

Edgar Filing: Valera Pharmaceuticals Inc - Form 425

Valera Pharmaceuticals Inc
Form 425
December 13, 2006

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 is a transcript of a conference call hosted by Indevus Pharmaceuticals, Inc. (Indevus) and Valera Pharmaceuticals, Inc. (Valera) on Tuesday, December 12, 2006 at 9:00 am EST to discuss the proposed transaction pursuant to the terms of the Agreement and Plan of Merger, dated as of December 11, 2006, by and among Indevus, Valera and Hayden Merger Sub, Inc., a wholly-owned subsidiary of Indevus, pursuant to which Indevus will acquire Valera.

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 forward-looking statements include, but are not limited to, statements about the benefits of the proposed business combination transaction involving Indevus and Valera, including future financial and operating results, Indevus plans, objectives, expectations and intentions, the expected timing of completion of the transaction, and other statements that are not historical facts. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are set forth in Indevus filings with the Securities and Exchange Commission. These include risks and uncertainties relating to: the ability to obtain the requisite Indevus and Valera stockholder approvals; the ability to obtain regulatory approvals of the transaction on the proposed terms and schedule; 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; the need to acquire and develop new products; reliance on intellectual property and having limited patents and proprietary rights; general worldwide economic conditions and related uncertainties; and the effect of changes in governmental regulations. Indevus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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

Edgar Filing: Valera Pharmaceuticals Inc - Form 425

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.

[CONFERENCE CALL TRANSCRIPT]

Operator

Good day, ladies and gentlemen. Thank you for your patience, and welcome to the Joint Indevus Pharmaceuticals and Valera Pharmaceuticals Acquisition Conference Call. My name is Fab, and I'll be your coordinator for today.

As a reminder, this conference is being recorded for replay purposes. I would now like to turn the presentation over to your host for today's call, Mr. Brooke Wagner, Vice President, Corporate Communications of Indevus Pharmaceuticals. Please proceed, sir.

Brooke Wagner *Indevus Pharmaceuticals VP of Corporate Communications*

Thank you, Fab. Good morning everyone, this is Brooke Wagner, VP of Corporate Communications at Indevus Pharmaceuticals. Thank you for joining us on the call this morning to discuss the proposed merger of Indevus and Valera in a stock-for-stock transaction. The order of the call today will be Dr. Glenn Cooper, Chairman and Chief Executive Officer of Indevus Pharmaceuticals, followed by Indevus' President and Chief Operating Officer, Tom Farb.

After Tom will be Dr. David Tierney, President and Chief Executive Officer of Valera Pharmaceuticals. Also on the call today for the Q&A portion, is Michael Rogers, Chief Financial Officer of Indevus and Andrew Dreschler, Chief Financial Officer of Valera. John Tucker, Executive Vice President of Sales and Marketing of Indevus and Dr. Bobby Sandage, Executive Vice President and head of R&D at Indevus are also on the call for Q&A.

Before Glenn begins, I must inform you that today's call is being recorded and a replay will be available on the Indevus website at www.indevus.com or via the Valera website at www.valerapharma.com, as well as by dialing (888) 286-8010 in the U.S. and Canada or (617) 801-6888 from international locations. The pass code for the replay is 67443390. The replay should be available by noon eastern this morning and remain available until January 11th.

I must also remind everyone that various remarks during this conference call about expected benefits resulting from the proposed merger, future expectations and plans and prospects for the combined company 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 as a result of various important factors including risks related to the proposed merger and integration of the companies, as well as those discussed in each company's press releases and SEC filings including our respective Form 10-Q and Form 10-K filings and other documents that will be filed in conjunction with today's announcement. The information in this conference call related to projections, development plans and other forward-looking statements is subject to the safe harbor.

Thank you very much for your attention, and I will now turn the call over to Dr. Glenn Cooper, Chairman and Chief Executive Officer of Indevus Pharmaceuticals.

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Thank you, Brooke, and good morning everyone. This morning we announce, that subject to shareholder and other customary regulatory approvals, Indevus Pharmaceuticals will acquire all outstanding shares of Valera Pharmaceuticals in a stock-for-stock transaction. The Boards of both companies unanimously approved this transaction last evening.

From the Indevus perspective, this transaction arose from the fundamental work we've been doing seeking new product opportunities that will complement and expand our growing franchise in urology and men's health. Indevus possesses an excellent urology specialty sales and marketing organization of approximately 100 individuals who've been engaged in co-promoting SANCTURA for overactive bladder, promoting DELATESTRYL for male hypogonadism, planning for the 2007 launch of SANCTURA XR and the anticipated 2008 launch of NEBIDO, a unique long-acting injectable for male hypogonadism. Post-2008 market instruction candidates include Pro 2000 for the prevention of HIV and other STDs and pascagone for stuttering.

Our business development efforts have focused intensively on identifying late-stage and particularly marketed or soon to be marketed products that would immediately leverage our sales and marketing infrastructure. In 2004, we did a terrific deal with PLIVA for the co-promotion of SANCTURA that provided Indevus a significant infusion of cash milestones which, to date, have totaled \$170 million, and which have allowed us to form our specialty sales force, the cost of which has been substantially reimbursed by co-promotion fees from PLIVA, and more recently our new partner, Esprit Pharma.

The co-promotion and sales force reimbursement fees are scheduled to run through the end of 2008, at which time our royalties on SANCTURA and SANCTURA XR will continue. Our plan has been for our sales force to become self-sustainable beyond 2008 from NEBIDO revenues as well as revenues from additional new products which we would acquire or in-license.

The acquisition of Valera accelerates this business plan and essentially takes two very good, but relatively small specialty biopharmaceutical companies and creates out of the box a larger, stronger and more dynamic company that instantly will be an emerging leader in urology and men's health with a pipeline both exciting and compelling in its rationale.

