

Valera Pharmaceuticals Inc  
Form 425  
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**Subject Company: Valera Pharmaceuticals, Inc.**  
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**FOR IMMEDIATE RELEASE**

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**INDEVUS PHARMACEUTICALS ANNOUNCES FIRST QUARTER FISCAL 2007**

**FINANCIAL RESULTS**

LEXINGTON, MA, February 7, 2007 Indevus Pharmaceuticals, Inc. (NASDAQ: IDEV) today announced its consolidated results of operations for the first quarter of fiscal 2007, ended December 31, 2006. The Company will host a conference call and webcast today beginning at 9:00 am eastern time (details follow below).

The Company reported revenues of \$13.2 million and a consolidated net loss of \$10.3 million or \$0.18 per share for the quarter ended December 31, 2006. This compares to revenues of \$9.0 million and a consolidated net loss of \$11.9 million or \$0.25 per share for the quarter ended December 31, 2005.

At December 31, 2006, the Company had consolidated cash and cash equivalents totaling approximately \$73.4 million.

We have started our fiscal year on a very positive note and we are rapidly executing on our strategy of developing a focused urology and endocrinology franchise, said Glenn L. Cooper, M.D., chairman and chief executive officer of Indevus. Our recently announced agreement to acquire Valera Pharmaceuticals is a transforming event for the Company. The completion of the acquisition, coupled with the planned filing of our NDA for NEBIDO® and the pending approval of SANCTURA XR, position 2007 to be one of the most dynamic years in the Company's history.

I am extremely pleased with our first quarter accomplishments. In addition to our pending Valera acquisition, we have made significant advancements in sales and marketing and business development and I am particularly pleased with the clinical development and regulatory progress on our two lead products, SANCTURA XR and NEBIDO, continued Dr. Cooper. We are actively working with our partner Esprit Pharma on the launch plan for SANCTURA XR and assuming an August approval, we would anticipate a September launch. In regards to NEBIDO, we remain very satisfied with the progress of our on-going pharmacokinetic trial. We continue to anticipate reporting results in late-May or early-June and filing an NDA during the summer. All of the data we have seen to date indicates NEBIDO should meet the FDA's approvability criteria.

## Recent Highlights

The Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for SANCTURA XR to treat patients with overactive bladder. Following the submission of the NDA, the Company received a \$10 million milestone payment from Esprit Pharma, the Company's partner in the U.S. for SANCTURA<sup>®</sup> and SANCTURA XR. The Prescription Drug User Fee Act (PDUFA) target action date for SANCTURA XR is August 13, 2007.

The Company announced that it licensed the rights to sell SANCTURA XR in certain territories outside the U.S. to Madaus GmbH. Under the terms of the agreement, Madaus has the rights to sell SANCTURA XR outside the U.S. except in Canada, Japan, Korea and China, where Indevus and Madaus will share equally in the economics.

The Company announced that it out-licensed worldwide rights for aminocandin to Novexel, S.A., a spin-out of sanofi-aventis. Indevus received an up front payment of \$1.5 million and under the terms of the agreement the Company will receive \$2.0 million upon initiation of Phase II clinical trials, potential milestones totaling an additional \$41 million and royalties on all future sales of aminocandin.

On December 12, 2006, the Company announced that it signed a definitive agreement to acquire Valera Pharmaceuticals in a stock transaction for \$7.75 per share, plus contingent payments of up to \$3.50 per share based on the achievement of future product milestones. The Company filed a preliminary S-4 registration statement with the SEC on January 29, 2007. The transaction is expected to be completed on or around April 30, 2007.

Indevus and Valera announced that they entered into a co-promotion agreement under which Indevus's sales force will co-promote VANTAS<sup>®</sup> in the United States. Indevus began co-promoting VANTAS on January 15, 2007.

In January, the Company announced its joint collaboration agreement with Alkermes, Inc., for the development of ALKS 27, an inhaled formulation of trospium chloride for the treatment of chronic obstructive pulmonary disease (COPD). The announcement followed the completion of extensive feasibility work, preclinical studies, and a successful phase I study in healthy volunteers. The companies plan to initiate a phase IIa study in the first half of 2007 and pending results of the phase IIa study, plan to engage a partner for future development and commercialization.

## **Financial Results**

Total consolidated revenues for the quarter ended December 31, 2006 were \$13.2 million, an increase of 47% from the \$9.0 million reported for the quarter ended December 31, 2005. Revenue for the quarter ended December 31, 2006 consisted primarily of \$5.6 million from the amortization of upfront and milestone revenue for SANCTURA received from the Company's partner, \$2.5 million of SANCTURA royalties, \$2.2 million in sales force subsidy, \$1.9 million from product sales of SANCTURA to Esprit, and \$0.6 from sales of DELATESTRYL.

