

INDEVUS PHARMACEUTICALS INC

Form S-3

December 28, 2005

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As filed with the Securities and Exchange Commission on December 28, 2005

Registration No. 333-

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

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FORM S-3

REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

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**INDEVUS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or other jurisdiction of

incorporation or organization)

**04-3047911**

(I.R.S. Employer

Identification No.)

**33 Hayden Avenue**

**Lexington, MA 02421-7966**

**(781) 861-8444**

(Address, including zip code, and telephone number, including area code of registrant's principal executive offices)

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

**33 Hayden Avenue**

**Lexington, MA 02421-7966**

**(781) 861-8444**

**(Name, address, including zip code and telephone number, including area code, of agent for service)**

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**Josef B. Volman, Esq.**

**Burns & Levinson LLP**

**125 Summer Street**

**Boston, MA 02110-1624**

**(617) 345-3000**

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APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this Registration Statement:

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: "

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. "

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. "

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**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(1)</b>	<b>Proposed Maximum Aggregate Offering Price(1)</b>	<b>Amount of Registration Fee(1)(2)</b>
Common Stock, Par Value \$.001 per share	10,000,000	\$ 4.95	\$ 49,500,000	\$ 5,297.00

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- (1) Estimated in accordance with Rule 457(c) of the Securities Act solely for the purpose of computing the amount of registration fee based on the average of the high and low prices of the registrant's Common Stock as reported on The Nasdaq National Market on December 22, 2005.
  - (2) Calculated in accordance with Rule 457(o) of the Securities Act.
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**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**INFORMATION CONTAINED IN THIS PROSPECTUS IS SUBJECT TO COMPLETION OR AMENDMENT. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT BECOMES EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL AND IS NOT A SOLICITATION OF AN OFFER TO BUY IN ANY STATE IN WHICH AN OFFER, SOLICITATION OR SALE IS NOT PERMITTED.**

**SUBJECT TO COMPLETION, DATED DECEMBER 28, 2005**

**PROSPECTUS**

**INDEVUS PHARMACEUTICALS, INC.**

**10,000,000 SHARES**

**COMMON STOCK, \$.001 PAR VALUE PER SHARE**

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The shares of common stock of Indevus Pharmaceuticals, Inc. covered by this prospectus may be offered and sold to the public by Indevus from time to time in one or more issuances.

Our common stock is quoted on the Nasdaq National Market under the symbol IDEV. The closing sales price of our common stock on the Nasdaq National Market on December 22, 2005 was \$5.13 per share.

This prospectus provides you with a general description of the shares that we may offer. Each time we sell shares, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading *Where You Can Find More Information* before you make your investment decision.

We will sell the shares to underwriters or dealers, through agents, or directly to investors.

**Investing in these securities involves a high degree of risk. You should carefully consider the RISK FACTORS beginning on page 4 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 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 \_\_\_\_\_, 20\_\_.**

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**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under the shelf process, we may, from time to time, issue and sell to the public any part or all of the shares described in the registration statement in one or more offerings up to an aggregate of 10,000,000 shares.

This prospectus provides you with a general description of the securities we may offer. Each time we offer securities, we will provide you with a prospectus supplement that will describe the specific amounts, prices, and terms of the securities we offer. The prospectus supplement also may add, update, or change information contained in this prospectus. You should read both this prospectus and, if applicable, any prospectus supplement together with the information incorporated by reference in this prospectus. See [Where You Can Find More Information](#) and [Information Incorporated by Reference](#) for more information.

We may sell the securities to or through underwriters, dealers, or agents or directly to purchasers. We and our agents reserve the sole right to accept and to reject in whole or in part any proposed purchase of securities. A prospectus supplement, which we will provide to you each time we offer securities, will provide the names of any underwriters, dealers, or agents involved in the sale of the securities, and any applicable fee, commission, or discount arrangements with them.

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone else to provide you with different information. If anyone provides you with different information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any document incorporated by reference in this prospectus is accurate only as of the date on the front cover of the applicable document or as specifically indicated in the document. Our business, financial condition, results of operations and prospects may have changed since that date.

