INDEVUS PHARMACEUTICALS INC
Form 10-K
December 14, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended September 30, 2005

or

¨ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the transition period from to

Commission File No. 0-18728

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 Number)**
33 Hayden Avenue **Lexington, MA** **(Address of principal executive offices)**	**02421-7966** **(Zip Code)**

Registrant s telephone number, including area code: (781) 861-8444

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $.001 par value per share

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). YES x NO ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): YES ¨ NO x

The aggregate market value of the voting and non-voting common equity (excluding preferred stock convertible into 622,000 shares of Common Stock and having voting rights on certain matters equivalent to 568,750 shares of Common Stock) held by non-affiliates of the registrant was approximately $130,000,000, based on the last sales price of the Common Stock as of March 31, 2005. Shares of Common Stock held by each executive officer and director and each person who beneficially owns 10% or more of the outstanding Common Stock and individuals or entities related to such persons have been excluded. This determination of affiliate status may not be conclusive for other purposes.

As of December 12, 2005, 47,165,289 shares of Common Stock, $.001 par value per share, of the registrant were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

See Part III hereof with respect to incorporation by reference from the registrant s definitive proxy statement for the fiscal year ended September 30, 2005 to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 and the Exhibit Index beginning on page number 51 hereto.

PART I

Note Regarding Forward Looking Statements

Statements in this Form 10-K that are not statements or descriptions of historical facts are forward looking statements under Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA® (trospium chloride tablets) 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 events and trends and do not relate to historical matters identify forward-looking statements. Readers 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 Form 10-K. 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 Form 10-K. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward looking statements. See Risk Factors.

Unless the context indicates otherwise, Indevus , the Company , we , our and us refer to Indevus Pharmaceuticals, Inc., and Common Stock to the common stock, $.001 par value per share, of Indevus. Our registered trademark SANCTURA is assigned in the U.S. to Esprit Pharma Holding Company (subject to our co-exclusive right to use it) and NEBIDO is a registered trademark of Schering AG, Germany that we exclusively license in the United States. We have pending trademark applications for SANCTURA XR. Other trademarks, trade names and service marks used in this Form 10-K are the property of their respective owners.

ITEM 1. ***Business***

Overview

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®, 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.

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® in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual dysphoric disorder.

Indevus Pharmaceuticals, Inc. is a Delaware corporation. Our principal office is located at 33 Hayden Avenue, Lexington, Massachusetts 02421-7971, and our main telephone number is (781) 861-8444. Reports, proxy statements and other information concerning us may be accessed and reviewed through our website: http://www.indevus.com.

Recent Development

In December 2005, we entered into an agreement to acquire Delatestryl®, (testosterone enanthate), a marketed injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient Pharmaceuticals, Inc. (Savient) (the Delatestryl Agreement). The Delatestryl Agreement is expected to close in January 2006 subject to certain contractual and financial conditions. Upon closing, we will make an initial cash payment to Savient of $5.0 million and will be committed to pay a total of approximately $3.3 million for Delatestryl inventory, including our assumption of Savient s previous obligation to purchase approximately $1.1 million of additional Delatestryl inventory. We expect to commence selling Delatestryl upon closing. Under the terms of the Delatestryl Agreement, we will pay royalties to Savient for three years following the closing of the transaction based upon the cumulative net sales of Delatestryl. The royalty rate will be 5% on the first $5 million of cumulative net sales following closing increasing to 10% on cumulative net sales between $5 million and $10 million. The royalty rate on cumulative net sales above $10 million will be 25%, subject to a minimum annual payment of $300,000 following the quarter in which cumulative net sales reach $10 million.

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

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.

The following table outlines the products in our core focus area:

Product Name	Indication/Use	Status*	Commercial Rights
SANCTURA	Overactive bladder	Marketed	U.S. Licensed to Esprit
SANCTURA XR	Overactive bladder	Phase III	Worldwide
NEBIDO	Hypogonadism	Pre-NDA	U.S.
PRO 2000	HIV and STD prevention	Phase III	Worldwide
IP 751	Interstitial cystitis/pain	Phase I	Worldwide

* See Government Regulation.

SANCTURA

General. On August 23, 2004, we launched SANCTURA (trospium chloride tablets), a muscarinic receptor antagonist for the treatment of OAB. We co-promote SANCTURA in the U.S. with our marketing partner Esprit. SANCTURA is indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency and urinary frequency.

SANCTURA belongs to the anticholinergic class of compounds and binds specifically to muscarinic receptors. These compounds relax smooth muscles, such as the detrusor muscle in the bladder, thus decreasing bladder contractions. Overactive or unstable detrusor muscle function is believed to be one of the principal causes of OAB symptoms. Current treatments in the U.S. for OAB include compounds in the same class as SANCTURA.

OAB is a medical condition whose symptoms include urinary frequency, urgency, and urge incontinence, the accidental loss of urine that occurs after the strong, sudden urge to urinate. An estimated 33 million Americans suffer from OAB. In 2004, the market for drugs to treat OAB was approximately $1.3 billion in the United States. OAB represents a significant clinical problem with potential medical, hygienic, and social consequences. When untreated, this condition can lead to disability, dependence, and isolation from the community. It is most prevalent among the elderly and strikes women twice as frequently as men.

We licensed exclusive rights to develop and market SANCTURA in the U.S. from Madaus GmbH (Madaus) in December 1999. In addition, Madaus currently manufactures and sells us commercial quantities of SANCTURA in bulk form.

Development Program. On May 28, 2004, the FDA approved the New Drug Application (NDA) for SANCTURA. The NDA included data from 34 clinical studies conducted in the U.S. and Europe involving approximately 3,000 subjects.

Our development program for SANCTURA has included two randomized, double-blind, placebo-controlled Phase III trials conducted in the U.S. that were submitted in the NDA. A total of 523 patients were studied at 51 sites in the first of these trials. The three-month trial measured the effects of 20 milligrams (mg) of SANCTURA versus placebo, twice daily, on symptoms of OAB. Patients treated with SANCTURA experienced statistically significantly fewer toilet voids per day at the end of the three-month trial than did patients on placebo. SANCTURA treated patients also experienced statistically significantly fewer episodes of urge urinary

incontinence per day at the end of the three-month trial than did placebo patients. Treatment with SANCTURA also led to a significant improvement (decrease) in average urgency severity, another key symptom of OAB.

A nine-month open label period followed the conclusion of this three-month trial. A total of 407 of the original 523 patients opted to continue treatment into the open-label phase of this trial. Two hundred and four patients originally randomized to placebo in the double-blind phase were switched to SANCTURA, while 203 patients continued with SANCTURA treatment. After treatment for up to one year, patients continuing on SANCTURA treatment maintained comparable and sustained efficacy for the entire treatment period. Patients who crossed over from placebo to SANCTURA rapidly experienced a similar degree of efficacy which was also sustained for the entire nine-month period. Treatment with SANCTURA was also well tolerated, and the most frequently reported adverse events were dry mouth at 11.3% and constipation at 8.8%.

Additional data analyses from this trial showed that treatment with SANCTURA reduced urgency severity and was associated with onset of action beginning as early as three days after initiation of therapy. Urgency severity is not yet approved in any labeling. Additional data from this trial demonstrated that early patient response to treatment with SANCTURA is an accurate predictor of long-term therapeutic success.

Our second Phase III trial included a total of 658 patients studied at 52 sites in the United States. The trial measured the effects of 20 mg of SANCTURA given twice daily versus placebo on symptoms of OAB. Patients treated with SANCTURA experienced statistically significantly fewer toilet voids per day at the end of the 12-week trial than did patients on placebo. The improvement (decrease) in number of toilet voids for the SANCTURA group compared with the placebo group was observed at each follow-up visit during the trial. SANCTURA-treated patients also experienced statistically significantly fewer episodes of urge urinary incontinence per day at the end of the 12-week trial than did patients on placebo. This improvement (decrease) in incontinence episodes for the SANCTURA group was observed beginning at week 1 and continued throughout the study. SANCTURA-treated patients experienced statistically significantly increased volume voided per void beginning at week 1 and continuing through week 12 than did placebo patients. In addition to these endpoints, the trial assessed the effect of SANCTURA on daytime sleepiness using the Stanford Sleepiness Scale (SSS). The changes in average SSS scores were minimal and comparable for the SANCTURA and placebo treatment groups at weeks 1, 4 and 12. SANCTURA was well tolerated in this trial as well, as evidenced by its adverse event profile that included the most common adverse events associated with the antimuscarinic class of drugs, dry mouth and constipation.

Across the two U.S. Phase III trials, the most common adverse events considered possibly related to treatment were dry mouth (20.1% for SANCTURA vs. 5.8% for placebo), constipation (9.6% for SANCTURA vs. 4.6% for placebo) and headache (4.2% for SANCTURA vs. 2.0% for placebo). Like other products in this class, SANCTURA is contraindicated in patients with or at risk for urinary retention, gastric retention, uncontrolled narrow-angle glaucoma and in patients who have demonstrated hypersensitivity to the drug or its ingredients.

Commercialization. We currently co-promote SANCTURA in the U.S. with Esprit. To support the commercialization of SANCTURA and provide a platform for future growth, we have established a sales and marketing infrastructure including our specialty sales force consisting of 85 sales representatives who call on urologists and other prescribers specializing in treating patients with OAB. Effective July 1, 2005, Esprit acquired the rights to market SANCTURA in the U.S. from Odyssey Pharmaceuticals, Inc. (Odyssey), a specialty-branded subsidiary of PLIVA d.d. (PLIVA). See AGREEMENTS.

SANCTURA XR

General. SANCTURA XR (trospium chloride tablets) is under development as a once daily formulation of SANCTURA, our currently marketed product for the treatment of OAB. SANCTURA XR belongs to a class of anticholinergic compounds known as muscarinic receptor antagonists. Current treatments in the U.S. for OAB include compounds in the same class as SANCTURA XR.

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SANCTURA XR is a quaternary amine, which we believe provides significant differentiation to the tertiary amine compounds currently being marketed for the treatment of OAB. Quaternary amines are highly charged and hydrophilic with a limited ability to cross lipid membranes.

Development Program. In September 2005, we initiated the Phase III clinical program for SANCTURA XR. The program consists of two 12-week, double-blind, placebo-controlled studies totaling 1,200 patients at approximately 120 sites in the United States. The objective of the trials is to evaluate the effects of once-daily dosing of trospium chloride on urinary frequency, urge incontinence, and other related symptoms associated with OAB. As a result of the initiation of the Phase III program, we received a $10 million milestone payment from Esprit, our co-promotion partner for SANCTURA and SANCTURA XR in the United States.

Our formulation of SANCTURA XR was developed under a development and license agreement with Shire Laboratories, Inc. (Shire) signed in March 2003. We have completed pharmacokinetic and safety studies with several once-a-day formulations, including our lead formulation that was used in our Phase II study and is being tested in our Phase III program.

