

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): June 12, 2020

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))

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 Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADMP	Nasdaq Capital Market

Item 1.01 Entry into a Material Definitive Agreement

On June 12, 2020, Adamis Pharmaceuticals Corporation (the “Company” or “Adamis”) entered into a license agreement (the “Agreement”) with Matrix Biomed, Inc. (“Matrix” or the “Licensor”) to license rights under patents, patent applications and related know-how of Matrix relating to Tempol, an investigational drug. The exclusive license includes the worldwide use under the licensed patent rights and related rights of Tempol for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection. In addition, the exclusive license includes the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. In consideration for Matrix providing the rights under its patent rights and related know-how relating to Tempol within the licensed fields, Adamis paid Matrix \$250,000 and also issued to Matrix 1,000,000 shares of Adamis Series B Convertible Preferred Stock (“Series B Preferred”).

Under the Agreement, the Company will be responsible for funding preclinical and clinical development relating to products developed for the licensed fields of use, and for matters relating to compliance of any licensed products or development and testing of licensed products with laws and regulations. Licensor will provide, and the Company will purchase from Licensor, Tempol material for preclinical or clinical work or use in licensed products, and Licensor will provide the Company with other information and materials relating to testing and development of products within the licensed fields of use. The Agreement provides for the creation of a joint steering committee with members from the Company and Licensor to meet periodically and discuss issues relating to the development, testing and approval of products within the licensed fields of use.

Under the Agreement, if any products are commercialized, profits (as defined in the Agreement) from sales of licensed products will be shared equally between the parties. Profits are generally determined as net sales of licensed products less costs incurred by the Company for manufacturing, marketing and distribution of licensed products.

The Agreement contains other covenants of the Company and Licensor relating to, among other matters, funding of testing and development of licensed products, confidentiality, compliance with laws, and other matters. The Agreement includes customary provisions regarding prosecution, maintenance, infringement and enforcement of the licensed patents, books and records, indemnification and other matters. The Company may not sublicense its rights under the Agreement without the consent of Licensor, and neither party may assign its rights under the Agreement without the consent of the other party. The term of the Agreement continues until the expiration of the last to expire of the patents licensed under the Agreement and will terminate or may be terminated earlier upon the occurrence of certain other events including an uncured breach of the Agreement or failure to satisfy certain covenants. The Company may also terminate the Agreement with advance written notice to Licensor.

The Series B Preferred was established pursuant to a Certificate of Designation of Preferences, Rights and Limitations filed with the Delaware Secretary of State. Each share of Series B Preferred will automatically convert into one share of Common Stock after the occurrence of a Capital Event as defined in the Certificate of Designation. “Capital Event” is defined as the filing and effectiveness of an amendment to the Company’s certificate of incorporation (or similar charter documents) to either (i) increase the number of shares of Common Stock the Company is authorized to issue or (ii) effect a reverse split of the Common Stock, in either event sufficient to permit the issuance of shares of Common Stock upon conversion of all outstanding shares of Series B Preferred Stock. The conversion rate of the Series B Preferred is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions or other events.

The foregoing description of certain terms of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement that the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the period ended June 30, 2020, or other report that the Company may file with the Securities and Exchange Commission (the “SEC”).

Item 3.02 Unregistered Sales of Equity Securities.

The information provided in response to Item 1.01 of this Report is incorporated by reference into this Item 3.02. The shares of Series B Preferred, and the shares of common stock that are issuable upon conversion of the Series B Preferred, were issued in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"), and/or Regulation D under the Securities Act. Matrix represented that it was an accredited investor, as defined in Rule 501 of Regulation D, and that it was acquiring the securities for its own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the Act.

