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): October 15, 2021

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 October 18, 2021, Adamis Pharmaceuticals Corporation (the "Company") issued a press release announcing that the U.S. Food & Drug Administration ("FDA") has approved the Company's ZIMHI ™ (naloxone HCL Injection, USP) 5 mg/0.5 mL product. ZIMHI is a high-dose naloxone injection product FDA-approved for the treatment of opioid overdose. The approval was pursuant to the FDA's review of the Company's New Drug Application ("NDA"), which was resubmitted to the FDA in May 2021, pursuant to the Food, Drug & Cosmetic Act, as amended. 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.

A copy of the Company's press release is filed with this Report as Exhibit 99.1.

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 the anticipated timing and commercial success of the launch of ZIMHI and its ability to successfully commercialize the products and product candidates described in this Report, itself or through commercialization partners; future regulatory actions relating to the ZIMHI product; the Company's beliefs concerning the benefits, enforceability, and extent of intellectual property protection afforded by patents and patent applications that it owns or has licensed and its rights under applicable license agreements, and its ability to enforce its patents and other intellectual property rights against third parties; the Company's expectations concerning future growth; expectations and statements about the Company's strategies, objectives, future goals and achievements; and other statements concerning our future operations, activities and financial results. 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 the results anticipated by such forward-looking statements. There can be no assurances that ZIMHI will be able to compete successfully in the market. We cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. 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 and additional risks, uncertainties, and other factors are described in greater detail in Adamis' filings from time to time with the SEC, including its annual report on Form 10-K for the year ended December 31, 2020, and subsequent filings 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1	Press release dated October 18, 2021.

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: October 18, 2021

By: /s/ David C. Benedicto
Name: David C. Benedicto
Title: Chief Financial Officer

Exhibit 99.1

Adamis Receives FDA Approval for ZIMHI

New High-Dose Naloxone Product for the Treatment of Opioid Overdose

SAN DIEGO, Oct. 18, 2021 (Globe Newswire) -- Adamis Pharmaceuticals Corporation (Nasdaq: ADMP) today announced that the U.S. Food and Drug Administration (FDA) has approved Adamis' ZIMHI ™ (naloxone HCL Injection, USP) 5 mg/0.5 mL product. ZIMHI is a high-dose naloxone injection product FDA-approved for use in 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), drug overdoses resulted in approximately 96,779 deaths in the United States during the 12-month period ending March 2021, which was a 29% increase over the prior 12-month period. Drug overdoses are now the leading cause of death for Americans under age 50, with more powerful synthetic opioids, like fentanyl and its analogues, responsible for the largest number of those deaths.

Dr. Jeffrey Galinkin, an anesthesiologist, and former member of the FDA Advisory Committee for Anesthetics, Analgesics and Addiction Products, commented, "I am pleased to see this much needed high dose naloxone product will become part of the treatment tool kit as a countermeasure to the continued surge in fentanyl related deaths. The higher intramuscular doses of naloxone in ZIMHI should result in more rapid and higher levels of naloxone in the systemic circulation, which in turn, should result in more successful resuscitations."

Dr. Dennis J. Carlo, President and CEO of Adamis, stated, "We are very excited by this approval and are working with our commercial partner, US WorldMeds, to make this much-needed, lifesaving product readily available to the market. ZIMHI provides the highest systemic levels of naloxone compared to any of the nasal or intramuscular products currently available."

P. Breckinridge Jones, Sr., CEO of US WorldMeds, added, "We are pleased with the approval and now look forward to commercially marketing ZIMHI in the United States. US WorldMeds has a proven track-record of successfully commercializing pharmaceutical products and have a First-in-Class and only FDA-approved product, LUCEMYRA® (lofexidine), for the treatment of withdrawal symptoms associated with abrupt opioid discontinuation. We are confident we can leverage our existing commercial infrastructure and presence in the opioid dependence market to speed the uptake of ZIMHI and combat the growing opioid crisis. We are preparing for the full commercial launch of ZIMHI which is planned for the first quarter of 2022."

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. The Company's ZIMHI (naloxone) Injection product is approved for the treatment of opioid overdose. Tempol is in development for the treatment of patients with COVID-19 and a Phase 2/3 clinical trial is underway. For additional information about Adamis Pharmaceuticals, please visit www.adamispharmaceuticals.com.