Cost of product revenue for the quarter ended December 31, 2006 was \$4.3 million, an increase of 129% from the \$1.9 million reported for the quarter ended December 31, 2005. Cost of product revenue relates primarily to sales of SANCTURA to Esprit at cost and costs associated with DELATESTRYL. Included in the cost of product revenue for the December 31, 2006 quarter was a \$1.1 million non-cash charge to write-down the value of DELATESTRYL inventory.

Research and development expenses for the quarter ended December 31, 2006 were \$9.9 million, a decrease of 4% from the \$10.3 million reported for the quarter ended December 31, 2005. Marketing, general and administrative expenses for the quarter ended December 31, 2006 were \$9.0 million, an increase of 8% from the \$8.3 million reported for the quarter ended December 31, 2005.

Interest expense for the quarter ended December 31, 2006 included \$1.3 million in connection with the Company's July 2003 issuance of Convertible Notes.

## **Conference call and webcast**

The Company will hold a conference call and webcast to discuss these results at 9:00 AM eastern time on February 7, 2007. The live call may be accessed by dialing 800-299-0148 from the U.S. and Canada, and 617-801-9711 from international locations. The participant passcode is 37699579. A replay of the call will be available beginning at 11:00 AM on February 7, 2007 and lasting until 12:00 AM on March 7, 2007. To access the replay, please dial 888-286-8010 from the U.S. and Canada, and 617-801-6888 from international locations, using the passcode 89838839.

The press release and the live webcast will be accessible by visiting the Investors section of the Company's website, <http://www.indevus.com>. An archived version of the call will be accessible at the same web address for 30 days following the live call.

## **About Indevus**

Indevus is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. The Company's marketed products include SANCTURA<sup>®</sup> for overactive bladder, which it co-promotes with its

partner Esprit Pharma, Inc. and DELATESTRYL<sup>®</sup> to treat male hypogonadism. The compounds in development include SANCTURA XR<sup>®</sup>, the once-daily formulation of SANCTURA, NEBIDO<sup>®</sup> for male hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, pagoclone for stuttering, and aminocandin for serious fungal infections, for which the Company recently licensed worldwide rights to Novexel S.A. On December 12, 2006, the Company announced that they had entered into a definitive agreement under which the Company will acquire Valera Pharmaceuticals, Inc.

#### **About SANCTURA and SANCTURA XR**

SANCTURA<sup>®</sup> and SANCTURA XR<sup>®</sup> belong to a class of anticholinergic compounds known as muscarinic receptor antagonists. These compounds relax detrusor 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.

SANCTURA and SANCTURA XR possess a quaternary ammonium structure that may be instrumental in the low incidence of CNS side-effects. At therapeutic concentrations in vitro, SANCTURA does not interact with drugs metabolized by the Cytochrome P-450 system, a metabolic pathway commonly associated with drug-drug interactions, and the majority of the absorbed dose is excreted largely unchanged into the urine.

Patients who have urinary retention, gastric retention, uncontrolled narrow-angle glaucoma or hypersensitivity to SANCTURA should not use SANCTURA.

#### **About DELATESTRYL**

DELATESTRYL<sup>®</sup> is an injectable testosterone preparation for the treatment of male hypogonadism. DELATESTRYL is contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate.

#### **Forward Looking Statements**

Except for the descriptions of historical facts contained herein, this press release contains 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<sup>®</sup>, SANCTURA XR<sup>®</sup> and NEBIDO<sup>®</sup>; the early stage of products under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR and NEBIDO<sup>®</sup>; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO; 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; the ability to obtain the requisite Indevus and Valera stockholder approvals as well as complete the

merger; the risk that the businesses will not be integrated successfully; the risk that the cost savings and any other synergies from the transaction may not be fully realized or may take longer to realize than expected; market acceptance for the transaction and approved products; risks of regulatory review and clinical trials; disruption from the transaction making it more difficult to maintain relationships with customers, employees or suppliers; competition and its effect on pricing, spending, third-party relationships and revenues; reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity; valuation of our Common Stock; risks related to repayment of debts; risks related to increased leverage; general worldwide economic conditions and related uncertainties; the effect of changes in governmental regulations 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.

