

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): September 30, 2004

Access Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware 0-9314 83-0221517

(State of Incorporation) (Commission File Number) (I.R.S. Employer
Identification No.)

2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (214) 905-5100

Item 8.01 Other Events

On October 1, 2004, Access Pharmaceuticals, Inc. announced that the results from the Phase I clinical trial of AP5346 a DACH Platinum Polymer Therapeutic were presented on Friday, October 1, 2004 at the 16th EORTC-NCI-AACR Symposium in Geneva, Switzerland as a poster presentation. A copy of the press release regarding this announcement is attached as Exhibit 99.1 and is incorporated into this current report by reference.

Item 9.01 Financial Statements Information and Exhibits.

(c) Exhibits

99.1 Press Release of Access Pharmaceuticals, Inc. dated October 1, 2004.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Access Pharmaceuticals, Inc.
(Registrant)

By: /s/ Stephen B. Thompson

Stephen B. Thompson
Vice President and
Chief Financial Officer

Dated October 1, 2004

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EXHIBIT INDEX

Exhibit
Number Description

99.1 Press Release of Access Pharmaceuticals, Inc. dated October 1, 2004

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ACCESS NEWS

Contact: Company

Kerry P. Gray
President & CEO
(214) 905-5100

Contact: Investor Relations

Steve Laird
Genesis Select
(203) 341-0214

Donald C. Weinberger
Wolfe Axelrod
(212) 370-4500

ACCESS PHARMACEUTICALS, INC. ANNOUNCES
PRESENTATION OF AP5346 POLYMER PLATINATE
PHASE I CLINICAL TRIAL RESULTS

-Study Shows Drug Has Favorable Toxicity Profile and Displays Efficacy -

DALLAS, TEXAS, October 1, 2004, ACCESS PHARMACEUTICALS, INC. (AMEX: AKC) announced today that the results from the Phase I clinical trial of AP5346 a DACH Platinum Polymer Therapeutic were presented on Friday, October 1, 2004 at the 16th EORTC-NCI-AACR Symposium in Geneva, Switzerland as a poster presentation.

The study was designed to identify the maximum tolerated dose, dose limiting toxicities, the pharmacokinetics of the platinum in plasma and the possible antitumor activity of AP5346. The open-label, non-randomized, dose-escalation Phase I study was performed at two European centers. AP5346 was administered as an intravenous infusion over one hour, once a week on days 1, 8 and 15 of each 28-day cycle to patients with solid progressive tumors. The presentation reports on results in 19 patients with a broad cross-section of tumor types, with doses ranging from 80-1,280 mg Pt/m².

Of the 19 patients, 7 were not evaluable for tumor response, principally due to withdrawal from the study prior to completing the required cycle. Of the 12 evaluable patients, 2 exhibited a response, 1 of whom demonstrated a partial response and 1 of whom experienced stable disease. The patient responding was a

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melanoma patient with a lung metastasis, which a CT scan revealed a tumor decrease of greater than 50%. Also of note, a patient with cisplatin resistant cervical cancer showed a short lasting significant reduction in lung metastasis after 3 doses. However, due to toxicity, the patient could not be retreated to determine whether the partial response could be maintained.

David P. Nowotink, Ph.D., Senior Vice President Research and Development at Access who presented the poster in Geneva stated, "In Phase I oncology studies, patients treated are generally end-stage, having failed numerous treatments including, in most cases, platinum therapy. We are, therefore, very encouraged that we saw evidence of efficacy of AP5346 in this study, as it is not unusual that promising drugs may not display any signs of efficacy in this type of patient population."

The dose limiting toxicity was established as neutropenia. Other dose related toxicities included

nausea, vomiting, asthenia, fatigue and diarrhea. Renal toxicity, electrolyte imbalances and anemia were also observed which occurred principally at the highest doses administered.

Dr. Nowotnik continued, "The toxicities associated with AP5346 are those expected of a platinum agent and are manageable in cancer therapy. One important finding was that an expected toxicity was not seen. The active agent of AP5346 is a DACH Platinum, which is also the active agent of oxaliplatin, for which an acute neurotoxicity, peripheral neuropathy, is the most frequently observed dose-limiting toxicity. There was no evidence of any acute neurotoxicity associated with AP5346 during the Phase I study. This finding is consistent with our preclinical data. It has recently been reported in the scientific literature that the acute neurotoxicity associated with oxaliplatin probably results from oxalic acid, which is released from oxaliplatin in the body. AP5346 is formulated without oxalic acid which may account for this favorable toxicity profile."

AP5346 was developed based on the principles of polymeric drug delivery in order to improve the therapeutic index (greater activity and less toxicity) of platinum agents. As growing tumors establish their blood supply, they develop vasculature which is permeable to circulating large molecules such as AP5346. Also tumors often have poor drainage systems that allow for these large molecules to be trapped and concentrated in tumors. AP5346 was also designed to remain inactive in the plasma, and to become activated only after entering the tumor cell. The results of the Phase I study suggest that only a small fraction of the platinum is released from the polymer in plasma, indicating that this design goal was met.

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Recently, additional preclinical studies of AP5346 have been completed which further add to the strong preclinical package which has been developed for AP5346. In a platinum resistant animal tumor model, AP5346 was significantly more effective than oxaliplatin.

Dr. Nowotnik continued "Demonstrating superiority in a platinum resistant animal tumor model is yet another piece of supportive data which adds to our excitement for the potential of AP5346 in the treatment of numerous cancers."

Access Pharmaceuticals, Inc. is an emerging pharmaceutical company focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities. Access markets Aphthasol(R) and is developing products for mucositis and other oral indications. Access is also developing unique polymer platينات for use in the treatment of cancer and has an extensive portfolio of advanced drug delivery technologies including vitamin mediated targeted delivery, oral delivery, and nanoparticle aggregates.

This press release contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and that involve risks and uncertainties, including but not limited to statements made relating to the results of our polymer platinate program, the results of

preclinical and clinical studies for our polymer platinate products, indications of efficacy of AP5346 in patients in a clinical study, the resumption of supply of Aphthasol(R), projected milestone payments, the OraDisc(TM) program and our ability to achieve milestones. These statements are subject to numerous risks, including but not limited to the uncertainties associated with research and development activities, clinical trials, our ability to raise capital, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations, future cash flow, the timing and receipt of licensing and milestone revenues, projected future revenue growth and our ability to generate near term revenues, the future success of the Company's marketed products Aphthasol(R) and products in development including polymer platinate, OraDisc(TM) and our Mucositis technology, our ability to develop products from our platform technologies, our ability to manufacture amlexanox products in commercial quantities, our sales projections and the sales projections of our licensing partners, our ability to achieve licensing milestones and other risks detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2003, and other reports filed by us with the Securities and Exchange Commission.

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