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): January 10, 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**

(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 January 10, 2022, Adamis Pharmaceuticals Corporation (the "Company") issued a press release announcing that it had submitted a Fast Track Application to the U.S. Food & Drug Administration ("FDA") for the Company's Tempol product candidate for the treatment and prevention of COVID-19. The Company has commenced a Phase 2/3 clinical trial, which is ongoing, to examine the safety and efficacy of Tempol in adult patients with confirmed COVID-19 infection. Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions and the request can be initiated by the drug company at any time during the development process. The FDA will review the request and decide based on whether the drug fills an unmet medical need in a serious condition. There are no assurances that the FDA will grant Fast Track designation for the Company's Tempol product candidate.

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. 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 opinions and beliefs of the Company and third parties concerning the potential of Tempol as a treatment for COVID-19 and the results of previous studies of Tempol; the Company's beliefs concerning the safety and effectiveness of Tempol or the Company's other product candidates; the timing, progress or results of the Company's Phase 2/3 clinical trial for Tempol or other studies or trials relating to Tempol; the Company's beliefs concerning the outcome of its Fast Track application to the FDA relating to Tempol; the Company's ability to commercialize its product candidates, itself or through commercialization partners; the Company's beliefs concerning the benefits, enforceability, and extent of intellectual property rights and protection afforded by patents and patent applications that it owns or has licensed; and other statements concerning the Company's future operations and activities. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, which may cause the Company's actual results to be materially different from the results anticipated by such forward-looking statements. There are no assurances that the FDA will grant Fast Track designation for the Company's Tempol product candidate. There can be no assurances regarding the timing, progress or outcome of trials or studies relating to Tempol, or that Tempol will be found to be safe and effective in the treatment of COVID-19 or any other indication. 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 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, 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 January 10, 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: January 10, 2022

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

Exhibit 99.1

Adamis Pharmaceuticals Submits Fast Track Application to FDA for Tempol for the Treatment and Prevention of COVID-19

SAN DIEGO, Jan. 10, 2022 (GLOBE NEWSWIRE) -- Adamis Pharmaceuticals Corporation (Nasdaq: ADMP) today announced the submission of a Fast Track Application to the U.S. Food and Drug Administration (FDA) for Tempol for the treatment and prevention of COVID-19. Tempol is currently being studied in a Phase 2/3 clinical trial in adult patients with confirmed COVID-19 infection. Tempol has been shown to have antiviral, anti-inflammatory, and antioxidant activity. Although recent oral antiviral drugs have been approved by the FDA, the Company believes that Tempol would provide an unmet medical need because of its unique mechanism of action and safety profile.

Shyam Kottilil, MBBS, Ph.D., Professor of Medicine at the University of Maryland School of Medicine (UMSOM), Chief of the Division of Clinical Care and Research at UMSOM's Institute of Human Virology, and Principal Investigator for the ongoing Tempol clinical trial, commented: "We are currently observing extremely high COVID-19 infection rates and we urgently need additional safe and effective oral agents. I am pleased with the conduct of the ongoing clinical trial thus far. If positive effects are observed and result from Tempol's ongoing clinical trial, I believe that this drug should be expedited through the approval process. Tempol as an oral antiviral and anti-inflammatory agent may be an important countermeasure, if proven safe and effective in this trial."

Dr. Dennis J. Carlo, President and Chief Executive Officer of Adamis, commented, "Our ongoing clinical trial is continuing, as we see a surge in COVID-19 infections in the U.S. and worldwide. Concerns have been expressed about potential safety questions for EUA approved antivirals such as mutagenesis and drug-drug interactions (Molnupiravir: long-term safety questions linger as approvals approach (pharmaceutical-technology.com)) (https://www.fda.gov/media/155050/download). We are thus applying for Fast Track designation to the FDA to expedite the regulatory approval pathway for Tempol. Because Tempol has both anti-inflammatory and antiviral effects, we believe that Tempol fulfills an unmet medical need as an oral agent, focusing on multiple aspects of the pathogenesis of COVID-19 disease."

Recently, researchers from the National Institutes of Health (NIH) highlighted Tempol as a potential home antiviral treatment for COVID-19 (https://covid19.nih.gov/news-and-stories/tempol-potential-home-treatment-covid-19).

The Company also recently announced (https://ir.adamispharmaceuticals.com/news-releases/news-release-details/adamis-pharmaceuticals-announces-publication-human-immune) the results of a published study in collaboration with Stanford University researchers suggesting that Tempol has strong, broad in-vitro anti-cytokine activity. Suppression of inflammatory cytokines with an antioxidant may be a beneficial treatment strategy in COVID-19 infection.

About the Phase 2/3 Clinical Trial

Additional information about the trial can be found on www.clinicaltrials.gov using the identifier NCT04729595.

Adamis has licensed exclusive worldwide rights under patents, patent applications and related know-how of the third part licensor relating to Tempol for certain licensed fields including the treatment of respiratory diseases including asthma, respiratory syncytial virus, influenza and COVID-19, and for the reduction of radiation-induced dermatitis in patients undergoing treatment for cancer.

About Fast Track Designation

Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions and the request can be initiated by the drug company at any time during the development process. FDA will review the request and decide based on whether the drug fills an unmet medical need in a serious condition. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the drug company is encouraged throughout the entire drug development and review process.

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 (https://www.zimhi.com/). 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 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 the following statements: the opinions and beliefs of NIH researchers summarized in the NIH article discussed in this press release concerning the potential of Tempol as a treatment for COVID-19 and the results of previous studies of Tempol; the Company's beliefs concerning the safety and effectiveness of Tempol or the Company's other product candidates; the timing, progress or results of the Company's Phase 2/3 clinical trial for Tempol or other studies or trials relating to Tempol; the Company's beliefs concerning the outcome of its Fast Track application to the FDA relating to Tempol; the Company's ability to commercialize the product candidates described in this press release, itself or through commercialization partners; the Company's beliefs concerning the benefits, enforceability, and extent of intellectual property rights and protection afforded by patents and patent applications that it owns or has licensed; and other statements concerning the Company's future operations and activities. 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 that the FDA will grant Fast Track designation for the Company's Tempol product candidate. There can be no assurances regarding the timing, progress or outcome of trials or studies relating to Tempol, or that Tempol will be found to be safe and effective in the treatment of COVID-19 or any other indication. In addition, as previously disclosed, each of the Company and its US Compounding Inc. subsidiary has received a subpoena from the U.S. Attorney's Office for the Southern District of New York issued in connection with a criminal investigation. Accordingly, all forward-looking statements are subject to the outcome of this investigation and any related governmental investigations or proceedings. 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 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, 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.

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