

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): October 6, 2005

PRO-PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada

000-32877

04-3562325

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

189 Wells Avenue, Newton, Massachusetts
(Address of principal executive offices)

02459
(Zip Code)

Registrant's telephone number, including area code: (617) 559-0033

Not Applicable

(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:

- 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))

Item 8.01 Other Events.

On October 6, 2005, Pro-Pharmaceuticals, Inc. issued a news release announcing final Phase I results. Pharmacokinetics analysis indicates 5-FU, in combination with DAVANAT(R), remains significantly longer in the bloodstream of cancer patients, potentially increasing 5-FU's efficacy while lowering toxicity. A copy of Pro-Pharmaceuticals news release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

99.1 News release of Pro-Pharmaceuticals, Inc. dated October 6, 2005.

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 thereunto duly authorized.

PRO-PHARMACEUTICALS, INC.

By: /s/ David Platt

David Platt
Chief Executive Officer

Date: October 6, 2005

Pro-Pharmaceuticals Announces Final Phase I Results

NEWTON, Mass.--(BUSINESS WIRE)--Oct. 6, 2005--Pro-Pharmaceuticals, Inc. (Amex: PRW):

- Pharmacokinetics Analysis Indicates 5-FU, in Combination with DAVANAT(R), Remains Significantly Longer in the Bloodstream of Cancer Patients, Potentially Increasing 5-FU's Efficacy While Lowering Toxicity

Pro-Pharmaceuticals, Inc. (Amex: PRW), a developer of novel carbohydrate compounds that enable the targeted delivery of chemotherapy drugs to cancer cells, today announced that the pharmacokinetics analysis of cancer patients in the sixth and final cohort of Phase I indicates 5-Fluorouracil (5-FU) remained in the bloodstream significantly longer when co-administered with DAVANAT(R), thereby potentially increasing 5-FU's efficacy while lowering its toxicity.

"DAVANAT(R) is a powerful target delivery technology within a new paradigm that may enhance the safety and efficacy profile of a variety of FDA-approved chemotherapy drugs," said David Platt, Ph.D., Chief Executive Officer, Pro-Pharmaceuticals. "In addition to our positive Phase I results with 5-FU, we have had positive preclinical results with irinotecan (Camptosar(R)-Pfizer, Inc., NYSE:PFE), doxorubicin, oxaliplatin, paclitaxel, cisplatin (PLATINOL(R)- Bristol-Myers Squibb Company, NYSE:BMJ) and bevacizumab (AVASTIN(R)- Genentech, Inc., NYSE:DNA) in combination with DAVANAT(R), as well as other polysaccharide compounds. We look forward to confirming the target delivery capability of DAVANAT(R) in Phase II/III clinical trials."

Specific pharmacokinetics data includes:

- 5-FU was administered at a dose of 500 mg/m². As body surface area of the patients ranged between 1.55 and 2.38 m², the actual 5-FU administered to certain cancer patients ranged between 775 and 1,190 mg/m² per day for four consecutive days.
- Concentration time profiles showed no marked differences between groups or study days.
- Peak systemic levels were generally achieved at the end of infusion. 5-FU disappeared in a bi-phasic manner thereafter.
- Systemic exposure to 5-FU Area Under the Curve (AUC 0-last) and peak 5-FU systemic Concentrations (C_{max}) tended to increase with repeated doses of 5-FU. These two pharmacokinetics parameters have almost the same profiles for days one through four.
- Systemic exposure to 5-FU (AUC 0-last) and peak 5-FU systemic Concentrations (C_{max}) tended to increase with high doses of DAVANAT(R) (between 150 and 280 mg/m²).
- Total systemic clearance values ranged between 1.16 and 4.65 L/min. The highest clearance was achieved at day one and after giving between 150 and 280 mg/m² of DAVANAT(R). 5-FU systemic clearance tended to decrease with increased doses of DAVANAT(R) thereafter.
- Half-life values of 5-FU ranged between 28 and 137 minutes compared with historical 5-FU data of between 8 and 20 minutes.

DAVANAT(R) also enhanced 5-FU anti-tumor activity. The third- and fourth-line cancer patients in Phase I had solid tumors that averaged more than 100mm coming into the study, had progressive disease and were refractory to 5-FU. 5-FU is effective with a narrow margin of safety, and has known side effects such as severe gastrointestinal and hematological toxicity.

The disease was stabilized in 14 of 26 patients with measurable disease. Six of ten patients were stabilized at the highest dose level (sixth and final cohort). Efficacy results are based on Response Evaluation Criteria in Solid Tumors (RECIST) following completion of the second cycle of treatment. According to RECIST, stable disease is defined as "Neither sufficient shrinkage to qualify for Partial Response (more than 30% shrinkage) nor sufficient increase to qualify for Progressive Disease (greater than 20% increase) taking as reference the smallest sum longest diameter since the treatment started". Phase I data also indicates that DAVANAT(R)/5-FU was well

tolerated. Dose Limiting Toxicity and Maximum Tolerated Dose were not reached at the highest dose level when DAVANAT(R) (280 mg/m²) was administered alone or in combination with 5-FU (500 mg/m²).