Item 8.01 Other Events

On June 15, 2020, the Company issued a press release announcing the entering into of the license agreement with Matrix described in Item 1.01 above. The press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Forward Looking Statements

This Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may relate to future events or our future results of operations and may include, without limitation, the following statements: the company's beliefs concerning the safety and effectiveness of the compounds and drug product candidates that are the subject of the license agreement described in this Report; the results of any future clinical trials that the company or Matrix may conduct relating to the compounds and drug product candidates described in this Report; the ability to fund future product development; future revenues expected from any products that may be developed and approved for marketing by the FDA and other regulatory authorities; the company's ability to commercialize any product candidates that are the subject of the license agreement described in this Report, itself or through commercialization partners; the company's beliefs concerning the safety and effectiveness of any product candidates that may be developed; and the intellectual property protection that may be afforded by any of the licensed patents or patent applications. 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 are only predictions, are not guarantees, involve known and unknown risks, uncertainties and other factors, and concern matters that could subsequently differ materially from those described in this Report, which may cause the company's actual results to be materially different from those contemplated by these forward-looking statements. There can be no assurances regarding the timing, cost or outcome of any current or future trials that may be conducted relating to the compounds and products described in this Report. There can be no assurances that we or any commercialization partners will file any New Drug Applications with the FDA regarding any of the drugs or products that are the subject of the license agreement described in this Report, or that any such NDAs will be approved by the FDA. In addition, forward-looking statements concerning our anticipated future activities assume that we can obtain sufficient funding to support such research, development and commercialization 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. In addition, the forward-looking statements included in this Form 8-K represent the Company's views as of the date of this Form 8-K. The Company anticipates that subsequent events and developments may cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as required by applicable laws. These forward-looking statements should not be relied upon as representing the Company's views as of any date after the date of this Form 8-K. Certain of these risks, uncertainties, and other factors are described in greater detail in the Company's filings from time to time with the SEC, 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 June 15, 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: June 15, 2020

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

Adamis Pharmaceuticals Announces License to Patent Rights Regarding Tempol, an Investigational Anti-inflammatory and Antioxidant Drug for the Treatment of Respiratory Diseases Including COVID-19

SAN DIEGO, CA --(June 15, 2020)- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) (“Adamis”) announced today that it had entered into an agreement to license patent rights and related know-how relating to Tempol, an investigational drug. The license includes the worldwide use under the licensed patent rights of Tempol for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection. In addition, the exclusive license includes the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. A phase 2 radiation dermatitis clinical study has already been successfully completed, and discussions have been held with the U.S. Food and Drug Administration (FDA) regarding the design of a pivotal phase 3 study. The license was obtained from Matrix Biomed, Inc.

In consideration for Matrix providing the exclusive rights under its patent rights and related know-how relating to Tempol within the licensed fields, Adamis paid Matrix \$250,000 following signing of the definitive agreement. Adamis will also issue to Matrix 1,000,000 shares of Adamis convertible preferred stock, which will be convertible into an equal number of shares of common stock after and contingent on an increase in the number of available authorized shares of common stock under the company’s restated certificate of incorporation. Under the agreement, if any products are commercialized, net profits will be equally distributed between the parties.

Coronavirus disease [Novel Coronavirus Disease (COVID-19), a human betacoronavirus] represents a global health problem. Just within the U.S., the American Hospital Association estimates that the financial impact in losses for America’s hospitals and health systems could exceed \$200 billion by mid-2020. Therefore, identification of new drugs and biologics for treating COVID-19 infection is urgently needed. Most common symptoms at onset include fever, cough, sore throat, sneezing, rhinorrhoea (runny nose) and fatigue. In severe cases, this can progress to pneumonia, acute respiratory distress syndrome (ARDS), acute cardiac injury and eventually death. ARDS occurs when there is damage to the lungs resulting in fluid building in the small air sacs of the lungs. This fluid causes a decrease in the oxygen supply to vital organs which can eventually lead to death.

Tempol has demonstrated anti-inflammatory, anticoagulant, and antioxidant activity. Tempol specifically targets ARDS, which is the major cause of death of COVID-19. Both inflammatory cytokines and reactive oxygen species (ROS) generated from cells of the immune system (macrophages and neutrophils) damage the lungs in ARDS patients. In animal models, Tempol has been shown to decrease proinflammatory cytokines (cytokine storm) such as TNF- α , IL-1 β , IL-6, IL-10, NF-k β , ICAM-1, HIF-1a, HIF-2a and others. In addition, Tempol works as an antioxidant and decreases the harmful effects of ROS. ROS is a type of unstable molecule that contains oxygen and easily reacts with other molecules in the cell. It can cause damage to all macromolecules, i.e., lipids, DNA, RNA and proteins. In addition, Tempol has also been shown to decrease platelet aggregation and clotting, a problem observed in many COVID-19 patients. 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. Additional published studies, in which animals were infected with betacoronavirus, show that Tempol treatment resulted in increased survival and decreased viral load. Taken together, this scientific data argue for the use of Tempol in preventing and treating the most severe death related lung manifestation of COVID-19. Tempol has already been shown to be safe in multiple human clinical studies.