Unless otherwise indicated, in this prospectus, [Indevus](#), [the Company](#), [we](#), [us](#) and [our](#) refer to [Indevus Pharmaceuticals, Inc.](#) and its subsidiaries.

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**SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS**

Statements in this prospectus, and the documents incorporated by reference into this prospectus, that are not statements or descriptions of historical facts are forward-looking statements under Section 21E of the Securities Exchange Act of 1934, as amended, (the Exchange Act ) and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the SEC, 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) and SANCTURA XR (once-a-day SANCTURA); 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 predict or indicate future 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 and SANCTURA XR; the early stage of product candidates under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA and SANCTURA XR; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR; dependence on third parties for manufacturing, marketing and clinical trials; competition; need for additional funds and corporate partners, including for the development of our products; failure to acquire and develop additional product candidates; history of operating losses and expectation of future losses; product liability and insurance uncertainties; risks relating to the Redux-related litigation; our reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity; valuation of our common stock; risks related to repayment of debts; risks related to increased leverage; and other risks. The forward-looking statements represent our judgment and expectations as of the date of this prospectus. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward-looking statements. See Risk Factors.



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**INDEVUS PHARMACEUTICALS, INC.**

Indevus is a biopharmaceutical company engaged in the acquisition, development and commercialization of pharmaceutical products and product candidates primarily focused in the areas of urology, gynecology and men's health. We currently market SANCTURA for overactive bladder ( OAB ) and we have six compounds in clinical development.

Our urology, gynecology and men's health portfolio contains one marketed product and four compounds in development. SANCTURA, launched in August 2004, is co-promoted with Esprit Pharma Holding Company ( Esprit ). SANCTURA XR, currently in Phase III trials, is a once-a-day formulation of SANCTURA. NEBIDO<sup>®</sup>, for male hypogonadism, was licensed from Schering AG, Germany ( Schering ) in July 2005. PRO 2000 is a topical microbicide for the prevention of infection by HIV and other sexually-transmitted diseases ( STDs ). IP 751 is for pain and inflammatory disorders, including interstitial cystitis.

In December 2005, we entered into an agreement to acquire Delatestryl<sup>®</sup> (testosterone enanthate), a marketed injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient Pharmaceuticals, Inc. The acquisition of Delatestryl is expected to close in January 2006 subject to certain contractual and financial conditions.

Additional compounds in development include pagoclone, a GABA (gamma amino butyric acid) receptor modulator which we are developing for the treatment of stuttering, and aminocandin, an echinocandin for systemic fungal infections. In addition, we are receiving royalties under a patent we licensed to Eli Lilly & Company ( Lilly ) based on net sales of Sarafem<sup>®</sup> in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual dysphoric disorder.

**Our Strategy**

Our goal is to become a leading biopharmaceutical company focused in urology, gynecology and men's health. The key elements of our strategy that we employ in our efforts to achieve our goal include:

- (1) Identifying and acquiring products and product candidates with differentiating features and defined specialty markets within our core focus area.
- (2) Adding value to acquired development stage compounds through research, pre-clinical development, clinical testing and regulatory review activities.
- (3) Commercializing products independently with our specialty sales force or in collaboration with corporate partners in order to help ensure broader penetration of target markets.

**Core Focus Area Urology, Gynecology, Men's Health**

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In the urology, gynecology and men's health markets, we believe we have developed strong capabilities in product development based on our research and development organization and in sales and marketing based on our subsidized 85 person specialty sales force and our marketing organization.

Through our business development efforts and our research and development capabilities, we have a robust late-stage product pipeline. We believe our capabilities will enable us to continue to successfully acquire, develop and commercialize products and product candidates and achieve our strategic goal of becoming a leading biopharmaceutical company in our core focus area.

Indevus Pharmaceuticals, Inc. is a Delaware corporation. Our principal office is at 33 Hayden Avenue, Lexington, Massachusetts 02421-7966 and our main telephone number is (781) 861-8444.