In June 2005, we announced results from a pilot Phase II study of SANCTURA XR. The trial was a two-week, multi-center, placebo-controlled, double-blind study designed to evaluate the efficacy and safety of SANCTURA XR in 148 patients with OAB. The common symptoms of overactive bladder, such as urgency, frequency and incontinence episodes were measured daily.

SANCTURA XR, administered as a single daily 60 mg dose, was found to improve all of the symptoms and signs of overactive bladder. The magnitude of improvement compared to placebo was very similar to those observed with SANCTURA in earlier studies. In addition, patients treated with SANCTURA XR indicated they had an improved quality of life compared to placebo treated patients. The most common anticholinergic side effects were dry mouth (8% of the placebo treated patients compared to 12% of the SANCTURA XR treated patients) and constipation (none reported in the placebo treated patients vs. 2% of the SANCTURA XR treated patients).

We expect to file an NDA with the FDA in the second half of calendar 2006. Our partner, Esprit, has the right to market SANCTURA XR upon approval in the U.S. and we are exploring partnership opportunities outside the U.S. for SANCTURA XR.

NEBIDO

General. In July 2005, we licensed the exclusive U.S. rights for NEBIDO from Schering. Currently under development as testosterone replacement therapy in male patients with hypogonadism, NEBIDO is a depot preparation for intramuscular injection. NEBIDO has been approved and launched in Europe as the first injectable product for treating hypogonadism requiring dosing only once every 10 to 14 weeks.

Hypogonadism is characterized by a deficiency in endogenous testosterone production resulting in abnormally low levels of circulating testosterone. Testosterone deficiency is accompanied by symptoms of different severity which include sexual dysfunction, reduced muscle mass and strength, depressed mood and osteoporosis.

We believe NEBIDO is highly differentiated when compared to the current testosterone replacement therapies available today. Based on the benefits of its 10 to 14 week dosing regimen, NEBIDO has the potential to offer an attractive treatment option to current therapies that require either more frequent injection or daily application of topical gels and patches. It is an intramuscular depot injection which was designed to provide replacement testosterone in hypogonadal men for up to 3 months before requiring the next injection. Because of the unique

characteristics of the depot pharmacokinetics of testosterone, only the dosing frequency needs to be adjusted, not the dose.

Development Program. Schering has obtained approvals throughout Europe (by Mutual Recognition Procedure with Finland as Reference Member State, including first national approval November 25, 2003, EU approval July 7, 2004; new EU member states approval March 27, 2005). Subsequently, testosterone undecanoate has been approved in over 40 countries under the trade names NEBIDO and Reandron, and is currently pending actions by regulatory authorities in an additional 20 countries.

Pursuant to a pre-IND meeting with the FDA, we will conduct a single, pharmacokinetic study following 100 hypogonadal men for approximately six months to supplement the existing clinical database. We anticipate starting this trial in the first quarter of calendar 2006 and filing an NDA in the first quarter of calendar 2007. The existing database from Schering s clinical development program contains over 300 patients that have been treated up to 4 years in 5 clinical trials. These studies assessed the pharmacokinetic parameters of various dosing regimens of NEBIDO. These studies determined that dosing every 12 weeks following a loading interval between the first 2 injections of 6-8 weeks provides effective testosterone replacement in patients with hypogonadism. We intend to commercialize NEBIDO in the U.S. utilizing our specialty sales force.

PRO 2000

General. PRO 2000 is under development as a topical vaginal microbicide to prevent the sexual transmission of HIV and certain other sexually transmitted infections including herpes, chlamydia and gonorrhea. Topical microbicides represent a new class of protective substances that are designed to be applied vaginally before sexual contact. Topical microbicides have the potential to offer a female-controlled supplement or an alternative to condoms; the only product currently known to prevent HIV transmission and to reduce the risk of infection by other STDs.

We believe that PRO 2000 may block HIV infection and other sexually transmitted infections by preventing their attachment and entry into cells. Laboratory studies have shown that the drug is active against HIV, herpes simplex virus, chlamydia and the bacterium that causes gonorrhea. In government-sponsored tests, vaginally applied PRO 2000 was shown to be efficacious in mouse models for genital herpes infection and gonorrhea, and in a simian model for vaginal HIV infection.

HIV infection usually leads to AIDS, a life-threatening impairment of the immune system. The World Health Organization estimates that 5 million new adult HIV infections occurred worldwide in 2004 with the majority of the infections arising from heterosexual intercourse. Other STDs, such as genital herpes, chlamydia and gonorrhea, can lead to serious complications, especially in women, and can increase the risk of HIV infection. The Kaiser Family Foundation and the World Health Organization have estimated that there are approximately 15 million new STD cases each year in the U.S. and more than 340 million worldwide.

Development Program. In October 2005, we announced the initiation of a second large, multi-national Phase III trial sponsored by the Microbicides Development Programme (MDP), an international partnership to develop and test vaginal microbicides. The MDP was established in February 2002 with funding of approximately $22.7 million from the United Kingdom s Department for International Development. The program is administered by the Clinical Trials Unit of the Medical Research Council (MRC) and Imperial College in London, and involves researchers in the U.K., Cameroon, South Africa, Tanzania, Uganda and Zambia. An estimated 10,000 women will be enrolled in this trial that is expected to last approximately 3 to 4 years and include interim analyses of safety and efficacy data conducted by an independent data safety monitoring board.

In February 2005, we announced the initiation of a large, multi-national Phase II/III clinical trial sponsored by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIH). The trial is designed to examine the safety and effectiveness of two candidate topical microbicides, including PRO 2000, in preventing HIV infection in women. Approximately 3,200 women will be enrolled in the study at multiple sites in Africa and the U.S. and is expected to last 30 months and include interim analyses of safety and efficacy data conducted by an independent data safety monitoring board.

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Also in February 2005, findings from a study performed at the Mount Sinai School of Medicine were presented at the 12th Conference on Retroviruses and Opportunistic Infections. These data demonstrated that PRO 2000 retains activity against HIV and the herpes simplex virus following intervaginal administration to HIV-infected women. The study, funded by the NIH, marks the first time that the anti-viral activity of a microbicide has been demonstrated following human application.

Prior to the initiation of the Phase III trials in 2005, a number of pre-clinical and early clinical studies with PRO 2000 had been completed under the sponsorship of government agencies and research organizations in the U.S., Europe, Africa and India. Pre-clinical development with PRO 2000 included an NIH-funded study with 28 female macaque monkeys, divided equally into one control group and three treatment groups that received gels with 0.5% PRO 2000, 2% PRO 2000, and 4% PRO 2000 concentrations. All of the control animals were infected within two weeks after receiving the simian human immunodeficiency virus, and went on to develop AIDS symptoms. Of the treated animals, none in the 0.5% group, and only one each in the 2% and 4% groups became infected and developed disease.

In June 2003, we announced the initiation of a Phase II clinical trial in Uganda funded by the European Commission. The 180 participant study assessed the safety of PRO 2000. The preliminary results showed no adverse effects and no unexpected safety issues.

In October 2000, dosing and follow-up for a Phase I/II clinical trial of PRO 2000 was completed by the NIH at sites in the U.S. and South Africa. This study was designed to assess safety and acceptability in healthy, sexually active women and HIV-infected, sexually abstinent women. No serious side effects were reported in this trial, and the investigators concluded that PRO 2000 was safe and well-tolerated in both groups of women. Previous Phase I clinical trials conducted in Europe with support from the MRC of the United Kingdom showed a promising safety and acceptability profile for the drug in healthy, sexually abstinent women. Other Phase I clinical trials to evaluate the safety of male exposure to PRO 2000 showed that it was safe and well-tolerated. The Company is currently considering strategic partners for future development and commercialization of PRO 2000.

IP 751

General. IP 751 is a non-psychoactive synthetic derivative of tetrahydrocannabinol (THC) in pre-clinical development to treat interstitial cystitis. IP 751 appears to suppress inflammatory cytokines, including IL-1 beta and matrix metalloproteinases (MMPs) through a peroxisome proliferators-activated receptor (PPAR)-gamma-mediated mechanism, which are implicated in pain and inflammation.

We believe IP 751 also has a broad potential to treat other pain and inflammatory conditions such as arthritis, post-operative pain, and musculoskeletal injuries. In addition, IP 751 may be useful in treating non-inflammatory conditions such as headache and neuropathic pain, as well as other specialty focused indications. Pre-clinical studies suggest that IP 751 may lack the gastrointestinal ulceration associated with NSAIDs (non-steroidal anti-inflammatory agents) and the cardiovascular effects seen with cyclooxygenase-2 (COX-2) inhibitors.

Interstitial cystitis is an extremely painful and often debilitating condition that results in recurring discomfort or pain in the bladder and the surrounding pelvic region. Interstitial cystitis is far more common in women than in men. Of the estimated 1 million Americans with interstitial cystitis, approximately 90% are women.

Development Program. In March 2005, we announced the results of a study conducted at the University of Pittsburgh that showed that administration of IP 751 significantly reduces the bladder overactivity observed in an animal model of interstitial cystitis. IP 751 suppressed the overactivity in a dose dependent manner and at the highest doses completely reversed the excessive bladder contractility to normal function. In addition, IP 751

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appeared to have no effect on the normal voiding mechanism of the bladder. We have now completed additional studies confirming these results. We expect to begin the clinical program for IP 751 in interstitial cystitis in calendar 2006.

We also believe that IP 751 will have significant applications in multiple areas of chronic and acute pain, including neuropathic and inflammatory pain. An IND has been filed with the FDA, and an initial phase I clinical trial designed to assess the safety of IP 751 showed that it was well tolerated, with no clinically significant adverse events and no evidence of psychotropic activity. In December 2002, we successfully completed a phase II trial for IP 751 in neuropathic pain. In this trial, patients experienced significantly less pain when treated with IP 751 compared with placebo, and showed no significant differences in adverse events in comparison to placebo. Most notably, the lack of psychoactive properties related to IP 751 was confirmed in this study. We are currently considering strategic partners for future development and commercialization of IP 751.

Our Other Products

In addition to the products and product candidates in our core focus area, we have products and product candidates that address certain other specialty medical areas.

The following table summarizes the status of our other products:

Product Name	Indication/Use	Status*	Commercial Rights
Sarafem	Premenstrual Dysphoric Disorder	Marketed	Worldwide-licensed to Lilly
Pagoclone	Stuttering	Phase II	Worldwide
Aminocandin	Systemic fungal infections	Phase I	Worldwide

* See Government Regulation.

