Adamis Pharmaceuticals Announces Third Quarter 2018 Financial Results and Business Update

November 9, 2018

SAN DIEGO, Nov. 09, 2018 (GLOBE NEWSWIRE) -- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced financial results for the third quarter ended September 30, 2018 and a business update.

Dr. Dennis J. Carlo, President and Chief Executive Officer of Adamis Pharmaceuticals, stated, “The third quarter of 2018 was a significant one for Adamis. We opened the quarter by announcing an agreement with Sandoz to sell and distribute Symjepi in the U.S. In August, we strengthened our cash position with an underwritten equity offering which netted approximately $37.6 million and closed the quarter by announcing FDA approval for our Symjepi™ low dose (0.15 mg) product. This represents our second approved product using our Symject™ injectable platform. In addition, the company continued product development on our late-stage product candidates including the naloxone injection (APC-6000) and beclomethasone HFA (APC-1000) and announced the addition of a sublingual tadalafil product candidate to the development pipeline. To continue this momentum, Adamis is targeting additional milestones for the fourth quarter.”

Product Updates

Symjepi™ (epinephrine) Injections (0.30mg and 0.15mg)

In the third quarter, the company entered into a commercialization and distribution agreement with Sandoz, a division of Novartis, to market and sell Symjepi™ in the U.S. The company also granted Sandoz a right of first negotiation for territories outside the U.S. On September 27th, the FDA approved the lower dose (0.15mg) Symjepi product. The company is continuing to support Sandoz in preparing for the commercial launch of both products.

APC-8000 (sublingual tadalafil)

The company has completed the testing of its sublingual tadalafil tablet product candidate in human patients. If analysis of the results of the testing is positive, the company’s goal is to file a New Drug Application (NDA) before the end of the fourth quarter.

APC-6000 (naloxone)

Progress has continued on the company’s naloxone injection product candidate for the treatment of opioid overdoses. Drug overdoses are now the leading cause of death for Americans under 50 years of age. According to statistics published by the Centers for Disease Control and Prevention (CDC), in 2017 drug overdoses resulted in approximately 72,000 deaths in the United States. The proliferation of more powerful synthetic opioids, such as fentanyl, may lead to an increase in the number of deaths from opioid overdoses. The company’s goal is to file an NDA before the end of the fourth quarter.

APC-1000 (beclomethasone)

With development complete on the company’s beclomethasone metered dose inhaler, and with the clearance from the FDA to begin Phase 3 trials, Adamis intends to begin enrolling patients into the pivotal study in December.

APC-4000 (fluticasone)

Development and manufacturing for the patented “dry powder inhaler” technology that the company acquired from 3M was completed in the first half of the year. We are now completing the drug development work, which includes loading the drug substance onto the tape in order to demonstrate proper dosing.

Drug Outsourcing Division

The company’s wholly-owned subsidiary, US Compounding received notice of allowance for a patent in the US for its novel combination product for treating and/or preventing gastrointestinal conditions including ulcers in horses and other livestock. This patent will strengthen its portfolio of veterinary products.

Third Quarter Financial Results

Revenues were approximately $3.8 million and $3.4 million for the three months ended September 30, 2018 and 2017, respectively. The increase in revenues for the three months ended September 30, 2018, compared to the comparable period of 2017, reflected an increase in sales of USC’s compounded and non-compounded pharmaceutical formulations.

Selling, general and administrative expenses (“SG&A”) for the three months ended September 30, 2018 and 2017 were approximately $6.5 million and $5.7 million, respectively. Compensation expense for SG&A employees increased by approximately $409,000 for the three months ended September 30, 2018, compared to the comparable period of 2017, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with stock options grants and other employee benefits. SG&A expenses for the third quarter of 2018 compared to the comparable period of 2017, also increased by approximately $96,000 in patent expenses and $76,000 in PDUFA fees. Approximately $206,000 of the increase in the 2018 period compared to the same period of 2017 was due to increases in accounting, audit and other professional fees, depreciation, selling expenses, IT consulting expenses, taxes, travel expenses and other related expenses.