Valera has been on our radar screen for about a year. We've been following their progress in commercializing their first product Vantas for advanced prostate cancer, and in moving pipeline products closer to marketing approval. In our discussions, we found them to be a talented and capable organization with a unique polymer-based drug delivery platform that permits potent drugs to be smoothly and conveniently administered to patients over extended periods of time. Valera's therapeutic focus overlaps perfectly with our therapeutic focus, urology and endocrinology.

Endocrinology is not foreign territory for Indevus since the thought leaders most productive prescribers for testosterone-therapies are urologists and endocrinologists and we are already detailing DELATESTRYL to endocrinologists. Upon closing, Indevus will have a very late-stage product portfolio which, from my personal perspective, will be one of the most exciting portfolios in the specialty pharma space. The combined companies will have three products on the market immediately post-closing and five new product launches within two years. Two launches in 2007 and three in 2008. Three of these five new launches will come from the Valera pipeline.

Let me give you a quick rundown of my view of Valera's products, then Tom Farb will describe the transaction and talk about operational synergies. Following that, David Tierney will give you his views of the transaction. Vantas is a unique, soft subcutaneous implant manufactured in Valera's excellent manufacturing facility in Cranbury, New Jersey. Vantas delivers the LHRH agonist histrelin continuously over a one-year period. The product was approved for marketing in the U.S. in late 2004 and its approval and launch is pending in Europe.

It competes in the U.S. market in excess of \$600 million for LHRH agonists for advanced prostate cancer. Most of them, one to six-month injectables. Vantas is a safe, effective and highly convenient once yearly alternative for thousands of men. Valera reported Vantas' net product sales for the three-months ending September 30, 2006 of approximately \$3 million and the nine-months ending September 30, 2006, of approximately \$14.6 million.

Although there have been pricing pressures in the category of LHRH agonists due to Medicare reimbursement regulations, we believe that Vantas can experience volume growth in the future with an expanded sales force effort beyond the approximately 25 Valera sales reps currently promoting the product. Indevus and Valera have today also entered into a separate co-promotion agreement whereby our 85-person sales force will begin actively co-promoting Vantas to an expanded number of urologists beginning in January for a two-year term regardless of whether the merger closes.

So, in about a month from now, this co-promotion agreement will boost the total number of sales reps behind Vantas from 25 to approximately 110 individuals. There's an excellent overlap between our current universal SANCTURA prescribers and the urologists who potentially may

prescribe Vantas. With the combined efforts of both companies, the greater share of voice behind Vantas should result in increased awareness, utilization and sales of this unique product.

Indevus will receive a royalty on net sales of Vantas plus incentive payments related to incremental revenues generated by the co-promotion effort. Following the closing of this merger agreement, we expect to expand the Indevus sales force so it is highly beneficial for the two sales organizations to begin working together immediately.

Supprelin-LA is a 12-month implant of the same LHRH agonist histrelin for the treatment of central precocious puberty, a pediatric endocrinology disorder where children develop puberty too quickly. Supprelin LA, which has received orphaned drug status pending at the FDA with a regulatory action date of May 3, 2007. Upon approval, Supprelin LA would compete in an approximately \$75 million U.S. market currently served by a single product, a once a month injectable product.

We believe that fewer than 1,000 pediatric endocrinologists treating this condition can be effectively accessed with our specialty sales force and that a significant percentage of children and parents might opt for single once yearly subcutaneous implant versus potentially painful monthly injections.

Valstar is a drug previously approved in the U.S. for the treatment of BCG refractory bladder cancer in patients who are not candidates for cystectomy or bladder removal. This is a very important medicine since it is the only FDA-approved drug for this indication. Valstar was previously withdrawn from the market because of manufacturing issues. Valera recently acquired rights to the drug and has been working successfully, I believe, to solve these issues with the FDA and, upon reintroduction to the marketplace, our sales force will have another excellent product to promote to urologists.

Another near-term opportunity is not a drug but a medical device, which Valera has been developing. A biodegradable stent designed to be inserted into the ureter after kidney lithotripsy to keep the ureter open and clear of stone debris. Currently, conventional nondegradable stents are used for this purpose and a second procedure is always required to remove the stent. Annually, approximately 800,000 stents are inserted in the U.S. post-kidney lithotripsy.

A biodegradable ureteral stent is in the realm of the holy grail for urologist. A device that performs its function, then safely and naturally dissolves without a need for surgical removal. If current ongoing pre-clinical animal studies confirm the excellent data observed in previous studies, we would envision clinical trials next year, followed by 510K device application with the FDA. We believe our current urology sales force will be perfectly positioned to sell a biodegradable ureteral stent and if the product is approved and performs clinically, as we hope it will, then the commercial potential is substantial.

Valera is also developing a delivery system for octreotide using its advanced polymer technology. Octreotide is a hormonal treatment used to substantially reduce growth hormone levels in patients with acromegaly and other related conditions. The Valera product is a subcutaneous implant designed to deliver octreotide for six months. Octreotide is currently marketed by Novartis as Sandostatin in both daily and monthly injectable formulations. In 2005, the worldwide sales of Sandostatin were in excess of \$900 million.

Specifically for acromegaly, the U.S. Sandostatin market for this disorder is approximately \$200 million, consisting mostly of monthly injections. The octreotide implant demonstrated excellent activity in a previous Phase I-II trial in acromegaly patients and is currently about to begin a Phase II trial. If successful, a Phase III trial could begin in the second half of 2007. We believe that a six-month octreotide implant might be a convenient alternative to monthly injections for patients with acromegaly and are extremely excited about this product which, I personally believe, might have the greatest commercial potential of any of Valera's products.