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**RISK FACTORS**

*Investing in our company involves a high degree of risk. Before purchasing the common stock you should carefully consider the following risk factors in conjunction with the other information contained in this prospectus, including the financial statements in our Annual Report on Form 10-K for the year ended September 30, 2005. 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 Related to Our Business**

***We are dependent on SANCTURA.***

We currently derive substantially all of our revenue from Esprit under the SANCTURA Agreement. SANCTURA is our only FDA-approved product and we believe that revenues derived under the SANCTURA Agreement will continue to account for substantially all of our revenue for the foreseeable future. We are highly dependent on Esprit for the commercialization and marketing of SANCTURA and for performance of its obligations under the SANCTURA Agreement. The failure of Esprit to perform its obligations under this agreement could adversely affect our business, financial condition and results of operations. In particular, if sales of SANCTURA do not increase, we are unlikely to derive royalties in excess of the minimum royalties under the SANCTURA Agreement and, after the minimum royalty period expires in June 2008, our royalty revenue may decrease substantially. SANCTURA may suffer from generic penetration after the expiration of the market exclusivity period in May 2009 and competes with many once-a-day and other formulations of products to treat OAB. Our long-term success will be highly dependent on our ability to successfully develop, manufacture and commercialize SANCTURA XR. If SANCTURA does not continue to achieve market acceptance or if Esprit provides notice to us that it does not intend to pay us the development milestone related to FDA approval of SANCTURA XR causing the rights to SANCTURA XR to revert to us, then the marketing of SANCTURA XR may be adversely affected and if efforts to develop and market SANCTURA XR are unsuccessful, our business, financial condition and results of operations may be materially adversely affected.

Because our marketing resources are limited, we may be unable to devote sufficient resources to SANCTURA to achieve increasing market acceptance of SANCTURA in the highly competitive marketplace for overactive bladder therapies. Our failure to expend the resources to adequately promote SANCTURA would have a material adverse effect on our business and results of operations.

Moreover, because we have fewer sales representatives than our competitors, our sales force may be unable to detail successfully to physicians who prescribe overactive bladder medications. We may not be able to retain our current sales representatives. Even if we hire additional representatives, they may not be effective in promoting the sale of SANCTURA. The failure of our sales representatives to be successful in selling SANCTURA would have a material adverse effect on operating results.

***We are dependent on third parties to manufacture SANCTURA***

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We are currently dependent on Madaus to manufacture SANCTURA and on other third parties in the supply chain, including the manufacturer of trospium chloride, the active pharmaceutical ingredient. If Madaus or any of the other third parties were unable to 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.

*We may not compete successfully in the overactive bladder market*

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Competition in the overactive bladder market is intense, has increased since the launch of SANCTURA in August 2004 and is expected to increase further. SANCTURA may not compete successfully with current drug therapies for overactive bladder or with new drugs which may reach the market in the future. SANCTURA competes with drugs and other therapies for overactive bladder marketed by many large, multinational companies who have substantially greater marketing and financial resources and experience than us. In addition, antimuscarinic and antispasmodics for overactive bladder are the subject of testing or commercialization efforts by other companies, including certain treatments for which NDAs have already been filed or may be filed in the future. Launches of other competitive products are expected to 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.

Our license for SANCTURA does not include any patents that we expect to use in commercializing the product for overactive bladder. 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. We cannot predict whether any patents will issue on the applications we have filed for SANCTURA XR, an extended release, once-a-day formulation of SANCTURA. 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 were unable to obtain a patent on such formulation we would have to rely solely on market exclusivity for this formulation, which would be shorter than five years.

### ***We have regulatory and guideline risks***

On May 28, 2004, the FDA approved SANCTURA. The FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of SANCTURA. In addition, although SANCTURA 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.

If SANCTURA were to 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.

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 SANCTURA is sold.

Government agencies promulgate regulations and guidelines directly applicable to us and SANCTURA. 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 SANCTURA or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of SANCTURA.

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Acceptable levels of reimbursement for costs of developing and manufacturing of pharmaceutical products and treatments related to those pharmaceutical products by government authorities, private health insurers and other organizations, such as HMOs, will have an effect on the successful commercialization of, and attracting collaborative partners to invest in the development of, our products and product candidates. 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

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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. 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 may not be able to obtain a satisfactory financial return on our own manufacture and commercialization of any future products.

