INDEVUS PHARMACEUTICALS INC
Form S-8
January 08, 2008
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As filed with the Securities and Exchange Commission on January 8, 2008

Registration No. 333-115921

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

REGISTRATION STATEMENT ON

FORM S-8

UNDER

THE SECURITIES ACT OF 1933

INDEVUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3047911**
(State or other jurisdiction of Incorporation)	**(I.R.S. Employer I.D. number)**

33 Hayden Avenue

Lexington, MA 02421

(781) 861-8444

(Address and telephone number of Registrant s principal executive offices)

2004 EQUITY INCENTIVE PLAN, AS AMENDED

(Full Title of Plan)

Glenn L. Cooper, M.D., President, Chief Executive Officer and Chairman

33 Hayden Avenue

Lexington, MA 02421

(781) 861-8444

(Address and telephone number of agent for service)

COPY TO:

Josef B. Volman, Esq.

Burns & Levinson LLP

125 Summer Street

Boston, MA 02110-1624

(617) 345-3000

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, $.001 Par Value Per Share	3,000,000(1)	$6.80(2)	$20,400,000	$802.00(3)

(1) Pursuant to Rule 416 promulgated under the Securities Act an additional undeterminable number of shares of Common Stock is being registered to cover any adjustment in the number of shares of Common Stock pursuant to the anti-dilution provisions of the 2004 Equity Incentive Plan, as amended. The Registrant previously registered 6,000,000 shares under the 2004 Equity Incentive Plan, including 3,000,000 shares which were covered under an initial Registration Statement originally filed on May 27, 2004 and an additional 3,000,000 shares which were covered under a subsequent Registration Statement originally filed on October 6, 2006.

(2) Based on the average of the high and low sales price of the Common Stock as of January 3, 2008 and estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act. In addition, pursuant to Rule 416(c) under the Securities Act, this Registration Statement also covers an indeterminate amount of interests to be offered or sold pursuant to the employee benefit plan described herein.

(3) The Registrant previously paid filing fees of $3,666 in the aggregate with respect to the 6,000,000 shares previously registered. For purposes of calculating the registration fee, the maximum offering price per share has been estimated at $6.80 with respect to 3,000,000 shares of Common Stock to be registered at prices computed on the basis of fluctuating market prices pursuant to Rule 457(c) under the Securities Act.

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PART I

EXPLANATORY NOTE

A total of 6,000,000 shares of the Common Stock, $.001 par value per share, of Indevus Pharmaceuticals, Inc. (the Company) were registered by an initial registration statement on Form S-8, Registration No. 333-115921, filed on May 27, 2004 and a subsequent registration statement on Form S-8, Registration No. 333-115921, filed on October 6, 2006. These shares are to be issued in connection with the Company s 2004 Equity Incentive Plan, as amended (the 2004 Plan).

On January 24, 2007, the Board of Directors of the Company authorized, subject to stockholder approval, an amendment to the 2004 Plan for the sole purpose of increasing the number of shares reserved for issuance thereunder from 6,000,000 shares to 9,000,000 shares. The stockholders of the Company approved this amendment on April 17, 2007. The purpose of this Registration Statement (the Registration Statement) is to increase the number of shares covered by the earlier registration statements from 6,000,000 shares to 9,000,000 shares.

The first part of this Registration Statement has been prepared in accordance with the requirements of Form S-8 and is intended to be used to register shares to be issued and sold pursuant to the 2004 Plan. The Reoffer Prospectus filed as part of this Registration Statement has been prepared in accordance with the requirements of Form S-3 and may be used for reofferings or resales of Common Stock to be acquired by the participants in the Plan who are deemed control persons of the Company as discussed further below.

Except for the information contained in Part I hereof relating to the Reoffer Prospectus, pursuant to Instruction E to Form S-8 regarding the registration of additional securities of the same class under an employee benefit plan for which a registration filed on Form S-8 is effective, all items have been omitted herefrom other than the facing page; statements that the contents of the earlier registration statements pertaining to the 2004 Plan are incorporated by reference; required opinions and consents; the signature page; and information required in this Registration Statement that was not in the earlier registration statement.

The documents containing the information specified in Part I of this Form S-8 will be sent or given to employees as specified by Rule 428(b)(1). In accordance with the instructions to Part I of Form S-8, such documents will not be filed with the Commission either as part of this registration statement or as prospectuses or prospectus supplements pursuant to Rule 424.

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REOFFER PROSPECTUS

INDEVUS PHARMACEUTICALS, INC.

465,100 shares of Common Stock

This Reoffer Prospectus relates to the resale of 465,100 shares (the Shares) of Common Stock, par value $.001 per share (the Common Stock) of Indevus Pharmaceuticals, Inc. (Indevus and the Company), which are issuable, subject to vesting and certain other conditions, pursuant to (i) restricted stock awards (Restricted Stock Awards) and performance stock awards (Performance Stock Awards) granted to certain executive officers of the Company, as well as (ii) Deferred Stock Units granted to certain directors of the Company (Deferred Stock Units), all as granted under the 2004 Plan (such executive officer and directors being collectively referred to herein as the Selling Stockholders). The Restricted Stock Awards, the Performance Stock Awards and the Deferred Stock Units are collectively referred to herein as the Securities . The Reoffer Prospectus is being filed as part of a Registration Statement on Form S-8 to enable each of the Selling Stockholders to sell the Shares issuable to each of him or her in the public market from time to time.

The Restricted Stock Awards subject to this Reoffer Prospectus include (i) 50,000 Shares that vest in equal annual installments aggregating approximately 16,666 per year in each of October 2007, 2008 and 2009 and (ii) 113,300 Shares that vest in equal annual installments aggregating approximately 37,766 per year in each of October 2008, 2009 and 2010. The Restricted Stock Awards are subject to transfer restrictions, forfeiture and acceleration provisions.