Sarafem

We receive royalties under a patent we licensed to Lilly based on net sales of Sarafem in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual syndrome. In January 2003, Galen Holdings PLC (Galen) announced the completion of the acquisition of the sales and marketing rights to Sarafem from Lilly. Our patent on Sarafem expires in November 2007 unless additional extensions are applicable.

Pagoclone

General. Pagoclone is under development as a treatment for persistent developmental stuttering. Pagoclone is a novel, non-benzodiazepine, GABA-A receptor modulator. Clinical targets to date have included panic and generalized anxiety disorders (GAD). In early 2005, we were granted a new method of use patent in the U.S. that covers the use of pagoclone as a therapeutic agent for stuttering. Stuttering is a disease of uncertain etiology that affects approximately three million adults and children in the United States. The treatment for stuttering consists mainly

of behavioral modification and speech therapy. There are currently no drugs approved in the U.S. for the treatment of stuttering.

According to the National Stuttering Association (NSA), stuttering is defined as a communication disorder involving distruptions, or disfluencies, in a person s speech. In addition to producing disfluencies, people who stutter often experience physical tension and struggle in their speech muscles, as well as embarrassment, anxiety, and fear about speaking.

Development Program. In July 2005, we initiated a Phase II trial of pagoclone in patients with persistent developmental stuttering. The 8-week, double-blind, placebo-controlled trial is being conducted in approximately

120 adults at 16 investigational sites in the United States. Assessments in the trial include standard measures of speech fluency using the Stuttering Severity Instrument 3, as well as ancillary measures to evaluate disability and quality of life of the enrolled stuttering patients. In a subset of the clinical centers, functional brain imaging assessments will be collected as potential biomarkers of the effects of pagoclone in the treatment of stuttering. Results from the Phase II trial are expected in the middle of calendar 2006.

Prior to the initiation of the Phase II stuttering trial, over 1,500 patients had participated in clinical studies with pagoclone, including three Phase II clinical trials that demonstrated statistically significant efficacy, two in panic disorder conducted by us and one in GAD conducted by Pfizer Inc. (Pfizer), then our licensee. Pfizer s most recent data in two Phase II GAD trials and one Phase III panic disorder trial did not show statistically significant efficacy. In all of the clinical trials, pagoclone was well-tolerated, with no clinically significant differences with respect to adverse events, such as sedation and withdrawal effects as compared with placebo.

As a result of the prior clinical programs by us, our licensor and Pfizer, we have an extensive database for pagoclone including toxicology, pharmacology and manufacturing packages. Upon completion of the ongoing Phase II study, we will evaluate the commercialization options for pagoclone.

Aminocandin

General. Aminocandin is a member of a new class of anti-fungal compounds, known as echinocandins, in development for the treatment of a broad spectrum of systemic, invasive fungal infections. Echinocandins function by inhibiting a key component of the cell wall of fungi, and lack cross-resistance with older antifungal agents. Echinocandins are the first new class of anti-fungal agents to be developed and introduced in approximately 30 years. They are designed to be fungicidal, that is, to destroy fungi rather than simply to inhibit their growth, and to have broad-spectrum activity against multiple fungi that cause serious systemic infections. Examples of such infections include aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, cryptococcosis and zycomycosis.

Three classes of antifungals, polyenes, azoles and echinocandins, are currently available for systemic fungal infections. In patients treated with these agents, treatment failures are primarily due to anti-fungal resistance and adverse events. Polyenes act by binding to fungal cell membranes and causing the fungus to leak electrolytes. A polyene known as amphotericin has been the standard for treating serious fungal infections for over 40 years and remains the first-line anti-fungal for many infections. Although this agent has a broad spectrum of fungicidal activity, its dose-limiting nephrotoxicity and adverse events often limit its clinical application. Azoles, including fluconozole, itraconazole and voriconazole, are the most commonly prescribed anti-fungal agents. They inhibit the synthesis of ergosterol by blocking the enzymatic activity of 14-alpha-demethylase. Azoles do not actually kill the fungus, but rather inhibit the spread of the fungus, allowing the body s immune system to control the infection. Prolonged use of azoles leads to fungal resistance to these drugs, and many fungal types do not respond to azoles.

Aminocandin has shown *in vitro* and *in vivo* activity against a number of candida and aspergillus fungal species. The worldwide market for anti-fungal agents that target invasive fungal infections is currently estimated at $3.5 billion.

Development Program. In October 2004, we commenced a multi-dose Phase I trial of aminocandin. During dose escalation, we saw some local vein irritation as doses and concentrations increased causing us to interrupt the trial. We believe we have identified the formulation issues that caused such vein irritation and we are currently working on reformulations of the intravenous dosage form and will be testing the new formulations in pre-clinical models.

Results of a Phase I clinical trial of the intravenous formulation of aminocandin completed in June 2004 showed that it was well tolerated among healthy volunteers and demonstrated a prolonged duration of anti-fungal

activity following single-dose administration. The trial was designed to test the safety and tolerance of rising single doses of intravenously administered aminocandin among approximately 40 healthy volunteers. Secondary objectives included the pharmacokinetic assessment of aminocandin in plasma and urine, and the determination of *in vitro* fungicidal activity of the serum collected from the volunteers.

Dose levels achieved during this trial were approximately seven-fold higher than the anticipated clinical dose and were all well tolerated. Of particular note was the absence of infusion-related histamine reactions, a recognized effect of other drugs in the echinocandin class, and the lack of a significant infusion-associated rise in plasma histamine levels, even at the highest doses and concentrations of administered drug. Furthermore, following single intravenous doses, significant fungicidal activity was observed in patients serum samples for up to one week. These results indicate the possibility that the compound might be amenable to a weekly dosing regimen as opposed to other echinocandins which are generally once-a-day drugs.

We believe aminocandin has a favorable systemic safety profile as well as certain differentiating properties. We are currently evaluating options for development and commercialization of aminocandin.

AGREEMENTS

SANCTURA. In November 1999, we entered into an agreement with Madaus under which we licensed exclusive rights under Madaus patents and know-how to develop and market certain products, including SANCTURA in the United States. In exchange for these rights, we agreed to pay Madaus potential regulatory and sales milestone payments and royalties on net sales of the licensed products or, if sublicensed by us, a portion of royalties received by us from our sublicensee on net sales of the licensed product by the sublicensee, in lieu of royalty payments. We are responsible for all clinical development and regulatory activities and costs related to licensed products in the United States. In December 2002, we entered into a manufacturing agreement with Madaus whereby Madaus will produce and sell to us commercial quantities of SANCTURA in bulk form.

In March 2003, we signed a development and license agreement with Shire under which Shire will develop extended release formulations of SANCTURA enabling SANCTURA to be constituted as a once-a-day formulation and granted us exclusive worldwide rights under Shire s related patents and know-how. The agreement includes potential future development and commercialization milestone payments from us to Shire, as well as royalties based on potential future sales of extended release SANCTURA. We will be responsible for all development costs and the commercialization of extended release formulations of SANCTURA under this agreement.

In April 2004, we entered into a license, commercialization and supply agreement with PLIVA through its specialty-branded subsidiary, Odyssey, for the U.S. commercialization of SANCTURA for OAB (the SANCTURA Agreement). In May 2005, we, PLIVA and Esprit entered into an Amendment and Consent Agreement (the Amendment and Consent Agreement), which became effective as of July 1, 2005, pursuant to which we amended certain provisions of the SANCTURA Agreement and consented to the acquisition by Esprit of the rights to market SANCTURA in the U.S. from PLIVA and the assumption by Esprit of PLIVA s obligations under the SANCTURA Agreement. Upon the effectiveness of the Amendment and Consent, the effective royalty rates increased and we became entitled to annual minimum royalties of $5.6 million, $7.9 million, and $10.5 million for the first three years of the Amendment and Consent Agreement, respectively. Additionally, the annual sales force subsidy was increased to $8.8 million through December 31, 2007 and extended for one additional year at an annual rate of $4.4 million. Further, Esprit is not subject to minimum detail and sales force requirements. Esprit granted Indevus the right to co-promote one of Esprit s future products on terms to be negotiated. Except if the context indicates otherwise, all references to the SANCTURA Agreement shall mean the agreement as amended by the Amendment and Consent.

Under the SANCTURA Agreement, we received $30.0 million upon the initial signing, $120.0 million upon the approval of SANCTURA by the FDA in May 2004 and $10.0 million upon initiation of the SANCTURA XR

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Phase III clinical trial program in September 2005. In addition, we are eligible to receive approximately $45.0 million in future payments contingent upon the filing and approval of an NDA for SANCTURA XR, as well as a payment of $20.0 million related to the achievement of a long-term commercialization milestone in 2013. Esprit will not have an obligation to pay the development milestone of approximately $35.0 million related to the FDA approval of the NDA for SANCTURA XR or the $20.0 million long-term commercialization milestone and the rights to SANCTURA XR will revert to us if Esprit provides notice to us no later than the approval date that it does not intend to proceed with the launch of SANCTUA XR.

For the six months following the approval of SANCTURA, called the co-promotion period, we received a commission based on net sales of SANCTURA, a portion of which funded our own sales force and certain advertising and promotional costs. We were co-promoting SANCTURA with PLIVA through a joint sales force of approximately 500 sales representatives. We established a sales force initially numbering approximately 280 representatives promoting SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians.

We exercised our right to convert the SANCTURA Agreement into a royalty-bearing structure effective November 29, 2004 (the Conversion). Upon the Conversion approximately 200 of our primary care sales representatives became PLIVA employees and PLIVA became responsible for promotional, advertising and sales force-related costs. Effective upon the Conversion we began receiving royalties on net sales of SANCTURA and a sales force subsidy at an annual rate of approximately $7.7 million.

Under the SANCTURA Agreement, we supply SANCTURA to Esprit, which is responsible for product distribution. We are responsible for conducting and funding the development of SANCTURA XR and we are eligible to receive additional payments upon achievement of regulatory milestones for SANCTURA XR.

NEBIDO. In July 2005, we licensed exclusive U.S. rights from Schering to market NEBIDO, a long-acting injectable testosterone preparation for the treatment of male hypogonadism (the Schering Agreement). We will be responsible for the development and commercialization of NEBIDO in the United States. Schering will be responsible for manufacturing and supplying finished product to us. We agreed to pay to Schering up to $30.0 million in up-front, regulatory milestone, and commercialization milestone payments, including a $7.5 million up-front payment paid in August 2005 and a $5.0 million payment due upon approval by the FDA to market the product. We also agreed pay to Schering 25% of net sales of NEBIDO to cover both the cost of finished product and royalties.

PRO 2000. In June 2000, we licensed exclusive, worldwide rights from Paligent, Inc. (formerly HeavenlyDoor.com and Procept, Inc.) (Paligent) to develop and market PRO 2000, in exchange for an up-front payment, future milestone payments, and royalties on net sales. We are responsible for all remaining development and commercialization activities for PRO 2000.

