

INDEVUS PHARMACEUTICALS INC
Form SC14D9C
January 06, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14D-9

Solicitation/Recommendation Statement under Section 14(d)(4)

of the Securities Exchange Act of 1934

INDEVUS PHARMACEUTICALS, INC.

(Name of Subject Company)

INDEVUS PHARMACEUTICALS, INC.

(Names of Persons Filing Statement)

Common Stock, par value \$0.001 per share

(Title of Class of Securities)

454072109

(CUSIP Number of Class of Securities)

Glenn L. Cooper, M.D.

Chief Executive Officer and Chairman

Indevus Pharmaceuticals, Inc.

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Lexington, Massachusetts 02421-7966

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(Name, address and telephone numbers of person authorized to receive
notices and communications on behalf of the persons filing statement)

With copies to:

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Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.

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Conference Call Transcript

IDEV Indevus Pharmaceuticals, Inc. Merger & Acquisition Announcement

Event Date/Time: Jan 06, 2009 / 01:30PM GMT
CORPORATE PARTICIPANTS

Robin DeCarlo

Indevus Pharmaceuticals, Inc. Senior Director, Corporate Communications

Glenn Cooper

Indevus Pharmaceuticals, Inc. Chairman & CEO

Michael Rogers

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Biotech Stock Research Analyst

Andy Baker

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PRESENTATION

Operator

Good day, ladies and gentlemen and welcome to the Indevus Pharmaceuticals call to discuss the recently announced definitive merger agreement with Endo Pharmaceuticals. My name is Francis and I will be your coordinator for today. At this time, all participants are in listen-only mode. We will conduct a question-and-answer session towards the end of this conference. (Operator Instructions). As a reminder, this conference is being recorded for replay purposes. I would now like to turn the call over to Robin DeCarlo, Senior Director of Corporate Communications. Please proceed, ma'am.

Robin DeCarlo *Indevus Pharmaceuticals, Inc. Senior Director, Corporate Communications*

Thanks, Francis. Good morning, everyone. This is Robin DeCarlo, Senior Director of Corporate Communications at Indevus. Thank you for joining us on the call this morning to discuss the announcement made last evening that Indevus and Endo have entered into a merger agreement. Dr. Glenn Cooper, Chairman and Chief Executive Officer of Indevus, will lead this morning's call.

Before Glenn begins, I would like to remind everyone that this conference call is for informational purposes only and is not an offer to buy or the solicitation of an offer to sell any securities. The tender offer discussed on this call has not yet been commenced. The solicitation and the offer to buy shares of Indevus common stock will only be pursuant to an offer to purchase, letter of transmittal and related materials that Endo Pharmaceuticals intends to file with the U.S. Securities and Exchange Commission.

Indevus intends to file with the U.S. Securities and Exchange Commission and mail to its stockholders a tender offer solicitation recommendations taken on Schedule 14D-9 in connection with the tender offer. When they are available, stockholders of Indevus should read these materials carefully because they contain important information, including the terms and conditions of the offer.

When they are available, stockholders will be able to obtain the offer to purchase, the letter of transmittal and related documents without charge from the U.S. Securities and Exchange Commission's website at www.sec.gov or by directing your request to Indevus Pharmaceuticals, Inc., Attn: General Counsel, 33 Hayden Avenue, Lexington, Massachusetts 02421-7966 or by phone at 781-861-8444. Stockholders are urged to read carefully those materials when they become available prior to making any decisions with respect to the offer.

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I would also like to draw everyone's attention to the fact that this call will include certain forward-looking statements, within the meaning of the federal securities laws. These forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ, perhaps materially, from those that are presented today. A description of these risks and uncertainties can be found in Indevus' public filings with the SEC. Copies of Indevus' public filings are available on the SEC's website at www.sec.gov and on the Investors' page of the Indevus website at www.indevus.com. Indevus undertakes no obligation to update or revise its forward-looking statements or to update the reasons its actual results might differ materially from those anticipated in statements today.

I must also inform you that today's call is being recorded and a replay will be available on our website at www.indevus.com, as well as by dialing 888-286-8010 in the U.S. and Canada or 617-801-6888 from international locations. The passcode for the replay is 94686397. The replay should be available by 11 a.m. Eastern this morning and will remain available until February 4. I'll now turn things over to Glenn.