The Performance Stock Awards include (i) up to 75,000 Shares that vest on October 16, 2009 (the 10/09 Awards), and (ii) up to 186,800 Shares that vest on October 30, 2010 (the 10/10 Awards), and the amount of such awards is determined in accordance with, and subject to, the achievement of certain milestones related to the market price of Indevus Common Stock, and vesting is dependent on the respective recipient remaining employed by Indevus on October 16, 2009 and October 30, 2010, as applicable. The number of shares the recipient is entitled to receive, if any, at such time is dependent on the market price at which Indevus Common Stock trades for 20 consecutive business days at any time during the three year period prior to such vesting date. With regards to the 10/09 Awards, depending on such prices as may be attained, the applicable Selling Stockholder could receive either (i) 45,000, (ii) 60,000, (iii) 75,000, or (iv) no Shares. With regards to the 10/10 Awards provided to the Chief Executive Officer of Indevus, depending on such prices as may be attained, the Selling Stockholder could receive either (i) 41,300, (ii) 55,000, (iii) 68,800, or (iv) no Shares. With regards to the 10/10 Awards provided to the President of Indevus, depending on such prices as may be attained, the Selling Stockholder could receive either (i) 16,800, (ii) 22,400, (iii) 28,000, or (iv) no Shares. With regards to the 10/10 Awards provided to certain Executive Vice Presidents of Indevus, depending on such prices as may be attained, each Selling Stockholder could receive either (i) 13,500, (ii) 18,000, (iii) 22,500, or (iv) no Shares.

This Reoffer Prospectus also includes Deferred Stock Units (DSUs) pertaining to an aggregate of 40,000 Shares, comprised of grants of 8,000 DSUs held by each of five directors who are Selling Stockholders. Each DSU represents a right to receive one share of Indevus common stock. Each grant of 8,000 DSUs vests in three equal annual increments on April 30, 2008, 2009 and 2010. Upon the earlier of the recipient s retirement from the Board of Directors of the Company or five (5) years from the date of grant, any DSUs that are vested and have not terminated are converted into common stock and distributed to the recipient, unless further deferred by the recipient.

The 2004 Plan covers an aggregate of 9,000,000 shares of Common Stock which may be issued pursuant to stock options, restricted stock and other awards granted under the 2004 Plan. On January 26, 2004, the Board of Directors of the Company adopted the 2004 Plan which was subsequently approved by the stockholders on March 9, 2004. On December 6, 2005, the Board of Directors authorized an amendment to the 2004 Plan for the sole purpose of increasing the number of Shares reserved for issuance thereunder from 3,000,000 Shares to 6,000,000 Shares which was subsequently approved by the stockholders on March 7, 2006. On January 24, 2007, the Board of Directors authorized an amendment to the 2004 Plan for the sole purpose of increasing the number of Shares reserved for issuance thereunder from 6,000,000 Shares to 9,000,000 Shares which was subsequently approved by the stockholders on April 17, 2007.

Our 2004 Plan is intended to encourage ownership of Shares by selected employees, directors and consultants of the Company and our affiliates and to provide an additional incentive to such employees, directors and

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consultants to promote our success. Through January 3, 2008, 6,263,487 awards, net of cancellations, have been made pursuant to the 2004 Plan, 5,306,787 of which were grants of stock options, 350,400 were restricted stock awards, 566,300 were performance stock awards and 40,000 were deferred stock units.

The Selling Stockholders may sell all or a portion of the Shares from time to time in transactions on the Nasdaq National Market or other exchanges or markets on which the Shares may be traded, in the over-the-counter market, in negotiated transactions, through the writing of options on the Shares or a combination of such methods of sale or through other means. Sales may be effected at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices.

The Selling Stockholders may effect such transactions by selling the Shares to or through broker-dealers (including broker-dealers which may be affiliated with such Selling Stockholder) and such broker-dealers may receive compensation in the form of discounts, concessions or commissions from the Selling Stockholders or the purchasers of the Shares for whom such broker-dealers may act as agent or to whom they sell as principal or both (which compensation to a particular broker-dealer might be in excess of customary commissions). See Selling Stockholders and Plan of Distribution.

None of the proceeds from the sale of the Shares by the Selling Stockholders will be received by the Company. The Company has agreed to bear expenses in connection with the registration and sale of the Shares being offered by the Selling Stockholders. The Company has agreed to indemnify the Selling Stockholders against certain liabilities, including certain liabilities under the Securities Act of 1933, as amended (the Securities Act).

The Common Stock trades on the Nasdaq National Market under the symbol IDEV. On January 3, 2008, the last sale price of the Shares was $6.74.

THE SECURITIES OFFERED HEREBY INVOLVE A HIGH DEGREE OF RISK. SEE RISK FACTORS BEGINNING ON PAGE 6 OF THIS PROSPECTUS.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is January 8, 2008.

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WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), and in accordance therewith file reports and other information with the Securities and Exchange Commission (the SEC). These annual, quarterly and special reports, proxy statements and other information may be inspected, and copies of these materials may be obtained upon payment of the prescribed fees, at the SEC s Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549. In addition, we are required to file electronic versions of these materials with the SEC through the SEC s Electronic Data Gathering, Analysis and Retrieval (EDGAR) system. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. The SEC also maintains a Web site at http://*www.sec.gov* that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC. Our Common Stock is quoted on The Nasdaq Stock Market under the symbol IDEV . Reports, proxy statements and other information concerning us may also be reviewed at our Internet Site: http://www.indevus.com.

We have filed a Registration Statement on Form S-8 under the Securities Act of 1933 with the SEC with respect to the securities offered by this prospectus. This prospectus omits certain information contained in the Registration Statement on Form S-8, as permitted by the SEC. Refer to the Registration Statement on Form S-8, including the exhibits, for further information about Indevus and the Common Stock being offered pursuant to this prospectus. Statements in this prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. We are subject to the informational requirements of the Exchange Act, and in accordance therewith file reports and other information with the SEC. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above.

