

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): May 16, 2005

PRO-PHARMACEUTICALS, INC.

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(Exact name of registrant as specified in its charter)

Nevada

000-32877

04-3562325

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(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

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(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 May 16, 2005, Pro-Pharmaceuticals, Inc. issued a news release announcing that the Phase I data published in the American Society of Clinical Oncology's (ASCO) Annual Meeting Proceedings, indicates DAVANAT(R) and DAVANAT(R) /5-FU are well-tolerated in cancer patients with advanced solid tumors. The data show Dose Limiting Toxicity and Maximum Tolerated Dose were not reached. A copy of Pro-Pharmaceutical's news release is attached as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

99.1 News release of Pro-Pharmaceuticals, Inc. dated May 16, 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/ Carl Lueders

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Carl Lueders  
Chief Financial Officer

Date: May 18, 2005

Pro-Pharmaceuticals' Phase I Data Show DAVANAT/5-FU Well-Tolerated in Cancer Patients with Advanced Solid Tumors

NEWTON, Mass.--(BUSINESS WIRE)--May 16, 2005--

Disease Stabilized in 54% of Patients with Measurable Disease; 60% Stabilized at Highest Dose Level; 71% Received Additional Cycles

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 Phase I data published in the American Society of Clinical Oncology's (ASCO) Annual Meeting Proceedings, indicates DAVANAT(R) and DAVANAT(R) /5-FU are well-tolerated in cancer patients with advanced solid tumors. The data show Dose Limiting Toxicity (DLT) and Maximum Tolerated Dose (MTD) were not reached when DAVANAT(R) (280 mg/m<sup>2</sup>) was administered alone or in combination with 5-FU (500 mg/m<sup>2</sup>).

Of the 40 patients enrolled in the Phase I trial, 28 completed the study (26 had measurable disease and 2 were non-measurable). The disease stabilized in 14 (54%) of the 26 patients with measurable disease and 12 (46%) had progressive disease. Of the 14 stabilized patients, 10 (71%) received additional cycles of DAVANAT(R) /5-FU. Six of the ten patients in the sixth and final cohort (highest dose level) were stabilized.

Of the 28 patients who completed the study, 18 (64%) had colorectal cancer: 10 (55%) were stabilized, 7 (39%) had disease progression and 1 was non-measurable. Efficacy results are based on Response Evaluation Criteria in Solid Tumors (RECIST) following completion of the second cycle of treatment.

The Phase I data reflects refractory cancer patients with a minimum of 12 weeks to live who had recurrent or metastatic solid tumors that include colorectal, liver, pancreatic, prostate and breast cancers. Three patients had serious adverse events, thought to be at least possibly related to DAVANAT(R): dehydration, dyspnea and thrombocytopenia. One unrelated on-study death occurred, due to unexpectedly rapid disease progression. Adverse events of DAVANAT(R)/5-FU were similar to those expected for 5-FU alone.

"DAVANAT(R) is a powerful target delivery technology within a new paradigm that may enhance the safety and efficacy profile of existing FDA-approved chemotherapy drugs," said David Platt, Chief Executive Officer, Pro-Pharmaceuticals. "We look forward to confirming the efficacy and safety of DAVANAT(R) /5-FU in the Phase II/III clinical trials."

#### Phase I Clinical Trial

The Phase I open-label trial was designed for cancer patients with advanced solid tumors that were not amenable to surgery, radiation, or chemotherapy and have 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/m<sup>2</sup> in the first cohort to 280 mg/m<sup>2</sup> in the sixth and final cohort, while the dose level of 5-FU was held constant at 500 mg/m<sup>2</sup>. The Phase I study closed in March.

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.

#### Phase II Clinical Trial

The Company initiated a Phase II clinical trial of its lead anti-cancer compound DAVANAT(R)/5-FU in refractory colorectal cancer patients. The study will evaluate the efficacy and safety of DAVANAT(R)/5-FU for colorectal cancer patients using the same regimen as the final cohort of Phase I: 280 mg/m<sup>2</sup> of DAVANAT(R) and 500 mg/m<sup>2</sup> of 5-FU. The objectives for the Phase II study are to document the complete and partial response and the rate of stable disease with

DAVANAT(R)/5-FU therapy when administered in monthly cycles to patients whose tumor has failed to respond to, or has progressed despite standard first- and second-line chemotherapy, and to evaluate the safety of DAVANAT(R)/5-FU in this population. Dosing of patients in Phase 11 began this month.

#### DAVANAT(R)

DAVANAT(R) is a proprietary polysaccharide in a CARBOSOME(TM) formation that enables the targeted delivery of chemotherapy drugs to protein receptors (lectins) that are unique 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. The Company has been conducting pre-clinical studies for irinotecan, doxorubicin, oxaliplatin, paclitaxel, cisplatin, and most recently with bevacizumab both in combination with DAVANAT(R) and 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](http://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 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. Glyco-Upgrade and CARBOSOME are trademarks of Pro-Pharmaceuticals.

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