INDEVUS PHARMACEUTICALS INC
Form 8-K
December 20, 2007

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): December 19, 2007

Indevus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	000-18728	04-3047911
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

33 Hayden Avenue

Lexington, MA 02421-7966

(Address of principal executive offices)

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

(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))

Section 8 Other Events

Item 8.01 Other Events.

On December 19, 2007, Indevus Pharmaceuticals, Inc. (the Company) issued a press release announcing that it has received a non-approvable letter from the U.S. Food and Drug Administration (FDA) for VALSTAR(TM) related to its chemistry, manufacturing and controls (CMC) NDA supplement submitted to the FDA in May 2007. The letter was received following the Company s response to an August 2007 approvable letter. The VALSTAR-specific issues that caused the 2002 withdrawal of the product from the market have been satisfactorily resolved. However, during a recent FDA pre-approval inspection of the Company s third-party manufacturing facility for VALSTAR, deficiencies were identified that require resolution prior to approval. The Company believes that successfully addressing the deficiencies at the manufacturing plant is the only remaining item for product approval. Upon resolution, which the Company expects to occur within several months, the Company will respond to the FDA and request re-inspection of the facility. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

Section 9 Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued on December 19, 2007

Forward-Looking Statements

This filing may 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 SANCTURA, SANCTURA XR, NEBIDO, VANTAS and SUPPRELIN LA; effectiveness of our sales force; competition and its effect on pricing, spending, third-party relationships and revenues; dependence on third parties for supplies, particularly for histrelin, manufacturing, marketing, and clinical trials; risks associated with being a manufacturer of some of our products; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO, VANTAS, SUPPRELIN LA and VALSTAR; reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity, changes in reimbursement policies and/or rates for SANCTURA, VANTAS, SUPPRELIN LA, DELATESTRYL and any future products; acceptance by the healthcare community of our approved products and product candidates; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR, NEBIDO, and VALSTAR; product liability and insurance uncertainties; risks relating to the Redux-related litigation; need for additional funds and corporate partners, including for the development of our products; history of operating losses and expectation of future losses; uncertainties relating to controls over financial reporting; difficulties in managing our growth; valuation of our Common Stock; risks related to repayment of debts; risks related to increased leverage; general worldwide economic conditions and related uncertainties; and other risks. Indevus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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.

INDEVUS PHARMACEUTICALS, INC.

Dated: December 20, 2007

By: /s/ Michael W. Rogers

Michael W. Rogers

Executive Vice President,

Treasurer and Chief Financial Officer