Adamis intends to defend against kaléo claims and pursue all available legal remedies available to the company against kaléo, and if appropriate, its outside counsel.

The Company's press release is filed as exhibit 99.1 to this Report.

Forward-Looking Statements

This Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future results of operations, including, but not limited to the following statements: the outcome of the patent infringement lawsuit filed by kaléo; the Company's ability to successfully enforce and defend its intellectual property rights; the potential costs associated with the patent infringement lawsuit filed by kaléo; any future actions of the FDA arising from the patent infringement lawsuit filed by kaléo; the impact of the patent infringement lawsuit on our business, results of operations and financial position; the Company's beliefs concerning drug overdoses in the United States, illicit use of opioids in the United States, and deaths due to fentanyl and other opioids; use of naloxone to help treat opioid overdoses; the potential for future growth in the naloxone market; the Company's beliefs concerning the timing and outcome of the FDA's review of the Company's NDA relating to its naloxone product candidate; the Company's ability to successfully develop its naloxone product candidate and other product candidates; and the outcome of any discussions with third parties concerning commercialization of the product. Such forward-looking statements include those that express plans, anticipation, intent, contingencies, goals, targets or future development and/or otherwise are not statements of historical fact. These statements are only predictions, are not guarantees, involve known and unknown risks, uncertainties and other factors, and concern matters that could subsequently differ materially from those described in this press release, which may cause the Company's actual results to be materially different from those contemplated by these forward-looking statements. There are no assurances concerning the outcome of the patent lawsuit filed by kaléo. The lawsuit could require material financial resources and consume significant management time to resolve, regardless of the outcome of the proceedings. The lawsuit, or an adverse outcome in the litigation, could have a material adverse effect on our naloxone product candidate and the Company's business, financial conditions and results of operations. In addition, there can be no assurances that the FDA will approve the Company's NDA relating to its naloxone product candidate or will give final approval to the Company's proposed brand name for the product, concerning the timing of any such approval, that the product will be commercially successful if approved and introduced, or concerning the outcome of any discussions with third parties concerning commercialization of the product. The FDA review process is subject to a number of uncertainties. The FDA could request additional or different submissions or request additional data, information, materials or clinical trials or studies, all of which could affect the timing and outcome of the review process. As a result, there can be no assurances regarding the timing or the outcome of the FDA's review process. In addition, forward-looking statements concerning our anticipated future activities assume that we are able to obtain sufficient funding to support such activities and continue our operations and planned activities. As discussed in our filings with the Securities and Exchange Commission, we may require additional funding, and there are no assurances that such funding will be available if required. You should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as may be required by applicable law, we undertake no obligation to update or release publicly the results of any revisions to these forward-looking statements or to reflect events or circumstances arising after the date of this Report on Form 8-K. Certain of these risks, and additional risks, uncertainties, and other factors are described in greater detail in the Company's filings from time to time with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and subsequent filings with the SEC, which the Company strongly urges you to read and consider, all of which are available free of charge on the SEC's web site at http://www.sec.gov.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release issued May 21, 2019.

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.

ADAMIS PHARMACEUTICALS CORPORATION

Dated: May 21, 2019

By: /s/ Robert O. Hopkins
Name: Robert O. Hopkins
Title: Chief Financial Officer

Exhibit 99.1

Adamis Pharmaceuticals Announces Patent Litigation Regarding Its Higher Dose Naloxone Injection Product

SAN DIEGO, CA --(May 21, 2019)- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced that on May 20, 2019, it received notice that it had been named and served as a defendant in a lawsuit filed by kaléo Inc. in the United States District Court for the District of Delaware regarding Adamis' higher dose naloxone injection product candidate for the treatment of opioid overdose, for which Adamis has previously submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) that is being reviewed by the agency. The complaint alleges, among other things, that the company's product candidate infringes patents purportedly held by kaléo relating to its naloxone auto-injector product. The action was filed under the provisions of the Hatch-Waxman Act in response to Adamis' Paragraph IV certification regarding the kaléo patents as part of the company's NDA process, and results in an automatic stay of any final approval by the FDA of Adamis' NDA. Adamis does not anticipate this stay would interrupt or delay the FDA's ongoing review of the NDA; however, if the patent dispute is unresolved by the time the FDA was prepared to grant an approval, the company believes that the agency would grant conditional approval until the sooner of October 4, 2021 or until final resolution of the matter before the court, whichever occurs sooner.

Adamis believes that its naloxone injection product, which combines a generic formulation of naloxone with Adamis' proprietary injection device, does not infringe any valid and enforceable patent held by kaléo and that kaléo's complaint is without merit. Adamis intends to defend against kaléo claims and pursue all available legal remedies available to the company against kaléo and, if appropriate, its outside counsel.

Background

In December 2018, Adamis filed an NDA relating to its higher dose naloxone injection product. In March 2019, Adamis received a notice from the FDA that the NDA was sufficiently complete to permit a substantive review with a target action date of October 31, 2019. As is part of this kind of application, Adamis' NDA included Paragraph IV certification with respect to certain patents listed in the FDA's Orange Book for kaléo, Inc.'s EVZIO® product. As contemplated under the applicable federal laws and procedures, Adamis certified that each was invalid, unenforceable, or will not be infringed by the Adamis naloxone injection product and sent a notice letter to kaléo informing kaléo of the Paragraph IV certification.

About Naloxone Injection

Naloxone is an opioid antagonist used to treat narcotic overdoses. Naloxone, which is generally considered the drug of choice for immediate administration for opioid overdose, blocks or reverses the effects of the opioid, including extreme drowsiness, slowed breathing, or loss of consciousness. Common opioids include morphine, heroin, tramadol, oxycodone, hydrocodone and fentanyl. According to statistics published by the Centers for Disease Control and Prevention, in 2017, drug overdoses resulted in approximately 72,000 deaths in the United States – nearly 200 deaths per day. Drug overdoses are now the leading cause of death for Americans under 50, and the proliferation of more powerful synthetic opioids, such as fentanyl and its analogues, could result in future increases in the number of deaths resulting from opioid overdoses. Based on the current opioid epidemic, particularly involving the more potent fentanyl narcotics, the company and others have published reports supporting the need for a higher dose naloxone product.

In December 2018, the joint meeting of the Anesthetic and Analgesic Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee voted in favor of adding labeling language that recommends co-prescription of naloxone for all or some patients prescribed opioids. Medicare (HHS) has also recommended co-prescribing naloxone with opioids under certain conditions. These recommendations could significantly increase the naloxone market.

About Adamis

Adamis Pharmaceuticals Corporation is a specialty biopharmaceutical company primarily focused on developing and commercializing products in various therapeutic areas, including respiratory disease and allergy. The company's SYMJEPI ™ (epinephrine) Injection 0.3mg and SYMJEPI (epinephrine) Injection 0.15mg products are FDA approved for use in the emergency treatment of acute allergic reactions, including anaphylaxis. The company's subsidiary, U.S. Compounding, Inc., compounds sterile prescription drugs, and certain nonsterile drugs for human and veterinary use, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States.

Adamis Forward Looking Statements

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