In April 2003, we amended the terms of the PRO 2000 licensing agreement. Paligent agreed to relinquish a potential future $0.5 million milestone payment and provide us with an option to acquire all rights to PRO 2000 by a certain future date in exchange for an immediate $0.5 million payment and an optional buyout payment by us. In September 2004, we exercised this option and made a $0.5 million buyout payment to Paligent for the acquisition of all rights to PRO 2000.

In July 2005, we entered into the Collaborative Research and Licensing Agreement with the MRC, an agency of the United Kingdom. In exchange for the right to have PRO 2000 included in the MRC s approximately 10,000 person Phase III clinical trial studying the prevention of the transmission of HIV and other sexually-transmitted diseases to be conducted primarily in Africa and India and the right to use the results of this trial, we agreed to grant to the MRC a non-exclusive license to PRO 2000 solely for its use in the Phase III trial and also to supply, at no cost to the MRC, all PRO 2000 and placebo required for the Phase III trial. The MRC will be responsible for all other trial costs. Additionally, we agreed to make PRO 2000 available to all communities in need of the product, including developing countries, and to supply to the MRC PRO

2000 to be

distributed in developing countries at our cost plus a markup pursuant to a supply agreement to be negotiated. We will pay the MRC a minimal royalty on sales of PRO 2000 in non-developing countries.

IP 751. In June 2002, we licensed exclusive, worldwide rights to IP 751 from Manhattan Pharmaceuticals, Inc. (formerly known as Atlantic Technology Ventures, Inc.) (Manhattan), in exchange for an up-front licensing payment, potential development milestones and royalty payments. In August 2003, we terminated the license and acquired from Manhattan all its intellectual property rights to IP 751 in exchange for a combination of cash and equity payments from us to Manhattan. In August 2003, we also entered into an agreement with Sumner Burstein, Ph.D., the owner of certain intellectual property rights related to IP 751 under which Dr. Burstein granted to us an exclusive, worldwide license to these rights in exchange for up-front, milestone and royalty payments. We are responsible for the clinical development, regulatory review activities and commercialization of this compound.

Pagoclone. In February 1994, we licensed from Rhone-Poulenc Rorer, S.A., now Aventis, S.A. (Aventis) exclusive, worldwide rights for the manufacture, use and sale of pagoclone under patent rights and know-how related to the drug, except that we granted Aventis an option to sublicense from us, under certain conditions, rights to market pagoclone in France. In exchange, we paid Aventis a license fee and agreed to make milestone payments based on clinical and regulatory developments, and to pay royalties based on net sales through the expiration of the composition of matter patent. If sublicensed by us, we would pay to Aventis a portion of receipts from the sublicensee in lieu of payments. Under the terms of our agreement with Aventis, we are responsible for all costs of developing, manufacturing, and marketing pagoclone.

Aminocandin. We licensed exclusive, worldwide rights to aminocandin from Aventis in April 2003. In exchange for these rights and for Aventis inventory of aminocandin, we made an up-front payment to Aventis and are obligated to pay potential milestone payments and royalties on future sales. Under the Aventis agreement, we are responsible for all development and commercialization activities for both intravenous and oral formulations of aminocandin. Aventis has agreed to manufacture the key component of aminocandin, using its proprietary fermentation technology.

Sarafem. In June 1997, we entered into an agreement with Lilly, under which we sublicensed to Lilly exclusive, worldwide rights under a Massachusetts Institute of Technology (MIT) patent that was licensed exclusively by MIT to us and which is directed to the use of fluoxetine to treat certain conditions and symptoms associated with PMS. In July 2000, Lilly received approval for fluoxetine, which is marketed under the trade name Sarafem, to treat a severe form of PMS. Lilly s composition of matter patent on fluoxetine expired in July 2001. The Lilly agreement provided for milestone payments and royalties based on net sales of fluoxetine attributable to the approved indication in the U.S. up to an annual maximum limit. In December 2002, we entered into a renegotiated licensing agreement with Lilly providing us an initial payment upon the signing of the agreement and future royalty payments from Lilly based on net sales of Sarafem in the U.S. from October 1, 2002 until the November 2007 expiration of our patent related to Sarafem unless additional extensions are applicable. In addition, the agreement includes other potential milestone payments to us from Lilly. In January 2003, Galen Holdings PLC announced the completion of the acquisition of the sales and marketing rights to Sarafem from Lilly. Pursuant to our agreement with Lilly, the remaining milestone payments were accelerated and received by us from Lilly.

Citicoline. Effective January 22, 2004, we entered into a new agreement with Ferrer superseding our January 1993 agreement and covering the development, manufacture, and marketing of citicoline in the U.S. and Canada. Under the terms of the new agreement, we have granted Ferrer exclusive rights to our patents and know-how related to citicoline. In exchange, Ferrer agreed to assume all future development, manufacturing, and commercialization costs of citicoline. Indevus will receive 50% of all milestone payments made to Ferrer by a third party and royalties on net sales of the product. In October 2004, IVAX Corporation (IVAX) announced a licensing agreement between Ferrer and IVAX for citicoline. Under the terms of this agreement, IVAX will be responsible for fulfilling the requirements for FDA approval of citicoline for acute stroke and for commercializing citicoline in the United States.

MANUFACTURING AND MARKETING

General. We currently have no manufacturing capabilities. For both clinical trials and commercialized products, we rely on third parties to manufacture our products. We expect to market our products ourselves or through co-promotion or exclusive marketing arrangements with other pharmaceutical companies.

To the extent we enter into collaborative arrangements with pharmaceutical and other companies for the manufacturing or marketing of products, these collaborators are generally expected to be responsible for funding or reimbursing us all or a portion of the development costs, including the costs of clinical testing necessary to obtain regulatory clearances, and for commercial-scale manufacturing and marketing. These collaborators are expected to be granted exclusive or semi-exclusive rights to sell specific products in exchange for license fees, milestone payments, royalties, equity investments or other financial consideration. Accordingly, we will be dependent on such third parties for the manufacturing and, in some cases, for the marketing of products subject to the collaboration.

SANCTURA and SANCTURA XR. Pursuant to the SANCTURA Agreement, we are co-promoting SANCTURA with our sales force consisting of 85 sales representatives. The combined sales forces of Indevus and Esprit are promoting SANCTURA to urology specialists, obstetricians and gynecologists, and primary care physicians. Esprit is responsible for all advertising and promotional costs and for subsidizing our sales force at specified annual amounts through 2008.

In December 2002, we entered into a manufacturing agreement with Madaus, whereby Madaus produces and sells to us commercial quantities of SANCTURA in bulk form. We supply the finished product to Esprit at our cost, and under the SANCTURA Agreement, Esprit is responsible for product distribution. We also rely on other third party manufacturers in the supply chain, including the manufacturer of the active pharmaceutical ingredients and the packaging and finished product manufacturer.

NEBIDO. Pursuant to the Schering Agreement, we are responsible for the commercialization and marketing of NEBIDO in the U.S., either independently or with marketing partners. According to the Schering Agreement, Schering will be exclusively responsible for the manufacture and supply of finished product to us and the parties are negotiating a supply agreement related thereto. Schering currently manufactures NEBIDO for sale in Europe, however, the manufacturing facility, expected to be used for the manufacture of commercial product for sale in the U.S., has not yet been inspected for compliance with U.S. current Good Manufacturing Practices (cGMP).

PRO 2000. We are responsible for providing PRO 2000 for use in government-sponsored clinical trials. We will be dependent upon third-party contractors for the manufacture and delivery of these supplies. We intend to seek a partner for commercial manufacture, marketing and distribution of the product.

IP 751. We are responsible for manufacturing and marketing of this compound, either independently or through a corporate partner.

Pagoclone. We are responsible for manufacturing and marketing of pagoclone, either independently or through a corporate partner.

Aminocandin. We are responsible for commercialization activities for all formulations of aminocandin. Subject to negotiation of a supply agreement, Aventis has agreed to manufacture the key component of aminocandin, using its proprietary fermentation technology.

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COMPETITION

General. The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. Many companies, including major pharmaceutical companies and specialized biotechnology companies, are engaged in marketing or development of products and therapies similar to those being pursued by us. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and significantly greater experience in conducting clinical trials and other regulatory approval procedures, as well as in manufacturing and marketing pharmaceutical products, than we have. In the event we or our licensees market any products, we or they will compete with companies with well-established distribution networks and market position. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors.

SANCTURA. Current therapy for OAB includes anticholinergics, such as Detrol and Detrol LA (tolterodine) by Pfizer, Ditropan and Ditropan XL (oxybutynin) by Johnson & Johnson, Inc., Oxytrol (oxybutynin transdermal patch) by Watson Pharmaceuticals, Vesicare (solifenacin) by Astellas Pharma US, Inc. and Glaxo Smith Kline, Enablex (darifenacin) by Novartis A.G., and generic oxybutynin. Many of the products on the market for the treatment of OAB are available in once-a-day formulations, whereas SANCTURA is currently available as a twice-a-day formulation. Since launch, there have been over 300,000 prescriptions written for SANCTURA representing approximately $23 million of prescription value.

NEBIDO. Current preferred methods for treating male hypogonadism are through-the-skin and injectable treatments. Through-the-skin treatments include gels, such as AndroGel by Solvay and Testim by Auxilium, and transdermal patch systems, such as AndroDerm by Watson. There are several additional gel products in development. There are multiple injectable products currently marketed in the U.S. which require more frequent injections than NEBIDO. Testosterone supplements are also available in oral dose forms, however, they are not widely prescribed for use in the United States.

PRO 2000. Other than condoms, we are not aware of any product to prevent sexually-transmitted infections having been approved for use anywhere in the world. Approximately 60 new substances are being evaluated for this indication, but we believe only a few have reached the stage of development of PRO 2000. Advanced clinical stage topical microbicides include BufferGel by Reprotect, Inc., Savvy by Cellegy, Inc., Carraguard by The Population Council, and cellulose sulfate gel by Polydec Pharmaceuticals.

IP 751. Current treatments for interstitial cystitis are aimed at relieving symptoms and include Elmiron (pentosan polysulfate sodium), by Johnson & Johnson, and RIMSO 50 (dimethyl sulfoxide), by Edwards Life Sciences Research. As a first line of defense against mild discomfort, physicians may recommend aspirin and ibuprofen. Some patients have experienced improvement by taking antidepressants or antihistamines. In patients with severe pain, narcotic analgesics or longer acting narcotics may be necessary.

A variety of treatments are currently prescribed for pain and inflammatory disorders, including opioids, NSAIDs, COX-2 inhibitors and combinations of these drugs. The most prevalent types of pain are related to the back, post-operative recovery, osteoarthritis, diabetic neuropathy, rheumatoid arthritis and cancer. NSAIDs, the global leaders in pain treatment, include Celebrex (celecoxib) and Bextra (valdecoxib) by Pfizer. The principal marketed opioids include oxycontin and morphine.

