

INDEVUS PHARMACEUTICALS INC

Form S-8

January 08, 2008

Table of Contents

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**  
(State or other jurisdiction

of Incorporation)

**04-3047911**  
(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**

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form S-8

(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

<b>Title of Securities to be Registered</b>	<b>Amount to be Registered</b>	<b>Proposed Maximum Offering Price Per Share</b>	<b>Proposed Maximum Aggregate Offering Price</b>	<b>Amount of Registration Fee</b>
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.
-

**Table of Contents**

**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.

**Table of Contents**

**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

**Table of Contents**

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.**

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>Where You Can Find More Information</u>	1
<u>Information Incorporated by Reference</u>	2
<u>Special Note Regarding Forward Looking Statements</u>	3
<u>Indevus Pharmaceuticals, Inc.</u>	4
<u>Risk Factors</u>	5
<u>Use of Proceeds</u>	24
<u>Selling Stockholders</u>	25
<u>Description of Capital Stock</u>	26
<u>Shares Eligible for Future Sale</u>	28
<u>Plan of Distribution</u>	29
<u>Legal Matters</u>	31
<u>Experts</u>	31
<u>Disclosure of Commission Position on Indemnification for Securities Act Liabilities</u>	31

**Table of Contents**

**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 subsidiaries.



**Table of Contents**

**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.

**Table of Contents**

**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<sup>®</sup> (trospium chloride tablets), SANCTURA<sup>®</sup> XR (once-daily SANCTURA), NEBIDO<sup>®</sup>, (testosterone undecanoate), VANTAS<sup>®</sup> (histrelin implant for prostate cancer) and SUPPRELIN<sup>®</sup> 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 which 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<sup>®</sup> 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.

**Table of Contents**

**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 Novoxel 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.

---

**Table of Contents**

**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 SANCTURA 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.

## **Table of Contents**

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;

## Table of Contents

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.



---

**Table of Contents**

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.



## Table of Contents

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.



## **Table of Contents**

*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 exclusivity 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 trosipium 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;

## Table of Contents

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

## **Table of Contents**

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

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form S-8

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.

## **Table of Contents**

***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.



## **Table of Contents**

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.

## **Table of Contents**

### ***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 Laboratoires 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

## **Table of Contents**

BayerSchering, under which we license 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:

marketing success of SANCTURA, VANTAS and SUPPRELIN LA;

launch and marketing success of SANCTURA XR;

approval, launch and marketing success of NEBIDO;

the costs and progress of our research and development programs;

the timing and cost of obtaining regulatory approvals; and

the timing and cash flows of in-licensing or out-licensing products.

In addition, we continue to expend substantial funds for research and development, marketing, general and administrative expenses and manufacturing. We expect to continue to use substantial cash for operating activities in fiscal 2008 as we continue to fund our development activities for NEBIDO, the octreotide implant and other product candidates, as well as sales and marketing activities VANTAS, SUPPRELIN LA and VALSTAR. We are also co-promoting SANCTURA and SANCTURA XR.

We may seek or receive additional funding through corporate collaborations, strategic combinations or public or private equity and debt financing options. Any such corporate collaboration, strategic combination or financial transactions could result in material changes to the capitalization, operations, management and prospects for our business and no assurance can be given that the terms of any such transaction would be favorable to us or our security holders. If we raise additional funds by issuing equity securities, existing stockholders will be diluted and future investors may be granted rights superior to those of existing stockholders. There can be no assurance that additional financing will be available on terms acceptable to us or at all. If we sell securities in a private offering, we may have to sell such shares at a discount from the market price of our stock which could have a negative effect on our stock price. In addition, future resales of shares in the public market sold in a private offering could negatively affect our stock price.

As a result of the uncertainties and costs associated with business development activities, market conditions and other factors generally affecting our ability to raise additional funds, we may not be able to obtain sufficient additional funds to satisfy cash requirements in the future or may be required to obtain financing on terms that are not favorable to us. We may have to curtail our operations or delay development of our products.

### ***We have a history of losses and expect losses to continue.***

We have incurred substantial net losses over the past five fiscal years, including net losses of approximately \$31,800,000, \$68,200,000, \$53,200,000, \$50,600,000 and \$103,800,000 for fiscal years 2003, 2004, 2005, 2006 and 2007, respectively. At September 30, 2007 we had an accumulated deficit of approximately \$576,500,000.

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form S-8

We continue to experience losses and to use substantial amounts of cash in operating activities. We will be required to conduct significant development and clinical testing activities for the products we are developing and these activities are expected to result in continued operating losses and use of cash for the foreseeable future. We cannot predict the extent of future losses or the time required to achieve profitability.

## **Table of Contents**

### ***We may not be profitable in the future.***

We may never achieve or sustain profitability in the future. We expect to continue to experience fluctuations in revenue as a result of the timing of regulatory filings or approvals, product launches, license fees, royalties, product shipments, and milestone payments. We also continue to expect fluctuations in expense from the timing of clinical trials, payments to licensors for development milestones, and in licensing fees for new product candidates.

### ***We may be adversely impacted if our controls over external financial reporting fail or are circumvented.***

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes Oxley Act of 2002 to report annually on our internal control over financial reporting. If we, or our independent registered public accounting firm, determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees and as executive officers.

