

PRO PHARMACEUTICALS INC
Form 8-K
January 30, 2009
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 | 000-32877 | 04-3562325 |
| | (Commission File Number) | (I.R.S. Employer |
| (State or other jurisdiction of incorporation or organization) | | Identification No.) |
| 7 Wells Avenue, Newton, Massachusetts | 02459 | |
| (Address of principal executive offices) | (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