Unless otherwise indicated, in this prospectus, Indevus, the Company, we, us and our refer to Indevus Pharmaceuticals, Inc. and its subsidiar

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INFORMATION INCORPORATED BY REFERENCE

THIS PROSPECTUS IS PART OF A REGISTRATION STATEMENT ON FORM S-8 WE FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED IN THIS PROSPECTUS OR INCORPORATED BY REFERENCE. WE HAVE NOT AUTHORIZED ANYONE ELSE TO PROVIDE YOU WITH DIFFERENT INFORMATION. YOU SHOULD NOT ASSUME THAT THE INFORMATION IN THIS PROSPECTUS IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE ON THE FRONT PAGE OF THIS PROSPECTUS, REGARDLESS OF THE TIME OF DELIVERY OF THIS PROSPECTUS OR ANY SALE OF COMMON STOCK.

This prospectus does not contain all of the information set forth in the Registration Statement. The Commission allows us to incorporate by reference information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. Further, all filings we make under the Exchange Act after the date of the initial Registration Statement and prior to effectiveness of the Registration Statement shall be deemed to be incorporated by reference into this prospectus. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act:

(i) Our Annual Report on Form 10-K for the fiscal year ended September 30, 2007, including all material incorporated by reference therein, filed on December 12, 2007;

(ii) Our Current Reports on Form 8-K filed on April 17, 2007 (as amended by Forms 8-K/A filed May 10, 2007, June 22, 2007 and January 8, 2008); October 26, 2007, November 2, 2007, November 30, 2007, December 7, 2007 and December 20, 2007;

(iii) The description of our Common Stock, $.001 par value per share, which is set forth in our Registration Statement on Form 8-A declared effective on March 8, 1990, as amended, registering the Common Stock under the Exchange Act;

(iv) The Company s Registration Statement on Form S-8 filed May 27, 2004, as amended by a subsequent Registration Statement on Form S-8 originally filed on October 6, 2006 (Registration No. 333-115921) and all consents and opinions with respect thereto;

(v) All documents filed by the Company pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this Registration Statement and prior to the termination of this offering except the Compensation Committee Report on Executive Compensation and the performance graph included in the Proxy Statement filed pursuant to Section 14 of the Exchange Act; and

(vi) All other reports filed by us pursuant to Section 13(a) or 15(d) of the Exchange Act, since September 30, 2007.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request of such person, a copy of any and all of the documents that have been incorporated by reference in this prospectus (not including exhibits to such documents, unless such exhibits are specifically incorporated by reference in this prospectus or into such documents). Such request may be directed to: Indevus Pharmaceuticals, Inc., 33 Hayden Avenue, Lexington, Massachusetts 02421-7966, Attention: Chief Financial Officer, telephone (781) 861-8444.

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SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

Statements in this prospectus, and the documents incorporated by reference into this prospectus, that are not statements or descriptions of historical facts are forward-looking statements under Section 21E of the Securities Exchange Act of 1934, as amended, (the Exchange Act) and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA® (trospium chloride tablets), SANCTURA® XR (once-daily SANCTURA), NEBIDO®, (testosterone undecanoate), VANTAS® (histrelin implant for prostate cancer) and SUPPRELIN® LA (histrelin implant for central precocious puberty); our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux -related litigation. The words believe, expect, anticipate, intend, plan, estimate or other expressions whic or indicate future events and trends and do not relate to historical matters identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, this prospectus. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR, NEBIDO, VANTAS and SUPPRELIN LA; effectiveness of our sales force; competition and its effect on pricing, spending, third-party relationships and revenues; dependence on third parties for supplies, particularly for histrelin, manufacturing, marketing, and clinical trials; risks associated with being a manufacturer of some of our products; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO, VANTAS, SUPPRELIN LA and VALSTAR ; reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity, changes in reimbursement policies and/or rates for SANCTURA, VANTAS, SUPPRELIN LA, DELATESTRYL® and any future products; acceptance by the healthcare community of our approved products and product candidates; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR, NEBIDO, and VALSTAR; product liability and insurance uncertainties; risks relating to the Redux-related litigation; need for additional funds and corporate partners, including for the development of our products; history of operating losses and expectation of future losses; uncertainties relating to controls over financial reporting; difficulties in managing our growth; valuation of our Common Stock; risks related to repayment of debts; risks related to increased leverage; general worldwide economic conditions and related uncertainties; and other risks. The forward-looking statements represent our judgment and expectations as of the date of this prospectus. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward-looking statements. See Risk Factors.

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INDEVUS PHARMACEUTICALS, INC.

We are a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Our approved products include SANCTURA® and SANCTURA® XR for overactive bladder, which we co-promote with our partner Allergan, Inc. (Allergan), VANTAS® for advanced prostate cancer, SUPPRELIN® LA for central precocious puberty, and DELATESTRYL® for the treatment of hypogonadism. We market our products through an approximately 100-person specialty sales force.

Our core urology and endocrinology portfolio contains multiple compounds in development in addition to our approved products. Our most advanced compounds are NEBIDO® for male hypogonadism, VALSTAR for bladder cancer, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted diseases, the octreotide implant for acromegaly and a biodegradable ureteral stent used in association with the treatment of kidney stones.

In addition to our core urology and endocrinology portfolio, there are multiple compounds outside of our core focus area which we either currently outlicense for development and commercialization, or intend to outlicense in the future. These compounds include pagoclone for stuttering, ALKS 27 for chronic obstructive pulmonary disease which we have been jointly developing with Alkermes, Inc., aminocandin for systemic fungal infections for which we licensed the know-how to Novexel S.A. and IP 751 for pain and inflammation for which we recently licensed worldwide rights to Cervelo Pharmaceuticals, Inc.

Indevus Pharmaceuticals, Inc. is a Delaware corporation. Our corporate headquarters is located at 33 Hayden Avenue, Lexington, Massachusetts 02421-7971, and our main telephone number is (781) 861-8444.