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

Thank you, Robin. Ladies and gentlemen, the Board of Directors of Indevus has unanimously approved an offer from Endo Pharmaceuticals to purchase Indevus for a total consideration of up to \$7.50 per share, consisting of \$4.50 per share in cash upon closing, a further \$2 per share in cash upon the FDA approval of NEBIDO and a further \$1 per share in cash on the first approval of our octreotide implant for acromegaly or carcinoid syndrome.

Endo approached Indevus four months ago with a general expression of interest, and in the course of negotiating the transaction, we have gotten to know the company and its senior management and, in particular, I have gotten to know their CEO, Dave Holveck.

Endo is a highly successful and profitable specialty pharmaceutical company and their desire to diversify into our specialty areas of urology and endocrinology bodes well for our workforce, our market products and our products in development. We fully support Dave's vision for integrating products from different but related therapeutic areas and I believe that Dave's leadership, historical success and extensive experience in healthcare will provide the necessary leadership for the combined entity.

Also, we think this will be an excellent cultural fit, and I will enthusiastically place the legacy, which we have built, into the capable hands of Dave and his management team.

Consolidation within the specialty pharma space is common and inevitable and when we have thought about strategic transactions, we have thought about our key stakeholders: our shareholders, our employees and our customers. And let me address this offer from each of their perspectives.

For shareholders, this offer represents an immediate premium of 45% based on our closing price yesterday and a 59% premium over our 30-day volume-weighted average price. And should NEBIDO and octreotide be approved, as we hope and expect, the transaction value will represent an even more substantial premium to our shareholders.

While we are confident in the future of our business model and our pending regulatory approvals, there can be no doubt that 2009 will be a challenging year with respect to access to capital markets. As you are aware, we have certain specific challenges related to our convertible debt, our cash position and our current burn rate as we prepare to market NEBIDO, and we have been conscious of the issue of shareholder dilution as we plan the transition to profitability over the next two years. A cash offer, which recognizes both our current product revenues and our near future prospects in the form of appropriate contingent compensation, is, in our opinion, in the best interest of our shareholders.

Indevus has always been a company that values, appreciates and appropriately rewards its approximately 250 employees. One of the features of the Endo offer which attracted us is the extent to which Endo will be able to draw upon our workforce and talent pool. Our salesforce's effort will remain intact, and our manufacturing and R&D facility in Cranbury, New Jersey, which produces VANTAS, SUPPRELIN-LA and octreotide implants, will continue its operations.

Endo will also look to our corporate headquarters in Lexington, Mass. as a source of talent for their growing organization. We have special capabilities with respect to the development, marketing and commercialization of our products, and we know that Endo is excited to meet all our employees and incorporate as many as possible into the new organization.

Of particular interest to our shareholders in view of the contingent nature of the consideration, our current R&D and regulatory team will continue to work on the NEBIDO NDA resubmission and approval. Dr. Bobby Sandage will continue to lead the NEBIDO team's effort, working closely with Dr. Ivan Gergel, the head of R&D at Endo and I will continue to assist in the NEBIDO approval process as a non-paid consultant to Endo and Dave Holveck.

Our customers will experience a seamless transition. Patients who rely on our market products will receive an uninterrupted supply of products. Physicians who prescribe our products will continue to be served by our highly trained specialty sales reps. Our co-promotion and worldwide marketing partners will continue to receive the professional interactions they have come to expect, and all of our important pipeline drugs, such as VALSTAR for bladder cancer, Pagonclone for stuttering, octreotide implant for acromegaly and carcinoid, PRO 2000 for HIV prevention, will continue to get the full attention of Indevus and Endo development experts. Indevus and Endo will work tirelessly to make sure there is a smooth and well-executed transition to a merged company with a bright future for all our stakeholders.

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Endo will commence their tender offer within five days of the signing of the merger agreement, although we expect them to commence the tender offer tomorrow or Thursday. The tender offer will remain open for 45 calendar days. Assuming at least a majority of the outstanding shares are tendered and all regulatory approvals are obtained, Endo can consummate the tender offering and a tender closing will occur. Following the tender offer closing, a short-form merger will be consummated if 90% or more of Indevus shares are tendered during the tender period or Indevus will hold a stockholder meeting to close the merger if greater than the majority, but less than 90% of the shares are tendered.

