



## Adamis Pharmaceuticals Announces First Quarter 2020 Financial Results and Business Update

May 18, 2020

SAN DIEGO, May 18, 2020 (GLOBE NEWSWIRE) -- [Adamis Pharmaceuticals Corporation](#) (NASDAQ: ADMP) today announced financial results for the first quarter ended March 31, 2020 and provided a business update.

Dr. Dennis J. Carlo, President and Chief Executive Officer of Adamis Pharmaceuticals, stated, "We are pleased to have resubmitted our ZIMHI New Drug Application to the FDA to get us back on track for regulatory review. We are also very excited to be partnering with US WorldMeds to commercialize both our SYMJJEPI and ZIMHI products here in the U.S. Certainly, Adamis has been negatively affected by the COVID-19 outbreak and the various degrees of lockdowns, and it remains to be seen how quickly everyone can get back to a new normal. However, we continue to operate and progress on a number of objectives. We will continue these efforts to mitigate the financial impact of the pandemic."

### Product Updates

#### *SYMJEPI (epinephrine) Injection*

Earlier this month, the company announced that it had entered into an agreement with Sandoz Inc. providing for the mutually agreed return to Adamis of the marketing, promotion, and distribution rights to the company's SYMJJEPI<sup>®</sup> (epinephrine) Injection 0.3mg, SYMJJEPI<sup>®</sup> (epinephrine) Injection 0.15mg products currently marketed and available in the United States, and the termination of the commercialization agreement between Adamis and Sandoz, following a transition period, supported by a transition services agreement that is currently being negotiated. Adamis also simultaneously entered into an exclusive distribution and commercialization agreement with US WorldMeds, LLC (USWM) for the United States commercial rights for the SYMJJEPI products as well as the Company's ZIMHI<sup>™</sup> (naloxone HCl Injection, USP) 5mg/0.5mL product candidate.

In addition to the U.S., Adamis continues to seek opportunities to market SYMJJEPI into other territories and in October 2019, the company announced it had entered into an exclusive distribution and commercialization agreement with Emerge Health to seek registration and commercialize SYMJJEPI in both Australia and New Zealand.

#### *ZIMHI (naloxone) Injection*

Adamis has entered into an exclusive distribution and commercialization agreement with USWM for the U.S. commercial rights for ZIMHI<sup>™</sup> (naloxone HCl Injection, USP) 5mg/0.5mL product candidate. Under the terms of the Adamis/USWM agreement, US WorldMeds obtained U.S. rights to commercialize and distribute the SYMJJEPI products, upon the termination of Sandoz's commercial rights, and ZIMHI, if approved by the U.S. Food and Drug Administration, in exchange for an upfront payment and potential regulatory and commercial milestones totaling up to \$26 million. Additionally, after deducting the supply price and certain other deductions, including an allocation for USWM sales and distribution expenses from net sales of the products, Adamis and USWM will share equally in the net profits, as defined in the agreement.

Earlier today, the company announced the resubmission of the company's New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for its ZIMHI product candidate. The resubmission follows the company's meeting with the agency in February and is intended to address the issues raised by the FDA in the agency's November 2019 Complete Response Letter ("CRL").

#### *Drug Outsourcing Facility*

During the first quarter of 2020, sterile and non-sterile revenues from the company's wholly owned drug outsourcing facility, US Compounding (USC), decreased by approximately 6% in the first quarter compared to the same quarter in the prior year. Revenues from the sale of pharmaceutical formulations by USC were adversely affected by slowing demand due to the novel coronavirus outbreak. The company is seeking to mitigate the impact with the development and launch of products for which there has been a recent increase in demand.

### First Quarter Financial Results

Revenues were approximately \$4.7 million and \$4.9 million for the three months ended March 31, 2020 and 2019, respectively. The decrease of approximately 5.0% in the first quarter of 2020 compared to the comparable period of 2019 was impacted by the effect of the pandemic on demand for USC's products. Specifically, hospitals cancelled elective and non-emergency procedures, pain clinics were either shutdown or experienced a significant drop in office visits during the first quarter and the horse racing industry shut down.

Selling, general and administrative expenses ("SG&A") for the three months ended March 31, 2020 and 2019 were approximately \$6.1 million and \$8.0 million, respectively. The decrease was primarily attributable to decreases in wages, benefits and other compensation expenses, and to a lesser extent by decreases in operational expenses relating to the ceasing of sales of certain USC products, and decreases in patent, consulting, outside services, professional fees, PDUFA fees, depreciation and other related expenses.

Research and development expenses were approximately \$2.0 million and \$2.2 million for the three months ended March 31, 2020 and 2019, respectively, a decrease of approximately 7.3%. The decrease was primarily due to a decrease in development costs of our product candidates.

Cash and equivalents at the end of the first quarter was approximately \$10.5 million. In February 2020, the company completed a registered direct offering of common stock, and a concurrent private placement of warrants, resulting in estimated net proceeds of approximately \$6.2 million.

### Targeted Milestones

- Transition SYMJJEPI commercial responsibility from Sandoz to USWM;

- FDA approval and U.S. commercial launch of ZIMHI;
- Develop and launch new USC products to help offset the impact of pandemic; and
- Complete a Phase III ulcer study in horses.

#### Conference Call

Adamis will host a conference call and live webcast on Monday, May 18, 2020 at 2:00 pm Pacific Time to discuss its financial and operating results for the first quarter of 2020 as well as provide an update on business developments and activities.

US Dial-in (Toll Free): 1-877-423-9813

TOLL/International Dial-in: 1-201-689-8573

Conference ID: 13703885

Webcast: <http://public.viavid.com/index.php?id=139872>

In addition, a telephone playback of the call will be available after approximately 5:00 pm PT on May 18, 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 13703885.

#### 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. Please refer to [www.SYMJEPi.com](http://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, 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 impact of the recent COVID-19 outbreak and overall economic outlook on the company's present and future operations, employees, suppliers, supply chain, manufacturers and commercial partners; the company's beliefs concerning its ability to satisfactorily respond to the matters raised in the FDA's Complete Response Letter (CRL) and to successfully develop the additional information requested by the FDA at the company's Type A meeting with the FDA; 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 SYMJEPi 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 SYMJEPi, 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; 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 CRL or discussed in the Type A meeting, 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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