

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): November 9, 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))

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 2.02 Results of Operations and Financial Conditions

On November 9, 2020, Adamis Pharmaceuticals Corporation (the “Company”) announced certain financial results for the three and nine months ended September 30, 2020. A copy of the Company’s press release announcing this information and certain other information is attached hereto as Exhibit 99.1.

The information furnished in this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits**Exhibit No.** **Description**

[99.1](#) Press Release issued November 9, 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: November 9, 2020

By: /s/ Robert O. Hopkins

Name: Robert O. Hopkins

Title: Chief Financial Officer

Adamis Pharmaceuticals Announces Third Quarter 2020 Financial Results and Business Update

San Diego, California – November 9, 2020 – Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced financial results for the third quarter ended September 30, 2020 and provided a business update.

Dr. Dennis J. Carlo, President and Chief Executive Officer of Adamis Pharmaceuticals, stated, “We are excited to have US WorldMeds in full control of our SYMJJEPI product now that the transition from Sandoz has been completed. We expect to see the full impact of this transition going forward and I expect 2021 to be the breakout year for this product. We and our commercial partner eagerly await the FDA’s decision on our ZIMHI NDA which has a target PDUFA date of November 15th. We remain very excited about the remainder of this year and beyond.”

Product Updates

SYMJEPI (epinephrine) Injection

On July 1, 2020, Adamis’ new commercial partner, USWM began promoting SYMJJEPI[®] (epinephrine) Injection 0.3mg and SYMJJEPI[®] (epinephrine) Injection 0.15mg products through its field sales force in the U.S. USWM expects to focus its sales efforts on the high-prescribing allergists, pediatricians, and primary care physicians. The transition of sales and distribution from Sandoz to USWM was completed on October 31, 2020 and now USWM is fully responsible for sales and distribution of SYMJJEPI.

The company’s Australian partner, Emerge Health, which was acquired by Chiesi Farmaceutica in June, continues to work through the regulatory process with the Therapeutic Goods Administration (TGA) in Australia and the company expects a decision from the TGA sometime in the first half of 2021.

ZIMHI (naloxone) Injection

The FDA has provided a target action date (PDUFA) of November 15, 2020 with respect to the company’s resubmitted New Drug Application (NDA) relating to ZIMHI. The company continues to work with its commercial partner, as USWM prepares for the commercial launch of ZIMHI.

Tempol

Since licensing this product, the company has made some progress on the development of Tempol. Unfortunately, few therapies have been successful so far for the treatment of COVID-19. In preliminary results from a study in collaboration with Stanford University, Tempol inhibits the release of multiple cytokines from activated immune cells of COVID-19 patients. This new data now provides the additional scientific rationale needed to conduct clinical studies in early COVID-19 patients with Tempol. We are currently identifying sites that could conduct this trial. With the additional data from this study, the company continues to explore its options for government and other forms of funding to potentially support additional testing of Tempol.

Discussions with various groups continue to evolve on the funding and design of a large clinical study to examine the effects of Tempol for the treatment of radiation induced dermatitis. One of these groups, which was previously under the direction Dr. Stephen Hahn (current FDA commissioner), conducted successful clinical studies of Tempol for the treatment of radiation induced alopecia.

Drug Outsourcing Facility

Year to date, sterile and non-sterile revenues from the company's wholly owned drug outsourcing facility, US Compounding (USC), were adversely affected by slowing demand due to the COVID-19 outbreak. Revenues decreased by approximately 21% for the nine months ended September 30, 2020, compared to the same period in the prior year.

Third Quarter Financial Results

Revenues were approximately \$4.3 million and \$5.9 million for the three months ended September 30, 2020 and 2019, respectively. This decrease in revenues of approximately 27% year over year was primarily due to the COVID-19 pandemic which has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of outpatient or elective surgeries and other medical procedures and reductions in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products.

Selling, general and administrative expenses for the three months ended September 30, 2020 and 2019 were approximately \$5.8 million and \$5.3 million, respectively.

Research and development expenses were approximately \$1.7 million and \$3.3 million for the three months ended September 30, 2020 and 2019, respectively. The decrease was primarily due to completing work on ZIMHI and a decrease in development costs of our other product candidates.

