

INDEVUS PHARMACEUTICALS INC

Form 8-K

July 03, 2003

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): June 30, 2003

Indevus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

000-18728
(Commission File Number)

04-3047911
(IRS Employer Identification Number)

One Ledgemont Center

99 Hayden Avenue

Lexington, Ma 02421-7966

(Address of principal executive offices)

Registrant's telephone number, including area code: (781-861-8444)

Item 5. Other Events and Regulation FD Disclosure.

Press Release relating to Trospium

On June 30, 2003, Indevus Pharmaceuticals, Inc. (the Company) announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application (NDA) for trospium for the treatment of overactive bladder (OAB). The NDA was submitted to the FDA by the Company on April 28, 2003.

The NDA for trospium includes the results of 32 clinical studies involving over 2,700 subjects and patients, including 12 double-blind, placebo- or active-controlled studies, 12 clinical pharmacology and pharmacokinetic studies and 8 uncontrolled studies.

Trospium belongs to a class of anticholinergic compounds known as muscarinic receptor antagonists. These compounds relax smooth muscle tissue found in the bladder, thus decreasing bladder contractions. Overactive or unstable detrusor muscle function is believed to be the cause of overactive bladder.

The Press Release is attached hereto as Exhibit 99.1.

Charter Amendments

On April 2, 2002 the Company filed a Certificate of Amendment of Restated Certificate of Incorporation, as Amended of Interneuron Pharmaceuticals, Inc. with the Secretary of State of the state of Delaware evidencing the Company's name change from Interneuron Pharmaceuticals, Inc. to Indevus Pharmaceuticals, Inc. which was approved by the Company's stockholders on April 2, 2002. Such Certificate of Amendment is attached hereto as Exhibit 99.2.

On April 3, 2002 the Company filed a Certificate of Amendment of Certificate of Designation of Series C Preferred Stock of Indevus Pharmaceuticals, Inc. with the Secretary of State of the state of Delaware evidencing a change to the Certificate of Designation which was approved by the Company's stockholders on April 2, 2002. Such Certificate of Amendment is attached hereto as Exhibit 99.3.

By-Laws

The Company's By-Laws are attached hereto as Exhibit 99.4.

Item 7. Exhibits

- 99.1 Press Release of the Registrant dated June 30, 2003.
- 99.2 Certificate of Amendment of Restated Certificate of Incorporation, as Amended of Interneuron Pharmaceuticals, Inc. dated April 2, 2002.
- 99.3 Certificate of Amendment of Certificate of Designation of Series C Preferred Stock of Indevus Pharmaceuticals, Inc. dated April 2, 2002.
- 99.4 By-Laws of the Company.

This Form 8-K and the exhibits attached hereto contain forward-looking statements that involve risks and uncertainties that could cause the Company's actual results and financial condition to differ materially from those anticipated by the forward-looking statements. These risks and uncertainties are set forth in the Company's filings under the Securities Act of 1933 and the Securities Exchange Act of 1934 under "Risk Factors" and elsewhere, and include, but are not limited to: dependence on the success of trospium; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly trospium; the early stage of products under development; need for additional funds and corporate partners, including for the commercialization of trospium and the development of pagoclone and citicoline; failure to acquire and develop additional product candidates; history of operating losses and expectation of future losses; product liability and insurance uncertainties; risks relating to the Redux-related litigation; dependence on third parties for manufacturing and marketing; competition; risks associated with contractual arrangements; limited patent and proprietary rights; dependence on market exclusivity; valuation of our common stock; and other risks.

SIGNATURES

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 hereunto duly authorized.

INDEVUS PHARMACEUTICALS, INC.

Dated: July 3, 2003

By:

/s/ GLENN L. COOPER

Glenn L. Cooper, M.D.

President, Chief Executive Officer and Chairman