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 are successfully developed by us and 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.

***Our product candidates are early stage and may not be successful or achieve market acceptance.***

We currently have six compounds 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. We are unable to predict whether any of these product candidates 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, our products may not achieve or maintain market acceptance.

***We rely on the favorable outcome of clinical trials of our product candidates.***

Before obtaining regulatory approval for the commercial sale of any of the pharmaceutical products 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. Regardless of clinical trial results, the FDA may not approve marketing of the product. The costs to obtain regulatory approvals could be 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 our company, 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 have been three Phase II clinical trials of pagoclone that demonstrated statistically significant efficacy, two in panic disorder and one in GAD, other trials have failed to demonstrate statistically significant efficacy, prompting Pfizer to elect not to pursue further development of the compound and to return to us exclusive, worldwide development and commercialization rights to pagoclone.

***We will rely on third parties to commercialize and manufacture our products.***

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We have limited sales and marketing capabilities to market our products. Substantial additional funds will be required to complete development and commercialization of our products and, accordingly, 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 or our security holders. 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 obtain any collaborative arrangements, we will depend on the efforts of



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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 products, we would be materially adversely affected. Because we will generally retain a royalty interest in sales of products licensed to third parties, our revenues may be less than if we marketed products directly.

We currently contract with third parties for all of our manufacturing needs and do not manufacture any of our own products or product candidates. In order 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.

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 products 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. Currently, Schering's NEBIDO manufacturing facilities have not been approved by the FDA.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

### ***Our failure to acquire and develop additional product candidates will impair our ability to grow.***

We do not conduct our own research to discover new drug compounds. Instead, we depend on the licensing of compounds from others for development. 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 on terms we find acceptable or at all.

### ***We need additional funds in the future.***

Our existing cash resources will be insufficient to commercialize any of our current product candidates on our own. 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 2006 as we continue to fund our development activities, as well as marketing activities related to SANCTURA. We may seek 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

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changes to the capitalization, operations, management and prospects for our business and no assurance can be given that the terms of a strategic 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 depressive 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.

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Our cash requirements and cash resources will vary significantly depending upon the following principal factors:

marketing success of SANCTURA;

the costs, their reimbursements, and progress of research and development programs;

the timing and cost of obtaining regulatory approvals; and

whether we are successful in either in-licensing or out-licensing products.

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 \$1,500,000, \$17,600,000, \$31,800,000, \$68,200,000 and \$53,218,000 for fiscal years 2001, 2002, 2003, 2004, and 2005 respectively. At September 30, 2005 we had an accumulated deficit of approximately \$422,121,000.

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.

***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.

***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 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

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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 the 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, Redux-related judgments that are not covered by the Indemnity and Release Agreement with AHP may be insufficiently insured or uninsured. Such

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claims, if successful, could have a material adverse effect on our business, results of operations and financial condition. We are unable to predict whether the existence of such litigation may adversely affect our business.

*We rely on the protection provided by our intellectual property and have limited patent protection on 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 are not covered by any patents and, accordingly, we will be dependent on obtaining market exclusivity under the Waxman-Hatch Act for such products. 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 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 potential product 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 that we expect to use in the commercialization of the product for overactive bladder.

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;

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

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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 being developed by us may conflict with patents which have been or may be granted 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. 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.

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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.

### ***We may depend on market exclusivity for certain of our products.***

Assuming regulatory approvals are obtained, our ability to commercialize successfully certain drugs may depend on the availability of market exclusivity or patent extension under the Waxman-Hatch Act, which provides protections for certain new 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, its use or method of manufacture. We are relying on market exclusivity under the Waxman-Hatch Act for the twice-a-day formulation of SANCTURA.

### ***Our products may be unable to compete successfully with other products.***

Competition from other pharmaceutical companies is intense and is expected to increase. We are aware of existing products and of products under development by our competitors that address diseases we are targeting and competitors have developed or are developing products or technologies that are, or may compete with our products.

Many of the other 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. As a result, our products may not be able to compete successfully. In addition, royalties payable to us under certain conditions may be reduced or eliminated if there is generic competition.

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.

