

INDEVUS PHARMACEUTICALS INC
Form 425
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Valera Pharmaceuticals Reports 2006 Financial Results

Cranbury, N.J., February 22, 2007 Valera Pharmaceuticals (NASDAQ:VLRX), a specialty pharmaceutical company focused on the development, acquisition and commercialization of products for the urology and endocrinology markets, today announced financial results for the three months and full year ended December 31, 2006.

Valera also noted product milestones and other key events which occurred since the Company's last earnings report, including:

Initiation of Phase I/II studies for its naltrexone implant for drug addiction

The start of an expanded study for its biodegradable ureteral stent

Partnership with Indevus Pharmaceuticals for the co-promotion of VANTAS®, Valera's twelve month LHRH implant for prostate cancer

Proposed acquisition of Valera by Indevus in a tax-free stock-for-stock merger transaction, anticipated to close in April 2007

Fourth Quarter and Full Year 2006 Financial Results

Net product sales of VANTAS during the fourth quarter of 2006 were approximately \$3.2 million, primarily representing 2,324 units sold in the United States at an average net selling price of \$1,370. This compares to fourth quarter 2005 net sales of approximately \$5.2 million, based on 2,868 units sold at an average net selling price of \$1,801. This decline in product sales in the fourth quarter of 2006 compared to the fourth quarter of 2005 reflects, in part, pricing pressure for the class of LHRH drugs, exacerbated by changes in Medicare reimbursement rates, including certain Medicare carriers adopting a policy that segregates twelve-month products from other dosages, including one, three, four and six month injectable products, and reimbursing the injectables at higher annual rates.

Valera noted that fourth-quarter 2006 net product sales of approximately \$3.2 million represented a sequential improvement of 10% from approximately \$2.9 million in the third quarter of 2006. Correspondingly, U.S. VANTAS sales of 2,324 units in the fourth quarter of 2006 were up 18% from 1,968 units sold in the third quarter of 2006, offset by a 7% decline in average unit selling price, respectively, to \$1,370 from \$1,478. As previously reported, Valera believes that units shipped in the third quarter of 2006 had been adversely impacted by a loss in re-implantation procedures in that quarter due to the interruption in VANTAS shipments in the third quarter of 2005.

Also, in keeping with Valera's previously noted commitment to pursue options to mitigate the impact of the Medicare pricing environment, during the fourth quarter of 2006 the Company continued to shift more of its sales resources to attempt to capture non-Medicare market share. While still in its early stages, Valera believes that this strategy will open greater opportunities to

leverage the advantages of its twelve month VANTAS implant, including the convenience and efficiency for physicians in administering to the needs of their patients. In order to broaden the market penetration of VANTAS, on December 12, 2006 Valera entered into a co-promotion agreement with Indevus Pharmaceuticals (NASDAQ: IDEV) under which Indevus sales force began co-promoting VANTAS in the United States in mid-January 2007. Indevus and Valera also agreed to the acquisition of Valera by Indevus in a tax-free stock-for-stock merger, subject to approval of each company's shareholders and other customary closing conditions. Correspondingly, 2006 financial results reported by Valera include approximately \$0.8 million in merger related costs, primarily reflected in fourth quarter G&A expenses.

Net product sales for the years ended December 31, 2006 and 2005 were approximately \$17.8 million and \$26.8 million, respectively. The 33% decrease in net product sales was primarily due to lower net average selling prices due to decreased Medicare reimbursement rates of VANTAS as well as increased competition around pricing in the class of LHRH drugs. For the year ended December 31, 2006, Valera sold 11,663 units of VANTAS in the United States at a net average selling price of \$1,526 per unit as compared to 11,514 units at a net average selling price of \$2,327 for the year ended December 31, 2005. Also, in 2006, as a result of pre-launch shipments of VANTAS for Canada, Valera sold a total 169 units to Paladin Labs, its marketing partner in Canada. Thus, worldwide unit sales of VANTAS increased by 3%, or 318 units, for the year ended December 31, 2006, as compared to the year ended December 31, 2005.

As of December 31, 2006, cash and cash equivalents were approximately \$14.1 million, as compared to \$2.3 million at December 31, 2005. The net increase was primarily due to the proceeds Valera received from the initial public offering of common stock in February 2006.

Milestones and Key Events

Naltrexone Implant: During the fourth quarter of 2006, the Food and Drug Administration (FDA) accepted Valera's Investigational New Drug Application and Valera finalized all administrative arrangements with Johns Hopkins necessary to begin clinical studies for VP004, a subcutaneous implant utilizing Valera's Hydron technology to deliver naltrexone, over an extended period of time, for the treatment of opioid addiction. This Phase I/II clinical trial involves an open label study of the naltrexone implant in approximately a dozen healthy volunteers with a history of opioid abuse. The primary objective of the study is to investigate the extent of opiate blockade following morphine challenges. The lead investigator is the pioneering addiction researcher and renowned authority on naltrexone, Donald Jasinski, M.D., Professor of Medicine, Chief Center for Chemical Dependence, Johns Hopkins Bayview Medical Center.