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RISK FACTORS

The following factors should be reviewed carefully, in conjunction with the other information contained in this prospectus. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this prospectus and presented elsewhere by our management from time to time. If any of the following risks actually occur, our business, operating results or financial condition could be materially adversely affected. This could cause the market price of our common stock to decline, and could cause you to lose all or part of your investment. See Special Note Regarding Forward Looking Statements.

Risks Relating to Our Business

We will be dependent on our marketed products and the ability of Allergan to perform its obligations with respect to SANCTURA and SANCTURA XR.

We expect to derive a substantial portion of our revenue in fiscal 2008 from only three products, provided this will increase to four if we and Allergan are able to successfully launch SANCTURA XR which was approved by the FDA on August 3, 2007. One is SANCTURA, a treatment for overactive bladder, which we co-promote with our marketing partner, Allergan. The others are VANTAS, a product for the treatment of advanced prostate cancer, and SUPPRELIN LA, for the treatment of central precocious puberty. We believe that revenues derived under our agreement with Allergan and from the sale of VANTAS and SUPPRELIN LA will continue to account for a substantial portion of our revenue for the foreseeable future.

In October 2007, Allergan became our new partner with respect to SANCTURA and SANTURA XR in connection with its acquisition of Esprit. Our agreement with Allergan is referred to herein as the Allergan Agreement. We are highly dependent on Allergan for the commercialization and marketing of SANCTURA and SANCTURA XR in the U.S. and for performance of its obligations under the Allergan Agreement. Under the terms of the Allergan Agreement, Allergan will be responsible for all U.S. marketing and sales activities relating to SANCTURA, and SANCTURA XR when launched (we have the right to co-promote SANCTURA XR through March 2009). As such, we will depend on Allergan to devote sufficient resources to effectively market SANCTURA and SANCTURA XR. The failure of Allergan to effectively market SANCTURA or SANCTURA XR or perform its obligations under the Allergan Agreement, could materially adversely affect our business, financial condition and results of operations.

We currently market VANTAS and SUPPRELIN LA ourselves through our approximately 100-person specialty sales force. Our specialty sales force may not be able to successfully market and sell such products. Moreover, because our marketing resources are limited, we may be unable to devote sufficient resources to our marketed products to maintain, or achieve increasing, market acceptance of such products in their highly competitive marketplaces. If we are unable to successfully market and sell such products, it will have a material adverse effect on our business and results of operations.

Our product candidates may not be successfully developed or achieve market acceptance. In particular, we are dependent on FDA approval and market acceptance of NEBIDO.

We currently have multiple compounds or products which are in various stages of development and have not been approved by the FDA. These product candidates are subject to the risk that any or all of them are found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances or receive such clearances on a timely basis.

We expect to derive a substantial portion of our long term revenues from the market acceptance of NEBIDO if it is approved. On November 1, 2007 we announced that the FDA accepted for review our NDA for NEBIDO. The FDA Prescription Drug User Fee Act (PDUFA) target action date for NEBIDO is June 27, 2008. We would be materially adversely affected if we are unable to obtain FDA approval for NEBIDO or if the FDA should require additional testing prior to FDA approval. In addition, the FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of NEBIDO. Even if NEBIDO receives regulatory clearance, there can be no assurance that it will achieve or maintain market acceptance. If NEBIDO does not achieve market acceptance it will have a material adverse effect on our business and results of operations.

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We are unable to predict whether any of our other product candidates, such as VALSTAR and the octreotide implant, will receive regulatory clearances or will be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frames for commercialization of any products are long and uncertain. Even if these product candidates receive regulatory clearance, there can be no assurance that such products will achieve or maintain market acceptance which could have a material adverse effect on our business and results of operations.

The product candidates that we are attempting to develop differ from established treatment methods and will compete with a number of more established drugs and therapies manufactured and marketed by major pharmaceutical companies. If any of our products or product candidates fails to achieve market acceptance, we may not be able to market and sell the products successfully, which would limit our ability to generate revenue and could harm our business.

We may not compete successfully in the urology and endocrinology markets, including for sales of our products as well as the acquisition of additional compounds.

Our products compete in the urology and endocrinology markets. The competition in the urology and endocrinology markets is intense and is expected to increase. Our products compete with many current drug therapies or with new drugs which may reach the market in the future. Launches of other competitive products may occur in the near future, and we cannot predict with accuracy the timing or impact of the introduction of competitive products or their possible effect on our sales.

We compete against biotechnology companies, universities, government agencies, and other research institutions. Many of the companies who market or are expected to market competitive drugs or other products are large, multinational companies who have substantially greater marketing and financial resources and experience than us. We may not be able to develop products that are more effective or achieve greater market acceptance than competitive products. In addition, our competitors may develop products that are safer or more effective or less expensive than those we are developing or that would render our products less competitive or obsolete.

In addition, although we will have proprietary protection for VANTAS and other products we are developing, we could face competition from generic substitutes of these products and our other marketed products, such as SANCTURA. Because generic manufacturers are not exposed to development risks for such generic substitutes, these manufacturers can capture market share by selling generic products at lower prices, which can reduce the market share held by the original product.

Sales of competing products may cause a decrease in the selling price or units sold for our products, and could have a material adverse effect on our net product sales, gross margin and cash flows from operations. In the event our products were unable to be sold at the rate we currently anticipate, we could potentially have excess inventory, resulting in an impairment charge that could have a material adverse effect on our financial statements.

Many companies in the pharmaceutical industry also have substantially greater experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals and manufacturing and marketing products. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we compete with other companies in acquiring rights and establishing collaborative agreements for the development and commercialization of our products.