### ***We could be materially harmed if our agreements were terminated.***

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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 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 Madaus or Esprit, related to SANCTURA, our agreements with Aventis, under which we license pagoclone and aminocandin, or our agreement with Schering, under which we license NEBIDO, could substantially reduce the likelihood of successful commercialization of our product candidates which would materially harm us. The agreements with Esprit, Madaus, Aventis or Schering 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.

### *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, Noah D. Beerman, our chief business officer, Mark S. Butler, our chief administrative officer and general counsel, Michael W. Rogers, our chief financial officer,



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Bobby W. Sandage, Jr., our chief scientific officer, and John H. Tucker, our chief sales and marketing 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 among pharmaceutical and biotechnology companies is intense, and the loss of any qualified employees, or an inability to attract, retain and motivate highly skilled employees, could adversely affect our business and prospects. Competition to attract and retain pharmaceutical sales people is intense. We may not be able to attract additional qualified employees or retain our existing personnel.

### ***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 \$30,000,000. We may obtain additional coverage for products that may be marketed in the future, including SANCTURA XR. 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.

### ***If third parties on which we rely for clinical trials services do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates.***

We depend on independent clinical investigators and, in some cases, contract research organizations and other third-party service providers to conduct the clinical trials of our product candidates and expect to continue to do so. We rely heavily on these parties for successful execution of our clinical trials, but we do not control many aspects of their activities. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the general investigational plan and protocol. Our reliance on these third parties that we do not control does not relieve us of our responsibility to comply with the regulations and standards of the FDA relating to good clinical practices. 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.

## **Risks Related 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 are currently issued and outstanding. In addition, vesting of shares of our common stock

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subject to stock awards under our 1997 Equity Incentive Plan accelerates and outstanding options under our stock option plans become immediately exercisable upon certain changes in control of the Company, 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 the Company 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.

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*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 include:

market success of SANCTURA;

results of clinical studies and regulatory reviews;

partnerships, corporate collaborations, and strategic corporate transactions;

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 or the possibility of sales of our common stock or other financings;

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, and regulatory progress and delays;

proprietary rights;

Redux-related litigation developments;

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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 Nasdaq Stock Market were: \$10.00 and \$1.16 for fiscal 2001, \$12.83 and \$0.85 for fiscal 2002, \$6.90 and \$1.32 for fiscal 2003, \$10.25 and \$4.86 for fiscal 2004, and \$7.45 and \$2.41 for fiscal 2005. Our common stock is subject to delisting if our stock price drops below the bid price of \$1.00 per share. If we were to fail to meet any of the continued listing requirements for the Nasdaq Stock Market, our common stock could be delisted from the Nasdaq Stock 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.

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.

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

As of September 30, 2005, we had 47,165,289 shares of common stock issued and outstanding. Substantially all of these shares are eligible for sale without restriction. In addition, Wyeth has the right, under certain

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circumstances, to require us to register for public sale 622,222 shares of common stock issuable to it upon conversion of the Series B and 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. 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 September 30, 2005, we had reserved the following shares of our common stock for issuance:

10,817,308 shares issuable upon conversion of the \$72,000,000 Convertible Senior Notes issued in July 2003, which are due in July 2008 (the Convertible Notes );

11,858,295 shares issuable upon exercise of outstanding options and warrants, 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 and warrant holders if we issue additional securities below certain prices;

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

615,651 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.

*Increased leverage as a result of our convertible debt offering may harm our financial condition and results of operations.*

At September 30, 2005, we had \$72,000,000 of outstanding debt reflected in our balance sheet relating to our outstanding Convertible Notes. We may incur additional indebtedness in the future and the Convertible 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

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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 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 Convertible Notes;

to sell selected assets; or

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

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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.

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**USE OF PROCEEDS**

Unless otherwise indicated in the applicable prospectus supplement, we anticipate that the net proceeds, if any, from the sale of the securities that we may offer under this prospectus and any accompanying prospectus supplement will be used for:

the continued development and commercialization of SANCTURA and SANCTURA XR;  
clinical development of our other product candidates;  
acquiring and developing new products and product candidates; and  
working capital and general corporate purposes.

