

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): July 28, 2023

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 July 28, 2022, Adamis Pharmaceuticals Corporation (the "Company") issued a press release announcing that the Company has committed to fund an unrestricted research grant to the Leiden University Medical Center Anesthesia and Pain Research Unit. The funding will support the work of Albert Dahan, MD, PhD, an expert on opioid-induced respiratory depression (opioid overdose) and professor of anesthesiology at the University. Dr. Dahan has been working with the FDA to understand better methods of reversing fentanyl overdoses. The objective of the work will be to assess the efficacy of the Company's 5mg intramuscular ZIMHI product compared to 4mg of intranasal naloxone, and the respective number of doses required to reverse fentanyl-induced respiratory depression.

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

Cautionary Note Regarding 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. Forward-looking statements are identified by terminology such as "may," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar words. 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 may relate to anticipated future events or future results of operations, including, but not limited to, statements concerning (i) the creation of federal guidelines to remove barriers to access opioid reversal products at the state and local levels, (ii) the likelihood of passage of congressional legislation designed to improve access to naloxone, and (iii) the effectiveness of ZIMHI in reversing the effects of opioid overdose and the results of the study described in the press release filed as an exhibit to this Report. 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. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Adamis cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the 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, 2022, 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>.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	Press release issued by the Company dated July 28, 2023.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ADAMIS PHARMACEUTICALS CORPORATION

Dated: July 28, 2023

By: /s/ David J. Marguglio
Name: David J. Marguglio
Title: President



Adamis Pharmaceuticals to Fund ZIMHI[®] Clinical Study with University of Leiden Opioid Expert

SAN DIEGO, July 28, 2023 -- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP), a commercial-stage biopharmaceutical company, today announced the Company has committed to fund an unrestricted research grant to the Leiden University Medical Center (LUMC) Anesthesia and Pain Research Unit. The funding will support the work of Albert Dahan, MD, PhD, a world expert on opioid-induced respiratory depression (opioid overdose) and professor of anesthesiology at the University. Dr. Dahan has been working with the FDA since 2020 to understand better methods of reversing fentanyl overdoses.

“Data presented from our recent study conducted in collaboration with the U.S. Food and Drug Administration (FDA) indicated that faster and higher blood concentrations of naloxone are most effective in reversing overdoses from higher strength opioids, such as fentanyl,” said Dr. Dahan. “The objective of this collaboration with Adamis will be to assess the efficacy of 5mg intramuscular ZIMHI versus 4mg of intranasal naloxone, which is comparable to NARCAN[®] and the respective number of doses required to reverse fentanyl-induced respiratory depression.”

The prior study data referenced above by Dr. Dahan was presented in a summary report released by the Reagan-Udall Foundation of the FDA in March, which states that, “The most recent rise in overdose deaths is primarily driven by fentanyl and fentanyl analogs.” The summary goes on to highlight that “higher naloxone doses (than the current standard of care) may be required for an initial reversal of respiratory depression due to fentanyl.”¹

Eboo Versi, MD, PhD, CEO of Adamis, said, “These data from the FDA are supported by what we are hearing from first responders having to deal with fentanyl overdoses and poisoning, and this has resulted in tragic consequences.”

“Narcan is the standard of care to reverse an opioid overdose, but with fentanyl we are needing to use about three doses to achieve recovery,” said David B. Rausch, Director of the Tennessee Bureau of Investigation.

Samuel P. Chapman, Director of Parents for Safer Children, stated, “Prescription strength ZIMHI is the best remedy available for opioid overdose. If we had had some in the house when our son Sammy died, he would still be with us.”

“We believe that if ZIMHI demonstrates superiority in reversing fentanyl-induced respiratory depression in patients in the LUMC clinical study, national health organizations will update their emergency protocols to include the use of ZIMHI,” stated Dr. Versi. “Given the increased incidence of fentanyl poisoning, especially when combined with xylazine, there is now a need for a treatment that quickly results in high blood levels of naloxone as effected by ZIMHI. I believe that all first responders and harm reduction groups should have ZIMHI in their toolbox.”

About ZIMHI[®]

ZIMHI (naloxone HCl injection) is an FDA-approved, intramuscular injection of the highest available dose and concentration of naloxone that can rapidly enter the bloodstream for the emergency treatment of opioid overdose (also known as opioid induced respiratory depression). ZIMHI is available with discounted public interest pricing for first responders and other community health organizations, with additional information available via email to ZIMHIPublicHealthInfo@usworldmeds.com or at www.zimhi.com/public-service/.

¹ https://reaganudall.org/sites/default/files/2023-03/Understanding%20Fatal%20Overdoses_Slides_Day%201.pdf

About Adamis Pharmaceuticals

Adamis Pharmaceuticals Corporation is a commercial stage neuro-biotech company primarily focused on developing and commercializing products for the treatment of opioid overdose and substance use disorders. Adamis’ commercial products approved by the FDA include ZIMHI[®] (naloxone) Injection for the treatment of opioid overdose, and SYMJEP[®] (epinephrine) Injection for use in the emergency treatment of acute allergic reactions, including anaphylaxis. As a result of its recent merger transaction with DMK Pharmaceuticals, the Company is now focused on developing novel therapies for opioid use disorder (OUD) and other important neuro-based conditions where patients are currently underserved. The Company believes its technologies are at the forefront of endorphin-inspired drug design with its mono, bi- and tri-functional small molecules that simultaneously modulate critical networks in the nervous system. Adamis has a library of approximately 750 small molecule neuropeptide analogues and a differentiated pipeline that could address unmet medical needs by taking the novel approach to integrate with the body’s own efforts to regain balance of disrupted physiology. The Company’s lead clinical stage product candidate, DPI-125, is being studied as a potential novel treatment for OUD. Adamis also plans to develop the compound for the treatment of moderate to severe pain. The Company’s other development stage product candidates include DPI-221 for bladder control problems and DPI-289 for severe end stage Parkinson’s disease. For additional information about Adamis Pharmaceuticals, please visit our website and follow us on Twitter and LinkedIn.

Forward Looking Statements

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