The Indevus Board of Directors has recommended that stockholders tender their shares during the tender period and has filed a recommendation statement with the SEC, which has also been mailed to stockholders. With that, Mike Rogers, our CFO, and I will take your questions. Operator, go ahead.

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QUESTION AND ANSWER

Operator

(Operator Instructions). David Miller, Biotech Stock Research.

David Miller *Biotech Stock Research Analyst*

Good morning and thanks for holding this call. I appreciate the chance to offer some follow-up questions that didn't occur to us yesterday. The major question that I have has to do with the terms of whether the payment for NEBIDO approval is \$2 or \$1. You had some additional details about that in your press release, but it talked about a label restriction that affects the payment. Can you talk a bit more about that and what the sales targets kind of in a range might be for the additional \$1 payment if the label restriction exists?

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

Sure. Good question. I think it was the desire on Endo's part and our part to make sure that we covered possibilities as thoroughly as possible and didn't leave any gray zones in terms of interpretation of hitting the CVR targets. So, if NEBIDO is approved without a black box warning, which we do not expect to occur, we have had no indication that this will occur from our conversations with the FDA, then a \$2 per share payment would be made.

If in the very unlikely case that the drug would be approved with a black box warning, we would receive \$1 per share on approval, but have the opportunity to claw back that additional \$1 if a sales threshold target is met of \$125 million over four consecutive quarters. So that is really how the process would work.

Operator

Andy Baker, Jefferies & Co.

Andy Baker *Jefferies & Co. Analyst*

Thank you very much. A couple of questions. The first is can you just give us some feelings for when you what your sort of targeted, in your in your head, PDUFA date would be for octreotide implants? And also on the other, on the NEBIDO portion of the contingent value, you talk about potentially \$125 million of sales being the milestone if you get a black box warning. How did you come up with that number? Was that sort of what you think and when do you think you could hit that? Is that like a three years out to hit that number? And then the second on the whole

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process I guess, did you I knew you were approached by Endo Pharm. Did you talk to other people? Did you explore this in the market and see if there was a better offer out there for you? And if so, can you give us some thoughts around that process? And then finally, 45 days for a tender seems to be longer than most tenders. Just wondering why this is expected to run on a little longer?

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

All right, let me try to do them in reverse order, but I may need some help in remembering the series of questions. The 45-day (inaudible) period was a negotiated period. There is precedent in recent transactions. I believe the Lilly-ImClone tender period was 45 days and both sides were comfortable with that. We were not involved in a process at the time that Endo approached us. This was a negotiated transaction with one party right now and the deal has a non-shop provision associated with it.

The NEBIDO sales target of \$125 million this was really a kind of a gut call on our side that basically said, look, if in the event that in the unlikely event there is a black box and the product is still able to do well in the marketplace, and we define \$125 million as well, then we ought to get full consideration for it, and that is really how that was derived.

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And finally, the filing of the status, approval status for octreotide. Really there is a large Phase III multinational trial ongoing right now that will take place and conclude during 2009. We should have the results of that trial by the end of 2009 and commence our regulatory filings in 2010. And we would expect one file that we would have standard regulatory clocks, probably a 10-month clock.

Andy Baker *Jefferies & Co. Analyst*

Okay, great. And these contingent value rates, they will not be transferable, right? There will be no market for those. Once you get them, you just sit with them for until you get the money, you can't trade them?

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

That is correct. They will be associated with shareholders of record as a nontransferable right.

Andy Baker *Jefferies & Co. Analyst*

Okay, thank you.

Operator

Gary Nachman, Leerink.

Gary Nachman *Leerink Swann Analyst*

Hey, Glenn. If you guys do get a black box for NEBIDO, what do you think it would be for? The incidence rate of cost? Is there anything else that could warrant a black box then? Can you just remind us what the IP is for NEBIDO, and are there any new patents pending? What do you think the life is going to be for that product? Thanks.

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

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Well, first of all, let me be very clear. I do not believe there will be a black box. This is really a contractual contingency, but we have had absolutely no indication from our extension discussions with the FDA on this issue that this product would merit a box warning. This was simple contractual contingency language, so we don't think this is going to happen.