Ureteral Stent: On November 8, 2006, Valera announced that it completed proof-of-concept studies on a flexible, biodegradable polymer-based ureteral stent. The Company has since advanced this development program in a large porcine model study to establish safety and effectiveness necessary to support the submission of a 510k device application with the FDA. Valera believes that the successful development a pliable, biodegradable ureteral stent, which could be voided naturally from the body with the discharge of urine, potentially represents a significant advance over existing plastic and metallic ureteral stents which are non-degradable and require physician intervention to extract from the body. Valera further noted that, pending the outcome of the study, the 510k submission could occur by the end of 2007.

Indevus Pharmaceuticals: In December 2006, Indevus and Valera entered into to a co-promotion agreement for VANTAS in the United States. Effective January 15, 2007 the number of sales professionals essentially quadrupled to approximately 105 representatives to promote and support future growth opportunities for VANTAS. Additionally, the co-promotion agreement provides Valera with the option to elect to enter into negotiations with Indevus to grant Indevus a co-exclusive right to co-promote SUPPRELIN®-LA. Separately, Valera announced in December 2006 that it entered into a merger agreement with Indevus pursuant to which Indevus will acquire Valera in a tax-free stock-for-stock merger transaction. In a joint press release on December 12, 2006, David S. Tierney, M.D., President and CEO of Valera commented on the merger agreement, noting, "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." Additional information on the proposed merger of Indevus and Valera is provided below.

About Valera Pharmaceuticals

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. A second product, SUPPRELIN®-LA is a twelve-month implant currently under review by the FDA for the treatment of central precocious puberty. Additional information about Valera Pharmaceuticals is available at: <http://www.valerapharma.com>.

Proposed Indevus-Valera Merger

On December 12, 2006, Indevus Pharmaceuticals (NASDAQ: IDEV) and Valera jointly announced that they have entered into a definitive agreement under which Indevus will acquire Valera in a stock transaction valued at approximately \$120 million. The merger has been approved by the boards of directors of both companies and is expected to be completed on or around April 30, 2007. Closing of the merger is subject to approval of Valera's stockholders, approval of Indevus' stockholders, and other customary closing conditions.

Additional Merger Information and Where to Find It

In connection with the merger between Valera and Indevus, 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 Valera and Indevus. INVESTORS AND SECURITY HOLDERS OF VALERA AND INDEVUS 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 VALERA, INDEVUS 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 Valera or Indevus 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 Valera by contacting Valera Pharmaceuticals, Inc., 7 Clarke Drive, Cranbury, NJ 08512 Attn: Investor Relations. Investors and security holders may obtain free copies of the documents filed with the SEC by Indevus by directing a request to: Indevus Pharmaceuticals, Inc., 33 Hayden Avenue, Lexington, MA 02421-7966, Attn: Investor Relations.

Participants in the Merger Solicitation

Valera, Indevus and their respective executive officers and directors may be deemed to be participants in the solicitation of proxies from the stockholders of Valera and Indevus in favor of the merger. 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, 2006, which is being filed with the SEC on or about February 22, 2007. 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 preliminary proxy statement for Indevus' 2007 Annual Meeting of Stockholders, which was filed with the SEC on January 29, 2007. Investors and security holders may obtain more detailed information regarding the direct and indirect interests of Valera, Indevus and their respective executive officers and directors in the merger by reading the joint proxy statement/prospectus regarding the merger when it becomes available.

This press release contains forward-looking statements that are not historical facts but rather are based on current expectations, estimates and projections about Valera's industry, beliefs and assumptions. Words such as anticipates, expects, intends, plans, believes, seeks and estimates and variations of these words and similar expressions, are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, some of which are beyond Valera's control, are difficult to predict and could cause actual results to differ materially from those expressed, implied or forecasted in the forward-looking statements. In addition, the forward-looking events discussed in this press release might not occur. These risks and uncertainties include, among others, those described in

Risk Factors contained in Valera's Form 10-K which is being filed with the SEC on or about February 22, 2007, and as may be further updated from time to time, as well as Form S-4 filed by Indevus with respect to the proposed merger discussed above. You are cautioned not to place undue reliance on these forward-looking statements. You should read Valera's filings with the SEC, including Forms 10-K and 10-Q, the documents that Valera refers to therein and have filed as exhibits, and the Form S-4 filed by Indevus with respect to the proposed merger with the understanding that actual future results and events may be materially different from what Valera currently expects. The forward-looking statements included in this press release reflect Valera's views and assumptions only as of the date of this press release. Except as required by law, Valera undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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Financial Tables Follow

VALERA PHARMACEUTICALS, INC

STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

| | Three months ended December 31, | | Year ended December 31, | |
|--|------------------------------------|------------|----------------------------|------------|
| | 2006 | 2005 | 2006 | 2005 |
| Net product sales | \$ 3,196 | \$ 5,166 | \$ 17,845 | \$ 26,798 |
| Licensing revenue | 5 | 7 | 121 | 34 |
| Total net revenue | 3,201 | 5,173 | 17,966 | 26,832 |
| Operating costs and expenses: | | | | |
| Cost of product sales | 1,110 | 1,183 | 5,107 | 5,966 |
| Research and development | 1,860 | 1,519 | 7,574 | 5,930 |
| Selling and marketing | 2,434 | 2,523 | 12,139 | 10,754 |
| General and administrative | 2,556 | 1,371 | 8,154 | 5,500 |
| Amortization of intangible assets | 27 | | 79 | |
| Total operating costs and expenses | 7,987 | 6,596 | 33,053 | 28,150 |
| Loss from operations | (4,786) | (1,423) | (15,087) | 1,318 |
| Interest income | 193 | 21 | 967 | 70 |
| Interest expense | 1 | (18) | (26) | (21) |
| Loss before income taxes | (4,592) | (1,420) | (14,146) | (1,269) |
| (Benefit from) provision for income taxes | (191) | 75 | (207) | 75 |
| Net loss | \$ (4,401) | \$ (1,495) | \$ (13,939) | \$ (1,344) |
| Basic and diluted net loss per share | \$ (0.29) | \$ (0.90) | \$ (1.03) | \$ (0.81) |
| Basic and diluted weighted average number of shares outstanding | 14,935 | 1,667 | 13,580 | 1,667 |
| Proforma basic and diluted net loss per share | \$ (0.29) | \$ (0.14) | \$ (0.96) | \$ (0.13) |
| Proforma basic and diluted weighted average number of shares outstanding | 14,935 | 10,855 | 14,547 | 10,590 |

Note: Proforma weighted average shares assumes conversion of preferred shares into common shares as of the beginning of each period.

VALERA PHARMACEUTICALS, INC

BALANCE SHEETS

(in thousands, except par value)

| | December 31, 2006 | December 31, 2005 |
|---|----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 14,069 | \$ 2,340 |
| Accounts receivable, net of allowances of \$257 and \$385 at December 31, 2006 and 2005, respectively | 2,661 | 4,488 |
| Inventories, net | 5,911 | 3,191 |
| Prepaid and other current assets | 877 | 726 |
| Total current assets | 23,518 | 10,745 |
| Property, plant and equipment, net | 7,849 | 4,194 |
| Deferred offering costs | | 1,378 |
| Intangible assets, net of accumulated amortization of \$79 at December 31, 2006 | 446 | |
| Other non current assets | 152 | 215 |
| Total assets | \$ 31,965 | \$ 16,532 |
| LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT) | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,594 | \$ 1,421 |
| Accrued liabilities | 3,318 | 4,607 |
| Note payable | | 1,525 |
| Deferred revenue current | | 329 |
| Capital lease obligations current | 9 | 18 |
| Total current liabilities | 5,921 | 7,900 |
| Capital lease obligations long term | 13 | |
| Deferred revenue long term | 300 | 300 |
| Commitments and contingent liabilities | | |
| Series A 6% Cumulative Convertible Preferred Stock, \$0.001 par value; 0 and 7,000 shares issued and outstanding; liquidation preference \$0 and \$7,598 at December 31, 2006 and December 31, 2005, respectively | | 13,604 |
| Series B 10% Cumulative Convertible Preferred Stock, \$0.001 par value; 0 and 22,069 shares issued and outstanding; liquidation preference \$0 and \$20,221 at December 31, 2006 and 2005, respectively | | 15,082 |
| Series C 6% Cumulative Convertible Preferred Stock, \$0.001 par value; 0 and 11,600 shares issued and outstanding; liquidation preference \$0 and \$12,590 at December 31, 2006 and 2005, respectively | | 11,239 |
| Shareholders equity (deficit): | | |
| Common stock, \$0.001 par value; 30,000 authorized, 14,937 and 1,667 shares issued and outstanding at December 31, 2006 and 2005, respectively | 15 | 2 |
| Additional paid-in-capital | 79,316 | 8,696 |
| Deferred stock-based compensation | | (630) |
| Accumulated deficit | (53,600) | (39,661) |
| Total shareholders equity (deficit) | 25,731 | (31,593) |
| Total liabilities and shareholders equity (deficit) | \$ 31,965 | \$ 16,532 |