Cash and equivalents at the end of the third quarter was approximately \$12.4 million. This amount includes proceeds from an equity offering completed in September which provided net proceeds of approximately \$10.7 million.

Targeted Milestones

- FDA approval and U.S. commercial launch of ZIMHI;
 - Apply for government and other forms of funding for Tempol trial in COVID-19 patients; and
 - Ex-US partnerships for SYMJEPi and ZIMHI.
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Conference Call

Adamis will host a conference call and live webcast on Monday, November 9, 2020 at 2:00 pm Pacific Time to discuss its financial and operating results for the third quarter of 2020 as well as provide an update on business developments and activities.

US Dial-in (Toll Free): 1-855-327-6838

TOLL/International Dial-in: 1-604-235-2082

Conference ID: 10011804

Webcast: <http://public.viavid.com/index.php?id=142367>

In addition, a telephone playback of the call will be available after approximately 5:00 pm PT on November 9, 2020. To listen to the replay, call toll free 1-844-512-2921 within the United States or 1-412-317-6671 when calling internationally (toll). Please use the replay PIN number 10011804.

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 SYMJJEPI (epinephrine) Injection products are approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis. Adamis' naloxone injection product candidate, ZIMHI, for the treatment of opioid overdose is currently under FDA review with a target action date of November 15, 2020. Adamis is developing additional products, including treatments for acute respiratory diseases, such as COVID-19, influenza, asthma and COPD. 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.

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 impact of the COVID-19 outbreak and overall economic outlook on the company's present and future operations, employees, suppliers, supply chain, manufacturers and commercial partners; the timing and results of the FDA's review of the company's resubmitted NDA for ZIMHI; the company's beliefs concerning the results of studies or clinical trials that the company has conducted relating to ZIMHI or its other products or product candidates; the company's beliefs concerning its ability to commercialize ZIMHI and its other products and product candidates; the company's beliefs concerning the success of the transition of commercialization and marketing of its SYMJJEPI products from Sandoz to USWM; the company's beliefs concerning the ability of its product candidates to compete successfully in the market; the company's beliefs concerning the safety and effectiveness of SYMJJEPI, ZIMHI or its other products and product candidates; the company's beliefs concerning its commercialization strategies; the company's beliefs concerning the anticipated timing of any commercial launch of its ZIMHI product; the company's beliefs concerning the timing or outcome of discussions with the FDA or others concerning the design and funding for trials relating to use of Tempol as a therapeutic treatment for COVID-19 or radiation induced dermatitis, or the timing or outcome of any such trials; statements about strategies, objectives and our future goals and achievements; future financial results of the company and its subsidiaries; future development and regulatory actions concerning the company's product candidates; the timing and progress of current and future clinical trials or studies; expectations and goals for future growth, including without limitation future growth in revenues from sales of compounded sterile pharmaceutical formulations; anticipated commencement and completion dates for clinical trials; product development timelines; anticipated dates for commercial introduction of products; guidance regarding future periods; 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 these forward-looking statements. There can be no assurances concerning the timing or outcome of future action by the FDA relating to our resubmitted NDA for ZIMHI. In addition, there can be no assurance that the FDA will conclude that the company's resubmitted NDA satisfactorily responds to the matters raised in the FDA's previous Complete Response Letter, that the FDA will approve our resubmitted NDA relating to ZIMHI, or concerning the timing of any future action by the FDA on our resubmitted NDA. The FDA's review processes can extend beyond, and in some cases significantly beyond, anticipated or target completion or action dates due to the timing of the FDA's review process, FDA requests for additional data, information, materials or clarification, difficulties scheduling an advisory committee meeting, FDA workload issues, extensions resulting from the submission of additional information or clarification regarding information already in the submission, issues relating to the COVID-19 pandemic, or other reasons. We may not achieve one or more of the target future milestones described in the press release either within the anticipated time periods or at all. 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. Failure to timely obtain required funding would adversely affect us and could require us to materially reduce or suspend operations or one or more clinical trials or other product development activities, or delay or prevent our ability to realize the results contemplated by such forward looking statements. In addition, 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, 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>. Except to the extent required by law, any forward-looking statements in this press release speak only as the date of this press release, and Adamis expressly disclaims any obligation to update any forward-looking statements.

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