### ***As we continue to evolve from a company that was primarily involved in development to one also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.***

In order to continue to expand our current sales and commercialize our other product candidates, particularly NEBIDO, we currently anticipate that we will need to add some managerial, selling, operational, financial and other employees over the next two years. Expansion may place a strain on our management, operational and financial resources. Moreover, higher than expected market growth of our products, the acquisition or in-licensing of additional products, as well as the development and commercialization of our other product candidates or marketing arrangements with third parties, could accelerate our hiring needs beyond our current expectations. To manage further growth, we will be required to continue to improve existing, and implement additional, operational and financial systems, procedures and controls. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth and we may not be able to hire, train, retain, motivate and manage required personnel. Our failure to manage growth effectively could limit our ability to achieve our business goals.

As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls that could expose us to an increased risk of the occurrence of financial or accounting irregularities or fraud.

### ***We may be unable to integrate successfully the businesses of Valera and realize the anticipated benefits of the merger.***

In April 2007, we completed our merger with Valera Pharmaceuticals, Inc. The success of the merger will depend, in part, on our ability to realize the anticipated synergies, growth opportunities and cost savings from integrating Valera's business with our business. Our success in realizing these benefits and the timing of this realization depend upon the successful integration of the operations of Valera. The integration of two independent companies is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies include, among other factors:

coordinating geographically separated organizations, systems and facilities, including complexities associated with managing the combined businesses at two separate locations;

## Table of Contents

combining the sales force territories and competencies associated with the sale of products presently sold by Indevus or Valera;

integrating personnel from different companies while maintaining focus on providing consistent, high-quality products and customer service;

unforeseen expenses or delays associated with the merger; and

performance shortfalls as a result of the diversion of management's attention to the merger.

If we are unable to successfully combine the businesses of Indevus and Valera in a manner that permits the combined company to achieve the cost savings and operating synergies anticipated to result from the merger, such anticipated benefits of the merger may not be realized fully or at all or may take longer to realize than expected. In addition, it is possible that the integration process could result in the loss of key employees, the disruption or interruption of, or the loss of momentum in, inconsistencies between each company's standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, suppliers and employees or our ability to achieve the anticipated benefits of the merger, or could reduce our earnings or otherwise adversely affect the business and financial results of the combined company.

***We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect our stock price, operating results and results of operations.***

We may acquire companies, businesses and products that complement or augment our existing business. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Integrating any newly acquired business or product could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our on-going business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire companies, business or product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we may consummate in the future, whether as a result of unidentified risks, integration difficulties, regulatory setbacks and other events, our business, results of operations and financial condition could be adversely affected. If we acquire product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval, the costs of manufacturing, and the market for such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

In addition, we will likely experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants and other advisors in connection with our efforts. Even if our efforts are successful, we may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect our results of operations for particular quarterly or annual periods.

---

## **Table of Contents**

### ***We depend upon key personnel and consultants.***

We have a small number of employees and are dependent on certain executive officers and scientific personnel, including Glenn L. Cooper, our Chief Executive Officer, Thomas F. Farb, our President and Chief Operating Officer, Noah D. Beerman, our Chief Business Officer, Mark S. Butler, our Chief Administrative Officer and General Counsel, Michael W. Rogers, our Chief Financial Officer, and Bobby W. Sandage, Jr., our Chief Scientific Officer. Our business could be adversely affected by the loss of any of these individuals. In addition, we rely on the assistance of independent consultants to design and supervise clinical trials and prepare FDA submissions.

Competition for qualified employees, including sales people, among pharmaceutical and biotechnology companies is intense. If key employees terminate their employment, or insufficient numbers of employees are retained to maintain effective operations, our sales, marketing or development activities and prospects might be adversely affected. In addition, we might not be able to locate suitable replacements for any key employees that leave Indevus or offer employment to potential replacements on reasonable terms.

### **Risks Relating to Our Common Stock and Other Securities**

#### ***We may issue preferred stock with rights that could affect your rights and prevent a takeover of the business.***

Our board of directors has the authority, without further approval of our stockholders, to fix the rights and preferences, and to issue up to 5,000,000 shares of preferred stock, 244,425 of which were issued and outstanding as of January 3, 2008. In addition, vesting of shares of our common stock subject to awards under our 2004 Equity Incentive Plan accelerates, and outstanding options under our stock option plans become immediately exercisable, upon certain changes in control of Indevus, except under certain conditions. In addition, Delaware corporate law imposes limitations on certain business combinations. These provisions could, under certain circumstances, delay or prevent a change in control of Indevus and, accordingly, could adversely affect the price of our common stock.

#### ***We have never paid any dividends on our common stock.***

We have not paid any cash dividends on our common stock since inception and do not expect to do so in the foreseeable future. Any dividends on our common stock will be subject to the preferential cumulative annual dividend of \$0.1253 per share and \$1.00 per share payable on our outstanding Series B preferred stock and Series C preferred stock, respectively, held by Wyeth and dividends payable on any other preferred stock we may issue.

#### ***If we pay cash dividends on our common stock, certain holders of our securities may be deemed to have received a taxable dividend without the receipt of any cash.***

If we pay a cash dividend on our common stock which results in an adjustment to the conversion price of our outstanding convertible notes, holders of such notes may be deemed to have received a taxable dividend subject to U.S. federal income tax without the receipt of any cash.