In particular, our marketed products and near term product candidates compete against the following products:

SANCTURA and SANCTURA XR, if launched, compete against anticholinergics, such as Detrol and Detrol LA (tolterodine) by Pfizer, Ditropan and Ditropan XL (oxybutynin) by Johnson & Johnson, Inc., Oxytrol (oxybutynin transdermal patch) by Watson Pharmaceuticals, Vesicare (solifenacin) by Astellas Pharma US, Inc. and Glaxo Smith Kline, Enablex (darifenacin) by Novartis A.G., generic oxybutynin, and generic oxybutynin extended release;

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VANTAS competes against TAP Pharmaceutical Products Lupron and Aventis Eligard, both multiple injection formulations that deliver leuprolide; Watson Pharmaceuticals Trelstar, a multiple injection formulation that delivers triptorelin; AstraZeneca s Zoladex, a biodegradable rod that delivers goserelin for up to three months; and BayerSchering s Viadur, a rigid metal implant that releases leuprolide over a 12-month period;

NEBIDO, if approved and launched, will compete against gels, such as AndroGel by Solvay and Testim by Auxilium, transdermal patch systems, such as AndroDerm by Watson, and multiple injectable products currently marketed in the U.S. which require more frequent injections than NEBIDO;

SUPPRELIN LA competes against TAP Pharmaceutical Products Lupron Depot-PED; and

VALSTAR, if approved and launched, is the only product approved by the FDA for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (CIS) of the urinary bladder.

Physicians may not prescribe, and patients may not accept, our products if we do not promote our products effectively. Factors that could affect our success in marketing our products include:

the adequacy and effectiveness of our sales force and that of any co-promotion partners;

the adequacy and effectiveness of our production, distribution and marketing capabilities;

the success of competing products, including generics; and

the availability and extent of reimbursement from third-party payors.

In addition, we do not conduct our own research to discover new drug compounds. Instead, we depend on the acquisition of compounds from others for development through licensing, partnerships, corporate collaborations, strategic corporate transactions or company acquisitions. Therefore, in order to grow, we must continue to acquire and develop additional compounds. The success of this strategy depends upon our ability to identify, select and acquire compounds that meet the criteria we have established. Identifying suitable compounds is a lengthy, complex and uncertain process. In addition, we compete with other companies with substantially greater financial, marketing and sales resources, for the acquisition of compounds. We may not be able to acquire the rights to additional compounds through licensing or strategic acquisitions of selected assets or businesses, on terms we find acceptable or at all.

We rely on third parties with respect to manufacturing, distribution and commercialization of certain of our products as well as products we have out-licensed.

We are currently dependent on Madaus GmbH (Madaus) to manufacture SANCTURA, Bayer Schering Pharma AG (BayerSchering) to manufacture NEBIDO and third parties to manufacture SANCTURA XR. We are also dependent on third parties in the supply chain, for the manufacture of trospium chloride, the active pharmaceutical ingredient in SANCTURA and SANCTURA XR, as well as for the packaging of SANCTURA and SANCTURA XR. If Madaus or any of these third parties were unable to achieve or maintain compliance with FDA requirements for manufacturers of drugs sold in the U.S., we would need to seek alternative sources of supply, which could create disruptions in the supply of SANCTURA, SANCTURA XR or NEBIDO. In addition, we are reliant on third parties for manufacturing relating to our non-core product candidates, such as PRO 2000 and pagoclone. Reliance on third-party manufacturers for the manufacture of most of our products, entails risks to which we would not be subject if we manufactured these products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us.

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Any manufacturing facilities for any of our compounds are subject to FDA inspection both before and after NDA approval to determine compliance with cGMP requirements. There are a limited number of contract manufacturers that operate under cGMP that are capable of manufacturing our products. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or commercialize them. Facilities used to produce our compounds may not have complied, or may not be able to maintain compliance, with cGMP. The cGMP regulations are complex and failure to be in compliance could lead to non-approval or delayed approval of an NDA which would delay product launch or, if approval is obtained, may result in remedial action, penalties and delays in production of material acceptable to the FDA.

We expect to seek corporate partnerships for the manufacture and commercialization of our products. We may not be successful in finding corporate partners and the terms of any such arrangements may not be favorable to us. If we are unable to obtain any such corporate partners, development of our product candidates could be delayed or curtailed, which could materially adversely affect our operations and financial condition.

Any collaborative partners may not be successful in commercializing our products or may terminate their collaborative agreements with us. If we enter into any collaborative arrangements, we will depend on the efforts of these collaborative partners and we will have limited or no control over the development, manufacture and commercialization of the products subject to the collaboration. If certain of our collaborative partners terminate the related agreements or fail to develop, manufacture or commercialize our products, we would be materially adversely affected. Because we expect generally to retain a royalty interest in sales of products licensed to third parties, our revenues may be less than if we marketed products directly.

We have out-licensed to third parties the development and commercialization efforts of many of our non-core products and product candidates such as aminocandin and IP 751. We are dependent on such third parties with respect to development and commercialization of such products and product candidates and we have limited or no influence over their efforts and activities. Reliance on third parties for such efforts entails risks, many of which we would not be subject if we developed these products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the licensing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us. In addition, the occurrence of any such events or any other failure by these third parties to adequately develop or commercialize these products or product candidates could materially adversely effect our operations and financial condition.

As a manufacturer of some of our products, we are subject to risks of reliance on single suppliers, interruptions on the manufacturing process and regulatory requirements.

As a manufacturer of some of our products and product candidates, we are subject to a variety of risks, including risks pertaining to reliance on single suppliers, interruptions on the manufacturing process and regulatory requirements.

We currently rely on single suppliers for some of our products and product candidates, including in particular histrelin, the active ingredient in VANTAS, SUPPRELIN LA and the octreotide implant. Any alternate sources of these raw materials and services may not be immediately available to us and may not meet specifications or requirements of us or the FDA. Consequently, if any of our suppliers are unable or unwilling to supply us with these raw materials in sufficient quantities with the correct specifications, or provide services on commercially acceptable terms, we may not be able to manufacture our products or our product candidates in a timely manner or at all, which could materially adversely effect our operations and financial condition.

