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): December 1, 2020

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))

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

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

On December 1, 2020, Adamis Pharmaceuticals Corporation ("Adamis" or the "Company") issued a press release announcing the Company's planned response to the Complete Response Letter ("CRL") that the Company received in November 13, 2020, from the U.S. Food & Drug Administration ("FDA") regarding the Company's resubmitted New Drug Application ("NDA") for its ZIMHI™ high-dose naloxone injection product for the treatment of opioid overdose.

A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated into this item by reference.

Forward Looking Statements

This Current Report on Form 8-K 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 information, data and actions that the FDA may require in connection with any resubmitted NDA relating to ZIMHI; the company's beliefs concerning the timing and outcome of any appeal and FDA formal dispute resolution process that the company may initiate; the company's beliefs concerning the results of any future studies or clinical trials that the company may conduct relating to ZIMHI; the company's beliefs concerning the timing and outcome of the FDA's review of the company's 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. The FDA may require additional studies or other actions, data or information, prior to any resubmission of the NDA. 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, concerning the timing or costs of any additional actions that may be required in connection with any resubmission of the NDA, that the FDA will approve any resubmitted NDA relating to our ZIMHI product or concerning the timing of any future action by the FDA on our NDA, that the company will be successful in any formal dispute resolution appeal process with the FDA, 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 will 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. 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 Report speak only as the date of this Report, and Adamis expressly disclaims any obligation to update any forward-looking statements.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1	Press release dated December 1, 2020.

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: December 1, 2020

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

Exhibit 99.1

Adamis Pharmaceuticals Describes Planned Response to ZIMHI Complete Response Letter

SAN DIEGO, Dec. 01, 2020 -- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced a planned response to 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, received November 13, 2020, identified deficiencies that the FDA determined must be corrected before the Agency can approve the NDA, and provided recommendations needed for resubmission. FDA had not previously identified those deficiencies. Adamis intends to address all the deficiencies raised in the CRL and request that FDA approve the NDA. All of the company's responses to the deficiencies will be submitted before year end. The company will then ask the FDA for a Type A meeting. If the matter cannot be resolved with the FDA Division that sent the CRL, Adamis intends to appeal the matter within the agency through a Formal Dispute Resolution.

Dr. Dennis J. Carlo, President and Chief Executive Officer of Adamis Pharmaceuticals, stated, "We believe our high dose naloxone product (ZIMHI) offers a greater possibility to save lives given the high rates of synthetic opioid (fentanyl) overdoses. As the COVID-19 pandemic increases, the number of deaths due to opioid overdoses has also risen. Currently, only lower dose naloxone products are available. Recently, the injectable Evzio products have been discontinued, leaving no available intramuscular products approved for the layperson. This leaves a therapeutic vacuum that our high dose product would automatically fill and potentially save thousands of lives."

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 2018, drug overdoses resulted in approximately 67,000 deaths in the United States – greater than 185 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 allergy, opioid overdose, respiratory and inflammatory disease. The company's SYMJEPI (epinephrine) Injection products are approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis. In addition to its ZIMHI, naloxone injection product candidate, Adamis is developing additional products, including treatments for acute respiratory diseases, such as COVID-19, influenza, asthma and COPD. The company's subsidiary, U.S. Compounding, Inc., compounds sterile prescription drugs, and certain nonsterile drugs for human and veterinary use by hospitals, clinics, surgery centers, and vet clinics throughout most of the United States.

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 information, data and actions that the FDA may require in connection with any resubmitted New Drug Application (NDA) relating to ZIMHI; the company's beliefs concerning the timing and outcome of any appeal and formal dispute resolution process that the company may initiate; the company's beliefs concerning the results of any future studies or clinical trials that the company may conduct relating to ZIMHI; the company's beliefs concerning the timing and outcome of the FDA's review of the company's 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. The FDA may require additional studies, or other actions, data or information, prior to any resubmission of the NDA. 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, concerning the timing or costs of any additional actions that may be required in connection with any resubmission of the NDA, that the FDA will approve any resubmitted NDA relating to our ZIMHI product or concerning the timing of any future action by the FDA on our NDA, that the company will be successful in any formal dispute resolution appeal process with the FDA, 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 will 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.

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