Finally, with respect to product development, Valera's Hydron implant technology is a unique and proprietary polymer system that can be adapted to deliver many kinds of drugs over extended periods of time. We believe that the Indevus business development group, which has been highly successful in in-licensing and out-licensing deals, could reach out to biotechnology and pharmaceutical companies and explore product development opportunities that might enhance the delivery of other companies' drugs and further leverage the Valera manufacturing operations in the future.

Now, let me turn this over to Tom Farb for discussion of the transaction.

Tom Farb *Indevus Pharmaceuticals President and COO*

Thank you. As Glenn has discussed, the acquisition of Valera is a strong strategic fit for Indevus. It is the combination of two complementary organizations that, after closing, will be a stronger company with a high degree of focus on urology and men's health and endocrinology. The transaction merges Indevus' expertise in drug development and its greater reach in specialty market marketing with Valera's expertise in development of polymer-based delivery systems and specialty manufacturing. Most importantly, the combination immediately leverages our existing sales force and allows us to realize full commercial value from our sales force.

The transaction is structured as a tax-free stock-for-stock purchase of Valera and is expected to close on approximately April 30, 2007, subject to regulatory approvals. On closing, each share of Valera will receive \$7.75 per share of Indevus stock or 1.06 shares of Indevus stock, subject to a symmetrical 10% collar. Under this collar, each Valera share will be converted into not more than 1.1766, let me repeat that, 1.1766 shares of Indevus common stock and not less than 0.9626 again, I'll repeat that, 0.9626 shares of Indevus common stock.

Based on the number of Valera shares expected to be exchanged in the transaction, the aggregate value of the transaction is approximately \$120 million. In addition, contingent on the approval of Supprelin-LA, for central precocious puberty, there will be a payment of \$1.00 per share for each share of Valera stock. On approval of their ureteral stent, there will be a payment of \$1.00 per share. And, on approval of the octreotide implant for acromegaly, there will be a payment of \$1.50 per share.

All of these contingent payments will be made in Indevus stock to Valera shareholders of record at the closing. The Supprelin payment obligation expires in three years and the stent and octreotide payment obligations expire in five years. Also, as Glenn mentioned, pursuant to a separate agreement, the two companies will begin to promote Vantas in January, which will allow Indevus to immediately realize economics from the sale of Vantas and begin the process of growing the brand.

Indevus will invest in the training of its sales force and in marketing programs as well as in a significant amount of primary and secondary details. In return, Indevus will receive royalties of 13.5% on sales up to a baseline level and 30% on sales above that baseline level. On sales to specific specialty pharmacy accounts, the royalty will be 35%. Importantly, we expect this transaction will be accretive within two years. Additionally, our analysis indicates that the acquisition of Valera will significantly boost our earnings per share upon the achievement of profitability.

If we were to look back at our fiscal year, 2006, ending September on a pro forma, latest 12-month basis, the combined company would have had \$70 million in revenue and would have ended the year with \$95 million in cash. Looking forward to our fiscal 2007, assuming the two companies have been combined for the entire year, we would expect total revenues to be approximately \$80 million. And, for our fiscal year 2008, we would expect combined revenues of approximately \$100 million.

Our interest in this transaction is not based on one particular product or on just Vantas, Valera's currently-marketed product, but in the complementary basket of opportunities afforded us by Vantas, Supprelin-LA, Valstar, the octreotide implant, the ureteral stent and future partnerable applications of Valera's Hydron implant technology. Because of the excellent alignment of our current sales force with these new product opportunities, introducing these products to the market will not result in significant incremental sales force expenses in the future.

We are very pleased that upon completion of the transaction and, subject to the approval of the Indevus Board of Directors, James Gale, Chairman of the Board of Directors of Valera, will join the Indevus Board of Directors. Jim is the Chief Investment Officer of the Corporate Opportunity Funds and Life Sciences Opportunities Fund, affiliates of Sanders Morris Harris. Sanders Morris Harris is currently the largest shareholder of Valera Pharmaceuticals. In addition, Affiliated Funds of Sanders Morris Harris and another 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.

I would like to especially acknowledge the accomplishments of David Tierney and his team, who we have known for over a year. David has done a remarkable job in building Valera and in achieving significant success. David will provide consulting services during a transition period after the completion of this transaction. We all look forward to working further with David and his team. Thank you, David.

I'd like to make a few comments on the combination of the companies. Although we plan to continue to employ the vast majority of employees in New Jersey, there are certainly organizational savings to be had in combining two public companies. These days, the regulatory costs of being a public company are substantial and there are duplicative costs especially in the senior management ranks. We estimate the combined savings to be approximately \$5 million per year.

However, I would like to emphasize the fantastic complementarities between the two organizations, as these are even more important than the savings. First of all, Indevus has no internal manufacturing capabilities. All of our products are manufactured by third-party relationships. Valera

has a unique and world-class GMP manufacturing facility which has passed multiple FDA and EU inspections with flying colors, including a recent FDA pre-approval inspection for Supprelin-LA.

Valera also has a small, very productive, R&D function dedicated to polymer-based drug delivery. Post-closing, we will retain these functional groups at their current location in New Jersey. We view having a facility in New Jersey an important area for pharma expertise as a real asset. Also, the current approximately 25-person Valera sales force has done an excellent job with Vantas and we look forward to working with these representatives and their district managers in our co-promotion of the product and post-closing we will be expanding our sales force.

In conclusion, we are excited about the opportunity to work with Valera in a successful combination of the companies. And, we firmly believe that this transaction represents considerable value and appeal for the shareholders of both companies.

I would now like to turn the call over to David Tierney, CEO of Valera.

