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): September 21, 2022

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**

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 September 21, 2022, Adamis Pharmaceuticals Corporation (the "Company") issued a press release announcing that the third planned interim analysis of the Phase 2/3 clinical trial examining the effects of the Company's Tempol product candidate in high risk subjects with early COVID-19 infection did not achieve its primary endpoint, as measured by comparing the rate of sustained clinical resolution of symptoms of COVID-19 at day 14 of Tempol versus placebo. The independent Data Safety Monitoring Board ("DSMB") conducting the interim review recommended that the study be halted early due to lack of efficacy. The DSMB did note that no safety concerns were identified in the subjects that received Tempol. Based on the recommendation from the DSMB, the Company has halted the trial and will evaluate the unblinded data from the trial to determine the next developmental steps for Tempol.

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, and the press release filed as an exhibit with this Report, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including risks and uncertainties related to the next developmental steps for Tempol and the other factors referred to in the press release filed as an exhibit with this Report under the heading "Forward Looking Statements." These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. In addition, forward-looking statements concerning our anticipated future activities assume that we have sufficient funding to support such activities and continue our operations and planned activities, which may not be the case. 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 the Company's filings from time to time with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2021 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 September 21, 2022.

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: September 21, 2022

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

Exhibit 99.1

Adamis Provides Update on the Phase 2/3 Trial of Tempol in COVID-19 Positive High-Risk Subjects

- ***Interim data from the Phase 2/3 clinical trial of Tempol did not demonstrate statistical significance of its primary endpoint of clinical resolution of COVID-19 symptoms at day 14 versus placebo***

- ***Independent Data Safety Monitoring Board recommends halting the trial.***

SAN DIEGO, Sept. 21, 2022-- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced that the third planned interim analysis of the Phase 2/3 clinical trial examining the effects of Tempol in high risk subjects with early COVID-19 infection did not achieve its primary endpoint, as measured by comparing the rate of sustained clinical resolution of symptoms of COVID-19 at day 14 of Tempol versus placebo. The independent Data Safety Monitoring Board (DSMB) recommended that the study be halted early due to lack of efficacy. The DSMB did note that no safety concerns were identified in the subjects that received Tempol. Based on the recommendation from the DSMB, the Company has halted the trial and will now evaluate the unblinded data from the trial to determine the next developmental steps for Tempol.

"We are obviously disappointed that the study did not meet its endpoints," said Ron Moss, MD, Chief Medical Officer of Adamis. "Much of the preclinical work on Tempol for COVID-19 examined the effects of the drug on severe illness. This trial did not meet its primary endpoint, but we are exploring the possibility that vaccinations and the less virulent variants (Omicron) during the trial period may have obscured an effect of Tempol. This speculation is based on the lower-than-expected observed hospitalization rate in this trial (less than 1%) compared to other COVID-19 treatment trials. We will continue to analyze the data to determine if we believe Tempol can be utilized in other COVID patient populations including those with more severe illness or immunocompromised. I would like to thank our clinical research partners, the trial investigators and all the trial subjects for their participation."

David J. Marguglio, Adamis' CEO added, "Though we are certainly frustrated with these results, we remain bullish on ZIMHI® (launched in 2022) and SYMJEPI® and our team is increasing sales and improving manufacturing efficiencies for our commercial products."

Phase 2/3 Trial

The trial "A Phase 2/3, Adaptive, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Effects of Tempol (MBM-02) in Subjects With COVID-19 Infection" was designed to enroll approximately 248 high risk subjects with early COVID-19 infection age 18 years of age and older. Eligible subjects with positive COVID-19 infection within five days of study entry plus at least one co-morbidity were randomized one-to-one to receive either Tempol or placebo. Co-morbidities include age of 65 or older, hypertension, diabetes, obesity, cancer, immunodeficiency and in the opinion of the investigator the risk factor is not acutely life-threatening. Patients randomized to Tempol received 800mg daily in two divided oral doses of 400mg capsules for up to 21 days. Similarly, placebo capsules were administered twice daily to subjects in the placebo group for up to 21 days.

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 has been conducted. For additional information about Adamis Pharmaceuticals, please visit our website and follow us on Twitter and LinkedIn.

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 statements concerning the following matters: the next developmental steps for Tempol; possible factors affecting the results of the Phase 2/3 clinical trial for Tempol; possible use of Tempol in other COVID patients including those with more severe illness; the Company's beliefs concerning the mechanisms of action, safety and effectiveness of Tempol; the Company's beliefs concerning the ability of its products and product candidates to compete successfully in the market; and the Company's believes concerning improvement of manufacturing efficiencies for its commercial products. 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 are no assurances concerning the next developmental steps for Tempol; that vaccinations or less virulent variants of COVID-19 during the trial period affected the results of the Phase 2/3 clinical trial; that the Company will explore the use of Tempol with other categories of COVID patients; or that sales of the Company's commercial products will increase or that manufacturing efficiencies will be achieved. In addition, forward-looking statements concerning our anticipated future activities assume that we have sufficient funding to support such activities and continue our operations and planned activities. 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 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, 2021, 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 website at http://www.sec.gov.

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