

Edgar Filing: Valera Pharmaceuticals Inc - Form 425

Valera Pharmaceuticals Inc
Form 425
December 12, 2006

Filed by Indevus Pharmaceuticals, Inc.

pursuant to Rule 425 under the Securities Act of 1933

and deemed filed pursuant to Rule 14a-12

under the Securities and Exchange Act of 1934, as amended

Subject Company: Valera Pharmaceuticals, Inc.

Commission File No.: 000-51768

FOR IMMEDIATE RELEASE

Contact:

For Indevus:

Michael W. Rogers
Exec. VP and Chief Financial Officer
(781) 402-3405
Brooke D. Wagner

For Valera:

Stuart Z. Levine, Ph.D.
Director, Investor Relations
(609) 235-3202

VP Corporate Communications

(781) 402-3410

INDEVUS PHARMACEUTICALS TO ACQUIRE VALERA PHARMACEUTICALS

Acquisition Establishes Indevus as a Leader in Urology and Men's Health

Companies to Host Joint Conference Call Today at 9:00 a.m. EST

LEXINGTON, MA, and CRANBURY, N.J., December 12, 2006 Indevus Pharmaceuticals, Inc. (NASDAQ: IDEV) and Valera Pharmaceuticals, Inc. (NASDAQ: VLRX) today announced that they have entered into a definitive agreement under which Indevus will acquire Valera in a stock transaction for \$7.75 per share, or an aggregate value of approximately \$120 million, plus contingent payments of up to \$3.50 per share based on the achievement of future product milestones.

Valera is a specialty pharmaceutical company focused on the development and commercialization of urology and endocrinology products. The Company markets VANTAS® for advanced prostate cancer and has multiple products in clinical development including SUPPRELIN®-LA for central precocious puberty. The Company has filed a New Drug Application (NDA) for SUPPRELIN-LA and under the Prescription Drug User Fee Act (PDUFA), the FDA is expected to complete its review and act upon this NDA submission by May 3, 2007. The Company also expects to submit a supplemental NDA in the first half of 2007 for VALSTAR®, which is indicated for the treatment of BCG-refractory bladder cancer. Other products in development by Valera include a biodegradable ureteral stent for post-kidney stone lithotripsy and an octreotide implant for the treatment of acromegaly.

The acquisition of Valera firmly establishes Indevus as an emerging leader in the specialty areas of urology and men's health and fully leverages our national sales force, said Glenn L. Cooper, M.D., chairman and chief executive officer of Indevus. Upon closing, Indevus' robust product portfolio will include three marketed products and the combined company anticipates five new product launches within two years, including three products from Valera.

The Indevus and Valera strategies and objectives are very consistent and this combination is a perfect match. Importantly, we expect that this transaction will be accretive within 2 years and will significantly increase earnings per share upon the achievement of profitability, continued Dr. Cooper. We see tremendous value in Valera. Our product portfolios are complementary and target the urology and endocrinology specialty physician bases of both companies. In addition to VANTAS, SUPPRELIN-LA and VALSTAR, there is a significant value opportunity in Valera's Hydron implant technology platform, their biodegradable ureteral stent program, and their octreotide implant. Valera's products fit extremely well with our current focused portfolio of marketed and late stage products, including SANCTURA® and SANCTURA XR for overactive bladder, NEBIDO® and DELATESTRYL® for male hypogonadism, PRO 2000 for the prevention of HIV and other STDs, as well as pagoclone for stuttering. We are very excited to announce this transaction.

We have greatly admired Indevus as a company and we believe this partnership is a smart fit for Valera. As we entered into discussion for a co-promotional arrangement with Indevus, it became apparent that our product offerings, the patient and physician benefits, and the potential for shareholder returns would be enhanced by leveraging the strengths of the combined companies, stated David S. Tierney, M.D., president and chief executive officer of Valera. After surveying a range of strategic alternatives, we concluded that this transaction was in the best interests of Valera's shareholders. We are excited to bring Valera's growing portfolio of approved and development stage products into Indevus' organization given Indevus' proven commercialization reach and ability to bring pipeline products to market.

Upon completion of the transaction and subject to the approval of the Indevus board of directors, James C. Gale, chairman of the board of directors of Valera and chief investment officer of the Corporate Opportunities Funds and Life Sciences Opportunities Fund, affiliates of Sanders Morris Harris, will join the Indevus board of directors. Sanders Morris Harris is currently the largest shareholder of Valera Pharmaceuticals. Additionally, Dr. Tierney will provide consulting services during a transition period after the completion of the transaction. Valera's facility in Cranbury, New Jersey, which contains significant manufacturing operations and research and development capabilities, will be maintained and become an integral part of Indevus' operations.