#### **Additional Merger Information and Where to Find It**

In connection with the merger between Indevus and Valera, Indevus filed a registration statement on Form S-4 with the SEC on January 29, 2007, containing a preliminary joint proxy statement/prospectus and other relevant materials. The information in such preliminary joint proxy statement/prospectus is not complete and may be changed. Such preliminary joint proxy statement/prospectus is not an offer to sell and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The final joint proxy statement/prospectus will be mailed to the stockholders of Indevus and Valera. **INVESTORS AND SECURITY HOLDERS OF INDEVUS AND VALERA ARE URGED TO READ THE FINAL JOINT PROXY STATEMENT/PROSPECTUS AND THE OTHER RELEVANT MATERIALS WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT INDEVUS, VALERA AND THE MERGER.** The registration statement and joint proxy statement/prospectus and other relevant materials (when they become available), and any other documents filed by Indevus or Valera with the SEC, may be obtained free of charge at the SEC's web site at [www.sec.gov](http://www.sec.gov). In addition, investors and security holders may obtain free copies of the documents (when they are available) filed with the SEC by Indevus by directing a request to: Indevus Pharmaceuticals, Inc., 33 Hayden Avenue, Lexington, MA 02421-7966, Attn: Investor Relations. Investors and security holders may obtain free copies of the documents filed with the SEC by Valera by contacting Valera Pharmaceuticals, Inc., 7 Clarke Drive, Cranbury, NJ 08512 Attn: Investor Relations.

#### **Participants in the Merger Solicitation**

Indevus, Valera and their respective executive officers and directors may be deemed to be participants in the solicitation of proxies from the stockholders of Indevus and Valera in favor of the merger. Information about the executive officers and directors of Indevus and their ownership of Indevus common stock is set forth in Indevus' Annual Report on Form 10-K for the year ended September 30, 2006, which was filed with the SEC on December 7, 2006, as amended by the Annual Report on Form 10-K/A filed with the SEC on January 26, 2007, and the proxy statement for Indevus' 2006 Annual Meeting of Stockholders, which was filed with the SEC on January 30, 2006. Information regarding Valera's directors and executive officers and their ownership of Valera common stock is set forth in Valera's Annual Report on Form 10-K for the year ended December 31, 2005, which was filed with the SEC on March 20, 2006. Investors and security holders may obtain more detailed information regarding the direct and indirect interests of Indevus, Valera and their respective executive officers and directors in the merger by reading the joint proxy statement/prospectus regarding the merger when it becomes available.

## INDEVUS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

For the three months ended December 31, 2006 and 2005

(Amounts in thousands except per share data)

(Unaudited)

|  | For the three months<br>ended December 31, |             |
|--|--|-------------|
|  | 2006                                       | 2005        |
| <b>Total revenues</b>                  | \$ 13,151                                  | \$ 8,974    |
| <b>Costs and expenses:</b>             |  |             |
| Cost of revenues                       | 4,276                                      | 1,870       |
| Research and development               | 9,919                                      | 10,320      |
| Marketing, general and administrative  | 9,003                                      | 8,308       |
| Total costs and expenses               | 23,198                                     | 20,498      |
| <b>Loss from operations</b>            | (10,047)                                   | (11,524)    |
| Investment income                      | 1,040                                      | 886         |
| Interest expense                       | (1,292)                                    | (1,292)     |
| <b>Net loss</b>                        | \$ (10,299)                                | \$ (11,930) |
| <b>Net loss per common share:</b>      |  |             |
| Basic and diluted                      | \$ (0.18)                                  | \$ (0.25)   |
| <b>Weighted average common shares:</b> |  |             |
| Basic and diluted                      | 55,847                                     | 47,166      |

## INDEVUS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in thousands)

(Unaudited)

|  | December 31,<br>2006 | September 30,<br>2006 |
|--|----------------------|-----------------------|
| Cash, cash equivalents and marketable securities | \$ 73,367            | \$ 76,125             |
| Other assets                                     | 18,085               | 16,182                |
| Total assets                                     | \$ 91,452            | \$ 92,307             |
| Convertible notes                                | \$ 72,000            | \$ 72,000             |
| Deferred revenue                                 | 133,327              | 127,474               |
| Other liabilities                                | 19,247               | 17,163                |
| Capital  | 349,852              | 348,345               |

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|   |           |           |
|---|-----------|-----------|
| Accumulated deficit                         | (482,974) | (472,675) |
| Total stockholders' deficit                 | (133,122) | (124,330) |
| Total liabilities and stockholders' deficit | \$ 91,452 | \$ 92,307 |