Pagoclone. According to the National Center for Stuttering, current treatment programs for this condition include speech therapies that are physical, psychological and nutritional, designed to reduce the tension on the vocal chords. We are not aware of any pharmaceutical products approved for the treatment of, or being developed for stuttering at this time.

Aminocandin. There are several new echinocandins approved or under development for the treatment of esophageal candidiasis, invasive candidemia/candidiasis, or aspergillosis. Cancidas (caspofungin), by Merck &

Co., is available in the U.S. for the treatment of esophageal candidiasis and is also approved for the treatment of aspergillosis in patients intolerant or refractory to other therapies. MYCAMINE (micafungin), by Astellas Pharma US, Inc, is available in the U.S. for the treatment of esophageal candidiasis. Vicuron Pharmaceuticals received an approvable letter in May 2004 from the FDA for anidulafungin. In September 2005, Pfizer announced that it had completed the acquisition of Vicuron Pharmaceuticals and is pursuing the approval of anidulafungin for both esophageal candidiasis and invasive candidemia/candidiasis.

PATENTS AND PROPRIETARY RIGHTS

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We have and continue to pursue a number of methods to establish and maintain market exclusivity for our products and product candidates, including seeking patent protection, the use of statutory market exclusivity provisions and otherwise protecting our intellectual property. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

SANCTURA. There are no existing U.S. composition of matter patents covering the use of orally administered SANCTURA to treat OAB. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Waxman-Hatch Act, provides for a period of market exclusivity in the U.S. for SANCTURA for five years following the date of FDA approval, May 28, 2004. This is the exclusivity period provided for drugs containing an active ingredient not previously approved by the FDA. We intend to seek more extensive market exclusivity protection for the SANCTURA brand through the development of SANCTURA XR, a once-a-day formulation of the drug. We have filed several patent applications with respect to SANCTURA XR.

NEBIDO. We licensed from Schering rights under a U.S. patent application covering composition of matter for NEBIDO and methods of treating diseases or symptoms associated with deficient endogenous levels of testosterone with NEBIDO.

PRO 2000. We hold an exclusive license to intellectual property relating to PRO 2000, including five issued U.S. patents: two covering the composition of matter issued in June 2000 and April 2002, two covering the use of PRO 2000 to prevent or treat HIV infection, which were issued in March and October 1997, respectively, and one covering the use of PRO 2000 to prevent pregnancy issued in September 1999. A similar contraception patent has also been issued in South Africa. Composition and use claims are under review in several other territories, including Europe, Canada and Japan.

IP 751. In June 2002, we licensed exclusive, worldwide rights to IP 751 from Manhattan. In August 2003, we entered into an agreement with Sumner Burstein, Ph.D., the individual owner of certain intellectual property rights related to IP 751, under which Dr. Burnstein granted to us an exclusive worldwide license to these rights. In August 2003, we also entered into a renegotiated agreement with Manhattan whereby all remaining rights to IP 751 owned by Manhattan were assigned to us. The IP 751 patent portfolio includes patents and patent applications covering compositions of matter, formulations and uses of IP 751 and analogs.

Pagoclone. We licensed from Aventis rights under U.S. and foreign patents and patent applications covering compositions of matter, processes, and metabolites of pagoclone. A U.S. composition of matter patent was issued in October 1990 and four related U.S. patents were issued in February and March 1996 and February and October 1997. In addition, we hold exclusive rights to two sets of patent applications that cover uses and methods of manufacture as well as a U.S. patent directed to the use of pagoclone to treat stuttering that was granted in February 2005.

Aminocandin. We hold an exclusive, worldwide license from Aventis to patents and patent applications related to aminocandin. The patent portfolio for aminocandin includes five sets of patents and patent applications

that cover composition of matter, methods and processes of manufacture and compounds related to aminocandin, including a U.S. composition of matter patent issued January 2004.

Citicoline. U.S. patents were issued to us in September and October 1998 and in February 1999 relating to the use of citicoline in the protection of brain tissue from cerebral infarction following ischemic stroke. Except in the U.S. and Canada, we licensed worldwide rights to these patents to Ferrer in 1997. The rights in the U.S. and Canada were subsequently assigned to Ferrer by us in 2005. In exchange, we are entitled to royalties from Ferrer on net sales. In May 2000, we were awarded a U.S. patent, including claims directed to a composition of matter, for a hyperhydrated form of citicoline. Patents and patent applications corresponding to this U.S. patent exist in various foreign jurisdictions, which are now being pursued by Ferrer.

GOVERNMENT REGULATION

In the process of licensing, developing, manufacturing, and marketing pharmaceutical products, we are required to be in compliance with regulations codified in the United States, including within individual states, and internationally. The most significant of these regulations for our business is the U.S. Federal Food, Drug, and Cosmetic Act, including amendments such as the Prescription Drug Marketing Act of 1987, the Prescription Drug User Fee Act (PDUFA) of 1992, and the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Waxman-Hatch Act), but our activities may also come under the jurisdiction of other Federal statutes and laws, such as the Controlled Substances Import and Export Act and the Federal Trade Commission Act, and those of specific state legislatures, as well as under laws governing the pharmaceutical business in the European Union and other nations and markets. Compliance with these regulations may have a significant impact on operating expenses and business timelines in ways that may be difficult to predict and could materially affect our business.

Therapeutics. Prior to U.S. commercialization, our products require regulatory clearance by the FDA, as would also be required by comparable agencies in most foreign countries. The nature and extent of requirements may differ with respect to different products. In order to test, produce and market pharmaceutical products in the U.S., mandatory procedures and safety standards, approval processes, and manufacturing and marketing practices established by regulation and maintained by the FDA must be satisfied.

An investigational new drug application (IND) is required before clinical use in humans in the U.S. of a new drug compound or biological product. The IND generally requires inclusion of detailed information about product manufacture and control, the results of pre-clinical (animal) studies evaluating the safety and efficacy of the drug, and detailed descriptions of the clinical investigations in humans intended to be undertaken.

Clinical trials are normally done in three phases, although the phases may overlap. Phase I trials are concerned primarily with the safety and pharmacokinetics of the product. Phase II trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase III trials are expanded clinical trials intended, among other things, to gather additional information on safety and effectiveness needed to clarify the product s benefit-risk relationship, to discover less common side effects and adverse reactions, and to generate information for proper labeling of the drug. Reports on the progress of each phase of clinical testing are submitted to the FDA and may require the modification, suspension or termination of clinical trials if it is deemed that an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase IV, or post-marketing, studies to be conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit an NDA for approval of a drug. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. There can be no assurance that the FDA or any foreign health authority will grant an approval on a timely basis, or at all. The FDA may deny an NDA, in its sole

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discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer s quality control and manufacturing procedures conform to cGMP regulations. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Clinical trial sites and manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase IV, or post-marketing studies, may be required to provide additional data on safety or to provide support for changes in product labeling, or to gain approval for the use of a product for clinical indications other than those for which the product was initially approved. In addition, the FDA or foreign regulatory authority requires post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Also, if there are modifications to an approved drug, including changes in manufacturing process or manufacturing facility, an application seeking approval of such changes may be required to be submitted to the FDA or foreign regulatory authority, that may affect production timelines or product availability.

Patent Term Extension and Market Exclusivity. Under the Waxman-Hatch Act, a patent which claims a product, use or method of manufacture covering drugs and certain other products may be extended for up to five years to compensate the patent holder for a portion of the time required for development and FDA review of the product.

With regards to compounds not having patent protection, the Waxman-Hatch Act also establishes periods of market exclusivity. These are periods of time following approval of a drug during which the FDA may not approve applications for certain similar or identical drugs from other sponsors unless those sponsors provide their own safety and effectiveness data. Under the Act, a company which does not have a patent on a compound may obtain five years of market exclusivity if the FDA determines such compound to be a chemical entity which has not been the subject of an approved NDA. The period of market exclusivity under the Act is considerably shorter than the exclusivity period afforded by patent protection, which may, in the case of some patents, extend for up to twenty years from the patent s earliest priority date.

SANCTURA, approved for marketing in the U.S. on May 28, 2004, has been granted five years of market exclusivity under the Waxman-Hatch Act.

Other products developed and marketed by Indevus may be entitled to patent extension under the Act, though there can be no assurance that Indevus will be able to obtain either the patent term extension or marketing exclusivity provisions or that other parties will not challenge our rights to such patent extension or market exclusivity.

General. The Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration Modernization Act of 1997, the Public Health Service Act, and other federal and state statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, and refusal to permit products to be imported into the U.S. by the FDA as well as refusal to approve product applications, refusal to allow entry into government supply contracts, withdrawal of previous approval of applications, or criminal prosecution. The Federal Trade Commission also may assess civil penalties for violations of requirements relating to advertising claims for non-prescription and food products.

EMPLOYEES

As of September 30, 2005, we had 147 full-time employees. None of our employees is represented by a labor union and we believe our employee relations are satisfactory. We are highly dependent upon certain key personnel and believe our future success will depend in large part on our ability to retain such individuals and attract other highly skilled management, marketing and scientific personnel.

ITEM 1A. ***Risk Factors***

The following factors should be reviewed carefully, in conjunction with the other information contained in this Report and our consolidated financial statements. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this Form 10-K and presented elsewhere by our management from time to time. See Part I 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

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

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 trospium 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.

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

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

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 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.

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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 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.

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 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 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 exclusively 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
- 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. 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.

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, 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 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.

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;

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 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

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.

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.

ITEM 1B. ***Unresolved Staff Comments***

None.

ITEM 2. ***Properties***

We lease our current corporate headquarters of approximately 45,100 square feet in Lexington, MA at an annual rent of approximately $1.1 million. The initial term of this lease expires in December 2010.

We are obligated for the lease of our prior corporate headquarters of approximately 22,800 square feet in Lexington, MA. We currently do not occupy this space and incurred a charge in fiscal 2005 relating to its non-use. The lease provides for annual rent of approximately $550,000 and expires in April 2007.

ITEM 3. ***Legal Proceedings***

Product Liability Litigation. On September 15, 1997, we announced a market withdrawal of our first prescription product, the weight loss medication Redux (dexfenfluramine hydrochloride capsules) C-IV, which had been launched by Wyeth, our licensee, in June 1996. The withdrawal of Redux was based on a preliminary analysis by the FDA of potential abnormal echocardiogram findings associated with certain patients taking Redux or the combination of fenfluramine with phentermine. These observations, presented to us in September 1997, indicated an incidence of abnormal echocardiogram findings in approximately 30% of such patients. Although these observations reflected a preliminary analysis of pooled information and were difficult to evaluate because of the absence of matched controls and pretreatment baseline data for these patients, we believed it was prudent, in light of this information, to withdraw Redux from the market.