Dr. David Tierney *Valera Pharmaceuticals President and CEO*

Thank you, Glenn and Tom, and good morning, everyone. I'd first like to say that I'm particularly excited about today's news. I truly believe our decision to join forces with Indevus Pharmaceuticals is in the best interest of both of our companies and would clearly strengthen our position as a leader as a specialty pharmaceutical company.

I'm extremely proud of what we've accomplished here at Valera Pharmaceuticals. We've worked hard, we've taken risks and never stopped evolving. And, through that process we've developed a portfolio, including Vantas for the treatment of prostate cancer as well as a pipeline of late-stage products for the treatment of urological and endocrine conditions, diseases and disorders. In addition to research and development, we've also developed competencies in manufacturing and a strong sales and marketing team that calls on the urology community.

It is important to note that our Hydron implant technology has been our key differentiator over the last several years and we're very proud of what we bring to the partnership with Indevus in that regard. We believe that the Hydron technology offers significant advantages over existing drug delivery systems. Our implants, using the Hydron technology, can be adapted to deliver many kinds of drugs over an extended period of time. It is important to note that Valera owns the manufacturing know-how to develop products using this technology and are able to control and maximize the potential commercial uses of this technology.

That said, I believe we are now ready for the next step in our evolution. Looking at our industry, we're very much looking forward to combining our R&D and commercialization best practices with those at Indevus to even further extend our reach in our shared markets, better serve our patients, physicians and position us in the best way for the long term. The two companies in reality have barely scratched the surface and we are very excited about the possibilities that lie ahead for both of us.

Let me say again, by saying that we are enormously proud of what Valera has accomplished over the last six years and very excited about our future as part of the new combined company and after closing, we look forward to a smooth integration with the Indevus team. Now, I will turn over to Glenn.

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Okay. Thanks, David. Before we open to the call to questions, I'd like to conclude by saying that, in my opinion, 2007 is going to be an amazingly active and productive one for this newly-combined company. Here are some of the anticipated highlights: the approval and launch of SANCTURA XR; the approval and launch of Supprelin-LA; the submission of the application to re-launch Valstar; the submission of the NEBIDO NDA; initiation of the co-promotion of Vantas; the initiation of the pegoclone stuttering Phase III trials; the initiation of the octreotide Phase III trial of acromegaly; the submission of the 510K for the biodegradable ureteral stent. We look forward to keeping our investors updated along the way and we look forward now to answering your questions about this transaction. Operator, we can now start the Q and A session.

QUESTION AND ANSWER

Operator

And your first question comes from the line of Vinny Jindal of ThinkEquity.

Vinny Jindal *ThinkEquity Analyst*

Hey guys, thanks for taking my question. My first question is, obviously Indevus' relationship with Esprit is very important to the marketing of your products. I was curious, have you begun discussions with them to add the products you plan to acquire into their bag when they're marketing SANCTURA XR as well?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

That's a very good question. No, we haven't had any discussions with Esprit about co-promoting any of these products. I think the focus of both companies right now is on the introduction of SANCTURA XR, which has considerable marketplace opportunities ahead of us and I think, as I've mentioned previously, there is certainly a realization on the part of both parties that a co-promotion effort of SANCTURA XR with a larger company that has a primary care sales force is highly desirable. I think both Esprit and Indevus believe that to be the case and that's where our focus is right now on SANCTURA XR with Esprit.

Operator

Your next question is from the line of Andrew Shopick, with Nutmeg Securities.

Andrew Shopick *Nutmeg Securities Analyst*

Yes, I'm wondering if you could clarify one thing here for me. Before any contingent stock rights, what would the percentage ownership be if this sale is completed under the existing terms between the Indevus management and the shareholders of Valera?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Okay, Mike Rogers will take that question.

Michael Rogers *Indevus Pharmaceuticals CFO*

Andy, assuming that I've heard your question right, the Valera percentage of the fully-diluted shares post-combination will be about 17% of the company.

Operator

Your next question comes from the line of David Maris with Banc of America.

David Maris *Banc of America Analyst*

Hi. On the Supprelin implant, maybe if the Indevus management could talk a little bit about what they view that opportunity or as they did due diligence, what they also thought of the pricing environment currently or going forward with the launch of that product?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

John Tucker will take that question.

John Tucker *Indevus Pharmaceuticals Executive VP of Sales and Marketing*

Hi, David, this is John. Yes, we're very excited by the Supprelin-LA implant. If you look at this market, there's only really one product and it's Lupron Depot P, the pediatric version and that has a run rate of about \$81 million per year. It's a very small specialty dominated by pediatric endocrinologists and there's really less than 500 of them in the U.S. so not only is it a relatively large market, it should be relatively easy for us to penetrate with our sales force.

We don't need a large sales force or a large advertising promotion spend to get there. It's important to note that this is a different product than Vantas so we do not have the price pressures we have in the advanced prostate cancer market. The Lupron P price per year ranges from 12 to \$15,000 per patient per year. So, it's very important to note that, again, it's an \$81 million market with a small advertising and promotion and a small physician base, but at a relatively high price that you can charge on the market.

Dr. Glenn Cooper *Indevus Pharmaceuticals President and CEO*

And, John, could you comment a little more about our market research.

John Tucker *Indevus Pharmaceuticals Executive VP of Sales and Marketing*

Sure. David, we did extensive market research talking to physicians and maybe more importantly, talking to parents of these children with CPP. And, either there's a lot of anxiety that these kids face before they go to the doctors every single month to get an injection. They have to be pulled out of school. The parents have to leave work early to go take these patients in these kids to get these deep injection shots. This is a simple once yearly implant.

So, instead of 12 to 15 injections during the year, it's just one simple procedure. And, overwhelmingly, our market research both with physicians and with parents showed a lot of enthusiasm, a high willingness to use this product so we're very excited about the potential of the product.