Any interruption in the supply or manufacturing of our products or product candidates may adversely impact sales of our products or the development of our product candidates. Any lack of supply during such the period of such interruption may have an adverse impact on our future sales because physicians may have elected to use alternative treatments during this time frame or may, as a result of this interruption, permanently switch to another product. For example, prior to the merger with Indevus, Valera experienced two separate disruptions in its manufacturing of VANTAS due to issues caused by its supply of histrelin. These difficulties delayed the manufacturing of VANTAS for several weeks and directly impacted Valera s supply of VANTAS in 2005. Also, VALSTAR was withdrawn from the market in 2002 due to a manufacturing problem. In the future, we may experience other disruptions in our manufacturing process for these and our products and product candidates which may adversely impact sales and development.

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Pharmaceutical products are required to be manufactured under regulations known as current good manufacturing practice, or cGMP. Before commercializing a new product, manufacturers must demonstrate compliance with the applicable cGMP regulations, which include quality control and quality assurance requirements, as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products generated through the use of their technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems or the failure to maintain compliance with existing or new regulatory requirements may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and civil or criminal sanctions.

We may also encounter problems with the following:

- production yields;
- raw materials;
- shortages of qualified personnel;
- compliance with FDA regulations, including the demonstration of purity and potency;
- changes in FDA requirements;
- controlling production costs; and
- development of advanced manufacturing techniques and process controls.

In addition, we are required to register our manufacturing facilities with the FDA and other regulatory authorities. The facilities are subject to inspections confirming compliance with cGMP or other regulations. If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, or revocation of pre-existing approval for a product, such as VANTAS or SANCTURA, which would eliminate a substantial source of our revenue and could materially adversely affect our operations and financial condition.

We also currently contract with third parties for most of our manufacturing needs and do not manufacture any of our own products or product candidates, except for VANTAS and SUPPRELIN LA. We do not currently have any substitute manufacturing facilities and arrangements in place with respect to our manufacturing facility now used for VANTAS and SUPPRELIN LA. As such, if we are unable to continue to use our current manufacturing facility for any reason, including regulatory non-compliance or otherwise, it could materially adversely affect our operations and financial condition. In addition, we cannot be certain that alternative manufacturing sources will be available on reasonable terms or at all.

To continue to develop products, apply for regulatory approvals and commercialize products, we will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. Certain of our requirements for supplies or clinical compounds are filled by purchase orders on an as-requested basis and are not the subject of long-term contracts. As a result, we cannot be certain that manufacturing sources will continue to be available or that we can continue to outsource the manufacturing of these products or product candidates on reasonable terms or at all.

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We rely on the protection provided by our intellectual property and have limited patent protection on some of our products and we are dependent on market exclusivity for some of our products.

Our future success will depend to a significant extent on our ability to:

- obtain and enforce patent protection on our products and technologies;
- maintain trade secrets; and
- operate and commercialize products without infringing on the patents or proprietary rights of others.

There can be no assurance that patent applications filed by us or others, in which we have an interest as assignee, licensee or prospective licensee, will result in patents being granted or that, if granted, any of such patents will afford protection against competitors with similar technology or products, or could not be circumvented or challenged.

In addition, certain products we are developing or selling are not covered by any patents and, accordingly, we will be dependent on obtaining market exclusively under the Waxman-Hatch Act for such products. Under the Waxman-Hatch Act, a company may obtain five years of market exclusivity if the FDA determines such compound to be a chemical entity that has not been the subject of an approved NDA in the past. The period of market exclusivity under the Waxman-Hatch Act is considerably shorter than the exclusivity period afforded by patent protection, which, in the case of some patents, may last up to twenty years from the earliest priority date of the patent directed to the product, our use or method of manufacture. If we are unable to obtain strong proprietary rights protection of our products after obtaining regulatory clearance, competitors may be able to market competing generic products by obtaining regulatory clearance, by demonstrating equivalency to our product, without being required to conduct the lengthy and expensive clinical trials required of us. Certain of our agreements provide for reduced royalties, or forgo royalties altogether, in the event of generic competition.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a product candidate can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing any advantage of the patent.

Our license for SANCTURA, a compound approved for use in the treatment of overactive bladder, does not include any patents used in the commercialization of the product. We do not otherwise currently own or have a license to issued patents that cover our SANCTURA product. Our ability to successfully commercialize SANCTURA in the U.S. will depend on the continued availability of market exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Waxman-Hatch Act, which provides protections for certain new products. The Waxman-Hatch Act provides for a period of market exclusivity in the U.S. for SANCTURA for five years from the date of FDA approval, May 28, 2004. The marketing of SANCTURA could be materially adversely affected if the period of market exclusivity is shortened. After this time, there may be generic versions of trospium chloride available to treat overactive bladder at significantly lower prices than SANCTURA, in which case sales of SANCTURA will likely decrease significantly.

Although we have patent applications that have been published pertaining to SANCTURA XR, the applications continue to be pending and we cannot predict whether any patents will issue on such applications. If granted, there can be no assurance that these patents can or will preclude eventual market erosion from new technologies or competing products. If we are unable to obtain a patent on such formulation we will have to rely solely on market exclusivity for this formulation, which will be shorter than five years.

Further, we will not have exclusive rights with respect to the sale of VALSTAR because the product candidate is not covered by any patents or orphan drug exclusivity. As a result, competitors may compete with us by, among other things, introducing a generic version of the product or a similar product that contains the active ingredient, valrubicin.

Our business may be materially adversely affected if we fail to obtain and retain needed patents, licenses or proprietary information. Others may independently develop similar products. Furthermore, litigation may be necessary:

to enforce any of our patents;

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to determine the scope and validity of the patent rights of others; or

in response to legal action against us claiming damages for infringement of patent rights or other proprietary rights or seeking to enjoin commercial activities relating to the affected product or process.

The products marketed by us or our licensees or being developed by us may infringe patents issued to competitors, universities or others. Third parties could bring legal actions against us or our sublicensees claiming patent infringement and seeking damages or to enjoin manufacturing and marketing of the affected product or the use of a process for the manufacture of such products. If any such actions are successful, in addition to any potential liability for indemnification, damages and attorneys fees in certain cases, we could be required to obtain a license, which may not be available, in order to continue to manufacture or market the affected product or use the affected process. If a license is not available to us, we may be forced to abandon the related product. The outcome of any litigation may be uncertain. Any litigation may also result in significant use of management and financial resources.