Dr. Dennis J. Carlo, President and CEO of Adamis commented: “We are hopeful that Tempol can be part of the solution to the current pandemic. We believe that Tempol’s multiple modes of action such as an antioxidant, an anticoagulant, and an anti-inflammatory may be more beneficial than targeting a single pathological pathway. Tempol has been the focus of numerous peer reviewed published articles by highly respected scientists from various institutions such as: Radiation Biology Branch of the National Cancer Institute, National Institute of Health, FDA Center for Drug Evaluation and Research, Georgetown University, University of Pittsburgh, University of Pennsylvania, Weizmann Institute, Johns Hopkins University, University of California San Diego, University of Texas and many more. Tempol has been shown to be involved in cellular metabolism, apoptosis (form of programmed cell death or cellular suicide), cell growth and development, stress response, inflammation, and angiogenesis. Its role in decreasing multiple pro-inflammatory cytokines and controlling both the overactive inflammatory response and the cytokine storm could lead to a treatment strategy that helps decrease the burden to our health care system by reducing hospitalizations and potentially saving the many lives of those infected with COVID-19.”

Dr. Ronald Moss, Chief Medical Office at Adamis, stated, “The previously published studies of Tempol provide a reasonable scientific rationale to begin immediate clinical testing against COVID-19 during this pandemic. We plan to utilize our clinical experience with respiratory viruses and government collaborations to focus on this urgent public health problem. To this end, Adamis will apply for government and other forms of funding to conduct clinical trials and will work closely with FDA to expedite the testing. Our goal is to obtain funding and test Tempol against COVID-19 as soon as possible. Clinical trial material is currently available, since Tempol is an investigational drug currently in human trials for other indications.”

About Adamis Pharmaceuticals

Adamis Pharmaceuticals Corporation is a specialty biopharmaceutical company primarily focused on developing and commercializing products in various therapeutic areas, including respiratory disease, allergy and opioid overdose. The company’s SYMJEPi (epinephrine) Injection 0.3mg and SYMJEPi (epinephrine) Injection 0.15mg products were approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis. In July 2019, Sandoz, Inc., announced it had fully launched both in the U.S. Please refer to www.SYMJEPi.com for additional product information. Adamis is developing additional products, including a naloxone injection product candidate, ZIMHI, for the treatment of opioid overdose, and a metered dose inhaler and dry powder inhaler product candidates for the treatment of asthma and COPD. The company’s subsidiary, U.S. Compounding, Inc., compounds sterile prescription drugs for human and veterinary use, and certain nonsterile drugs for use by hospitals, clinics and surgery centers 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 the safety and effectiveness of the compounds and drugs described in this press release; the results of any future clinical trials that the company or Matrix may conduct relating to the compounds and drug product candidates described in this press release; the company's ability to fund future product development and trials; future revenues expected from any products that may be developed and approved for marketing by the FDA and other regulatory authorities; 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 safety and effectiveness of any product candidates that may be developed; and the intellectual property protection that may be afforded by any of the licensed patents or patent applications. 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 are only predictions, are not guarantees, involve known and unknown risks, uncertainties and other factors, and concern matters that could subsequently differ materially from those described in this press release, which may cause Adamis' actual results to be materially different from those contemplated by these forward-looking statements. There can be no assurances regarding the timing, cost or outcome of any current or future trials that may be conducted relating to the compounds and products described in this press release. There can be no assurances that we or any commercialization partners will file any New Drug Applications with the FDA regarding any of the compounds or products described in this press release, or that any such NDAs will be approved by the FDA. In addition, forward-looking statements concerning our anticipated future activities assume that we can 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 may 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 our 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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