Since the withdrawal of Redux, we have been named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. To date, there have been no judgments against us, nor have we paid any amounts in settlement of any of these claims. The actions generally have been brought by individuals in their own right or on behalf of putative classes of persons who claim to have suffered injury or who claim that they may suffer injury in the future due to use of one or more weight loss drugs including Pondimin (fenfluramine), phentermine and Redux. Plaintiffs allegations of liability are based on various theories of recovery, including, but not limited to, product liability, strict liability, negligence, various breaches of warranty, conspiracy, fraud, misrepresentation and deceit. These lawsuits typically allege that the short or long-term use of Pondimin and/or Redux, independently or in combination (including the combination of Pondimin and phentermine, popularly known as fen-phen), causes, among other things, primary pulmonary hypertension, valvular heart disease and/or neurological dysfunction. In addition, some lawsuits allege emotional distress caused by the purported increased risk of injury in the future. Plaintiffs typically seek relief in the form of monetary damages (including economic losses, medical care and monitoring expenses, loss of earnings and earnings capacity, other compensatory damages and punitive damages), generally in unspecified amounts, on behalf of the individual or the class. In addition, some actions seeking class certification ask for certain types of purportedly equitable relief, including, but not limited to, declaratory judgments and the establishment of a research program or medical surveillance fund. On December 10, 1997, the federal Judicial Panel on Multidistrict Litigation issued an Order allowing for the transfer or potential transfer of the federal actions to the Eastern District of Pennsylvania for coordinated or consolidated pretrial proceedings.

On May 30, 2001, we entered into the Indemnity and Release Agreement with Wyeth, formerly American Home Products Corporation (AHP), pursuant to which Wyeth has agreed to indemnify us against certain classes of product liability cases filed against us related to Redux. Our indemnification covers plaintiffs who initially opted out of Wyeth s national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth has agreed to fund all future legal costs related to our defense of Redux-related product liability cases. The agreement also provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. We believe this total insurance coverage is sufficient to address our potential remaining Redux product liability exposure. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the AHP indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. Up to the date of the AHP indemnity and release agreement, our defense costs were paid by, or subject to reimbursement to us from, our product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by us or our insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to us by Wyeth, we agreed to dismiss our suit against Wyeth filed in January 2000, our appeal from the order approving Wyeth s national class action settlement of diet drug claims and our cross-claims against Wyeth related to Redux product liability legal actions.

Pursuant to agreements we have with Les Laboratories Servier, from whom we in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., the manufacturer of Redux, and other parties, we may be required to indemnify such parties for Redux-related liabilities.

General. Although we maintain certain product liability and director and officer liability insurance and intend to defend these and similar actions vigorously, we have been required and may continue to be required to devote significant management time and resources to these legal actions. In the event of successful uninsured or insufficiently insured claims, or in the event a successful indemnification claim were made against us and our officers and directors, our business, financial condition and results of operations could be materially adversely affected. The uncertainties and costs 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, or 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.

ITEM 4. ***Submission of Matters to a Vote of Security Holders***

Not applicable.

EXECUTIVE OFFICERS

The following table sets forth the names and positions of the executive officers of the Company:

Name	Age	Position
Glenn L. Cooper, M.D	52	President, Chief Executive Officer and Chairman
Noah D. Beerman	43	Executive Vice President, Chief Business Officer
Mark S. Butler	59	Executive Vice President, Chief Administrative Officer and General Counsel
Michael W. Rogers	45	Executive Vice President, Chief Financial Officer and Treasurer
Bobby W. Sandage, Jr., Ph.D.	52	Executive Vice President, Research and Development and Chief Scientific Officer
John H. Tucker	42	Executive Vice President, Chief Sales and Marketing Officer

Glenn L. Cooper, M.D. has been President, Chief Executive Officer and a director of the Company since May 1993 and Chairman since January 2000. Dr. Cooper was also President and Chief Executive Officer of Progenitor, Inc. from September 1992 to June 1994. Prior to joining Progenitor, Dr. Cooper was Executive Vice President and Chief Operating Officer of Sphinx Pharmaceuticals Corporation from August 1990. Dr. Cooper had been associated with Eli Lilly since 1985, most recently from June 1987 to July 1990 as Director, Clinical Research, Europe, of Lilly Research Center Limited; from October 1986 to May 1987 as International Medical Advisor, International Research Coordination of Lilly Research Laboratories; and from June 1985 to September 1986 as Medical Advisor, Regulatory Affairs, Chemotherapy Division at Lilly Research Laboratories. Dr. Cooper received an M.D. from Tufts University School of Medicine, performed his postdoctoral training in Internal Medicine and Infectious Diseases at the New England Deaconess Hospital and Massachusetts General Hospital and received an B.A. from Harvard College.

Noah D. Beerman joined the Company in June 1997 as Director of Business Development and subsequently was promoted to Executive Director in June 1998, Vice President in January 2000, and Senior Vice President in

August 2000. He was appointed Executive Vice President, Chief Business Officer in September 2004. Prior to joining Indevus, Mr. Beerman was vice president in charge of health care at Technology Management and Funding (TMF), a venture firm, from June 1995 to June 1997, where he developed and executed commercialization and business development strategies for TMF s biotechnology portfolio. He previously served in a variety of business development and scientific capacities at Creative BioMolecules from January 1994 to June 1995, Sandoz AG from January 1988 to December 1993, and Repligen from June 1984 to December 1987. Mr. Beerman received an M.B.A. from Northeastern University s High Technology Program and a B.S. in molecular genetics from the University of Rochester.

Mark S. Butler joined the Company in December 1993 as Senior Vice President, Chief Administrative Officer and General Counsel, and, in December 1995, was appointed Executive Vice President, Chief Administrative Officer and General Counsel. Prior to joining the Company, Mr. Butler was associated with the Warner-Lambert Company since 1979, serving as Vice President, Associate General Counsel since 1990, as Associate General Counsel from 1987 to 1990, Assistant General Counsel from 1985 to 1987 and in various other legal positions from 1979 to 1985. From 1975 to 1979, Mr. Butler was an attorney with the law firm of Shearman & Sterling. Mr. Butler received an Advanced Professional Certificate in Finance from the New York University School of Business, a J.D. from Fordham Law School and a B.A. from Holy Cross College.

Michael W. Rogers joined the Company in February 1999 as Executive Vice President, Chief Financial Officer and Treasurer. From February 1998 to December 1998, Mr. Rogers was Executive Vice President and Chief Financial and Corporate Development Officer at Advanced Health Corporation, a publicly-traded health care information technology company. From July 1995 to November 1997, he was Vice President, Chief Financial Officer and Treasurer of AutoImmune, Inc., a publicly-traded biopharmaceutical company. From July 1994 to July 1995, Mr. Rogers was Vice President, Investment Banking at Lehman Brothers, Inc. From 1990 to 1994, he was associated with PaineWebber, Inc., serving most recently as Vice President, Investment Banking Division. Mr. Rogers received an M.B.A. from the Darden School at the University of Virginia and a B.A. from Union College.

Bobby W. Sandage, Jr., Ph.D. joined the Company in November 1991 as Vice President-Medical and Scientific Affairs and was appointed Vice President, Research and Development in February 1992, Senior Vice President, Research and Development in February 1994 and Executive Vice President, Research and Development and Chief Scientific Officer in December 1995. From February 1989 to November 1991, he was Associate Director, Project Management for the Cardiovascular Research and Development division of DuPont Merck Pharmaceutical Company. From May 1985 to February 1989 he was affiliated with the Medical Department of DuPont Critical Care, most recently as associate medical director, medical development. Dr. Sandage is an adjunct professor in the Department of Pharmacology at the Massachusetts College of Pharmacy. Dr. Sandage received a Ph.D. in Clinical Pharmacy from Purdue University and a B.S. in Pharmacy from the University of Arkansas.

John H. Tucker joined the Company in April 2002 as Vice President, Sales and Marketing, was promoted to Senior Vice President in December 2003 and was appointed Executive Vice President, Chief Sales and Marketing Officer in September 2004. Mr. Tucker was previously at Ortho-McNeil Pharmaceuticals, a Johnson & Johnson company, from June 2001 to April 2002, where he developed and led a specialty sales, account and marketing team focused on the promotion of products in key urology markets. Mr. Tucker also served as senior director of trade relations, government sales and senior care at ALZA from January 2000 to June 2001 and director of national accounts at ALZA from January 1998 to January 1999. He has held a number of national sales and marketing management positions at VIVUS from February 1997 to January 1998 and UCB Pharma from January 1993 to January 1997. Mr. Tucker received an M.B.A. from New Hampshire College and a B.A. from Plymouth State College.

PART II

ITEM 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Price Range of Securities

Our Common Stock trades on the Nasdaq National Market under the symbol IDEV . The table below sets forth the high and low sales prices of our Common Stock as reported by the Nasdaq National Market for the periods indicated. These prices are based on quotations between dealers, do not reflect retail mark-up, mark-down or commissions, and do not necessarily represent actual transactions.

	High	Low
Fiscal Year Ended September 30, 2005:		
July 1 through September 30, 2005	$ 3.42	$ 2.55
April 1 through June 30, 2005	3.78	2.41
January 1 through March 31, 2005	6.08	2.73
October 1 through December 31, 2004	7.45	5.85
Fiscal Year Ended September 30, 2004:		
July 1 through September 30, 2004	$ 7.98	$ 4.86
April 1 through June 30, 2004	10.25	5.95
January 1 through March 31, 2004	7.74	5.74
October 1 through December 31, 2003	6.34	5.20

Approximate Number of Equity Security Holders

The number of holders of record of our Common Stock as of September 30, 2005 was approximately 536.

We have never paid a cash dividend on our Common Stock and anticipate that for the foreseeable future any earnings will be retained for use in our business and, accordingly, we do not anticipate the payment of cash dividends. Any dividends will be subject to the preferential dividend of $0.1253 per share payable on the outstanding Series B Preferred Stock ($30,000 per annum), $1.00 per share payable on the outstanding Series C Preferred Stock ($5,000 per annum) and dividends payable on any other preferred stock issued by us.

Securities Authorized for Issuance under Equity Compensation Plans

Provided below is information required by Regulation S-K, Item 201(d) relative to our equity compensation plans and arrangements as of September 30, 2005:

Plan category	Number of Securities to be issued upon	Weighted-average exercise price	Number of securities remaining available

	exercise of outstanding options and warrants (a)	of outstanding options and warrants (b)	for future issuance under equity compensation plans (Excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	11,848,295	$ 4.49	603,569
Equity compensation plans or arrangements not approved by security holders	10,000(1)	$ 6.19	12,082(2)
Total	11,858,295	$ 4.49	615,651

(1) Reflects warrants to purchase 10,000 shares of Common Stock issued to a consultant to the Company, not pursuant to a plan or arrangement specifically approved by security holders (see Note J of the Notes to Consolidated Financial Statements).

