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 16, 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 November 16, 2020, Adamis Pharmaceuticals Corporation ("Adamis" or the "Company") issued a press release announcing that after the close of U.S. markets on November 13, 2020, it received a Complete Response Letter ("CRL") 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 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 and provided recommendations needed for resubmission. The questions raised by the FDA related generally to new Chemistry, Manufacturing and Controls (CMC) issues. The Company is reviewing the CRL, plans to provide the FDA with additional analysis and information in order to attempt to satisfy the CRL items, and intends to request a Type A meeting or consider other options to resolve the issues.

A copy of the Company's press release is attached hereto as Exhibit 99.1 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 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 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; 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, and/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, 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 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 November 16, 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: November 16, 2020

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 16, 2020)- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) ("Adamis") today announced that after the close of business and the U.S. markets on November 13th, 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 the FDA 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 new Chemistry, Manufacturing and Controls (CMC) issues. It should be noted that no issues related to "extractables and leechables testing", that were associated with the previous initial CRL that the company received relating to the product, were noted by the FDA. The company's plan is to provide the FDA with additional analysis and information in order to attempt to satisfy the CRL items. The company will request a Type A meeting or consider other options to resolve the issues.

Dr. Dennis J. Carlo, President and CEO of Adamis, stated, "This is a very disappointing setback that was totally unexpected since we completed the extractables and leechables issues that were associated with the first CRL. To me, it is very surprising to have new issues brought up this late in the review process. We believe the comments and recommendations stated in the CRL can be addressed and overcome. With all of the factors that are currently contributing to a growing number of fatal overdoses during the COVID-19 pandemic, we believe there is a clear need for higher dose forms of intramuscular naloxone found in ZIMHI. We remain committed to this product and our mission to provide physicians and patients access to a higher dose of naloxone. As soon as reasonably possible, we will resubmit additional information and analysis of data to the FDA for 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 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.

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 information, data and actions that the FDA may require in connection with any resubmitted NDA relating to ZIMHI; 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. The FDA may require additional studies, and/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, 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.

Contact Adamis:

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