

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 23, 2004

PRO-PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other Jurisdiction of Incorporation)

000-32877

(Commission File Number)

04-3562325

(IRS Employer Identification No.)

189 Wells Avenue, Newton, Massachusetts

(Address of Principal Executive Offices)

02459

(Zip Code)

(617) 559-0033

(Registrant's Telephone Number, Including Area Code)

Not Applicable

(Former Name or Former Address, If Changed Since Last Report)

Item 5. Other Events and Regulation FD Disclosure

On June 23, 2004, Pro-Pharmaceuticals, Inc. issued a press release, which is attached hereto as Exhibit 99.1.

Item 7. Financial Statements and Exhibits

(c) Exhibits.

99.1 Press Release of Pro-Pharmaceuticals, Inc. dated June 23, 2004

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, Ph.D.
President and Chief Executive Officer

Date: June 23, 2004

Pro-Pharmaceuticals Reports Phase I for DAVANAT-1 in Refractory Cancer Patients is Now in Its Sixth and Final Cohort

NEWTON, Mass.--(BUSINESS WIRE)--June 23, 2004--

Results From the First Five Dose Escalations Indicate DAVANAT(R) in Combination With 5-fluorouracil (5-FU) is Well Tolerated in Patients With Advanced Solid Tumors

Pro-Pharmaceuticals, Inc. (AMEX:PRW), a developer of novel carbohydrate compounds for Targetedelivery(TM), today reported positive interim Phase I results of its lead compound DAVANAT(R) alone and in combination with the proven chemotherapeutic drug 5-FU (DAVANAT(R)-1) in refractory solid tumor patients. The Phase I study, which is currently in its sixth and final cohort, is expected to evaluate a total of 32 patients.

Commenting on the interim results, Eliezer Zomer, Ph.D., Pro-Pharmaceuticals' Vice President Product Development & Manufacturing, said, "Both DAVANAT and DAVANAT-1 were well tolerated in patients in their respective first and second cycles without any drug-related serious adverse events. The interim pharmacokinetics analysis for cohorts one through five indicated the mean exposure parameters, AUC(0-last) and Cmax, tended to increase with repeated dosing of 5-FU and with escalating doses of DAVANAT. We are very encouraged with the initial clinical activity and look forward to completing the Phase I study and to confirming the benefit of this combination therapy in the upcoming Phase II trial."

Dr. Zomer added, "5-FU is effective in the treatment of carcinoma of the colon, rectum, breast, stomach and pancreas. The drug is the primary chemotherapeutic agent used to treat solid tumors alone and in combination with other drugs. 5-FU is a very effective drug, yet is highly toxic with a narrow margin of safety, and has known side effects such as severe gastrointestinal and hematological toxicity."

David Platt, Ph.D., Pro-Pharmaceuticals' Chief Executive Officer and President, said, "The interim Phase I results are a clear indication of the power of our platform technology and demonstrate the potential for a paradigm shift in the way drugs are designed. Our mission is to 'glyco-upgrade' pre-approved FDA chemotherapy drugs and give them a 'Targetedelivery(TM)' mechanism by utilizing our Carbosome(TM) technology."

Phase I Clinical Trial

Phase I is an open-label study to evaluate the safety and tolerability of escalating doses of DAVANAT alone and in combination with a constant dose of 5-FU in patients with advanced solid tumors. Different doses of DAVANAT will be given alone in Cycle 1, and in combination with 5-FU in cycle 2. The study will determine the ability of cancer patients to tolerate escalating doses of DAVANAT while receiving a stable dose of 5-FU (500 mg/m²) for treatment. The primary objectives of the study are to: (1) determine the maximum tolerated dose of DAVANAT alone and when administered with a stable dose of 5-FU, (2) define the dose-limiting toxicities of DAVANAT alone and in combination with 5-FU, (3) determine the pharmacokinetic profile of 5-FU in the presence of DAVANAT (doses ranging from 30 mg/m² to 280 mg/m²), and (4) determine the effect of DAVANAT-1 on tumor size in patients with measurable disease.

The four clinical sites participating in the ongoing Phase I trial are: The Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center in Lebanon, NH; The University of Michigan Comprehensive Cancer Center in Ann Arbor, MI; The Ochsner Cancer Institute in New Orleans, LA; and Florida Oncology Associates in Jacksonville, FL.

Phase II Clinical Trial

In January 2004, Pro-Pharmaceuticals announced submission of a clinical protocol to the FDA for a Phase II clinical trial of DAVANAT-1 in refractory colorectal cancer patients. The study will evaluate the efficacy and safety of intravenous DAVANAT-1 when administered in monthly cycles as third-line therapy for metastatic colorectal cancer. The objectives for the Phase II study are to document the rate of response and stabilization of the disease with DAVANAT-1 therapy, and to evaluate the safety of DAVANAT-1 in this population.

Pre-clinical Studies

Initial studies were performed to test the reduction in toxicity of anti-cancer drugs, and demonstrated that DAVANAT might significantly decrease the toxicity of 5-FU and doxorubicin. Independent efficacy studies on co-administration of DAVANAT with anti-cancer drugs conducted at independent research laboratories demonstrated that DAVANAT might also increase efficacy of 5-FU, when tested in various animal models carrying human colon and breast tumors.

Pro-Pharmaceuticals is a drug development company commercializing a new generation of anti-cancer treatments using carbohydrate molecules to upgrade their safety and efficacy. Founded in 2000 and headquartered in Newton, MA, the Company is a leader in the use of structure-based drug design, an approach to drug discovery that integrates advanced biology and chemistry. Additional information is available at www.pro-pharmaceuticals.com.

FORWARD-LOOKING STATEMENTS

Any statements in this press release about future expectations, plans and prospects for the Company, including without limitation statements containing the words "believes," "anticipates," "plans," "expects," "will" 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's 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 press 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. Targetedelivery is a trademark of Pro-Pharmaceuticals.

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