The other question was IP. Well, IP we continue to be confident in the IP position of the product. The U.S. patents have not yet issued, but we are partners, Bayer Schering, who control the IP and everyone who has looked at the IP situation is very confident of a strong, long franchise related to excellent intellectual property protection.

Operator

Wayne Rothbaum, Quogue Capital.

Wayne Rothbaum *Quoque Capital*

Wayne Rothbaum Hi, good morning, guys. A quick question on this no shop, I think, Glenn, you talked about. So just to be clear then, you did not go out and seek other bids. Is that the understanding?

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Michael Rogers *Indevus Pharmaceuticals, Inc. EVP & CFO*

Yes, Wayne, we were not in a process at the time when Endo approached us and the company, in this deal, is prohibited from talking to other potential acquirers, except under very limited circumstances surrounding a superior proposal that would be received and the Board would determine it must pursue in order to fulfill its fiduciary obligations.

Operator

David Miller, Biotech Stock Research.

David Miller *Biotech Stock Research Analyst*

Hi, just a follow-up question. I just wanted to make sure that when you talk about \$125 million, you are talking about across the four-quarter period and not \$125 million per quarter, correct?

Michael Rogers *Indevus Pharmaceuticals, Inc. EVP & CFO*

That is right, David. It is anytime in the first five years after the first commercial sale that any four quarters reaches \$125 million.

Operator

Lei Huang, Summer Street Research.

Lei Huang *Summer Street Research Analyst*

Hi, if I can ask actually two questions. First, can you provide an update on VALSTAR and the facility inspection and the timing around that? And second, is there a clinical standard definition for severe cough in the case of NEBIDO, i.e. the way the Company analyzes severe cough incidence, is that the way the FDA would interpret it as well? Thanks.

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

Sure. On definitions of seriousness, which is the regulatory definition, FDA and international regulators refer to a standardized template of definitions of seriousness. So there is no interpretation in terms of what a physician thinks or what a company thinks. There is basically a checkbox kind of a system and if you fall into a particular category, it is categorized as serious. And that really helps to standardize everyone's view of things and makes for very little after-the-fact kind of guessing and interpretation. And FDA has been really focused on serious cases of cough, which we have been able to define are extremely uncommon and certainly we believe the FDA is going to be comfortable with the data in our resubmission package.

In terms of VALSTAR requalification, I think we are doing really well on that. We remain optimistic that VALSTAR will get re-qualified, re-launched during the first half of this year and are in very active communication with the FDA on this issue. Everyone wants to see the drug back on the market as soon as possible.

Operator

Kevin DeGeeter, Oppenheimer.

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Kevin DeGeeter *Oppenheimer & Co. Analyst*

A couple of questions here. First of all, I want to add my congratulations on what is clearly an attractive deal for shareholders, but a few housekeeping items. What is the breakup fee for this transaction if a superior bid is put forth and the Board accepts it?

Michael Rogers *Indevus Pharmaceuticals, Inc. EVP & CFO*

Kevin, it is \$20 million.

Operator

Scott Henry, Roth Capital.

Scott Henry *Roth Capital Analyst*

Thank you. Just from a, I guess, qualitative aspect, you are obviously very confident that you are not going to get a black box warning. I am just curious what you base that on. The first time around with the FDA, did discussions ever reach the labeling part of that process? And really just trying to get a sense on your basis for it. Does it stem just from your personal belief or does it stem from conversations with the FDA?

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

It is based on highly specific conversations with the FDA.

Operator

Ken Trbovich, RBC Capital Markets.

Ken Trbovich *RBC Capital Markets Analyst*

Thanks for taking the question. Dr. Cooper, I was wondering if you can help those of us who don't follow the Company to better understand, from a commercial preparation standpoint, what sort of efforts have gone into securing either managed care agreements or CPT codes that might be necessary for the next couple of products out of your pipeline?

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

Well, we have a very active managed care effort for all of our products. We are in prelaunch mode for NEBIDO and we have been working with our managed care partners on an ongoing basis. We were pretty much ready to roll at the time of our previous PDUFA date in August. We had anticipated pending FDA approval to be able to launch the product last September/October. So we have done a lot of the spadework and missionary work here, and we will just be refreshing that effort leading up to the '09 launch. And really it is going to be assuming the deal with Endo closes, we will be able to draw on their significant managed care group to help us with that effort. We have a good group, but we certainly had intended to build it out, but that will really come prepackaged with the Endo capabilities.