#### ***The price for our securities is volatile.***

The market prices for our securities and for securities of emerging growth companies have historically been highly volatile. Future announcements concerning us or our competitors may have a significant impact on the market price of our securities. Factors which may affect the market price for our securities, among others, include:

market success of SANCTURA and VANTAS;

successful launch and commercialization of SANCTURA XR;

successful commercialization of SUPPRELIN LA;

results of clinical studies and regulatory reviews;



**Table of Contents**

marketing approval of NEBIDO;

sales by Valera's former stockholders of significant amounts of Indevus common stock they received in the merger or upon conversion of any contingent stock rights;

partnerships, corporate collaborations and company acquisitions;

announcements by our corporate collaboration partners concerning our products, about which we generally have very limited control, if any, over the timing or content;

changes in the levels we spend to develop, acquire or license new compounds;

market conditions in the pharmaceutical and biotechnology industries;

competitive products;

sales, the possibility of sales, or buybacks of Indevus' common stock or other financings, including resales of stock, stock issued upon conversion of the contingent stock rights issued in connection with the merger, issuance of additional debt and entering into credit facilities;

our results of operations and financial condition including variability in quarterly operating results due to timing and recognition of revenue, receipt of licensing, milestone and royalty payments, regulatory progress and delays and timing and recognition of certain expenses;

fluctuations in results of operations of the combined company of Indevus and Valera due to factors that affect the combined company that are different from those that affected the independent results of operations of each of Indevus or Valera prior to the merger;

changes in proprietary rights of our, or our competitors, products;

Redux-related litigation developments;

public concern as to the safety or commercial value of our products; and

general economic conditions.

The high and low sales prices of our common stock as reported by the NASDAQ Global Market were: \$12.83 and \$0.85 for fiscal 2002, \$6.90 and \$1.32 for fiscal 2003, \$10.25 and \$4.86 for fiscal 2004, \$7.45 and \$2.41 for fiscal 2005, \$6.75 and \$2.50 for fiscal 2006 and \$8.06 and \$5.58 for fiscal 2007. Our common stock is subject to delisting if our stock price drops below the bid price of \$1.00 per share. If we fail to meet any of the continued listing requirements for the NASDAQ Global Market, our common stock could be delisted from the NASDAQ Global Market, the effects of which could include limited release of a market price of our common stock, limited liquidity for stockholders and limited news coverage and could result in an adverse effect on the market for our common stock.

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form S-8

The stock markets also experience significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of our common stock.

Further, in connection with the merger we agreed under certain circumstances to register up to approximately 6,200,000 shares (less any shares sold prior to the time of registration) of our common stock acquired by SMH

## **Table of Contents**

Capital Inc. (and affiliated entities), or SMH, in connection with the merger for resale under the Securities Act on a Registration Statement on Form S-3. When sales of Indevus common stock by SMH or any other former Valera stockholder occur, the market price of our common stock could decline. These sales may also make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate to raise funds through future offerings of common stock.

***Impairment charges pertaining to goodwill, identifiable intangible assets or other long-lived assets from our merger with Valera could have an adverse impact on our results of operations and the market value of our common stock.***

The total estimated purchase price pertaining to our merger with Valera has been allocated to Valera's net tangible assets, identifiable intangible assets, in process research and development and goodwill. To the extent the value of goodwill or identifiable intangible assets or other long-lived assets become impaired, we will be required to incur material charges relating to the impairment. Any impairment charges could have a material adverse impact on our results of operations and the market value of our common stock.

***The price for our common stock could be negatively affected if we issue additional shares or if third parties exercise registration rights.***

Wyeth has the right, under certain circumstances, to require us to register for public sale 622,222 shares of our common stock issuable to it upon conversion of the Indevus Series B and Series C preferred stock it owns. We have outstanding registration statements on Form S-3 relating to the resale of our shares of common stock and on Form S-8 relating to shares issuable under our 1989 Stock Option Plan, 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan, 2000 Stock Option Plan, and 2004 Equity Incentive Plan. In addition, shares of our common stock may be issued upon conversion of the contingent stock rights issued in connection with the merger with Valera. The possibility of sales of such shares, private sales of securities or the possibility of resale of such shares in the public market may adversely affect the market price of our common stock.

***Our stockholders could be diluted if we issue our shares subject to options, warrants, convertible notes, stock awards or other arrangements.***

As of January 3, 2008, we had reserved the following shares of our common stock for issuance:

10,817,308 shares issuable in the aggregate upon conversion of the Convertible Senior Notes issued in July 2003, which are due in July 2008, referred to herein as the Old Notes (of which \$75,000 remain outstanding) and the Convertible Senior Notes issued in August 2007, which are due in July 2009, referred to herein as the New Notes (of which \$71,925,000 remain outstanding);

14,062,000 shares issuable upon exercise of outstanding options, Performance Stock Awards and deferred stock units, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if Indevus issues additional securities below certain prices;

622,222 shares upon conversion of preferred stock owned by Wyeth, subject to anti-dilution provisions; and

2,712,000 shares reserved for grant and issuance under our stock option, stock purchase and equity incentive plans.

We may grant additional options, warrants or stock awards. To the extent such shares are issued, the interest of holders of our common stock will be diluted.

In addition, we are obliged to issue shares of common stock upon achievement of development milestones related to contingent stock rights, or CSRs, issued in connection with the merger with Valera. As a result of the May 3, 2007 FDA approval of SUPPRELIN LA and our possession of a specified amount of inventory of commercially sellable units, approximately 2,300,000 shares were issued. The achievement of future milestones related to two other outstanding CSRs could result in the issuance of shares totaling approximately \$40,600,000.

**Table of Contents**

***Leverage as a result of our outstanding convertible notes may harm our financial condition and results of operations.***

At January 3, 2008, we had \$72,000,000 of outstanding debt reflected on our balance sheet relating to the Old Notes and New Notes. There currently is \$75,000 of Old Notes outstanding with a maturity date of July 15, 2008. There currently is \$71,925,000 of New Notes outstanding with a maturity date of July 15, 2009.