Operator

Your next question is from the line of Gary Nachman, with Leerink Swan.

Gary Nachman *Leerink Swan Analyst*

Hi, good morning, gentleman. Could you talk about when and how much you plan to increase the sales force and would it be before the launch of SANCTURA XR and then would you increase it even more to maximize the NEBIDO opportunity? Just talk a little bit about what the right number is for this market in terms of targeting the urologists and endocrinologists?

John Tucker *Indevus Pharmaceuticals Executive VP of Sales and Marketing*

Hi, Gary. It's John, again. I'll tackle that one. Well, obviously, during the co-promote period here with Valera, you know we're going to keep our 85 representatives focused in urology and endocrinology selling SANCTURA and selling Vantas and we really think the added reach of the 85, to go from really 25 to 110 reps in the prostate cancer market gives us a great opportunity to expand usage with Vantas.

It's really that we're not finished with all of the targeting and sizing exercises we need, but it's safe to say it's going to be difficult for us to launch SANCTURA XR, Vantas, Supprelin-LA and Valstar with our 85-person sales force. So, we will need to expand to do that. We think that the Valera group is going to really form the core of that expansion, but we haven't finalized what the sales force looks like post integration.

Operator

Your next question is from the line of Wayne Rothbaum with Quogue Capital.

Wayne Rothbaum *Quogue Capital Analyst*

Hi, guys. Maybe I missed this part. Can you just walk me through again the financials of how this is going to affect the cash situation, cash position and the burn, or will it have an impact?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Mike will take that question, Wayne.

Michael Rogers *Indevus Pharmaceuticals CFO*

Sure, Wayne. There are a number of things. One is the nine-month loss for Valera is about \$10 million, so you can see what that is on a quarterly basis. We do know that we will have synergies in the deal that would be at least, as we see it right now and there's still more work to do, \$5 million a year. We would expect that burn rate would increase a little bit just by adding the Valera portfolio of products and the company.

However, in addition, we're also looking internally at certain things that we might do. For instance, with paxoclone, there's clearly an increased emphasis on out-licensing now. IP-751 is in the same category. So, there are things that we will do internally to negate any increased burn that we have by combining the two companies. There may be some small increase, but it is not going to be particularly significant.

Operator

Your next question comes from the line of Adam Cutler with JMP Securities.

Adam Cutler *JMP Securities Analyst*

Hi, thanks for taking the question. Wondering if you could go over two things; one is, why the higher royalty rate for the Vantas co-promotion partnership with certain specialty pharma accounts? And, the other thing is, it looks like there are a couple of other earlier-stage programs in Valera's pipeline on the website that didn't get mentioned, I think so far, and it may be because they're too early. But, I'm wondering if you can comment on what your intentions are with those?

Dr. David Tierney *Valera Pharmaceuticals President and CEO*

This is David Tierney here. Regarding the higher percentage rate on the co-promote, one area that we've certainly spent a lot of time and effort on in the last six to nine months is actually getting prescription business out of specialty pharmacies. And, we actually have a differential compensation program internally for our sales force to encourage them to get these commercial prescriptions because that's an important part of the business.

So, similarly, as we spoke to the folks at Indevus, we decided to put in place added incentives for the Indevus folks who actually get that specialty pharmacy business. So that is really the reason that we have this sort of staggered or the differential reimbursement rate especially around this specialty pharmacy business. John, before I go into the pipeline, do you want to comment on that?

John Tucker *Indevus Pharmaceuticals Executive VP of Sales and Marketing*

Yes. This is John, Adam. We look at specialty pharmacy as really a great opportunity for us to really stabilize some of the pricing pressures in the market. So, it's a key target for us. There's a couple strategies that we're going to work that Valera started that we're going to help them with to really target. We think that a pretty key segment of the business and start establishing relationships with the specialty pharmacy. We know that Supprelin-LA will potentially go through there as well as NEBIDO, so it's very important for us, cooperatively, to establish relationships with these key accounts.

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Let me take the question on other earlier-stage assets and the Indevus view of them. We think they're fantastic. We don't think that necessarily they belong within our portfolio, but they are certainly a very attractive partnerable assets, particularly Naltrexone implant for opioid addiction. This is a pretty hot area right now. There are a lot of companies heavily involved in this space and once the deal closes, we intend to target those companies very aggressively with out-licensing.

Similarly Desmopressin for nocturnal enuresis or bedwetting. That is an out-license candidate and there are many earlier-stage and frankly undisclosed programs within Valera that we think have enormous opportunities for out-licensing and some of them might even be larger opportunities than any of the ones currently on the table. We have a great business development function at Indevus. It's one of our strongest assets. BD is really the engine of our business model and we think if we put these partnerable assets into their bag to sell to their customers, i.e., other biotech or pharma companies, that there's considerable value in this early-stage pipeline.

Operator

Your next question is from the line of Elliot Wilbur with CIBC World Markets.

Elliot Wilbur *CIBC World Markets Analyst*

Yes, can you hear me alright?

Unidentified Company Representatives

Yes. Hi.

Elliot Wilbur *CIBC World Markets Analyst*

Okay, thank you. Good morning and congratulations on the deal. Wanted to ask a question, I guess most appropriate for David and/or John to maybe just give a quick background on Vantas. Why the product has disappointed relative to initial expectations? Understand that there has been some pricing erosion in the marketplace, but also the penetration, I guess, of the depot or the long-acting formulations maybe hasn't been as significant as expected.

I'm wondering, if you think about the interaction between pricing, uptake and then sort of percentage of the product that actually falls in the Medicare environment versus private-pay. What should we be thinking about going forward in terms of expectations for this product? It looks like maybe a year ago expectations were that the drug would do 70 to \$80 million in sales, now it looks like those expectations have come down by roughly 50%. The numbers seem to be in the 30 to \$40 million range.

