

**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): January 29, 2009

PRO-PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

000-32877

(Commission File Number)

04-3562325

(I.R.S. Employer
Identification No.)

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

02459
(Zip code)

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

(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 January 29, 2009, Pro-Pharmaceuticals, Inc. issued a news release announcing that the U.S. Food & Drug Administration (FDA), in a pre-New Drug Application (NDA) meeting held last December, indicated the Company will be required to conduct a Phase III trial to demonstrate superiority to the best standard of care for late stage colorectal cancer patients. As part of the Phase III trial, the Company plans to open the study to conduct a pharmacokinetic (PK) analysis of approximately 60 patients, which may allow the Company to file for an NDA for DAVANAT[®] as an adjuvant when administered with 5-Fluorouracil (5-FU), an FDA approved chemotherapy. The Company expects to enroll approximately 300 patients in the Phase III trial. Adjuvants are pharmacological or immunological agents that modify the effect of other agents, such as drugs or vaccines.

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 January 29, 2009.

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/ Anthony D. Squeglia

Anthony D. Squeglia
Chief Financial Officer

Date: January 29, 2009

FDA Provides Clear Path to NDA Submission for Pro-Pharmaceuticals' DAVANAT[®]

NEWTON, Mass.--(BUSINESS WIRE)--January 29, 2009--**Pro-Pharmaceuticals, Inc. (OTCBB: PRWP)** today announced that the U.S. Food & Drug Administration (FDA), in a pre-New Drug Application (NDA) meeting held last December, indicated the Company will be required to conduct a Phase III trial to demonstrate superiority to the best standard of care for late stage colorectal cancer patients. As part of the Phase III trial, the Company plans to open the study to conduct a pharmacokinetic (PK) analysis of approximately 60 patients, which may allow the Company to file for an NDA for DAVANAT[®] as an adjuvant when administered with 5-Fluorouracil (5-FU), an FDA approved chemotherapy. The Company expects to enroll approximately 300 patients in the Phase III trial. Adjuvants are pharmacological or immunological agents that modify the effect of other agents, such as drugs or vaccines.

The results of the Company's completed Phase I trial for late stage cancer patients indicate that DAVANAT[®] may improve the PK profile of 5-FU in patients by keeping the chemotherapy in the bloodstream longer with no increase in toxicity.

"Our strategy is to file an NDA to commercialize DAVANAT[®] as quickly as possible by demonstrating enhanced PK in combination with 5-FU. Our goal is to complete the Phase III trial and to demonstrate superiority to the best standard of care for late stage colorectal cancer patients," said David Platt, Ph.D., Chief Executive Officer, Pro-Pharmaceuticals, Inc. "To date, DAVANAT has been administered to approximately 100 cancer patients. In a Phase II trial for end-stage colorectal cancer patients, DAVANAT[®] extended median survival to 6.7 months with significantly reduced side effects, as compared with 4.6 months for the best standard of care."

The Company plans to file a Special Protocol Assessment (SPA) for the Phase III trial. The benefit of a successful SPA is that the FDA agrees that an uncompleted Phase III trial's design, clinical endpoints, and statistical analyses are acceptable for FDA approval. An SPA is a request for feedback from the FDA that allows a company to receive official evaluation and guidance on the design of pivotal trial protocols.

The Company is using DAVANAT[®], a galactomannan, to obtain more timely and efficient marketing approval of new formulations of previously approved therapeutics which incorporate the Company's proprietary drug by means of the Section 505 (b)(2) regulatory pathway. Section 505 (b)(2) allows the FDA to approve a drug on the basis of data in the scientific literature or data previously cited by the FDA as the basis for the approval of related drugs. The FDA has approved galactomannans for other uses, such as oral or topical delivery. The Company is seeking approval for co-administration of DAVANAT[®] with 5-FU for intravenous injection for the treatment of advanced colorectal cancer.

About DAVANAT[®]

DAVANAT[®], a new chemical entity, is a proprietary carbohydrate compound that is administered with chemotherapies and biologics to treat cancer. DAVANAT[®]'s mechanism of action is based on binding to lectins. DAVANAT[®] targets specific lectin receptors (Galectins) on cancer cells. Current research indicates that Galectins affect cell development and play important roles in cancer, including tumor cell survival, angiogenesis and tumor metastasis.

Pro-Pharmaceuticals, Inc. – Advancing Drugs Through Glycoscience®

Pro-Pharmaceuticals is engaged in the discovery, development, and commercialization of carbohydrate-based therapeutics for advanced treatment of cancer, liver, microbial, and inflammatory diseases. Initially, the product pipeline is focused on developing targeted therapeutics to treat cancer. The Company's technology also is being developed to explore the treatment of liver and kidney fibrosis. The Company is headquartered in Newton, Mass. 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. These forward-looking statements are based on management's current expectations and are subject to a number of factors and uncertainties, including results of our clinical trials, FDA response to a Special Protocol Assessment or submission of a Section 505(b)(2) New Drug Application, which could cause actual results to differ materially from those, described in such statements. We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements. More information about those risks and uncertainties is contained in the Company's most recent quarterly or annual report and other reports filed with the Securities and Exchange Commission. 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.

CONTACT:

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