The noteholders may decide not to convert the New Notes. If the price of our common stock at the time the New Notes become due does not exceed \$8.50 for a specified period, then we may not be able to redeem the New Notes to cause a conversion, and then we may be obligated to repay the holders of the New Notes in cash on the July 2009 due date.

We may incur additional indebtedness in the future and the Old Notes and New Notes do not restrict our future issuance of indebtedness. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

a portion of our cash flow from operations will be dedicated to the payment of any interest required with respect to outstanding indebtedness;

increases in our outstanding indebtedness and leverage will increase our vulnerability to adverse changes in general economic and industry conditions, as well as to competitive pressure; and

depending on the levels of our outstanding debt, our ability to obtain additional financing for working capital, capital expenditures, general corporate and other purposes may be limited.

Our ability to make payments of principal and interest on our indebtedness depends upon our future performance, which will be subject to the success of our development and commercialization of new pharmaceutical products, general economic conditions, industry cycles and financial, business and other factors affecting our operations, many of which are beyond our control. If we are not able to generate sufficient cash flow from operations or other sources in the future to service our debt, we may be required, among other things:

To seek additional financing in the debt or equity markets;

to refinance or restructure all or a portion of our indebtedness, including the old notes or any new notes that may be issued;

To sell selected assets; or

to reduce or delay planned expenditures on clinical trials, and development and commercialization activities.

Such measures might not be sufficient to enable us to service our debt. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms.

***Our convertible senior notes may not be rated or may receive a lower rating than anticipated.***

If one or more rating agencies rates our outstanding convertible senior notes, collectively referred to herein as the Notes, assigns the Notes a rating lower than the rating expected by investors, or reduces its rating in the future, the market price of the Notes would be harmed.

**Table of Contents**

*The price of the Notes may fluctuate significantly as a result of the volatility of the price for our common stock.*

Because the Notes are convertible into shares of our common stock, volatility or depressed prices for our common stock could have a similar effect on the trading price of the Notes.

*If we are unable to pay all of our debts, the noteholders will receive payment on the Notes only if we have funds remaining after we have paid any future secured indebtedness.*

The Notes are unsecured and are effectively subordinated in right of payment to any future secured indebtedness that we may incur to the extent of the value of the pledged assets. If some or all of our assets are pledged to secure other obligations, there may not be sufficient assets remaining to pay amounts due on any or all of the outstanding Notes. In addition, we may be unable to fulfill our obligations to offer to repurchase the Notes upon a change of control.

*The Notes will effectively be subordinated to the debt of our subsidiaries.*

Our right to receive any assets of any of our subsidiaries upon their liquidation or reorganization, and therefore the right of the holders of the Notes to participate in those assets, will be effectively subordinated to the claim of that subsidiary's creditors, including trade creditors. In addition, even if we were a creditor of any of our subsidiaries, our rights as a creditor would be subordinate to any security interest in the assets of our subsidiaries and any indebtedness of our subsidiaries senior to that held by us. Our subsidiaries have no obligation to pay any amounts due on the Notes or to provide us with funds for our payment obligations, whether by dividends, distributions, loans or other payments. Furthermore, we are not limited in or prohibited from transferring cash or other assets to our subsidiaries from time to time.

**Table of Contents**

**USE OF PROCEEDS**

We will receive no part of the proceeds from sales made under this Reoffer Prospectus. The Selling Stockholders will bear all sales commissions and similar expenses. Any other expenses incurred by us in connection with the registration and offering and not borne by the Selling Stockholders will be borne by us. See Plan of Distribution.

**Table of Contents****SELLING STOCKHOLDERS**

This prospectus relates to shares of Common Stock that may be acquired by the Selling Stockholders named below in connection with grants of the Securities pursuant to the 2004 Plan.

Each of the Selling Stockholders is an employee or director of the Company. The following table sets forth:

the name and principal position of each of the Selling Stockholders with the Company;

the number of shares of Common Stock the Selling Stockholders beneficially owned as of January 3, 2008;

the number of Shares acquired (or to be acquired) by the Selling Stockholders and being registered under this Registration Statement, some or all of which shares may be sold pursuant to this prospectus; and

the number of shares of Common Stock and the percentage, if 1% or more, of the total class of Common Stock outstanding to be beneficially owned by the Selling Stockholders following this offering, assuming the sale pursuant to this offering of all Shares acquired (or to be acquired) by the Selling Stockholders and registered under this Registration Statement.

There is no assurance that the Selling Stockholders will sell any or all of the shares offered by him or her under this Registration Statement. The information included in the table assumes that the Selling Stockholders will receive and elect to sell all of his Shares covered by this Prospectus.

Selling Stockholders	Position	Shares		Shares Beneficially	
		Beneficially Owned (1)	Shares Covered by this Prospectus (2)	Owned After this Offering Number (3)	Percentage (4)
Glenn L. Cooper	Chairman of the Board of Directors and Chief Executive Officer	3,206,088	110,800	3,164,088	3.3%
Thomas F. Farb	President and Chief Operating Officer	254,800	170,300	187,500	*%
Noah D. Beerman	Executive Vice President, Chief Business Officer	478,188	36,000	464,688	*%
Mark S. Butler	Executive Vice President, Chief Administrative Officer and General Counsel, Assistant Secretary	1,256,267	36,000	1,242,767	1.3%
Michael W. Rogers	Executive Vice President, Chief Financial Officer and Treasurer	1,578,055	36,000	1,564,555	1.6%
Bobby W. Sandage, Jr., Ph.D.	Executive Vice President, Research and Development, Chief Scientific Officer	1,502,621	36,000	1,489,121	1.6%
Andrew Ferrara	Director	12,500	8,000	12,500	*%
Michael E. Hanson	Director	54,375	8,000	54,375	*%
Stephen C. McCluski	Director	80,938	8,000	80,938	*%
Cheryl P. Morley	Director	80,938	8,000	80,938	*%

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form S-8

Malcolm Morville	Director	161,438	8,000	161,438	*%
------------------	----------	---------	-------	---------	----

\* Represents less than 1%.