About ZIMHI™ (naloxone HCL Injection, USP) 5 mg/0.5 mL

ZIMHI is a prescription medicine used in adults and children for the treatment of an opioid emergency, such as an overdose or a possible overdose with signs of breathing problems and severe sleepiness or not being able to respond. ZIMHI is to be given right away by a caregiver and does not take the place of emergency medical care. Get emergency medical help right away after the first dose of ZIMHI, even if the person wakes up.

IMPORTANT SAFETY INFORMATION

Do not use ZIMHI if you are allergic to naloxone hydrochloride or any of the ingredients in ZIMHI.
ZIMHI is used to temporarily reverse the effects of opioid medicines. The medicine in ZIMHI has no effect in people who are not taking opioid medicines.

Use ZIMHI right away if you or your caregiver think signs or symptoms of an opioid emergency are present, even if you are not sure, because an opioid emergency can cause severe injury or death.
Family members, caregivers, or other people who may have to use ZIMHI in an opioid emergency should know where ZIMHI is stored and how to give ZIMHI before an opioid emergency happens.
Get emergency medical help right away after using the first dose of ZIMHI. Rescue breathing or CPR (cardiopulmonary resuscitation) may be given while waiting for emergency medical help.

The signs and symptoms of an opioid emergency can return within several minutes after ZIMHI is given. If this happens, give additional injections using a new ZIMHI prefilled syringe every 2 to 3 minutes and continue to closely watch the person until emergency help is received.

ZIMHI may cause serious side effects, including sudden opioid withdrawal symptoms, which may include: body aches, fever, sweating, runny nose, sneezing, goose bumps, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, stomach cramping, increased blood pressure, or increased heart rate.

Other common side effects of ZIMHI include dizziness and injection site redness.
In infants under 4 weeks old who have been receiving opioids regularly, sudden opioid withdrawal may be life-threatening if not treated the right way. Signs and symptoms include: seizures, crying more than usual, and increased reflexes.

These are not all of the possible side effects of ZIMHI. Call your doctor for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS, contact Adamis Pharmaceuticals Corporation at 1-858-997-2400 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About LUCEMYRA® (lofexidine)

LUCEMYRA® (lofexidine), an oral tablet, is a central alpha 2-adrenergic agonist that reduces the release of norepinephrine to suppress the neurochemical surge that produces opioid withdrawal. It is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. In clinical trials, LUCEMYRA® significantly reduced the severity of withdrawal symptoms compared to placebo as reported by patients experiencing opioid withdrawal. LUCEMYRA® is usually administered in three 0.18 mg tablets taken orally four times daily at five- to six-hour intervals during the period of peak withdrawal symptoms (generally five to seven days following last use of opioids); total treatment may continue for up to 14 days. LUCEMYRA® should be discontinued with gradual dose reduction over two to four days.

Important Safety Information

LUCEMYRA® can cause serious side effects, including low blood pressure, slow heart rate, and fainting. Watch for symptoms of low blood pressure or heart rate, including dizziness, lightheadedness, or feeling faint at rest or when quickly standing up; if you experience these symptoms, call your healthcare provider right away and do not take your next dose of LUCEMYRA® until you have talked to your healthcare provider. Avoid becoming dehydrated or overheated and be careful not to stand up too suddenly from lying or sitting, as these may increase your risk of low blood pressure and fainting.

When your treatment is complete, you will need to stop taking LUCEMYRA® gradually, or your blood pressure could increase.

After a period of not using opioid drugs, you can become more sensitive to the effects of opioids if you start using them again. This may increase your risk of overdose and death.

Before taking LUCEMYRA®, tell your healthcare provider about all your medical conditions, including if you have low blood pressure, slow heart rate, any heart problems including history of heart attack or a condition called long QT syndrome, liver or kidney problems, or if you drink alcohol. Tell your healthcare provider if you are pregnant, plan on becoming pregnant, or are breastfeeding; it is not known if LUCEMYRA® can harm your unborn baby or whether LUCEMYRA® passes into your breast milk.

Especially tell your healthcare provider if you take benzodiazepines, barbiturates, tranquilizers, or sleeping pills, as taking these with LUCEMYRA® can cause serious side effects.

The most common side effects of LUCEMYRA® include low blood pressure or symptoms of low blood pressure such as lightheadedness, slow heart rate, dizziness, sleepiness, and dry mouth.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-833-LUCEMYRA®. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Click here to see full Prescribing Information.

Forward Looking Statements

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