Transaction Details

The merger will take the form of a tax-free stock-for-stock merger. Under the terms of the agreement, each share of Valera common stock will be exchanged for \$7.75 in Indevus common stock, provided the volume weighted average closing price for Indevus common stock is between \$6.59 and \$8.05 during the 25 trading day period ending five trading days prior to the meeting of Valera stockholders to vote on the merger. Each Valera share exchanged would be converted into not more than 1.1766 shares of Indevus common stock and not less than 0.9626 shares of Indevus common stock.

In addition, each share of Valera common stock will also be converted into three contingent stock rights (CSRs) relating to three Valera products in various stages of development. One

CSR is convertible into \$1.00 of Indevus common stock upon FDA approval of SUPPRELIN-LA and the availability of sufficient launch quantities, one CSR is convertible into \$1.00 of Indevus common stock upon FDA approval of the biodegradable ureteral stent and one CSR is convertible into \$1.50 of Indevus common stock upon FDA approval of the octreotide implant. The amount of Indevus common stock into which the CSRs convert will be determined by a formula based on the average stock price of Indevus prior to achievement of the applicable milestones and the CSRs convert into Indevus common stock only if the applicable milestones are achieved within three years of the closing of the merger in the case of SUPPRELIN-LA and within five years of the closing of the merger in the case of the biodegradable ureteral stent and the octreotide implant.

In connection with the transaction, certain affiliated funds of Sanders Morris Harris, Valera's largest shareholder, and one other large shareholder of Valera, have entered into voting agreements in which they have agreed to vote shares representing approximately 41% of Valera's outstanding shares in favor of the merger.

The merger has been approved by the boards of directors of Indevus and Valera and is expected to be completed on or around April 30, 2007. Closing of the merger is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act, approval of Valera's stockholders, approval of Indevus' stockholders and other customary closing conditions. UBS Investment Bank is acting as the exclusive financial advisor to Indevus in this transaction. Banc of America Securities LLC is acting as the exclusive financial advisor to Valera.

Co-promotion Agreement

Separately, Indevus and Valera have entered into a co-promotion agreement under which Indevus' sales force will co-promote VANTAS in the United States. 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.

Conference Call and Webcast

Indevus and Valera will host a joint conference call and webcast to discuss this announcement at 9:00 AM eastern time on December 12, 2006. The live call may be accessed by dialing 866-825-3209 from the U.S. and Canada, and 617-213-8061 from international locations. The participant passcode is 75311255. A replay of the call will be available beginning at approximately 11:00 AM on December 12, 2006 and lasting until 12:00 AM on January 11, 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 67443390.

The press release and the live webcast will be accessible by visiting the Investors section of the Indevus website, <http://www.indevus.com> or the Investors section of the Valera website,

<http://www.valerapharma.com>. An archived version of the call will be accessible at the same web addresses for 30 days following the live call.

About Indevus

Indevus is a biopharmaceutical company engaged in the acquisition, development and commercialization of products to treat urological, gynecological and men's health conditions. The Company's marketed products include SANCTURA[®] for overactive bladder and DELATESTRYL[®] to treat male hypogonadism. The compounds in development include SANCTURA XR[®], the once-daily formulation of SANCTURA, NEBIDO[®] for male hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, IP 751 is for interstitial cystitis, pagoclone for stuttering, and aminocandin, which the Company recently out-licensed to Novexel.

Patients who have urinary retention, gastric retention, uncontrolled narrow-angle glaucoma or hypersensitivity to SANCTURA should not use SANCTURA. DELATESTRYL is contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate.

About Valera

Valera Pharmaceuticals is a specialty pharmaceutical company focused on developing, acquiring, and commercializing products to treat urology and endocrinology diseases and disorders. Utilizing its innovative Hydron technology, Valera is developing soft, compact and flexible hydrogel-based implants which can be designed to release therapeutic agents at a controlled rate for up to twelve months. VANTAS[®], a patent protected once-per-year implant currently marketed by Valera for the palliative treatment of advanced prostate cancer, employs this drug delivery technology. Additional information about Valera Pharmaceuticals is available at: <http://www.valerapharma.com>

Forward Looking Statements

Except for the descriptions of historical facts contained herein, this press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. Such statements include, but are not limited to, the timing of completion of the transaction and potential purchase accounting charges. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include receipt of regulatory and stockholder approval, integration of the two companies post-closing, market acceptance for the transaction and approved products, management of rapid growth, risks of regulatory review and clinical trials, intellectual property risks, and the need to acquire additional products. The reader is referred to the documents that Indevus and Valera file from time to time with the Securities and Exchange Commission. Indevus and Valera do not undertake any obligation to publicly release the results of any revisions that may be made to any forward-looking statements to reflect the occurrence of anticipated or unanticipated events or circumstances after the date of such statements.

Additional Information and Where to Find It

In connection with the Merger between Indevus and Valera, Indevus intends to file with the SEC a registration statement on Form S-4, containing a joint proxy statement/prospectus and other relevant materials. 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 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. 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 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.