

INDEVUS PHARMACEUTICALS INC

Form 8-K

December 15, 2006

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 11, 2006

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**Indevus Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction

of incorporation)

**000-18728**  
(Commission File Number)

**33 Hayden Avenue**

**Lexington, MA 02421-7966**

(Address of principal executive offices)

**04-3047911**  
(IRS Employer

Identification Number)

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

(Former name or former address, if changed since last report)

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 8-K

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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))
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**Section 1 Registrant's Business and Operations**

**Item 1.01 Entry into a Material Definitive Agreement.**

On December 11, 2006, Indevus Pharmaceuticals, Inc. ( "Indevus" ) and Valera Pharmaceuticals, Inc. ( "Valera" ) entered into a Copromotion and Marketing Services Agreement (the "Agreement" ) pursuant to which Indevus' sales force and Valera will co-promote VANTAS in the United States. VANTAS is currently marketed by Valera for advanced prostate cancer. The terms of the Agreement provide Indevus with royalties of 13.5% on sales of VANTAS up to a specified unit level and increases to 30% above the specified level. For sales of VANTAS to specified specialty pharmacy accounts, Indevus will receive royalties of 35%. Indevus anticipates beginning to co-promote VANTAS in January 2007. The Agreement also contains provisions regarding the establishment of a joint committee for the discussion of promotional strategies and activities, marketing and supply obligations, training of sales force, confidentiality, maintenance of commercial liability insurance, indemnification and termination under certain circumstances.

The Agreement will be filed as an exhibit at a subsequent date, with portions omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment. The foregoing description of the Agreement is qualified in its entirety by reference to the full text of the Agreement.

**Section 8 Other Events**

**Item 8.01 Other Events.**

On December 13, 2006, Indevus issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted for review Indevus' New Drug Application (NDA) for SANCTURA XR (trospium chloride), the once-daily formulation of SANCTURA<sup>®</sup>, for the treatment of overactive bladder (OAB). The FDA Prescription Drug User Fee Act (PDUFA) target action date for SANCTURA XR is August 13, 2007. The NDA was submitted to the FDA by Indevus on October 12, 2006. A copy of this press release is attached hereto as Exhibit 99.1.

**Section 9 Financial Statements and Exhibits**

**Item 9.01 Financial Statements and Exhibits**

(d) *Exhibits.*

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release issued on December 13, 2006

This filing may contain forward-looking statements that involve risks and uncertainties that could cause Indevus' actual results and financial condition to differ materially from those anticipated by the forward-looking statements. These risks and uncertainties are set forth in Indevus 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<sup>®</sup> and SANCTURA XR; the early stage of products under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA, SANCTURA XR and NEBIDO<sup>®</sup>; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR; dependence on third parties for manufacturing, marketing and clinical trials; competition; need for additional funds and corporate partners, including for the development of our products; 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; Indevus' reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity; valuation of Indevus' common stock; risks related to repayment of debts; risks related to increased leverage; and other risks.

**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 15, 2006

By: /s/ Mark S. Butler  
Mark S. Butler  
Executive Vice President, Chief Administrative Officer and General  
Counsel