- (1) Includes shares of Common Stock owned (including the portion of the Shares covered by this Prospectus that pertain to the Restricted Stock Awards) and shares issuable upon exercise of options which are exercisable within 60 days of January 3, 2008. None of the Shares underlying the Performance Stock Award vest within 60 days of January 3, 2008 and thus such Shares are excluded from this column (although such Shares are being registered for resale).
- (2) For the executive officers of the Company, includes the Shares underlying the respective Restricted Stock Award and the maximum number of Shares that may vest under the respective Performance Stock Award. For each director, the column includes 8,000 Shares subject to deferred stock units. See [Shares Eligible for Future Sale](#) for additional information regarding these Securities.
- (3) Represents the number of shares of Common Stock owned on January 3, 2008 (assuming the resale of the Shares covered by this Prospectus) and shares issuable upon exercise of options which are exercisable within 60 days of January 3, 2008.
- (4) The percent of class in this column is calculated on the basis of 76,633,407 shares outstanding plus options exercisable within 60 days of January 3, 2008, the Shares covered by this prospectus, 10,817,308 shares to be issued in the aggregate upon conversion of our Notes, and excluding 622,222 shares of Common Stock issuable upon conversion of our outstanding preferred stock owned by Wyeth.



**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

*The following summary of our capital stock is subject in all respects to the applicable provisions of the Delaware General Corporation Law, which we refer to as the DGCL, our restated certificate of incorporation, as amended, our certificate of designation which sets forth the rights and preferences of certain of our preferred stock and our bylaws, as amended. The following summary of certain provisions of the common stock and preferred stock is not complete and may not contain all the information important to you. We encourage you to read this entire prospectus, the relevant provisions of the DGCL, our restated certificate of incorporation, our certificate of designation and our bylaws, which are incorporated by reference in their entirety into this prospectus.*

**Authorized Capital Stock**

Under our restated certificate of incorporation, as amended, we are authorized to issue up to 200,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share.

**Common Stock**

As of January 3, 2008, there were 76,655,088 shares of common stock issued and outstanding held of record by approximately 598 record holders. Holders of common stock are entitled to one vote at all meetings of stockholders for each share held by them. Holders of common stock have no preemptive rights and have no other rights to subscribe for additional shares or any conversion right or right of redemption. Holders of common stock are entitled to receive such dividends as may be declared by the board of directors out of funds legally available therefor. Subject to the rights of holders of preferred stock, if any, upon liquidation, all such holders are entitled to participate pro rata in our assets available for distribution. All outstanding shares of our common stock are fully paid and nonassessable.

**Preferred Stock**

Our restated certificate of incorporation authorizes the issuance of 5,000,000 shares of preferred stock. The board of directors, within the limitations and restrictions contained in the certificate of incorporation and without further action by our stockholders, has the authority to issue preferred stock from time to time in one or more series and to fix the number of shares and the relative rights, conversion rights, voting rights, rights and terms of redemption, liquidation preferences and any other preferences, special rights and qualifications of any such series. To the extent shares of preferred stock with voting rights are issued, such issuance affects the voting rights of the holders of our common stock by increasing the number of outstanding shares entitled to vote and, if applicable, by

## **Table of Contents**

the creation of class or series voting rights. In addition, while the issuance of preferred stock can provide flexibility in connection with acquisitions and other corporate purposes, any issuance of preferred stock could, under certain circumstances, have the effect of delaying or preventing a change in control of Indevus and may adversely affect the rights of holders of common stock. We currently have no agreements or arrangements to issue any additional shares of preferred stock or to establish or designate any additional series of preferred stock.

In November 1992 and June 1993, we sold 239,425 shares of Series B preferred stock and 5,000 shares of Series C preferred stock, respectively, to Wyeth, for an aggregate purchase price of \$3,500,000. Until the date Wyeth ceases to be the registered holder of all of the outstanding preferred stock of at least one series, we may not, without the approval of the majority of the outstanding shares of all series of preferred stock issued to Wyeth, (i) issue shares of stock having a preference or, except shares issued to Wyeth, ranking pari passu with the outstanding series; (ii) reclassify any shares of stock to shares having a preference over any such series; (iii) make any amendment to our certificate of incorporation or by-laws adversely affecting the rights of holders of such series; (iv) pay dividends or make any other distribution on any common stock, except a distribution payable entirely in common stock, unless at the same time a payment is made to the holder of such series equal to the amount the holder would have been entitled to had such holder converted its Series B and Series C preferred stock into common stock; (v) repurchase or redeem any shares of Indevus common stock; or (vi) guarantee any indebtedness of any third party, except a subsidiary.

In deciding all matters that come before a meeting of stockholders, other than the election of directors for which preferred stock is not entitled to vote, the holders of the Series B preferred stock and Series C preferred stock are entitled to cast an aggregate of 568,850 votes relating to the 622,222 shares of common stock issuable upon conversion of the respective shares of preferred stock. The holders of the common stock and preferred stock vote together as a single class, except for those matters on which holders of preferred stock are entitled to vote as a separate class.