(2) Reflects the number of shares of Common Stock issuable pursuant to the remaining number of Restricted Stock Awards issuable under our 1997 Equity Incentive Plan which are available for future issuance other than upon the exercise of an option, warrant or right (see Note J of the Notes to Consolidated Financial Statements).

ITEM 6. ***Selected Financial Data***

The selected financial data presented below summarizes certain financial data which has been derived from and should be read in conjunction with the more detailed consolidated financial statements of the Company and the notes thereto which have been audited by PricewaterhouseCoopers LLP, independent accountants, whose report thereon is included elsewhere in this Annual Report on Form 10-K along with said financial statements. See Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Fiscal Years Ended September 30,				
	2005	2004	2003	2002	2001
	(Amounts in thousands except per share)				
Statement of Operations Data:					
Revenues:					
Product revenue	$ 14,269	$ 9,740	$ 4,316	$ 3,439	$ 1,952
Contract and license fees	19,067	8,986	929	968	13,281
Total revenues	33,336	18,726	5,245	4,407	15,233
Cost of product revenue	8,593	7,950	1,073	733	417
Research and development	30,597	23,303	24,466	13,614	5,582
Marketing, general and administrative	41,983	51,916	11,105	8,090	7,238
Product withdrawal (1)					(5,582)
Income (loss) from operations	(47,837)	(64,443)	(31,399)	(18,030)	7,578
Investment income	3,142	1,396	664	987	1,811
Interest expense	5,170	5,170	1,077		
Income (loss) from operations	(50,047)	(68,212)	(31,812)	(17,586)	8,509
Provision for income taxes	(3,171)				
Cumulative effect of change in accounting principle (2)					(10,000)
Net loss	(53,218)	(68,212)	(31,812)	(17,586)	(1,491)
Preferred stock dividends	35	35	35	35	35
Net loss attributable to common stockholders	(53,253)	(68,247)	(31,847)	(17,621)	(1,526)
Loss per common share from operations- diluted	(1.13)	(1.43)	(0.68)	(0.38)	0.19
Loss per common share from cumulative effect of change in accounting principle-basic and diluted					(0.22)
Net loss per common share-basic and diluted	$ (1.13)	$ (1.43)	$ (0.68)	$ (0.38)	$ (0.03)
Weighted average common shares-diluted	46,977	47,542	46,930	45,896	45,628
Proforma amounts assuming the 2001 accounting change relating to revenue recognition is applied retroactively (2):					
Net income					$ 8,509
Preferred stock dividends					35
Net income attributable to common stockholders					8,474
Net income per common share:					
Basic					$ 0.19
Diluted					$ 0.19

	September 30,				
	2005	2004	2003	2002	2001
	(Amounts in thousands)				
Balance Sheet Data:					
Working capital	$ 79,233	$ 131,288	$ 73,866	$ 34,876	$ 23,970
Total assets	112,531	173,838	90,071	43,931	34,917

Convertible Notes, long-term	72,000	72,000	72,000		
Total liabilities including deferred revenue	227,667	236,868	83,817	6,700	6,160
Accumulated deficit	(422,121)	(368,903)	(300,691)	(268,879)	(251,293)
Total stockholders equity (deficit)	(115,142)	(63,038)	6,241	37,218	28,660

(1) Relates to the market withdrawal of Redux. See Note I of Notes to Consolidated Financial Statements.

(2) Relates to the adoption in fiscal 2001 of the provisions of Securities and Exchange Commission s Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements (SAB 101). As a result of the adoption of SAB 101, the Company recorded a noncash charge of $10,000,000 in fiscal 2001 for the cumulative effect of a change in accounting principle to defer license fee revenue previously recognized in fiscal 2000 related to a license agreement which provided the licensee with an option to license an alternative compound. The impact of the adoption of SAB 101 was to defer revenue recognized for such license agreement from fiscal 2000 to the fourth quarter of fiscal 2001 when the option lapsed.

ITEM 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion should be read in conjunction with our audited consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on this Form 10-K.

Description of the Company

We are 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 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. SANCTURA XR, currently in Phase III trials, is a once-daily formulation of SANCTURA. NEBIDO, for male hypogonadism, was licensed from Schering in July 2005. PRO 2000 is a topical microbicide for the prevention of infection by HIV and other STD s. IP 751 is for pain and inflammatory disorders, including interstitial cystitis.

Additional compounds in development include pagoclone for the treatment of stuttering and aminocandin for systemic fungal infections.

Recent Product Developments

SANCTURA

In April 2004, we entered into the SANCTURA Agreement for the U.S. commercialization of SANCTURA, which was launched in August 2004. Effective November 29, 2004, the SANCTURA Agreement was converted from a co-promotion agreement to a royalty-bearing structure and approximately 200 of our primary care sales representatives became PLIVA employees. Under this royalty-bearing structure, we received royalties from PLIVA based on net sales of SANCTURA, and PLIVA was responsible for promotional and advertising costs. Additionally, for the three years commencing November 29, 2004, PLIVA began subsidizing, at an annual rate of approximately $7,700,000, our specialty sales force which promotes SANCTURA to urology specialists, obstetricians and gynecologists, and other high prescribers.

In May 2005, we, PLIVA and Esprit, entered into the Amendment and Consent Agreement, whereby the Company consented to the acquisition by Esprit of the rights to market SANCTURA from PLIVA and the assumption by Esprit of PLIVA s obligations under the SANCTURA Agreement except for the minimum detail and sales force requirements which were waived. The Amendment and Consent Agreement also amended certain economic provisions of the SANCTURA Agreement. Esprit agreed to pay us increased royalties on net sales of SANCTURA at annual minimum amounts of $5,625,000, $7,875,000, and $10,500,000 for the first three years of the Amendment and Consent Agreement, respectively. Additionally, the annual sales force subsidy, paid monthly, was increased to $8,750,000 through December 31, 2007 and will be paid for one additional year at an annual rate of $4,375,000. Also, Esprit has granted us the right to co-promote one of Esprit s future products on terms to be negotiated.

Pursuant to the closing of the Amendment and Consent Agreement, on July 1, 2005 we received a payment of $5,849,000 relating to amounts due to us, including $1,434,000 for manufactured bottles of SANCTURA ordered by PLIVA, expected to be delivered to Esprit in fiscal 2006 and reflected as deferred revenue at September 30, 2005, and $998,000 related to reimbursed development costs, which was also reflected as deferred revenue and is being amortized into contract and license revenue over the term of the SANCTURA Agreement.

In June 2005, we announced results from a pilot Phase II study of SANCTURA XR. This was a two-week multi-center, placebo-controlled, double-blind study designed to evaluate the efficacy and safety of SANCTURA XR in 148 patients with overactive bladder. SANCTURA XR exhibited similar efficacy to previous results of the currently marketed SANCTURA which is given twice a day. In addition, SANCTURA XR was very well tolerated.

In September 2005, we initiated the Phase III clinical program for SANCTURA XR. The program consists of two 12-week, double-blind, placebo-controlled studies totaling 1,200 patients at approximately 120 sites in the United States. The objective of the trials is to evaluate the effects of once-daily dosing of trospium chloride on urinary frequency, urge incontinence, and other related symptoms associated with OAB. As a result of the initiation of the Phase III program, we received a $10,000,000 milestone payment from Esprit in September 2005.

We expect to file an NDA with the FDA for SANCTURA XR in the second half of calendar 2006.

NEBIDO

In July 2005, we entered into a License Agreement with Schering whereby we licensed exclusive U.S. rights from Schering to market NEBIDO, a long-acting injectable testosterone preparation for the treatment of male hypogonadism. Under the terms of the Schering Agreement, we are responsible for the development and commercialization of NEBIDO in the United States. Schering will be responsible for manufacturing and supplying commercial product to us. We will pay to Schering up to $30 million in up-front, regulatory milestone, and commercialization milestone payments, including a $7.5 million up-front payment made in July 2005 and $5.0 million upon approval by the FDA to market the product. We also agreed to pay to Schering 25% of net sales to cover both the cost of finished product and royalties. Pursuant to a pre-IND meeting with the FDA, we will conduct a single, pharmacokinetic study following 100 hypogonadal men for approximately six months to supplement the existing clinical database. We anticipate starting this trial in the first quarter of calendar 2006 and filing an NDA in the first quarter of calendar 2007.

PRO 2000

In October 2005, the MDC-sponsored and MRC-funded multi-national Phase III trial commenced. This trial involves researchers in the U.K., Cameroon, South Africa, Tanzania, Uganda and Zambia. An estimated 10,000 women will be enrolled in this trial that is expected to last approximately 3 to 4 years and include interim analyses of safety and efficacy data conducted by an independent data safety monitoring board. We contribute clinical supplies to this trial.

An NIH-sponsored Phase II/III clinical trial to assess the safety and effectiveness of PRO 2000 in blocking male to female HIV transmission began in February 2005 at sites in Africa and the United States. The study involves approximately 3,200 HIV-uninfected women, most of whom are at risk for acquiring HIV by virtue of living in regions where the rate of infection is high. The trial will also evaluate effectiveness against other sexually transmitted diseases. We contribute clinical supplies to this trial also.

In February 2005, findings from a study performed at the Mount Sinai School of Medicine were presented at the 12th Conference on Retroviruses and Opportunistic Infections. These data demonstrated that PRO 2000 retains activity against HIV and the herpes simplex virus following intravaginal administration to HIV-infected women. The study, funded by the NIH, marks the first time that the anti-viral activity of a microbicide has been demonstrated following human application.

IP 751

In March 2005, we announced the results of a study conducted at the University of Pittsburgh that showed that administration of IP 751, a novel synthetic cannabinoid, significantly reduces the bladder overactivity observed in an animal model of interstitial cystitis. IP 751 suppressed the

overactivity in a dose dependent manner and at the highest dose completely reversed the excessive bladder contractility to normal function. In addition, IP 751 appeared to have no effect on the normal voiding mechanism of the bladder. We have now completed a second study confirming these results. We expect to begin the clinical program for IP 751 in interstitial cystitis in calendar 2006.

Pagoclone

In July 2005, we initiated a Phase II trial of pagoclone in patients with persistent developmental stuttering. The trial is being conducted in 120 adults at 16 investigational sites in the United States. We expect to have results from this study in mid calendar 2006. In February 2005, we were granted a new U.S. patent covering the use of pagoclone for the treatment of stuttering.