So, are those the right numbers to think about in terms of how you guys view the opportunity or are there some potential inflection points in terms of uptake and/or pricing going forward that might actually allow you to exceed that? Thanks.

Dr. David Tierney *Valera Pharmaceuticals President and CEO*

It's David, here. Let me take a stab at it first and then I'll let John chime in here. I mean, clearly, this is a very unique marketplace and it's something that we've sort of been working with for the last couple of years. We certainly have seen pricing pressures you have in reality, in the last 12 months. The one area that we, and we've articulated this before, the areas where we sort of saw opportunity here, were really two-fold.

The first one that we recognize and we've mentioned it on previous conference calls were, that our 25-person sales rep force was really not getting the level of penetration that we needed out there, especially in the more rural areas and areas where we could not place representatives where, frankly, a 12 month implant truly makes sense for a lot of patients who live long distances from their physicians.

So, hence we looked towards co-promotion partners and that's sort of what largely stimulated the discussions which kind of led us to today and we truly believe by having over 100 people out there on the ground and detailing Vantas just the reach and awareness that we actually achieve out there will, in fact, really help boost volumes.

The other area which we sort of touched upon a little bit previously, is the one area also where we've also identified how can we actually affect our average selling price and John kind of talked about it, was by driving business through the specialty pharmacy and approximately 20% of the prostate cancer market is non-Medicare business and a sizeable portion of that actually goes through specialty pharmacies.

Those prescriptions that go through specialty pharmacies, get reimbursed to the company at a much high rate and hence, we have focused that as a key effort to try and drive more and more business through the specialty pharmacy. So, we think that effort will help stabilize our average selling price and that combined with obviously the greater reach out there, will clearly help boost volumes and that really is the strategy that we had embarked upon and clearly now has transitioned over to this venture and the new company that we're proposing with Indevus.

John Tucker *Indevus Pharmaceuticals Executive VP of Sales and Marketing*

Elliot, this is John and I'll just kind of add some more to what David said. He hit most of the points. This market is a very, very unique market. It has been under quite a bit of pricing pressure. We've really started to see that start to stabilize. There've been some things in the market that have caused that, but we've seen the actual pricing environment stabilize in the marketplace. It is truly about the reach into these offices.

We expect to double the amount of physicians that the brand is actually reaching right now with adding our sales force to the product. So, we're going to be able to extend the reach almost double the number of physician-targets. The pricing is starting to stabilize and, again, we're going to spend a lot of time and energy working with Valera on the specialty pharmacy putting pull-through programs in place that can target these physicians that are non-Medicare or have a large non-Medicare base, which really helped to continue to stabilize the ASP. So, we have an aggressive plan in place to do all of these things.

Operator

Your next question is from the line of David Miller with Biotech Stock Research.

David Miller *Biotech Stock Research Analyst*

Hi, good morning and thanks for taking my question. I also want to focus a little bit on Vantas. Doctors typically have to see their patients every six months or so to do a PSA screen and one of the emerging trends in the prostate cancer area for hormone sensitive men is to do hormone-pulsing to try to decrease the side effects of hormone therapy. So, given the fact that they're seeing these patients anyway and injections are relatively easy and the trend away from constant hormone, can you kind of factor that into your additional comments on where you see Vantas going? And, give us some idea of what your sales projections are, as far as a dollar figure?

Dr. David Tierney *Valera Pharmaceuticals President and CEO*

Well, this is David, here. Your point there regarding pulsing and, more importantly, intermittent therapy, this is really nothing new. We've actually lived with this frankly over the last number of years and the reality is if you look at the literature and the scientific data that's out there, there's no consensus on the clinical benefit and value of hormonal therapy with the exception, for some patients, it's a quality of life issue.

The other critical thing here is that there's no consensus on what the suitable duration is. If you look in the studies that have come out of Australia or come out of Europe, some of these studies can suggest anywhere from six to nine to twelve months. Again, there's no consensus, here. In terms of Vantas, the one thing that we truly recognize through our market research, I think I can't necessarily speak for the Indevus folks, but certainly for Valera if you look at the market research that we have done, we consistently see that the physicians that we interview and poll out there recognize that about 15 to 20% of their patients specifically would be deemed ideal candidates for implant therapy.

So, we certainly have never suggested and I'm not certain the Indevus folks will either ever suggest that Vantas is going to be capturing the dominant share of this market. We have simply believed, and market research bears that out, that there is a proportion of patients for whom a

long-term implant makes a lot of sense and that is a variety of patients either, as I mentioned, people who live long distances from their physicians, patients who basically have difficulty getting to the office. They're infirm. They're in nursing homes. They travel a lot. So, we think there is ample opportunity out there to actually grow this business.

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Let me just comment. This is Glenn, on financial projections. We think Vantas has a potential to be a larger product than it is right now and the co-promotion effort, I think, will tell the story in the next few months in terms of the detail of the promotion responsiveness of the larger sales force. As excited as we are about Vantas, it was not the main driver though for the acquisition.

The main driver really are the other products in the portfolio but Vantas is clearly also important. Valera has not, I believe, given financial projections going forward on Vantas. I think our position would be that once the deal closes, once we've had a chance to see how the co-promotion plays out, we would be giving financial projections on the product around the time of closing.

Operator

Your next question is from the line of Ben Cubit with M-Cap. Please proceed.

Ben Cubit *M-Cap Analyst*

Hello? Sorry. I got on the call a bit late so I apologize if you've already covered this, but my question was about the CSRs. Asking if, I guess, A) if you had the intention of listing them and if it's something that you hadn't thought about, if you would consider listing them?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Mike Rogers will take that.