As of January 3, 2008, we had 239,425 and 5,000 shares of Series B and Series C preferred stock outstanding, respectively.

## **Options, Stock Awards and Deferred Stock Units**

As of January 3, 2008, approximately 14,062,000 shares of Common Stock were issuable upon exercise of outstanding options, performance stock awards and deferred stock units, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if we issue additional securities below certain prices.

## **Transfer Agent And Registrar**

American Stock Transfer & Trust Company, New York, New York, serves as transfer agent and registrar for our common stock.

## **Nasdaq Global Market Listing**

Our common stock trades on The Nasdaq Global Market under the symbol IDEV.

---

**Table of Contents**

**SHARES ELIGIBLE FOR FUTURE SALE**

As of January 3, 2008, approximately 76,655,088 shares of Common Stock were outstanding. Substantially all of these shares are eligible for sale without restriction or under Rule 144. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including persons who may be deemed to be affiliates of Indevus as that term is defined under the Securities Act, is entitled to sell within any three-month period a number of restricted shares beneficially owned for at least one year that does not exceed the greater of (i) one percent of the then outstanding shares of Common Stock, or (ii) the average weekly trading volume in the Common Stock during the four calendar weeks preceding such sale. Sales under Rule 144 are also subject to certain requirements as to the manner of sale, notice and the availability of current public information about us. However, a person who is not an affiliate and has beneficially owned such shares for at least two years is entitled to sell such shares without regard to the volume or other requirements.

A stockholder of the Company has demand and piggy-back registration rights relating to 622,222 shares of Common Stock issuable upon conversion of preferred stock.

In addition to the registration statement covering 9,000,000 shares of Common Stock issuable under the 2004 Plan, of which this Prospectus forms a part, we have outstanding registration statements on Form S-3 relating to the resale of shares of Common Stock and on Form S-8 relating to our other compensation plans, including our 1989 Stock Option Plan, 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan, and the 2000 Employee Stock Option Plan (as amended, the Plans ) in order to permit holders of options and shares issued pursuant to the Plans, other than affiliates of Indevus, to sell, without restriction, shares of Common Stock issued pursuant to the Plans.

All of the shares of Common Stock issuable under the 2004 Plan, including the 465,100 Shares offered hereby, can be sold by the recipient thereof immediately upon vesting of the Securities. 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.

The 40,000 Shares vest in three equal annual increments on April 30, 2008, 2009 and 2010. Upon the earlier of each 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.

All such vesting dates are subject to extension of each vesting date if it occurs during a Black Out Period, generally meaning a period in which the recipient (including the Selling Stockholders) is unable to sell the Shares subject to the award at the applicable vesting date due to legal or contractual restrictions. The vesting dates

**Table of Contents**

are also subject to acceleration under certain circumstances, including certain changes in control of Indevus, except under certain conditions. Sales of the Shares of Common Stock subject to the Stock Awards or the possibility of sales of such Shares may adversely affect the market price of our Common Stock.

**PLAN OF DISTRIBUTION**

We are registering 465,100 shares of our common stock for possible sale by the Selling Stockholders. Unless the context otherwise requires, as used in this prospectus, Selling Stockholders includes the Selling Stockholders named in the table above and donees, pledgees, transferees or other successors-in-interest selling shares received from the Selling Stockholders as a gift, pledge, partnership distribution or other transfer after the date of this prospectus.

The Selling Stockholders may offer and sell all or a portion of the Shares covered by this prospectus from time to time, in one or more or any combination of the following transactions:

on The Nasdaq Global Market, in the over-the-counter market or on any other national securities exchange on which our shares are listed or traded;

in privately negotiated transactions;

in underwritten transactions;

in a block trade in which a broker-dealer will attempt to sell the offered shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

through purchases by a broker-dealer as principal and resale by the broker-dealer for its account pursuant to this prospectus;

in ordinary brokerage transactions and transactions in which the broker solicits purchasers; and

through the writing of options (including put or call options), whether the options are listed on an options exchange or otherwise. The Selling Stockholders may sell the Shares at prices then prevailing or related to the then current market price or at negotiated prices. The offering price of the shares from time to time will be determined by the Selling Stockholders and, at the time of the determination, may be higher or lower than the market price of our common stock on The Nasdaq Global Market or any other exchange or market.

The Shares may be sold directly or through broker-dealers acting as principal or agent, or pursuant to a distribution by one or more underwriters on a firm commitment or best-efforts basis. The Selling Stockholders may also enter into hedging transactions with broker-dealers. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of our common stock in the course of hedging the positions they assume with the Selling Stockholders. The Selling Stockholders may also enter into options or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of Shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). In connection with an underwritten offering, underwriters or agents may receive compensation in the form of discounts, concessions or commissions from the Selling Stockholders or from purchasers of the offered Shares for whom they may act as agents. In addition, underwriters may sell the shares to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or



## Table of Contents

commissions from the purchasers for whom they may act as agents. In connection with any particular offering pursuant to this shelf registration statement, an underwriter may engage in stabilizing transactions, short sales, syndicate covering transactions and penalty bids. The Selling Stockholders and any underwriters, dealers or agents participating in a distribution of the Shares may be deemed to be underwriters within the meaning of the Securities Act, and any profit on the sale of the Shares by the Selling Stockholders and any commissions received by broker-dealers may be deemed to be underwriting commissions under the Securities Act. Agents, underwriters, dealers or their affiliates, may be customers of, engage in transactions with or perform services for us, in the ordinary course of business.

