

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.

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(Exact name of registrant as specified in its charter)

Delaware 0-9314 83-0221517

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

2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207

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(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (214) 905-5100  
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Item 8.01 Other Events  
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On September 30, 2004, Access Pharmaceuticals, Inc. announced the receipt of approval of our new drug application for OraDisc(tm) A from the United States Food and Drug Administration. 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.  
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(c) Exhibits  
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99.1 Press Release of Access Pharmaceuticals, Inc. dated September 30, 2004.

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

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Stephen B. Thompson

Vice President and  
Chief Financial Officer

Dated September 30, 2004

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EXHIBIT INDEX

Exhibit  
Number Description

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99.1 Press Release of Access Pharmaceuticals, Inc. dated September 30, 2004

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ACCESS NEWS

Contact: Company

Contact: Investor Relations

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

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Steve Laird  
Genesis Select  
(203) 341-0214

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

ACCESS PHARMACEUTICALS, INC. ANNOUNCES  
FDA APPROVAL OF ORADISC(TM) A  
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DALLAS, TEXAS, September 30, 2004, ACCESS PHARMACEUTICALS, INC. (AMEX: AKC) announced today the receipt of approval of our new drug application for OraDisc(TM) A from the United States Food and Drug Administration (FDA).

OraDisc(TM) A is an improved delivery system for amlexanox, which has previously been approved by the FDA for the treatment of canker sores. The OraDisc(TM) technology is a proprietary mucoadhesive patch which gradually erodes and releases an active ingredient when applied to the inside of the mouth.

The approval of this new drug application provides for the use of the amlexanox mucoadhesive patch 2mg for the treatment of aphthous ulcers in adults and adolescents 12 years of age and older with a normal immune system.

Commenting on the approval, Kerry P. Gray, President and CEO of Access stated, "This is a landmark accomplishment for Access, we are proud not only of receiving the FDA approval but also the rapid development of this product which has taken only 4 years from the initial inventive steps. Importantly, we believe that gaining this approval is a validation not only of our business model but also the quality of our organization."

-More-

Access Pharmaceuticals, Inc.  
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In the clinical program undertaken by Access for OraDisc(TM) A, pediatric patients 12 years of age and older were included in the studies. This has enabled us to extend the potential use of amlexanox to include patients 12-17 years of age which is considered an important patient group for this indication.

As previously reported, Access has expanded development activities utilizing its OraDisc(TM) technology to include a range of consumer products. The approval of the amlexanox mucoadhesive patch is a strong validation of the OraDisc(TM) technology and the Company's ability to develop products in compliance with the strict guidelines necessary to conform with the FDA regulations.

Mr. Gray continued, "This is an important validation of the OraDisc(TM) platform technology. Access is currently developing numerous products which utilize this technology. The approval of OraDisc(TM) A

represents an important event for potential strategic partners."

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), the only FDA-approved product for the treatment of canker sores, 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 OraDisc(TM) program, the result of our polymer platinate program, the results of preclinical and clinical studies for our polymer platinate products, the resumption of supply of Aphthasol(R), projected milestone payments, our ability to achieve milestones and our ability to obtain strategic partnerships. 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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