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): November 25, 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 Exchange 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 November 25, 2019, Adamis Pharmaceuticals Corporation ("Adamis" or the "Company") issued a press release announcing that after the close of U.S. markets on November 22, 2019, it received a Complete Response Letter ("CRL") from the U.S. Food & Drug Administration ("FDA") regarding the Company's New Drug Application ("NDA") for its ZIMHI™ high-dose naloxone injection product for the treatment of opioid overdose. A CRL is issued by the FDA's Center for Drug Evaluation and Research when it has completed its review of a file and questions remain that preclude the approval of the NDA in its current form.

The CRL stated that the FDA determined that it cannot approve the Company's NDA in its present form.

The Company is reviewing the CRL and plans to request a meeting with the FDA to discuss the CRL and the Company's response to the CRL. A copy of the Company's press release is attached hereto as Exhibit 99.1 is incorporated into this item by reference.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release dated November 25, 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: November 25, 2019

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

Exhibit 99.1

Adamis Pharmaceuticals Receives a Complete Response Letter from the FDA Regarding ZIMHI

SAN DIEGO--(November 25, 2019) - Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) ("Adamis") today announced that after the close of U.S. markets on November 22nd, it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for Adamis' ZIMHI™ high-dose naloxone injection product for the treatment of opioid overdose. The CRL stated that theFDA determined it cannot approve the NDA in its present form and provided recommendations needed for resubmission.

A CRL is issued by the FDA's Center for Drug Evaluation and Research when it has completed its review of a file and questions remain that preclude the approval of the NDA in its current form. The questions raised by the FDA related generally to Chemistry, Manufacturing and Controls (CMC). The plan is to expand on the CMC testing that has already been provided to the FDA to satisfy the CRL items. No other clinical safety or efficacy issues were raised, and the New Drug Application will remain open until the CMC issues are resolved.

Dr. Dennis J. Carlo, President and CEO of Adamis, stated, "Obviously, we are very surprised and disappointed. With a growing number of fatal overdoses as a result of more potent opioids like fentanyl, we believe there is an obvious need for higher dose forms of naloxone and we remain committed to bringing ZIMHI to the market. We believe the comments and recommendations stated in the CRL are manageable and plan to fully cooperate with the FDA. We remain committed to this product and our mission to provide physicians and patients access to a higher dose of naloxone. We will take the Agency's suggestion and request a meeting as soon as reasonably possible to discuss our plan to resubmit the NDA."

About ZIMHI

ZIMHI is a high-dose naloxone injection product candidate intended for the treatment of opioid overdose. Naloxone is an opioid antagonist and is generally considered the drug of choice for immediate administration for opioid overdose. It works by blocking or reversing 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 (CDC) in 2017, drug overdoses resulted in approximately 72,000 deaths in the United States – greater than 195 deaths per day. Drug overdoses are now the leading cause of death for Americans under 50, and more powerful synthetic opioids, like fentanyl and its analogues, are responsible for the largest number of deaths from opioid overdoses.

About Adamis Pharmaceuticals

Adamis Pharmaceuticals Corporation is a specialty biopharmaceutical company primarily focused on developing and commercializing products in various therapeutic areas, including respiratory disease, allergy and opioid overdose. The company's SYMJEPI (epinephrine) Injection 0.3mg and SYMJEPI (epinephrine) Injection 0.15mg products both use the same injection device as used for ZIMHI and were approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis, and both were fully launched in the U.S. in July 2019. Please refer to www.SYMJEPI.com for additional product information. In addition to its ZIMHI (naloxone) injection product, Adamis is developing other products, including a metered dose inhaler and dry powder inhaler product candidates for the treatment of asthma and COPD. The company's subsidiary, U.S. Compounding, Inc., compounds sterile prescription drugs, and certain nonsterile drugs for patients, animals, hospitals, clinics and surgery centers throughout most of the United States.

Adamis Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 relate to future events or future results of operations, including, but not limited to the following statements: the company's beliefs concerning its ability to satisfactorily respond to the matters raised in the FDA's CRL; the company's beliefs concerning the results of any future studies or clinical trials that the company may conduct relating to ZIMHI or its other products or product candidates; the company's beliefs concerning the timing and outcome of the FDA's review of the company's New Drug Application (NDA) relating to the ZIMHI product or any resubmitted NDA; the company's beliefs concerning its ability to commercialize ZIMHI and its other products and product candidates; the company's beliefs concerning the ability of its product candidates to compete successfully in the market; the company's beliefs concerning the safety and effectiveness of ZIMHI or its other products and product candidates; the company's beliefs concerning its commercialization strategies; and the company's beliefs concerning the anticipated timing of any commercial launch of its ZIMHI product. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which may cause Adamis' actual results to be materially different from these forward-looking statements. There can be no assurances that the company will be able to satisfactorily respond to the matters raised in the FDA's CRL or concerning the timing of any resubmission by us of the NDA responding to the CRL, that the FDA will approve our NDA relating to our ZIMHI product or concerning the timing of any future action by the FDA on our NDA, regarding the commercialization options that the company will pursue if our NDA is approved, or that the product will be able to compete successfully in the market if approved and launched. 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 press release. Certain of these risks, uncertainties, and other factors are described in greater detail in Adamis' filings from time to time with the SEC, which Adamis 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. Except to the extent required by law, any forward-looking statements in this press release speak only as the date of this press release, and Adamis expressly disclaims any obligation to update any forward-looking statements.

Contact Adamis:

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