We and the Selling Stockholders may agree to indemnify an underwriter, broker-dealer or agent against certain liabilities related to the selling of the common stock, including liabilities arising under the Securities Act. We have also agreed to pay the costs, expenses and fees of registering the Shares of common stock; however, the Selling Stockholders will pay any underwriting discounts and commissions, transfer taxes and fees and expenses of legal counsel of the Selling Stockholders.

We are not aware that any Selling Stockholders have entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of its Shares. Upon our notification by the Selling Stockholders that any material arrangement has been entered into with an underwriter or broker-dealer for the sale of Shares through a block trade, special offering, exchange distribution, secondary distribution or a purchase by an underwriter or broker-dealer, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing certain material information, including:

the name of the Selling Stockholders;

the number of shares being offered;

the terms of the offering;

the names of the participating underwriters, broker-dealers or agents;

any discounts, commissions or other compensation paid to underwriters or broker-dealers and any discounts, commissions or concessions allowed or reallocated or paid by any underwriters to dealers;

the public offering price; and

other material terms of the offering.

The Selling Stockholders are subject to the applicable provisions of the Exchange Act and the rules and regulations under the Exchange Act, including Regulation M. This regulation may limit the timing of purchases and sales of any of the Shares of common stock offered in this prospectus by the Selling Stockholders. The anti-manipulation rules under the Exchange Act may apply to sales of shares in the market and to the activities of the Selling Stockholders and their affiliates. Furthermore, Regulation M may restrict the ability of any person engaged in the distribution of the shares to engage in market-making activities for the particular securities being distributed for a period of up to five business days before the distribution. The restrictions may affect the marketability of the Shares and the ability of any person or entity to engage in market-making activities for the shares.

To the extent required, this prospectus may be amended and/or supplemented from time to time to describe a specific plan of distribution. Instead of selling the Shares of common stock under this prospectus, the Selling Stockholders may sell the Shares of common stock in compliance with the provisions of Rule 144 under the Securities Act, if available, or pursuant to other available exemptions from the registration requirements of the Securities Act.



**Table of Contents**

**LEGAL MATTERS**

Certain legal matters with respect to the validity of the Shares will be passed upon for us by Burns & Levinson LLP, Boston, Massachusetts.

**EXPERTS**

The financial statements and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Report on Internal Control over Financial Reporting) incorporated in this prospectus by reference to the Annual Report on Form 10-K of Indevus Pharmaceuticals, Inc. for the year ended September 30, 2007, have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

Ernst & Young LLP, independent registered public accounting firm, has audited the financial statements and schedule included in Valera Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2006 as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. The financial statements of Valera Pharmaceuticals, Inc. and schedule are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

**DISCLOSURE OF COMMISSION POSITION ON**

**INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the Company as discussed in the section "Indemnification of Officers and Directors" in Part II of the Registration Statement on Form S-8, of which this prospectus is a part, the Company has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.



**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
Where You Can Find More Information	1
Information Incorporated by Reference	2
Special Note Regarding Forward-Looking Statements	3
Indevus Pharmaceuticals, Inc.	4
Risk Factors	5
Use of Proceeds	24
Selling Stockholders	25
Description of Capital Stock	26
Shares Eligible for Future Sale	28
Plan of Distribution	29
Legal Matters	31
Experts	31
Disclosure of Commission Position on Indemnification for Securities Act Liabilities	31

**Table of Contents**

**PART II**

**INFORMATION REQUIRED IN REGISTRATION STATEMENT**

**ITEM 3. INCORPORATION OF DOCUMENTS BY REFERENCE**

The following documents filed by the Company with the Commission (File No. 0-18728) pursuant to the Exchange Act are incorporated herein by reference:

- (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.

Any statement contained in any document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as modified or superseded, to constitute a part of this Registration Statement.

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.

**Table of Contents**

**ITEM 4. DESCRIPTION OF SECURITIES**

The class of securities to be offered is registered under Section 12 of the Exchange Act.

**ITEM 5. INTERESTS OF NAMED EXPERTS AND COUNSEL**

None.

**ITEM 6. INDEMNIFICATION OF OFFICERS AND DIRECTORS**

Section 145(a) of the Delaware General Corporation Law (the "DGCL") empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director or officer of the corporation, or is or was serving at the request of the corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. Under Section 145(a) of the DGCL, the termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

Section 145(b) of the DGCL empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

Section 145(c) of the DGCL further provides that to the extent that a present or former director or officer of a corporation has been successful in the defense of any action, suit or proceeding referred to in subsection (a) and (b) or in the defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him or her in connection therewith. Section 145(e) also provides that expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding may be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the corporation as authorized in Section 145. With respect to former directors and officers, such expenses (including attorneys' fees) incurred by such persons may be so paid upon such terms and conditions, if any, as the corporation deems appropriate.

**Table of Contents**

Section 145 additionally provides that the indemnification and advancement of expenses provided by Section 145 shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors, or otherwise; and that the scope of indemnification under Section 145 extends to the directors and officers of a constituent corporation absorbed in a consolidation or merger and persons serving at the request of the constituent corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise to the extent that the constituent corporation or such person, as applicable, would have had such power or rights if the separate existence of the constituent corporation had continued.