Phase I Clinical Trial

The Phase I multi-center, open-label trial was designed for cancer patients with advanced solid tumors that were not amenable to surgery, radiation, or chemotherapy, were refractory to 5-FU, and had a minimum of 12 weeks to live. The objectives of the study were to determine the Maximum Tolerated Dose and Dose Limiting Toxicity of DAVANAT(R) as a single agent, and when administered in combination with 5-FU; to determine the pharmacokinetic profile of 5-FU in the presence of DAVANAT(R); and, to determine the effect of DAVANAT(R)/5-FU on tumor size in patients with measurable disease.

The study design included a screening period followed by two consecutive 28-day treatment cycles: In cycle 1, patients were dosed with DAVANAT(R) intravenously as a single agent for four consecutive days, followed by a 24-day monitoring period. In cycle 2, patients were dosed intravenously with DAVANAT(R)/5-FU for four consecutive days, followed by a 24-day monitoring period. In the Phase I study, DAVANAT(R) was dose escalated from 30mg/m² in the first cohort to 280 mg/m² in the sixth and final cohort, while the dose level of 5-FU was held constant at 500 mg/m². The four renowned cancer centers that participated in the study are the Ochsner Cancer Institute in New Orleans, LA; Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center in Lebanon, NH; University of Michigan Comprehensive Cancer Center in Ann Arbor, MI; and, Florida Oncology Associates in Jacksonville, FL. The Phase I study closed in March. Additional information is available at www.asco.org (search word: DAVANAT).

Phase II Cholangiocarcinoma Trial

The Company recently submitted a clinical protocol for a Phase II study of its lead carbohydrate compound DAVANAT(R) with chemotherapeutic agent 5-FU for first line treatment of patients with cholangiocarcinoma (cancer of the bile duct). In May of this year, the U.S. Food & Drug Administration (FDA) approved an application for a "compassionate use" Investigational New Drug to continue treating a patient for cholangiocarcinoma with liver metastases who participated in the Company's Phase I trial. The patient has been treated for 11 months and continues to respond well.

Phase II Colorectal Cancer Trial

The Company has an ongoing Phase II clinical trial of DAVANAT(R)/5-FU in refractory colorectal cancer patients. Recruiting and treatment of patients is currently ongoing at three clinical sites. Additional information is available at www.clinicaltrials.gov.

About DAVANAT(R)

DAVANAT(R) is a proprietary polysaccharide in a CARBOSOME(TM) formation that target delivers chemotherapy drugs to protein receptors (lectins) that are specific to cancer cells.

Pro-Pharmaceuticals, Inc. - Advancing Drugs Through Glycoscience(R)

Pro-Pharmaceuticals is a drug development company commercializing a new generation of anti-cancer treatments using carbohydrate compounds to Glyco-Upgrade(TM) the safety and efficacy of FDA-approved chemotherapy drugs by target delivering the drug to cancer cells. The Company has been conducting pre-clinical studies for irinotecan, doxorubicin, oxaliplatin, paclitaxel, cisplatin, and bevacizumab both in combination with DAVANAT(R) as well as other polysaccharide compounds. Human colon and breast xenography are being used to optimize formulations and results show that DAVANAT(R) exhibits a broad spectrum of activity with tested drugs. Additional information is available at www.pro-pharmaceuticals.com.

FORWARD LOOKING STATEMENTS: Any statements in this news release about future expectations, plans and prospects for the Company, including without limitation statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements as defined in the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Because of uncertainties and risks facing the Company, many of which are outside of the Company's control, future events could cause actual results to differ materially from those indicated by such statements. More information about those risks and uncertainties is contained and discussed in the "Management Discussion and Analysis of Financial Condition and Results of Operations" and

"Risk Factors" sections of the Company's most recent quarterly or annual report and in the Company's other reports filed with the Securities and Exchange Commission. The forward-looking statements herein represent the Company's views as of the date of this news release and should not be relied upon to represent the Company's views as of a subsequent date. While the Company anticipates that subsequent events may cause the Company's views to change, the Company disclaims any obligation to update such forward-looking statements.

DAVANAT and Advancing Drugs Through Glycoscience are registered trademarks of Pro-Pharmaceuticals. Glyco-Upgrade and CARBOSOME are trademarks of Pro-Pharmaceuticals.

Camptosar(R) is a registered trademark of Pfizer, Inc., PLATINOL(R) is a registered trademark of Bristol-Myers Squibb Company, and AVASTIN(R) is a registered trademark of Genentech, Inc.

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