

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 20, 2021

ADAMIS PHARMACEUTICALS CORPORATION
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

0-26372
(Commission File Number)

82-0429727
(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 20, 2021, Adamis Pharmaceuticals Corporation (“Adamis” or the “Company”) issued a press release announcing that it had submitted to the U.S. Food and Drug Administration (“FDA”) an Investigational New Drug (“IND”) application for the investigational use of Tempol, an investigational drug, for the treatment of Coronavirus (COVID-19). 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 the safety and effectiveness of Tempol or the company’s other product candidates; the timing of funding for, or commencement or completion of, any studies or trials relating to Tempol; the availability of, and the company’s success in applying for and obtaining, government or other funding for studies or trials relating to Tempol or the timing or amount of any such funding; the results of any future studies or trials that the company may conduct relating to Tempol; the company’s ability to commercialize the product candidates described in this Report, itself or through commercialization partners; and other statements concerning our 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 can be no assurances regarding the outcome of our submission of the IND relating to investigational use of, or trials or studies relating to, Tempol, regarding the timing or the outcome of any applications or requests that we may submit for government or other funding for studies or trials relating to Tempol; concerning the timing or outcome of any such studies or trials; or that Tempol will be found to be safe and effective in the treatment of COVID-19 or any other indication. 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. 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, 2019 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>. 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 January 20, 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: January 20, 2021

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

Adamis Pharmaceuticals Announces IND Submission to FDA for Tempol for the Treatment of COVID-19

SAN DIEGO, Jan. 20, 2021 (GLOBE NEWSWIRE) -- [Adamis Pharmaceuticals Corporation](#) (NASDAQ: ADMP) (“Adamis”) announced today the submission of an Investigational New Drug (IND) to FDA for the investigational use of Tempol for the treatment of Coronavirus (COVID-19). The submission of the IND to FDA followed a Pre-IND meeting with FDA in which FDA gave specific recommendations on Chemistry, Manufacturing and Controls (CMC) and Clinical aspects to be included in the IND. The Company plans to seek government and/or non-government funding to study the treatment and prevention of COVID-19 with Tempol.

Tempol has demonstrated both potent anti-inflammatory, anticoagulant, and antioxidant activity. Both inflammatory cytokines and reactive oxygen species (ROS) from cells of the immune system called macrophages and neutrophils damage the lung in Acute Respiratory Distress Syndrome (ARDS). In animal models, Tempol has been shown to decrease proinflammatory cytokines (cytokine storm), and through its potent antioxidant activity has been shown to decrease the harmful effects of ROS. In addition, Tempol has been shown to decrease platelet aggregation, a problem observed in many COVID-19 patients. Numerous published articles describing animal models of ARDS show Tempol to cause a decrease in lung inflammation and preserve lung pathology associated with acute and chronic lung injury. To this end, Tempol has been shown to decrease the genes (HIF-1a and HIF-2a) associated with hypoxia. Hypoxia is a key indicator often associated with severe disease and a poor outcome. Controlling hypoxia and the cytokine storm can be considered essential to the successful treatment of COVID-19.

Dr. Dennis J. Carlo, President and CEO of Adamis commented: “With over 23 million COVID-19 infections in the US and over 394,000 deaths in the US (according to the CDC), additional treatments are urgently warranted. We believe that Tempol could play a pivotal role not only in the treatment of COVID-19, but actually in preventing hospitalization. With new mutations occurring in the virus, it is apparent there is an ongoing need for new therapies. The South African and other variants could very well evade the protection of antibody treatments and also bring up concerns about the efficacy of the current COVID-19 vaccines. Mutations can possibly render these vaccines less potent and could require them to be updated as with influenza vaccines.”

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, and asthma. 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 the safety and effectiveness of Tempol or the company's other product candidates; the timing of funding for, or commencement or completion of, any studies or trials relating to Tempol; the availability of, and the company's success in applying for and obtaining, government or other funding for studies or trials relating to Tempol or the timing or amount of any such funding; the results of any future studies or trials that the company may conduct relating to Tempol; the company's ability to commercialize the product candidates described in this press release, itself or through commercialization partners; and other statements concerning our 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 can be no assurances regarding the outcome of our submission of the IND relating to investigational use of, or trials or studies relating to, Tempol, regarding the timing or the outcome of any applications or requests that we may submit for government or other funding for studies or trials relating to Tempol; concerning the timing or outcome of any such studies or trials; or that Tempol will be found to be safe and effective in the treatment of COVID-19 or any other indication. 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. 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, 2019 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>. Except to the extent required by law, any forward-looking statements in this press release speak only as of the date of this press release, and Adamis expressly disclaims any obligation to update any forward-looking statements.

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