Article Seventh of Indevus Restated Certificate of Incorporation, as amended, provides that Indevus shall indemnify any person to the full extent permitted by the DGCL. In addition, Article V of Indevus By-Laws provides that Indevus shall, to the fullest extent permitted by Delaware law, indemnify any and all persons whom it shall have the power to indemnify against any and all of the costs, expenses, liabilities or other matters incurred by such persons by reason of having been officers or directors of Indevus, any subsidiary of Indevus or of any other corporation for which such person acted as officer or director at the request of Indevus. Indevus has entered into indemnification agreements with its directors and officers. These agreements provide for full indemnification, including indemnification for judgments or settlements against a director or officer in favor of Indevus, with certain exceptions. This indemnity could apply to liabilities under the Securities Act of 1933 in certain circumstances.

Section 102(b)(7) of the DGCL empowers a corporation to include a provision in its certificate of incorporation limiting a director's liability to the corporation or its stockholders for monetary damages for breaches of fiduciary duty as a director. Article SIXTH of Indevus Restated Certificate of Incorporation, as amended, provides that no director of Indevus shall be liable to Indevus or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to Indevus or its stockholders; (ii) for acts or commissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) under Section 174 of the DGCL (involving improper dividend payments, stock repurchases or redemptions); or (iv) for any transaction from which the director derived an improper personal benefit.

Section 145(g) of the DGCL also empowers a corporation to purchase and maintain insurance on behalf of any person who is or was a director or officer of the corporation or is or was serving at the request of the corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person or incurred by such person in any such capacity or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under Section 145. Indevus maintains insurance policies under which the directors and officers of Indevus are insured, within the limits and subject to the limitations of the policies, against certain expenses in connection with the defense of actions, suits or proceedings, and certain liabilities which might be imposed as a result of such actions, suits or proceedings, to which they are parties by reason of being or having been such directors or officers, which could include liabilities under the Securities Act of 1933.

**Table of Contents**

**ITEM 7. EXEMPTION FROM REGISTRATION CLAIMED**

Inapplicable

**ITEM 8. EXHIBITS**

**Exhibits Description of Document**

- 4.1 Provisions of the Restated Certificate of Incorporation of Indevus, as amended, that define the rights of securityholders of Indevus (incorporated by reference to Exhibit 3.4 to our Annual Report on Form 10-K filed with the SEC on December 14, 2005 and Exhibit 3.1 to our Quarterly Report on Form 10-Q filed with the SEC on May 10, 2007)
- 4.2 Provisions of the By-laws of Indevus, as amended and restated December 4, 2007, that define the rights of securityholders of Indevus (incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K filed with the SEC on December 7, 2007)
- 4.3 Amendment No. 5 to the 2004 Plan (1)
- 5 Opinion of Burns & Levinson LLP (1)
- 23.1 Consent of PricewaterhouseCoopers LLP (1)
- 23.2 Consent of Ernst & Young LLP (1)
- 23.3 Consent of Burns & Levinson LLP (included in Exhibit 5)
- 24.1 Power of Attorney (included in signature pages hereto)

---

(1) Filed herewith.

## **Table of Contents**

### **ITEM 9. UNDERTAKINGS**

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement
  - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;
  - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;  
provided, however, that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Lexington, Commonwealth of Massachusetts, on the 8<sup>th</sup> day of January, 2008.

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Glenn L. Cooper  
 Title: Chairman of the Board of

Directors and Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints jointly and severally, Glenn L. Cooper, M.D. and Michael W. Rogers, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement on Form S-8, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in facts and agents, or either of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

/s/ Glenn L. Cooper	Chairman of the Board of Directors and	January 8, 2008
<b>Glenn L. Cooper, M.D.</b>	Chief Executive Officer	
/s/ Andrew Ferrara	Director	January 8, 2008
<b>Andrew Ferrara</b>		
/s/ Michael E. Hanson	Director	January 8, 2008
<b>Michael E. Hanson</b>		
/s/ Stephen C. McCluski	Director	January 8, 2008
<b>Stephen C. McCluski</b>		
/s/ Cheryl P. Morley	Director	January 8, 2008
<b>Cheryl P. Morley</b>		
/s/ Malcolm Morville	Director	January 8, 2008
<b>Malcolm Morville, Ph.D.</b>		





**Table of Contents**

/s/ Michael W. Rogers	Executive Vice President Treasurer and	January 8, 2008
<b>Michael W. Rogers</b>	Chief Financial Officer (Principal Financial Officer)	
/s/ Dale Ritter	Senior Vice President, Finance	January 8, 2008
<b>Dale Ritter</b>	(Principal Accounting Officer)	

**Table of Contents**

**EXHIBIT INDEX**

**Exhibits Description of Document**

4.1	Provisions of the Restated Certificate of Incorporation of Indevus, as amended, that define the rights of securityholders of Indevus (incorporated by reference to Exhibit 3.4 to our Annual Report on Form 10-K filed with the SEC on December 14, 2005 and Exhibit 3.1 to our Quarterly Report on Form 10-Q filed with the SEC on May 10, 2007)
4.2	Provisions of the By-laws of Indevus, as amended and restated December 4, 2007, that define the rights of securityholders of Indevus (incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K filed with the SEC on December 7, 2007)
4.3	Amendment No. 5 to the 2004 Plan (1)
5	Opinion of Burns & Levinson LLP (1)
23.1	Consent of PricewaterhouseCoopers LLP (1)
23.2	Consent of Ernst & Young LLP (1)
23.3	Consent of Burns & Levinson LLP (included in Exhibit 5)
24.1	Power of Attorney (included in signature pages hereto)

---

(1) Filed herewith.