Accordingly, we will retain broad discretion as to the allocation of the net proceeds of this offering. We intend to invest the net proceeds of this offering in interest-bearing investment grade securities pending the above uses.

In addition, we may use a portion of the net proceeds of this offering to acquire or invest in businesses, products, services or technologies complementary to our current business, through mergers, acquisitions, in-licensing, joint ventures or otherwise.

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**DESCRIPTION OF CAPITAL STOCK**

This summary highlights selected information about our capital stock and the associated rights, and may not contain all of the information that is important to you. Under our restated certificate of incorporation, as amended, we are authorized to issue up to 120,000,000 shares of our common stock, \$.001 par value per share, and 5,000,000 shares of preferred stock. The following summary of certain provisions of the common stock and preferred stock is not complete and may not contain all the information you should consider before investing in the shares. We encourage you to read our restated certificate of incorporation, as amended, and our certificate of designation which sets forth the rights and preferences of certain of our preferred stock because they, and not this summary, define the rights of holders of common stock and preferred stock. We have filed our restated certificate of incorporation, as amended, and the certificate of designation with the SEC. See [Where You Can Find More Information](#) for information on how to obtain these documents.

**Common Stock**

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As of December 12, 2005, there were 47,165,289 shares of common stock issued and outstanding held of record by approximately 584 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.



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### **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 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) the repurchase or redemption of any shares of our common stock; or (vi) guarantee any indebtedness of any third party, except a subsidiary.

At December 12, 2005, we had 239,425 and 5,000 shares of Series B and Series C preferred stock outstanding, respectively.

### **Special Meetings of Shareholders; Shareholder Action By Written Consent**

Our by-laws permit any action required or permitted to be taken by our shareholders to be effected at a duly called annual or special meeting of shareholders or by unanimous consent in writing. Additionally, our by-laws authorize special meetings of our shareholders to be called by our board of directors or chairman of the board, our president, or one or more shareholders holding at least 20% of the outstanding shares of the corporation.

### **Anti-Takeover Effects Of Certain Provisions of our Restated Certificate of Incorporation, By-laws and Delaware Law**

As noted above, our board of directors, without shareholder approval, has the authority under our restated certificate of incorporation to issue preferred stock with rights superior to the rights of the holders of our common stock, subject to the limitations described above. In addition, vesting of shares of our common stock subject to stock awards under our 1997 Equity Incentive Plan accelerates and outstanding options under our stock option plans become immediately exercisable upon certain changes in control of us, except under certain conditions. In addition, the business combination provision contained in Section 203 of Delaware's General Corporation Law ( Section 203 ) defines an interested shareholder as any person that (i) owns, directly or indirectly, 15% or more of the outstanding voting stock of the corporation or (ii) is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock at any time within the three-year period immediately prior to the date on which it is sought to be determined whether such person is an interested shareholder; and the affiliates and the

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associates of such person. Under Section 203, a resident domestic corporation may not engage in any business combination with any interested shareholder for a period of three years following the date such shareholder became an interested shareholder, unless (i) prior to such date the board of directors of the corporation approved either the business combination or the transaction which resulted in the shareholder becoming an interested shareholder, or (ii) upon consummation of the transaction which resulted in the shareholder becoming an interested shareholder, the interested shareholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced (excluding for determining the number of shares outstanding (a) shares owned by persons who are directors and officers and (b) employee stock plans, in certain instances), or (iii) on or subsequent to such

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date the business combination is approved by the board of directors and authorized at an annual or special meeting of shareholders by at least 66% of the affirmative voting stock which is not owned by the interested shareholder. We did not elect-out of the statute and, therefore, the restrictions imposed by Section 203 apply to us. These provisions could, under certain circumstances, have the effect of delaying or preventing a change in control of Indevus and, accordingly, could adversely affect the price of our common stock.

## **Transfer Agent And Registrar**

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

## **Nasdaq Stock Market Listing**

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

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## **PLAN OF DISTRIBUTION**

We may sell any of the securities being offered pursuant to this prospectus:

directly to purchasers;

to or through underwriters;

through dealers or agents; or

through a combination of methods.