Michael Rogers *Indevus Pharmaceuticals, Inc. EVP & CFO*

Operator, if you could, Kevin DeGeeter asked the question Kevin DeGeeter from Oppenheimer, and I think he was going to ask two questions. If you could open up his line to let him ask his second question, I would appreciate that.

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Operator

Thank you. Kevin, your line is open.

Kevin DeGeeter *Oppenheimer & Co. Analyst*

Terrific. Thanks so much, Mike. I guess my one question pertains to do you expect to receive a service J-Code for NEBIDO and just how should we think about the economics back to the physician here for NEBIDO compared to short-acting injectables?

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

Yes, we do expect to get a J-Code. We already have one for VALSTAR. We already, as you know, have one for SUPPRELIN-LA and positioning versus the other products for those of you who aren't aware of the attributes of NEBIDO, this will be the first long-acting testosterone preparation, which can be injected once every 10 weeks. The existing injectable agents are short-acting, are given every two to three weeks, which is a relatively inefficient and inconvenient schedule. The other issues the other products are topical agents that are given with daily administration, which become a bit of a chore, a bit of a burden to patients and carry the unwelcome risks of transference of a hormonal drug substance to women or children.

So our market research has shown that there is a great desire for a long-acting, injectable product in the marketplace. The experience in Europe, where the drug has been on the market for many years now, is extremely positive where our partners, Bayer Schering Healthcare, have the product in a dominant position in most of the European markets where it is currently on sale.

Kevin DeGeeter *Oppenheimer & Co. Analyst*

And maybe one last question, if I can slip it in? Just to the point of clarification, will the record date for the contingent rights be the close or will there be a separate record date to determine who holds the contingent rights prior to the actual close of the transaction?

Michael Rogers *Indevus Pharmaceuticals, Inc. EVP & CFO*

Yes, Kevin, actually it's not a date; it is just, literally, whoever tenders their shares. So that whoever tenders the record will be kept of those shareholders. If some were tendered on day one, they would be the recordholder. If someone tendered on the last day, they would be the recordholder.

Kevin DeGeeter *Oppenheimer & Co. Analyst*

And if you go to short form and there isn't an active tender, it is presumably whoever holds the shares?

Michael Rogers *Indevus Pharmaceuticals, Inc. EVP & CFO*

Exactly.

Kevin DeGeeter *Oppenheimer & Co. Analyst*

Okay, terrific. Thanks, Mike.

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Michael Rogers *Indevus Pharmaceuticals, Inc. CFO*

Okay, you are welcome.

Operator

We have time for one more question. Jim Molloy, Caris & Co.

Jim Molloy *Caris & Co. Analyst*

Hi, thanks for taking my question. I wanted to follow up on NEBIDO. Obviously, this product was at the FDA prior to the approval letter. You guys are getting ready to launch. Could you talk a little bit about what you guys have budgeted in for your launch expenses as you were looking to roll this thing out?

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

Well, I am not sure that is our historical numbers are relevant on a going-forward basis. One of the really terrific aspects of this merger is that Endo will be able to give the entire launch plan a fresh look in the context of their organizational capabilities. Not only their cash position, which is, of course, extremely healthy compared to ours, but on the people side, they have a large and sophisticated salesforce that is capable of making primary care calls, something that our salesforce is not capable of.

And we have always been wrestling with how do we get the penetration into the primary care audience because a considerable number of scripts for hypogonadism are generated by internal medicine practitioners/primary care/family care physicians. And the combination of our urology/endocrinology specialty salesforce will be retained in this transaction and Endo's primary care salesforce means that they are going to be able to really right-size the effort to fully capitalize on NEBIDO's potential and the launch plans, the launch budgets they have put in place, we will leave that to them to articulate as time goes on.

Operator

And I will now turn the call back over Dr. Glenn Cooper for closing remarks.

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

Okay, thanks everyone, for attending the call. Robin DeCarlo, Mike Rogers will be available to take further questions throughout the day. We look forward to continuing to interact with you during the tender period. Thank you.

Operator

Thank you all for your participation in today's conference call. This concludes the presentation and you may now disconnect and have a good day.

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