We also rely upon unpatented proprietary technology and may determine in some cases that our interest would be better served by reliance on trade secrets or confidentiality agreements rather than patents. No assurance can be made that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to such proprietary technology or disclose such technology or that we can meaningfully protect our rights in such unpatented proprietary technology. We may also conduct research on other pharmaceutical compounds or technologies, the rights to which may be held by, or be subject to, patent rights of third parties. Accordingly, if products based on such technologies are commercialized, such commercial activities may infringe such patents or other rights, which may require us to obtain a license to such patents or other rights.

To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. Most of our consultants are employed by or have consulting agreements with third parties and any inventions discovered by such individuals will not necessarily become our property. There is a risk that other parties may breach confidentiality agreements or that our trade secrets become known or independently discovered by competitors, which could adversely affect us.

The successful commercialization of our products will depend on obtaining reimbursement at adequate levels from government authorities, private health insurers and Medicare/Medicaid for patient use of these products.

Sales of pharmaceutical products largely depend on the reimbursement of patients medical expenses by government healthcare programs, such as Medicare and Medicaid, and private health insurers. These third party payors control healthcare costs by limiting both coverage and the level of reimbursement for healthcare products. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services and altering reimbursement levels. The levels at which government authorities and private health insurers reimburse physicians or patients for the price they pay for our current marketed products or products we may develop could affect the extent to which we are able to commercialize these products.

We cannot be sure that reimbursement in the United States or elsewhere will be available for any pharmaceutical products we may develop or, if already available, will not be decreased in the future. The U.S. Congress recently enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While the program established by this statute may increase demand for our products, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our drug products. Any reduction in demand would adversely affect our business.

In particular, Future Medicare reimbursement levels may decline for VANTAS, which would have an adverse effect on our net product sales. Reimbursement levels are currently set by the numerous Medicare carriers in the United States which, in the aggregate, cover all fifty states. Certain Medicare carriers have a policy which sets the

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reimbursement rate for VANTAS based on our average selling price (ASP). Other Medicare carriers have a policy that applies the least costly alternative, or LCA, methodology to VANTAS. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent. VANTAS is currently the least costly alternative in the class of LHRH drugs. Further, certain Medicare carriers have a policy which segregates twelve-month products from all other dosages, including one, three, four and six month injectable products, and reimburses at different rates for these two groups of products, or a split policy. Finally, there are some Medicare carriers which state they have a policy which reimburses on an ASP or LCA methodology, but which we believe make payments based upon a split policy.

We are devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, in writing or in practice, we are at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. While we are challenging the basis for these reimbursement policies with the Medicare carriers, there is no guarantee that our challenge will be successful.

Significant uncertainty generally exists as to the reimbursement status of newly approved healthcare products. Our ability to achieve acceptable levels of reimbursement for product candidates will affect our ability to successfully commercialize, and attract collaborative partners to invest in the development of, our product candidates. Reimbursement may not be available for products that we may develop and reimbursement or coverage levels may reduce the demand for, or the price of products that we may develop. If we cannot maintain coverage for our existing marketed products or obtain adequate reimbursement for other products we develop, the market for those products may be limited.

Acceptable levels of reimbursement will also have an effect on our ability to attract collaborative partners to invest in the development of, our products and product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to obtain collaborative partners to manufacture and commercialize our products and product candidates, and may not be able to obtain a satisfactory financial return on our own manufacturing and commercialization of any future products.

To be successful, our product candidates must be accepted by the health care community, which can be very slow to adopt or be unreceptive to new products.

Our business is dependent on market acceptance of our products by physicians, healthcare payors, patients and the medical community. Medical doctors willingness to prescribe, and patients willingness to accept, our products depend on many factors, including:

- perceived safety and efficacy of our products;
- convenience and ease of administration;
- prevalence and severity of adverse side effects in both clinical trials and commercial use;
- availability of alternative treatments;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of our products;
- publicity concerning our products or competing products; and

our ability to obtain third-party coverage or reimbursement.

If our products are not accepted by physicians, healthcare payors, patients and the medical community, it will have a material adverse effect on our business and results of operations.

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We rely on the favorable outcome of clinical trials of our product candidates including NEBIDO and the octreotide implant.

Before obtaining regulatory approval for the commercial sale of any of the pharmaceutical product candidates we are developing, we or our licensees must demonstrate that the product is safe and efficacious for use in each target indication. The process of obtaining FDA and other regulatory approvals is lengthy and expensive. If clinical trials do not demonstrate the safety and efficacy of certain products under development, we will be materially adversely affected. The results of pre-clinical studies and early clinical trials may not predict results that will be obtained in large-scale testing or use. Clinical trials of products we are developing may not demonstrate the safety and efficacy of such products. In particular, NEBIDO has thus far demonstrated an acceptable safety profile in clinical trials, there can be no assurance that the safety profile of the drug would not change when taken in future trials or by a larger population of users.

Regardless of clinical trial results, the FDA may not approve marketing of the product. The costs to obtain regulatory approvals are considerable and the failure to obtain, or delays in obtaining, regulatory approval could have a significant negative effect on our business performance and financial results. Even if pre-launch approval of a product is obtained, the FDA is authorized to impose post-marketing requirements. A number of companies in the pharmaceutical industry, including Indevus, have suffered significant setbacks in advanced clinical trials or have not received FDA approval, even after promising results in earlier trials. For example, while there were multiple clinical trials of pagoclone that demonstrated statistically significant efficacy, while but other trials of pagoclone were unsuccessful. These unsuccessful trials prompted Pfizer (our previous licensee of this compound) to elect not to pursue further development of the compound and to return to us all rights to pagoclone which resulted in a material adverse impact on our stock price.

We rely on third parties to conduct certain of the clinical trials for our product candidates, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for or commercialize our product candidates.