Michael Rogers *Indevus Pharmaceuticals CFO*

Okay. The answer is that they won't be listed. They'll be non-transferable and will be issued to the shareholders of record at the time of closing.

Ben Cubit *M-Cap Analyst*

Is there a reason why you decided to go that route rather than I've just seen other deals where there's been contingent value rights where they've just listed them on the bulletin board just so that people can price them properly and realize value if they want?

Michael Rogers *Indevus Pharmaceuticals CFO*

We made a decision not to. There were some structural reasons in how we structured the deal and that were discussed by both parties, agreed to by the bankers, lawyers and so we're very comfortable with that.

Ben Cubit *M-Cap Analyst*

Okay, great, thanks.

Michael Rogers *Indevus Pharmaceuticals CFO*

Okay. Thank you.

Operator

Your next question is from the line of Michael Higgins with Wedbush Morgan Security.

Michael Higgins *Wedbush Analyst*

Good morning and thank you for taking my call.

Unidentified Company Representatives

Good morning, Michael.

Michael Higgins *Wedbush Analyst*

My question is since this seems to be a story of strategic fit between endocrinology and urology which are generally smaller markets than most. I wondered if you could comment on the increase in share of voice that you expect for each product in each target audience.

John Tucker *Indevus Pharmaceuticals Executive VP of Sales and Marketing*

Yes. Hi, Michael, it's John. Yes, in an advanced prostate cancer market, we expect about 100% increase in raw share voice based on the level of detailing we'll do with the Valera folks. As far as in endocrinology, our share voice is fairly low in there with DELATESTRYL. We're really seeing the top testosterone writers. We expect that to increase dramatically in the pediatric endocrinology offices as we get closer to the launch of Supprelin-LA.

Currently, Valera is not in those offices. But there's not a lot of representatives in that office. We don't think that it's going to be a high barrier to entry to have a significant share of voice especially in the pediatric endocrinologist where there's only one other product in this marketplace. So, I hope that answers your question.

Operator

Your next question is from the line of Robert Leboyer with Meyers and Associates.

Robert Leboyer *Meyers & Associates Analyst*

Good morning. The only question I have remaining is on the number of shares outstanding after the transaction and how many projected shares there'll be after all of these dollar payments?

Thomas Farb *Indevus Pharmaceuticals President and COO*

Mike Rogers just joined us. Mike, the question is what are the number of shares outstanding after the transaction?

Michael Rogers *Indevus Pharmaceuticals CFO*

Okay. As you may know, we have about 55.9 million shares outstanding and in the deal we will issue 16.5 million, approximately, based on the current exchange ratio.

Operator

Your next question is from the line of Martin Dent with New Jersey Law Journal.

Martin Dent *New Jersey Law Journal*

Hi. I was wondering if I could find out the names of the law firms and the attorneys who represented the two companies?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Indevus was represented by Skadden, Arps and Valera was represented by Pepper Hamilton.

Martin Dent *New Jersey Law Journal*

Okay, great. Could you tell me which offices of the two firms.

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Multiple offices that depended on the expertise required.

Operator

Your next question is from the line of Irena Revan with UBS.

Irena Revan *UBS Analyst*

Hi, thank you for taking my call. I'm calling on behalf of Annabelle Samimi. I just have a quick question about the CSRs. Again, I know that they expire within a few years and I was just wondering how Valera's shareholders are going to receive the value in the stock price if the events don't happen long after the closing of the acquisition?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Great question. Well, we expect that the timelines are perfectly compatible with the achievement of the milestones. So, from the Indevus side, we're certainly hoping that we'll achieve these milestones and Valera shareholders will receive value for the CSRs. Supprelin is a near-term opportunity where we're certainly encouraged by the excellent package that Valera has pending before the FDA.

The ureteral stent we think certainly is likely to happen within this three-year time frame and the octreotide implant which is further out with a five-year window. If the product is successful in getting into Phase III by the end of next year, then I think there's an excellent chance also of it hitting within that window. So, we think that this is a win-win for both sides. There'll be tremendous value generated to Indevus if these milestones are achieved and also corresponding significant value to Valera shareholders.

Operator

Your next question is a follow-up from the line of Andrew Shopick with Nutmeg Securities.

Andrew Shopick *Nutmeg Securities Analyst*

Thank you, operator. You're going to have to allow me to repeat a prior question and ask a new question. Please clarify, Mike, when I asked the question about the ownership, you said 17%. If you're issuing 16.5 million shares on a base of about 56 million, I'm coming up with 22-23% after the deal closes and that's before the CSRs.

Michael Rogers *Indevus Pharmaceuticals CFO*

Okay, Andy. You're exactly right. My answer earlier to you was Valera's percentage of the fully-diluted ownership of Indevus and that includes our outstanding converts and, as well, options that we have outstanding. So, you're right on both counts. Valera, as a percentage of the fully-diluted ownership will be about 17%, Valera's current shareholders as a percentage of our outstanding immediately post-deal will be between 22 and 23%.

Operator

Your next follow-up is from the line of Gary Nachman, with Leerink Swann.

Gary Nachman *Leerink Swann Analyst*

Hi and thanks for taking the follow-ups. Mike, regarding your pagoclone and cash burn comments from earlier, does that mean that you guys would not move forward into Phase III on your own? Are you still pushing forward with that program? I'd like to get a comment on that. And I want to confirm that we should be thinking of a mid-teen burn rate for the combined company. And what has been the burn rate for Valera? And, then lastly, what's the current gross margin for Vantas.