We may distribute the securities from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices. We may engage in at the market offerings of our common stock. An at the market offering is an offering of our common stock at other than a fixed price to or through a market maker. We may also determine the price or other terms of the securities offered under this prospectus by use of an electronic auction.

The prospectus supplement with respect to the securities being offered will set forth the terms of the offering, including the names of the underwriters, dealers or agents, if any, the purchase price of the securities, the net proceeds to us, any underwriting discounts and other items

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constituting underwriters' compensation, any discounts or concessions allowed or reallocated or paid to dealers and any securities exchanges on which the securities may be listed. Also, if applicable, we will describe in the prospectus supplement how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the underwriters' obligations with respect to the auction.

If underwriters are used in an offering, we will execute an underwriting agreement with the underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent, and the underwriters will be obligated to purchase all of the offered securities if any are purchased.

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If dealers are used in an offering, we will sell the securities to the dealers as principals. The dealers then may resell the securities to the public at varying prices which they determine at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

The securities may be sold directly by us or through agents we designate. If agents are used in an offering, the names of the agents and the terms of the agency will be specified in a prospectus supplement. Unless otherwise indicated in a prospectus supplement, the agents will act on a best-efforts basis for the period of their appointment.

Dealers and agents named in a prospectus supplement may be deemed to be underwriters (within the meaning of the Securities Act of 1933) of the securities described therein. In addition, we may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act of 1933 with respect to any resales thereof.

Underwriters, dealers and agents may be entitled to indemnification by us against specific civil liabilities, including liabilities under the Securities Act of 1933 or to contribution with respect to payments which the underwriters or agents may be required to make in respect thereof, under underwriting or other agreements. The terms of any indemnification provisions will be set forth in a prospectus supplement. Certain underwriters, dealers or agents and their associates may engage in transactions with, and perform services for us in the ordinary course of business.

Any common stock sold pursuant to a prospectus supplement will be eligible for listing and trading on the Nasdaq National Market, subject to official notice of issuance. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. The securities, other than the common stock, may or may not be listed on a national securities exchange or eligible for quotation and trading on Nasdaq.

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## **LEGAL MATTERS**

Burns & Levinson LLP, Boston, Massachusetts, will provide us with an opinion as to the legality of the issuance of the shares on our behalf.

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## **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, 2005, 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.



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**INFORMATION INCORPORATED BY REFERENCE**

**THIS PROSPECTUS IS PART OF A REGISTRATION STATEMENT ON FORM S-3 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. WE ARE NOT MAKING AN OFFER OF THESE SECURITIES IN ANY STATE WHERE THE OFFER IS NOT PERMITTED. 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, 2005, including all material incorporated by reference therein, filed on December 14, 2005;
- (ii) Our Current Reports on Form 8-K filed October 28, 2005, and December 16, 2005;
- (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; and
- (iv) All other reports filed by us pursuant to Section 13(a) or 15(d) of the Exchange Act, since September 30, 2003.

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

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**WHERE YOU CAN FIND MORE INFORMATION**

We are subject to the informational requirements of the Exchange Act, and in accordance therewith file reports and other information with the SEC. These annual, quarterly and special reports, proxy statements and other information may be inspected, and copies of these materials may

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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



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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-3 under the Securities Act of 1933 with the SEC with respect to the common stock being offered pursuant to this prospectus. This prospectus omits certain information contained in the Registration Statement on Form S-3, as permitted by the SEC. Refer to the Registration Statement on Form S-3, 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. 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.

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**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 in Part II of this prospectus entitled Indemnification of Officers and Directors , 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****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

The expenses in connection with the issuance and distribution of the securities being registered are set forth in the following table (all amounts except the registration fee are estimated):

SEC registration fee	\$ 5,297.00
Legal fees and expenses	10,000.00
Accounting fees and expenses	10,000.00
Printing fees and expenses	0.00
Miscellaneous	5,000.00
	<hr/>
Total	\$ 30,297.00
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All expenses in connection with the issuance and distribution of the securities being offered shall be borne by Indevus, other than underwriting discounts and selling commissions, if any.