We design the clinical trials for our product candidates, but we rely on academic institutions, private physician offices, corporate partners, contract research organizations and other third parties to assist in the managing and monitoring of these trials. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted the trials entirely on our own. For example, we are conducting certain clinical trials for the octreotide implant in Europe; however, we have employed a contract research organization to monitor the trials. We will also contract with a third party to handle the data management for these trials.

Although we rely on, and will continue to rely on, third parties to manage the data from our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. Moreover, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practice, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trials plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

We have regulatory and guideline and related pricing risks.

Our marketed products have been approved by the FDA. The FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of these products. In addition, although these products have thus far demonstrated an acceptable safety profile in clinical trials, there can be no assurance that the safety profile of the drugs would not change when assessed in future trials or when used by a larger patient population.

If our products become subject to efficacy or safety concerns, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, unexpected side effects or regulatory proceedings, the impact on our revenues could be significant.

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Government health care cost-containment measures can significantly affect our sales and profitability. These include federal, state, and foreign laws and regulations that negatively affect pharmaceutical pricing, such as Medicaid and Medicare, pharmaceutical importation laws, and other laws and regulations that, directly or indirectly, impose governmental controls on the prices at which our products are sold.

Government agencies promulgate regulations and guidelines directly applicable to us and our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our products.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to profitably sell our marketed products and any other products that we may develop. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has been enacted by Congress and signed by the President. Additionally, Medicare regulations implementing the prescription drug benefit became effective as of January 1, 2006. These and other regulatory and legislative changes or proposals may affect our ability to raise capital, obtain additional collaborators and market our existing products and any other products that we may develop. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subject the price of our products to governmental control, our ability to sell our current marketed products and other products we may develop in commercially acceptable quantities at profitable prices may be harmed.

Third-party payors are increasingly challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any products that may be offered by us in the future. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that we successfully develop and are approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of our products in those jurisdictions.

We have worldwide rights to market many of our products and product candidates. We intend to seek approval of and market our products outside of the U.S. For example, we have agreements to license VANTAS in Canada, South Africa, Asia and Argentina. To market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country ensure approval by regulatory authorities in other foreign countries or the FDA. Other than the approval of VANTAS for marketing in the European Union and certain other foreign jurisdictions, we may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market. If we fail to comply with these regulatory requirements or obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue from abroad will be adversely affected.

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We have product liability exposure and insurance uncertainties related to our products.

The use of products in clinical trials and the marketing of products may expose us to substantial product liability claims and adverse publicity. Certain of our agreements require us to obtain specified levels of insurance coverage, naming the other party as an additional insured. We currently maintain product liability and clinical trial insurance in the amount of $40,000,000. We may obtain additional coverage for products that may be marketed in the future. We may not be able to maintain or obtain insurance coverage, or to obtain insurance in amounts sufficient to protect us or other named parties against liability, at a reasonable cost, or at all. In addition, any insurance obtained may not cover any particular liability claim. We have indemnified certain licensors, licensees and contractors and may be required to indemnify additional licensors, licensees or contractors against product liability claims incurred by them as a result of products we develop or market. If uninsured or insufficiently insured product liability claims arise, or if a successful indemnification claim was made against us, our business and financial condition could be materially adversely affected. In addition, any payments made by us in connection with product liability litigation could result in significant charges to operations and would materially adversely affect our results of operations and financial condition.

The outcome of the Redux litigation could materially harm us.

On September 15, 1997, we announced a market withdrawal of our first commercial prescription product, the weight loss medication Redux, which had been launched by American Home Products Corporation (AHP), now Wyeth, our licensee, in June 1996. Following the withdrawal, we have been named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. The existence of such litigation may materially adversely affect our business. In addition, although we are unable to predict the outcome of any such litigation, if successful uninsured or insufficiently insured claims, or if a successful indemnification claim, were made against us, our business, financial condition and results of operations could be materially adversely affected. In addition, the uncertainties associated with these legal actions have had, and may continue to have, an adverse effect on the market price of our common stock and on our ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, and to obtain product liability insurance for other products at costs acceptable to us, or at all, any or all of which may materially adversely affect our business, financial condition and results of operations.

On May 30, 2001, we entered into an Indemnity and Release Agreement with AHP, now Wyeth, which provides for indemnification of Redux-related claims brought by plaintiffs who initially elected not to stay in the AHP national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension, a serious disease involving the blood vessels in the lungs. This agreement also provides for funding of all defense costs related to all Redux-related claims and provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the AHP indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. We are unable to predict whether the existence of such litigation may adversely affect our business.

Pursuant to agreements we have with Les Laboratories Servier, from whom we in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., the manufacturer of Redux, and other parties, we may be required to indemnify such parties for Redux-related liabilities. We are unable to predict whether such indemnification obligations, if they arise, may adversely affect our business.

We could be materially harmed if our agreements were terminated.

Our agreements with licensors and licensees generally provide the other party with rights to terminate the agreement, in whole or in part, under certain circumstances. Many of our agreements require us to diligently pursue development of the underlying product or product candidate or risk loss of the license or incur penalties. Depending upon the importance to us of the product that is subject to any such agreement, this could materially adversely affect our business. In particular, termination of our agreements with Allergan, Madaus, or Helsinn Chemicals SA and Helsinn Advanced Synthesis SA, related to SANCTURA and SANCTURA XR, our agreements with

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BayerSchering, under which we licenses NEBIDO, or our agreement with Aventis, under which we license pagoclone, would materially harm us. The agreements with Allergan, Madaus, Aventis or BayerSchering may be terminated by any of them if we are in material breach of our agreements with them or if we become insolvent or file for bankruptcy protection. Termination of the supply agreement with Plantex USA Inc. for the supply of valrubicin, the active pharmaceutical ingredient for VALSTAR, could significantly hinder the potential to commercialize VALSTAR.

We will need additional funds in the near future.

We believe that our existing cash resources will be sufficient to fund our planned operations through December 2008. Our cash requirements and cash resources will vary significantly depending upon the following principal factors: