

## Edgar Filing: Valera Pharmaceuticals Inc - Form 425

Valera Pharmaceuticals Inc  
Form 425  
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**Filed by Indevus Pharmaceuticals, Inc. pursuant to Rule 425**

**under the Securities Act of 1933, as amended,**

**and deemed filed pursuant to Rule 14a-12**

**under the Securities Exchange Act of 1934, as amended**

**Subject Company: Valera Pharmaceuticals, Inc.**

**Commission File No.: 000-51768**

The following are excerpted portions from the transcript of the conference call hosted by Indevus Pharmaceuticals, Inc. ( Indevus ) on Wednesday, February 7, 2007 at 9:00 am EST to discuss Indevus consolidated results of operations for the first quarter of fiscal 2007, ended December 31, 2006. The excerpted portions below relate to the pending merger of Indevus and Valera Pharmaceuticals, Inc. The excerpts do not contain a transcript of the entire conference call, and the transcript excerpts may contain inaccuracies in the reporting of the conference call. 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 playback of the call will be accessible by visiting the Investors section of the Company's website, <http://www.indevus.com>, and should be considered the authoritative source of this content. An archived version of the call will be accessible at the same web address for 30 days following the live call.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

### **Forward-Looking Statements**

This filing contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve a number of risks and uncertainties. Indevus cautions readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. Such risks and uncertainties include, but are not limited to: dependence on the success of SANCTURA®, SANCTURA XR and NEBIDO®; the early stage of product candidates under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA, SANCTURA XR and NEBIDO; 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 approvals of the stockholders of Indevus and Valera Pharmaceuticals, Inc. to the proposed merger as well as complete the merger; the risk that the businesses of Valera and Indevus will not be integrated successfully; the risk that the cost savings and any other synergies from the merger may not be fully realized or may take longer to realize than expected; market acceptance for the merger and approved products; risks of regulatory review and clinical trials; disruption from the merger making it more difficult to maintain relationships with customers, employees or suppliers; competition and its effect on pricing, spending, third party relationships and revenues; our 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; 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

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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 preliminary joint proxy statement/prospectus contained in the registration statement on Form S-4 filed by Indevus with the SEC on January 29, 2007. 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.

[TRANSCRIPT OF EXCERPTED PORTIONS OF CONFERENCE CALL]

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## Operator

Good day, ladies and gentlemen. Welcome to the Indevus Pharmaceuticals 2007 first-quarter earnings conference call. My name is Kami, and it will be my pleasure to be your coordinator today. As a reminder, this conference is being recorded for replay purposes.

I would now like to turn the presentation over to the Vice President of Corporate Communications, Mr. Brooke Wagner. Please proceed, sir.

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## **Brooke Wagner** *Indevus Pharmaceuticals, Inc. VP Corporate Communications*

Thank you, Kami. Good morning, everyone. Thank you for joining us on the call this morning to discuss the results of our 2007 first fiscal quarter. Opening the call today will be Michael Rogers, Executive Vice President and Chief Financial Officer, who will review the financial results for the quarter. After Mike's comments, Dr. Glenn Cooper, Chairman and Chief Executive Officer of Indevus, will make a few remarks, and then we will take questions. Also on the call today for the Q&A portion is Tom Farb, President and Chief Operating Officer, and John Tucker, Executive Vice President and Chief Sales and Marketing Officer.

Before Mike begins, I must inform you that today's call is being recorded and a replay will be available on our website at [www.indevus.com](http://www.indevus.com), as well as by dialing 888-286-8010 in the U.S. and Canada, or 617-801-6888 from international locations. If you dial in, the pass code is 898-388-39. The replay should be available by 11 a.m. eastern this morning, and will remain available until March 6th.

I must also remind everyone that remarks during this conference call about investor benefits resulting from a proposed merger with Valera Pharmaceuticals and plans and prospects for the combined company, as well as future expectations in general, constitute forward-looking statements for purposes of the Safe Harbor Provision under the Private Securities Litigation Reform Act of 1995. Actual results might differ materially from those indicated by these forward-looking statements. The risks and uncertainties are set forth in the Company's securities filings which we encourage you to read, including our Form 10-Q and 10-K filings, as well as those of Valera, and other documents that are and will be filed in conjunction with the acquisition. Appreciate your attention. At this point I will turn things over to Mike.

**Michael Rogers** *Indevus Pharmaceuticals, Inc. Exec. VP & CFO*

Okay. Thank you, Brooke, and good morning, everybody. Thanks for participating in the call. I would like to take a few minutes to review the Company's financial results for the first fiscal quarter ended December 31, 2006, and I will also give you an update on our outlook for the future.

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For the next two quarters, our cash burn is going to be above our recent mid-teens rate for several reasons. First is the obvious impact of the deal costs associated with the Valera acquisition. Second, upon closing, we will take on additional burn that Valera currently incurs. The Valera burn isn't particularly large, and ultimately, there are about \$5 million in annualized synergies that we will realize, but it will take a quarter or two for those synergies to materialize. Finally, assuming the acquisition closes on our currently planned end of April schedule, and Valera's product SUPPRELIN-LA is approved on its May 3rd PDUFA date, we will occur pre-launch and launch costs in the second and third quarter associated with the rollout of the product.

Overall, I remain quite comfortable with the current guidance we have given regarding revenues for 2007 and 2008. For fiscal 2007, assuming that Indevus and Valera were combined for the full fiscal year, we expect that revenues on a pro forma basis would be approximately \$80 million. For fiscal 2008, we expect revenues will be approximately \$100 million. Obviously there are a good number of assumptions in those figures, including the approval and launch of SANCTURA XR and SUPPRELIN-LA this year, the approval and launch of VALSTAR late this year or early next year, and the approval and launch of NEBIDO in the middle of calendar 2008.

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Overall, I'm very pleased with our financial performance, as all components continue to be in line with our expectation. Our net loss and cash burn continue to be on the low end of our expectation, and our balance sheet continues to be strong. As we look forward past the completion of our acquisition, we are all very excited about the additional growth drivers for the Company, and look forward to the additional products we will be adding to our portfolio from Valera. With that, I would like to pass this to Glenn, and I will be happy to answer any questions during the Q&A. Thank you.

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**Glenn Cooper** *Indevus Pharmaceuticals, Inc. Chairman, CEO*

Thank you, Mike, and good morning to everyone. Thanks for joining us. This has certainly been another extremely active quarter at Indevus, and I could not be more pleased with our achievements and progress we're making in the Company we're aggressively building.

Clearly our most significant corporate event during the first quarter was the announcement of a definitive agreement to acquire Valera Pharmaceuticals to expand our product portfolio in urology and endocrinology. Pending regulatory and shareholder approvals, the combined company would immediately have three urology products on the market, and we would anticipate five product approvals over the next two years. This acquisition will fully leverage our sales and marketing infrastructure, and will propel us towards our goal of becoming a major specialty pharmaceuticals company. While I refer you to Valera for discussion of the progress of their development programs, I would say that we're extremely pleased with the progress they're making on all their products, which includes SUPPRELIN-LA for central precocious puberty, which has a PDUFA date, as Mike mentioned, of May 3, 2007; VALSTAR for bladder cancer, and an octreotide implant for agromegaly, and a biodegradable ureteral stent.

A few weeks ago, we began to co-promote Valera's product VANTAS, a once-yearly implant of the LHRH agonist histrelin for the treatment of advanced prostate cancer. While it is too early to comment on the results of the co-promotion, I am optimistic that the two companies working together with a combined sales force of approximately 100 urology specialty reps will be able to increase the market share of Vantas among LHRH agonists, a category which in aggregate exceeds \$600 million in the U.S.

On the regulatory front, we have submitted an S-4 merger proxy to the SEC. Its review is pending. As previously stated, assuming positive votes by Indevus and Valera shareholders we would expect the deal to close by the end of April. In the interim, both companies have been working diligently on integration issues, and we expect to be in a position to operate smoothly as a combined entity upon closing.

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Let me conclude by talking about 2007 milestones. Assuming the successful closure of our Valera acquisition, 2007 will be a watershed year for potential product approvals and clinical and business milestones.

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Also during the summer, we should have the results of the Phase IIA study of ALKS 27, Valera's VALSTAR for bladder cancer and their biodegradable ureteral stent, and both could be approved by the end of the year. We should also have clarity during the year on the regulatory and partnering paths of pegoclone for stuttering. I am sure you will agree that 2007 is shaping up to be an exciting and transformational year for Indevus. So now let's open this up operator, to questions

and answers. Thank you.

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**QUESTION AND ANSWER**

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**Operator**

Your next question comes from the line of Juan Sanchez with Punk, Ziegel. Please proceed.

**Juan Sanchez** *Punk, Ziegel, & Co. Analyst*

Good morning, guys, and thank you for taking the question. I have a question about Valera's products, this biodegradable stent. Valera just announced that they are going to start a clinical trial, and I wonder if this is enough to submit the 510K or whatever it is to the FDA, or if you have to run some additional trials in humans?

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**Glenn Cooper** *Indevus Pharmaceuticals, Inc. Chairman, CEO*

Well, probably a better question for Valera, but let me answer it sort of in general, my perspective on 510Ks. I think clearly, it's possible, and there's no regulatory impediment to submitting a 510K based on animal data or, in fact, no data at all, just a predicate of something that's already on the market. So certainly Valera can submit a 510K probably at any time point, either prior to having animal data or post animal data. The reality is in the marketplace, one has to bring some clinical data to the table for urologists to use a product, such as a biodegradable stent, so assuming the merger closes, it would be our intention to run a clinical trial testing the stent in a number of patients for publication, either in conjunction with or prior to the 510K application process. But it is clearly a very significant milestone for Valera to have achieved to get the stent in the technical position to be able to go into a definitive pig study.

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**Operator**

Your next question is a follow-up question from the line of Elliott Wilbur with CIBC World Markets. Please go ahead.

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**Elliot Wilbur** *CIBC World Markets Analyst*

Thanks. I didn't hear this question asked previously. You talked about the high likelihood that you would expand the sales force post the combination with Valera, and I am just wondering sort of now that you have a little bit more chance to sort of, I guess, map out the targeting and logistics sort of around the co-promote deal, what should we be thinking about as kind of the triggering event for actually potentially increasing the size of the sales force? Would it simply be beyond the obvious closing of the deal, but would it be the approval for SUPPRELIN-LA, or do you think that you probably also want to have positive outcome for NEBIDO before you would actually consider expanding the sales force? Thanks.

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**John Tucker** *Indevus Pharmaceuticals, Inc. Exec. VP, Chief Sales & Marketing Officer*

Hi, Elliott, John Tucker. We're going to expand the group when we combine the companies, when we combine the sales force when the merger closes. We think that group which will be roughly around 100 would be enough to do what we need to do with SUPPRELIN-LA and Vantas, so I think we would be all set through that. The next trigger event might be a small incremental increase around NEBIDO, but that would be closer to approval and launch of NEBIDO before we would look to do that.

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**Operator**

Your next question is a follow-up question from the line of Michael Higgins with Wedbush Morgan Securities. Please go ahead.

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**Michael Higgins** *Wedbush Morgan Securities Analyst*

Hi. Thanks again. Just some follow-up on NEBIDO. Before I forget also, if you can talk about your cash needs this year as well.

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**Michael Rogers** *Indevus Pharmaceuticals, Inc. Exec. VP & CFO*

And, Michael, on your other question about capital raising or cash position, from our press release and this conversation, we have \$73 million as of 12/31. When you add the approval milestone, that gets you pretty close to about \$110 million. The current burn rate is about \$15 million per quarter. As I mentioned, it will go up in the second and third quarter probably fairly substantially based on deal costs and integration costs and so forth. However, based on our current operating plan for the combined companies and our cash on-hand plus the \$35 million, it gives us sufficient cash to operate into 2008, and certainly on a stand-alone basis, we have sufficient cash to operate well into 2008. So I think it is a little premature to talk about anything in the near term. Long-term, I think realistically, in order to get to cash flow positive, we would have to do a financing at some point, but I just think there are just too many factors right now that could affect the cash needs of the Company, including business development activities both on out-licensing and in-licensing, and importantly, the progress we make on our R&D programs and the success in commercializing our near-term and existing commercial products. So I hope that gives you at least a flavor for it, and you can kind of project out, but we do have a reasonable amount of cash today. We're pretty happy with our balance sheet.

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