**ITEM 15. INDEMNIFICATION OF OFFICERS AND DIRECTORS**

Article Seventh of the our Restated Certificate of Incorporation, as amended, states that we shall indemnify any person to the full extent permitted by the Business Corporation Law of the State of Delaware, as the same now exists or may hereafter be amended.

In addition to our Restated Certificate of Incorporation, Article V of our By-Laws states that we shall, to the fullest extent permitted by the laws of the state of incorporation, indemnify any and all persons whom we shall have the power to indemnify against any and all of the costs, expenses, liabilities or other matters incurred by such person by reason of having been officers or directors of the Company, any subsidiary of the Company or of any other corporation for which such person acted as officer or director at the request of the Company.

Subsection (a) of Section 145 of the Delaware General Corporation Law 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, 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), 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. 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

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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.

Subsection (b) of Section 145 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

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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 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 Court of Chancery or such other court shall deem proper.

Section 145 further provides that to the extent a director, officer 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 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, upon such terms and conditions, if any, as the corporation deems appropriate, 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.

Section 145 additionally provides that the indemnification provided by Section 145 shall not be deemed exclusive of any other rights to which the indemnified party may be entitled; and that the scope of indemnification extends to directors, officers, employees, or agents of a constituent corporation absorbed in a consolidation or merger and persons serving in that capacity at the request of the constituent corporation for another.

Section 145 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 against any liability asserted against such person or incurred by such person in any such capacity or arising out of such persons status as such whether or not the corporation would have the power to indemnify such person against such liabilities under Section 145.

We also have indemnification agreements with our officers and directors and have director and officer liability insurance.

**ITEM 16. EXHIBITS**

<b>Exhibits</b>	<b>DESCRIPTION OF DOCUMENT</b>
1.1	Form of Underwriting Agreement(1)
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)
4.2	Provisions of the By-laws of Indevus, that define the rights of securityholders of Indevus (incorporated by reference to Exhibit 99.4 to our Current Report on Form 8-K filed with the SEC on July 7, 2003)
5.1	Opinion of Burns & Levinson LLP
23.1	Consent of PricewaterhouseCoopers LLP
23.2	Consent of Burns & Levinson LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included in signature pages hereto).

(1) To be filed, if necessary, by amendment or as an exhibit to a report pursuant to Section 13(a), 13(c) or 15(d) of the Exchange Act.



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**ITEM 17. 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 the undertakings set forth in paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of 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.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a

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new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

For the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For purposes of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.



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**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-3 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 28th day of December, 2005.

**INDEVUS PHARMACEUTICALS, INC.**

By: /s/ GLENN L. COOPER, M.D.  
**Glenn L. Cooper, M.D.**

**President, Chief Executive Officer and Chairman**

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, his or her true and lawful attorney-in-fact and agent, each with the full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any way and all capacities, to sign any and all amendments (including post-effective amendments and registration statements filed pursuant to Rule 462) to this Registration Statement and to file the same, with 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 each said attorney-in-fact, or his substitute or substitutes, may 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, M.D.	President, Chief Executive Officer and Chairman	December 28, 2005
<b>Glenn L. Cooper, M.D.</b>		
/s/ HARRY J. GRAY	Director	December 28, 2005
<b>Harry J. Gray</b>		
/s/ MICHAEL E. HANSON	Director	December 28, 2005
<b>Michael E. Hanson</b>		
/s/ STEPHEN C. McCLUSKI	Director	December 28, 2005
<b>Stephen C. McCluski</b>		
/s/ CHERYL P. MORLEY	Director	December 28, 2005
<b>Cheryl P. Morley</b>		

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/s/ MALCOLM MORVILLE, PH.D.	Director	December 28, 2005
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<b>Malcolm Morville, Ph.D.</b>		
/s/ DAVID B. SHARROCK	Director	December 28, 2005
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<b>David B. Sharrock</b>		
/s/ MICHAEL W. ROGERS	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer)	December 28, 2005
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<b>Michael W. Rogers</b>		
/s/ DALE RITTER	Senior Vice President, Finance (Principal Accounting Officer)	December 28, 2005
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<b>Dale Ritter</b>		

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**EXHIBIT INDEX**

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