
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 15, 2017

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.)

11681 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

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.

Item 8.01 Other Events

On June 15, 2017, Adamis Pharmaceuticals Corporation (“Adamis” or the “Company”) issued a press release announcing that the U.S. Food & Drug Administration (“FDA”) has approved the Company’s Epinephrine Injection USP, 1:1000 (0.3 mg Pre-filled single dose syringe) (“PFS”) product for the emergency treatment of allergic reactions (Type I) including anaphylaxis. The press release also announced that the FDA approved the trade name of “Symjepi™” for the product. The approval was pursuant to the FDA’s review of the Company’s New Drug Application (“NDA”), which was amended and resubmitted in December 2016, pursuant to the Food, Drug & Cosmetic Act, as amended, relating to the Epinephrine PFS product. Symjepi provides two single dose syringes of epinephrine (adrenaline), which is used for emergency, immediate administration in acute anaphylactic reactions to insect stings or bites, allergic reaction to certain foods, drugs and other allergens, as well as idiopathic or exercise-induced anaphylaxis. In the press release, the Company indicated that it was in the process of exploring commercialization options and discussions with potential partners regarding commercialization of the product, and that in the interim, it expected to build inventory levels in preparation for an anticipated launch in the second half of this year. The Company also indicated in the press release that it was preparing for the submission of a second NDA to the FDA for a junior, lower dose version of the product.

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. These statements relate to anticipated future events or future results of operations, including, but not limited to, the following statements: the company’s beliefs concerning the timing and effectiveness of its commercialization strategies; the company’s beliefs concerning the anticipated timing and nature of a commercial launch of its Epinephrine PFS product; the ability of the Epinephrine PFS product to compete successfully in the market; the company’s ability to build inventory levels of the product in anticipation of a commercial launch; and the company’s beliefs concerning the timing and outcome of any future New Drug Application that the company may submit to the FDA relating to a junior, lower dose version of its Epinephrine PFS product. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which may cause the company’s actual results to be materially different from the results anticipated by these forward-looking statements. Statements in this Report concerning future events depend on several factors beyond the company’s control, including without limitation the following: adequate funding to support the activities contemplated by the forward-looking statements; the nature of any commercialization arrangements that may be entered into or the nature of any commercial launch of the product; the success of the Epinephrine PFS product in the marketplace and the actions of competitors in the marketplace; and the absence of unexpected regulatory developments or delays. There can be no assurances regarding the commercialization options that the company will pursue; that the company will enter into any agreements with potential partners regarding commercialization of the Epinephrine PFS product or what the terms of any such agreement might be; that the company’s Epinephrine PFS product will be commercially launched by the end of the year or what the nature of the launch may be; that the product will be able to compete successfully in the market; that the company will successfully build inventory levels in anticipation of a product launch; regarding actions that competitors may take in response to the FDA’s approval of the Epinephrine PFS product or any commercial launch of the product; or concerning the timing of a submission to the FDA of an NDA relating to a junior, lower dose version of the product or the timing or outcome of the FDA’s review of any such submission. Factors that might cause actual results to differ from the results anticipated by forward-looking statements made in this Report include, without limitation: funding limitations regarding anticipated activities; delays in entering into commercialization arrangements with potential partners or delays in commercialization of the Epinephrine PFS product; actions by competitors in the marketplace or otherwise; and unexpected adverse regulatory developments relating to the product or to the company’s anticipated NDA submission relating to a junior, lower dose version of the product. Certain of the above matters, and other risks, uncertainties, and other factors, are described in greater detail in Adamis’ filings from time to time 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 June 15, 2017.](#)

SIGNATURE

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, 2017

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

Adamis Pharmaceuticals Receives FDA Approval for Its Epinephrine Pre-Filled Syringe

SAN DIEGO—(June 15, 2017)— Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) (“Adamis”) today announced that the U.S. Food and Drug Administration (“FDA”) has approved Adamis’ EPINEPHRINE INJECTION, USP, 1:1000 (0.3 mg Pre-filled single dose syringe) (“PFS”) for the emergency treatment of allergic reactions (Type I) including anaphylaxis. The FDA has also approved the PFS trade name of Symjepi™.

Symjepi provides two single dose syringes of epinephrine (adrenaline), which is considered the drug of choice for immediate administration in acute anaphylactic reactions to insect stings or bites, allergic reaction to foods (such as nuts), drugs and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

Dr. Dennis J. Carlo, President and CEO of Adamis, stated, “We are very excited by this approval, and at the same time, are already preparing to submit our second NDA to the FDA. This second submission is for the junior version of Symjepi. We are committed to helping patients by providing them with additional therapeutic choices. With an anticipated lower cost, small size and user-friendly design, we believe Symjepi could be an attractive option for a significant portion of both the retail (patient) and non-retail (professional) sectors of the epinephrine market. We are currently in the process of exploring all of our commercialization options and in discussions with potential partners in order to facilitate broad patient access to this new epinephrine treatment option and to maximize the value of our important asset. In the interim, we expect to build inventory levels in preparation for an anticipated launch in the second half of this year.”

About Anaphylaxis

Anaphylaxis is a serious, sometimes life-threatening allergic reaction. The most common anaphylactic reactions are to foods, insect stings, medications and latex. According to information published by industry sources, up to 8% of U.S. children under the age of 18 have a food allergy, and approximately 38% of those with a food allergy have a history of severe reactions. Anaphylaxis requires immediate medical treatment, including an injection of epinephrine. The number of prescriptions for epinephrine products has grown annually, as the risk of anaphylaxis and allergic reactions have become more widely understood. The company estimates that sales of prescription epinephrine products in 2016 were at least \$1 billion, based on industry data.

About Adamis Pharmaceuticals

Adamis Pharmaceuticals Corporation is a specialty biopharmaceutical company focused on developing and commercializing products in the therapeutic areas of respiratory disease and allergy. The company's current specialty pharmaceutical products and product candidates include Epinephrine Injection pre-filled syringe product for use in the emergency treatment of acute allergic reactions, including anaphylaxis; albuterol (APC-2000) and fluticasone (APC-4000) dry powder inhaler products for the treatment of bronchospasm and asthma; and beclomethasone (APC-1000), a metered dose inhaler product for the treatment of asthma.

The Company's U.S. Compounding, Inc. subsidiary, which is registered as a drug compounding outsourcing facility under Section 503B of the U.S. Food, Drug & Cosmetic Act and the U.S. Drug Quality and Security Act, provides prescription compounded medications, including compounded sterile preparations and non-sterile compounds, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. USC's offerings broadly include, among others, injectable corticosteroids, hormone replacement therapies, hospital outsourcing formulations, urological preparations, ophthalmic preparations, topical compounds for pain and men's and women's health formulations.

Adamis Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 timing and outcome of any future New Drug Application (NDA) that the company may submit to the FDA relating to lower dose version of its Epinephrine PFS product; 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 its product candidates; the company's beliefs concerning its commercialization strategies; and the company's beliefs concerning the anticipated timing of a commercial launch of its Symjepi product. 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 regarding the commercialization options that the company will pursue, that the company's Symjepi product will be launched by the end of the year, that the product will be able to compete successfully in the market, or concerning the timing of a submission to the FDA of an NDA relating to a lower dose version of the product or the timing or outcome of the FDA's review of any such submission. Certain of these risks, uncertainties, and other factors are described in greater detail in Adamis' filings from time to time 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.

Contact Adamis:

Mark Flather
Senior Director, Investor Relations
& Corporate Communications
(858) 412-7951
mflather@adamispharma.com