Research and development expenses were approximately $3.9 million and $1.2 million for the three months ended September 30, 2018 and 2017, respectively. The increase in research and development expenses for the three months ended September 30, 2018, compared to the comparable

period of the prior year was due in part to an increase of approximately $2.5 million in development costs of our product candidates. This amount was partially offset by a decrease of approximately $134,000 in development costs primarily attributable to the APC-1000 and APC 5000 product candidates. Compensation expense for research and development increased by approximately $339,000 for the three months ended September 30, 2018, compared to the comparable period of 2017, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with stock options grants and other employee benefits. The company expects that research and development spending in the fourth quarter of 2018 will see an increase due to advancement of the company's pipeline development activities, which may include FDA filing fees for NDAs for the naloxone and tadalafil product candidates if those NDAs are filed before the end of 2018, fees and costs associated with initiating a Phase 3 trial for the beclomethasone product candidate, and other spending and expenses relating to our pipeline product candidates, related regulatory expenses and other development expenses.

At September 30, 2018, the Company had cash and cash equivalents of $32.0 million.

Net cash used in operating activities for the nine months ended September 30, 2018 and 2017, was approximately $20.4 million and $9.9 million, respectively. Net cash used in operating activities increased primarily due to the decrease in gross profit and the increase in operating expenses.

Targeted Future Milestones

- Commercial launch of Symjepi™ (epinephrine) Injection 0.3mg and 0.15mg in the U.S.;
- Announcement of a commercial partner on Symjepi for territories outside the U.S.;
- Filing an NDA for the naloxone injection product candidate;
- Filing an NDA for the sublingual tadalafil product candidate;
- Initiate pivotal Phase 3 studies of the beclomethasone product candidate in asthmatics;
- Growing net revenue of the company's outsourcing facility (US Compounding) by 30% over 2017.

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 and allergy. The company's Symjepi (epinephrine) Injections 0.3mg and 0.15mg were approved for use in the emergency treatment of acute allergic reactions, including anaphylaxis. Adamis recently announced a distribution and commercialization agreement with Sandoz, a division of Novartis Group, to market Symjepi in the U.S. Adamis is developing a sublingual tadalafil product candidate as well as additional product candidates, using its approved injection device, and a metered dose inhaler and dry powder inhaler devices. The company's subsidiary, U.S. Compounding, Inc., compounds sterile prescription drugs, and certain nonsterile drugs for human and veterinary use, to patients, physician clinics, hospitals, surgery centers and other clients 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. These statements relate to future events or future results of operations, including, but not limited to the following statements: the company's beliefs concerning timing and outcome of finalizing the commercialization arrangements and strategy for its Symjepi™ (epinephrine) Injection 0.3mg product; statements about strategies, objectives and our future goals and achievements; the company's ability to commercialize its product and product candidates; the company's beliefs concerning the ability of its products and product candidates to compete successfully in the market; the company's beliefs concerning the safety and effectiveness of its products and product candidates; expectations and goals for future growth; current or planned clinical trials or research and development activities; anticipated commencement and completion dates for clinical trials; anticipated dates for making regulatory filings with the FDA; product development timelines; anticipated dates for commercial introduction of products; guidance regarding future periods; the company's beliefs concerning the safety and effectiveness of its products and product candidates; and other statements concerning our future operations and activities. 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. We may not achieve one or more of the target future milestones described in the press release either within the anticipate 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 require significant additional funding to continue operations, and there are no assurances that such funding will be available. Failure to timely obtain required funding would adversely affect and could require us to materially reduce or suspend operations, or delay or prevent our ability to realize the results contemplated by such forward looking statements. 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. 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, 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, 2017, 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.

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

Source: Adamis Pharmaceuticals Corporation