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Let me take the first one, Gary, on pagoclone. Mike will take the burn rate and David Tierney, I think, Andy Dreschler, the gross margin. Pagoclone, we continue to be extremely bullish about this compound and it's all systems go for moving forward into Phase III. The only change that this transaction will bring to bear is that I think that we're going to be far more inclined to enter into a licensing agreement, co-promotion agreement, some kind of joint development agreement with pagoclone, than we were prior to doing this deal.

And, I think if you were to replay our last end of the year conference call, we were clearly, I think, articulating a shifting in our position on pagoclone at that time and this really solidifies the thinking that the product has the greatest value if it's entered Phase III and that'll happen in parallel with our currently ongoing out-licensing discussions. Now, burn rates, Mike?

Michael Rogers *Indevus Pharmaceuticals CFO*

Okay. Gary, as you know we've articulated even most recently just last week on our conference call that our burn rate we expected to continue to be in the mid-teens for at least the next couple quarters. So, prior to the deal closing, that's our base burn rate and post-deal, we do not expect that to go up much. Now, the only thing I'll say as we look forward just a little bit over the next couple quarters, is there are both deal costs and transition costs which we will incur that will push the burn rate up near term. But, post-deal we expect the burn rate to be in the same range as it is right now.

Andrew Dreschler *Valera Pharmaceuticals CFO*

Sure, and then just to address the other two questions on Valera's financials. The Vantas gross margins have ranged between 70% and 74% this year in the previous three quarters and during the first nine months of the year, we utilized 9 million of cash from operations.

Operator

Your next question is a follow-up from the line of Irena Revan, with UBS.

Irena Revan *UBS Analyst*

Yes, hi. This is a question about the European partnership on Vantas with that Spepharm Holding. Just wondering what the status of that is going to be and how that's going to transfer over with this merger.

Dr. David Tierney *Valera Pharmaceuticals President and CEO*

It is part of the Valera business and it will transfer over into Indevus at the time of closing. The relationship will remain exactly the same, ma'am.

Operator

Your next question is from the line of Jerry Wu with Visium.

Jerry Wu *Visium Analyst*

Good morning. I had a question on Vantas sales. The third quarter number was particularly weak. Now, I think that might have been related to some manufacturing issues in the second quarter. So, are you expecting a rebound off of those levels and then, separately, in terms of Vantas units sold, what's the break-out between re-implants versus new patient starts?

Dr. David Tierney *Valera Pharmaceuticals President and CEO*

Regarding the third quarter, as you correctly point out, in 2005, we had a manufacturing outage at the end of June, all of July and first half of August. So, we have historically we have this year, we've ended up having a weak Q-3 because of the lack of re-implantation business and we expect Q-4 will be higher.

In terms of re-implantation rate, it's very difficult to give a precise answer because of the kits—the actual implantation kit that we send out is really no different for a new patient or a re-implant patient. So, the best we can really guess is by looking at sort of customer accounts and market research and we sort of estimate, a 30 to 40% re-implantation rate is a reasonable number to work with but we cannot give a precise figure because sort of there's not an accurate way to track it.

Operator

Your next question is a follow-up from the line of Elliot Wilbur, with CIBC World Market.

Elliot Wilbur *CIBC World Markets Analyst*

A question for Mike on the CSRs. Is the right way to think about this is—I mean, it looks to me basically that Indevus share price doesn't move anywhere from today's close over the next couple of years, since sort of the maximum payout here is in the mid-\$50 million range; but, if the stock doubles or whatever, it could be significantly below that? Am I right in thinking about that sort of the mid-50 million range is kind of the max payout?

Michael Rogers *Indevus Pharmaceuticals CFO*

Yes, well that amount actually will be a pretty solid number. That would be the payout if we hit all of them. However, if our stock price does double, there'd be less dilution, Elliot. I think that's the way to look at it. So, we pay out \$1.00 a share at a point in time in Indevus stock and so, if that stock has doubled, then there'll be half the shares we would have otherwise issued as of today.

Operator

Your next question is a follow-up from the line of David Miller with Biotech Stock Research.

David Miller *Biotech Stock Research Analyst*

Hi, thanks for taking my follow-up. I just want to be clear, are you going to launch the Phase III trial for pagoclone before you get the partner or after?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Absolutely, yes. We're going to be launching that trial prior to partnership conclusion, but we think having done so, will greatly enhance the value of the asset and greatly enhance the probability of getting a great deal.

David Miller *Biotech Stock Research Analyst*

And, when?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

I can't predict when a deal's going to happen. We're just in the first round of discussion with multiple parties and deals have a certain pace to them so I really couldn't predict exactly when. But, hopefully, it will be a 2007 event.

Operator

Your next question is a follow-up from the line of Vinny Jindal, with ThinkEquity.

Vinny Jindal *ThinkEquity Analyst*

Thanks, another quick question on pagoclone. Clearly an SPA going to be important for the investment community to feel comfortable with the FDA's recognized stuttering as an indication, are potential partners you're talking to now, are they privy to the ongoing dialogues between you and the FDA on that SPA?

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Absolutely, they'll be fully informed about every stage of the dialogue as you'd expect in that kind of due diligence process.

Operator

There are no further questions in the queue at this time. I would now like to turn the call back over to Mr. Glenn Cooper for closing remarks:

Dr. Glenn Cooper *Indevus Pharmaceuticals Chairman and CEO*

Okay. Thank you everyone for participating this morning. Thank you very much to our new partners at Valera. And there I'm sure, will be many follow-up calls. They can be directed to Brooke Wagner at Indevus, Stu Levine at Valera. Certainly, Brooke will be on the road for the next couple of days his assistant will track him down and be able to track Mike and myself down if you have further calls. We'll be available by cell phone, to take any and all your questions. So, thank you very, very much.

Operator

Thank you for your participation in today's conference. This concludes the presentation. You may now disconnect. Have a wonderful day.