Aminocandin

Aminocandin is in development to treat systemic fungal infections. In October 2004, we commenced a multi-dose Phase I trial of aminocandin. During dose escalation, we saw some local vein irritation as doses and concentrations increased causing us to interrupt the trial. We believe we have identified the formulation issues that caused such vein irritation and we are currently working on reformulations of the intravenous dosage form and will be testing the new formulations in preclinical models. Overall, the product continues to have a favorable systemic safety profile. We plan to resume Phase I testing in 2006.

Delatestryl

In December 2005, we entered into an agreement to acquire Delatestryl®, (testosterone enanthate), a marketed injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient Pharmaceuticals, Inc. The Delatestryl Agreement is expected to close in January 2006 subject to certain contractual and financial conditions. Upon closing, we will make an initial cash payment to Savient of $5.0 million and will be committed to pay a total of approximately $3.3 million for Delatestryl inventory, including our assumption of Savient s previous obligation to purchase approximately $1.1 million of additional Delatestryl inventory. We expect to commence selling Delatestryl upon closing. Under the terms of the Delatestryl Agreement, we will pay royalties to Savient for three years following the closing of the transaction based upon the cumulative net sales of Delatestryl. The royalty rate will be 5% on the first $5 million of cumulative net sales following closing increasing to 10% on cumulative net sales between $5 million and $10 million. The royalty rate on cumulative net sales above $10 million will be 25%, subject to a minimum annual payment of $300,000 following the quarter in which cumulative net sales reach $10 million.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements that have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reported periods. These items are regularly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

Expected Term of the SANCTURA Agreement and Deferred Revenue

We are recording the $151,000,000 of initial and milestone payments received from PLIVA and the $10,000,000 milestone payment received from Esprit as deferred revenue and amortizing each component into revenue using the contingency-adjusted method over the estimated remaining duration of the SANCTURA Agreement commencing on the date such payments are earned. All of our obligations under the SANCTURA Agreement continue and our analysis of the term of the SANCTURA Agreement was not affected by Esprit s assumption of PLIVA s obligations. We believe the estimated term of the SANCTURA Agreement is a

significant estimate which affects revenue recognized and the balance of deferred revenue on our balance sheet and we explain our estimate of the expected twelve year term of the SANCTURA Agreement below.

The SANCTURA Agreement expires on the later of (i) the twelfth (12th) anniversary of the launch date of SANCTURA or (ii) the expiration of the last to expire patent included in the Indevus Patent Rights covering SANCTURA XR. Securities and Exchange Commission Staff Accounting Bulletin No. 104 (SAB 104) specifies that unless evidence suggests otherwise, service revenues should be recognized over the contractual term of the arrangement or the expected period over which services are expected to be performed, if longer. We considered the following factors in evaluating the expected duration of the SANCTURA Agreement:

- SANCTURA does not have marketing protection afforded by patents and is currently being marketed pursuant to five years of market exclusivity provided by the Waxman-Hatch Act;
- The potential of success in developing SANCTURA XR including the filing of an NDA and ultimate approval by the FDA to market SANCTURA XR;
- The potential of success in obtaining approval of patents covering SANCTURA XR and the protection such patents may afford;
- If protection from patents was not obtained for SANCTURA XR, the potential benefit of any reliance on market exclusivity that may be provided by the Waxman-Hatch Act;
- The strong competition in the overactive bladder market including competition from large pharmaceutical companies.

After considering all of the above, we estimated the expected term of the SANCTURA Agreement to be twelve years, consistent with the negotiated minimum term of the arrangement of twelve years from launch of SANCTURA. In the event development of SANCTURA XR was terminated prior to approval for marketing by the FDA the expected term of the arrangement would likely be less than twelve years. In the event SANCTURA XR is approved for marketing by the FDA, achieves an acceptable measure of market success, and we are able to obtain and benefit from patent protection for SANCTURA XR, the term of the arrangement may extend beyond the estimated twelve years.

We amortized $13,875,000 and $6,250,000 of deferred revenue into contract and license fee revenue in fiscal 2005 and 2004, respectively, and the balance of deferred revenue related to the initial and the subsequent milestone payments at September 30, 2005 is $140,874,000. We will reevaluate our estimate of the expected term of the SANCTURA Agreement when new information is known that could affect our estimate. If we change our estimate of the duration of the SANCTURA Agreement in the future and extend our estimate of its duration we would decrease the amount of periodic revenue to be recognized from the amortization of remaining deferred revenue. If we decrease our estimate of the duration of the SANCTURA Agreement in the future we would increase the amount of periodic revenue to be recognized from the amortization of remaining deferred revenue.

Insurance Claim Receivable

As of September 30, 2005, we had an outstanding insurance claim of approximately $3,700,000, for services rendered through May 30, 2001 by the group of law firms defending us in the Redux-related product liability litigation. The full amount of our current outstanding insurance claim is made pursuant to our product liability policy issued to us by Reliance Insurance Company (Reliance), which is in liquidation proceedings. Based upon discussions with our attorneys and other consultants regarding the amount and timing of potential collection of our claim on Reliance, we previously recorded a reserve against our outstanding and estimated claim receivable from Reliance to reduce the balance to the

estimated net realizable value of $1,258,000 reflecting our best estimate given the available facts and circumstances. We believe our reserve of approximately $2,400,000 against the insurance claim on Reliance as of September 30, 2005 is a significant estimate reflecting management s judgment. To the extent we do not collect the insurance claim receivable of $1,258,000, we would

be required to record additional charges. Alternatively, if we collect amounts in excess of the current receivable balance, we would record a credit for the additional funds received in the statement of operations.

Redux-Related Liabilities

At September 30, 2005, we have an accrued liability of approximately $600,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ significantly from the amount currently accrued at September 30, 2005. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

Revenue Recognition Policy

Product revenue consists of revenues from sales of products, commissions, royalties and reimbursements for royalties owed by us to Madaus pursuant to the SANCTURA Agreement. Contract and license fee revenue consists of revenue stemming from contractual initial and milestone payments received from customers, including amortization of deferred revenue from contractual payments, reimbursements from PLIVA for their share of SANCTURA promotion and advertising costs incurred by us, less an amount owed by us to PLIVA for our share of SANCTURA promotion and advertising costs incurred by PLIVA, sales force subsidies, and grants from agencies supporting research and development activities.

We record sales of product as product revenue upon the later of shipment or as title passes to our customer. In fiscal 2004, we commenced selling SANCTURA to PLIVA in bottles for resale and blister packs for distribution as samples.

Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize our licensed technologies and are generally reported to us in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based. If the royalty report for such period is received subsequent to the time we are required to report our results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, we recognize such royalty revenue in the subsequent accounting period when we receive the royalty report and when the amount of and basis for such royalty payments are reported to us in accurate and appropriate form and in accordance with the related license agreement.

Our business strategy includes entering into collaborative license and development or co-promotion agreements with strategic partners for the development and commercialization of our products or product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones and royalties on net product sales. Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. In multiple element arrangements where we have continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as we complete our performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement. We record such revenue as contract and license fee revenue.

Revenues from milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. Determination

as to whether a milestone meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue

over the term of the arrangement as we complete our performance obligations. Revenues from milestone payments related to arrangements under which we have no continuing performance obligations are recognized upon achievement of the related milestone. We record such revenue as contract and license fee revenue.

Under the SANCTURA Agreement, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue using the contingency-adjusted performance model. Under this model, when a milestone is earned, revenue is immediately recognized on a pro-rata basis in the period we achieve the milestone based on the time elapsed from inception of the SANCTURA Agreement to the time the milestone is earned over the estimated duration of the SANCTURA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the SANCTURA Agreement.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force Issue Number 00-21, Accounting Revenue Arrangements with Multiple Deliverables (EITF 00-21). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104 (SAB 104), unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements. In particular relating to the SANCTURA Agreement, the Company and PLIVA were contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by us, reimbursements from PLIVA for PLIVA s share were reflected in contract and license fee revenue. For promotion and advertising costs incurred by PLIVA, reimbursements to PLIVA for our share were reflected as a reduction of contract and license fee revenue.

Cash received in advance of revenue recognition is recorded as deferred revenue.

Results of Operations

Fiscal Year Ended September 30, 2005 Compared to Fiscal Year Ended September 30, 2004

Our net loss decreased $14,994,000 to $(53,218,000), or $(1.13) per share, basic, in fiscal 2005 from $(68,212,000), or $(1.43) per share, basic, in fiscal 2004. This reduced loss is primarily the result of increased revenues from SANCTURA and decreased sales and marketing expenses, partially offset by increased research and development expenses.

Total revenues increased $14,610,000, or 78%, to $33,336,000 in fiscal 2005 from $18,726,000 in fiscal 2004 primarily due to SANCTURA. Fiscal 2005 reflected a full year of revenues related to the marketing of SANCTURA and amortization of deferred revenue. Fiscal 2004 reflected only a partial year of revenues from the marketing of SANCTURA and six months of amortization of deferred revenue as SANCTURA was approved for marketing by the FDA on May 28, 2004 and launched in August 2004.

Product revenue, which includes royalties and sales of product, increased $4,529,000, or 46%, to $14,269,000 in fiscal 2005 from $9,740,000 in fiscal 2004. Royalties on SANCTURA were $6,742,000, including $1,789,000 of royalties due to Madaus, in fiscal 2005. This compares to $122,000 of royalties on SANCTURA, including $24,000 of royalties due to Madaus, in fiscal 2004. This increase is primarily due to a full year of marketing SANCTURA compared to only several months of marketing SANCTURA in fiscal 2004. Fiscal 2005 SANCTURA royalty

revenue included $1,758,000 of minimum royalties, including $352,000 of royalties due to Madaus, from Esprit. Partially offsetting increased SANCTURA royalty revenue in fiscal 2005 was a $1,440,000, or 20%, decrease in sales of product, including bottles and samples, to $5,839,000 in fiscal

2005 from $7,279,000 in fiscal 2004. Fiscal 2004 sales of product were higher as PLIVA had purchased product to satisfy initial orders and to provide samples for the launch of SANCTURA. Additionally, royalties from Lilly on sales of Sarafem decreased $648,000, or 28%, to $1,687,000 in fiscal 2005 from $2,335,000 in fiscal 2004.

Contract and license fee revenue increased $10,081,000, or 112%, to $19,067,000 in fiscal 2005 from $8,986,000 in fiscal 2004, and relates almost entirely to the SANCTURA Agreement. Amortization of deferred revenue increased $7,625,000, or 122%, to $13,875,000 in fiscal 2005 from $6,250,000 in fiscal 2004. This increase is primarily due to a full year of amortization in fiscal 2005 compared to six months of amortization in fiscal 2004. Fiscal 2005 also included $6,689,000 of sales force subsidy. Partially offsetting these increases was a decrease of $4,052,000 in contract and license fee revenue to $1,490,000 of net SANCTURA promotion and advertising costs due to PLIVA from us in fiscal 2005 reflected as a reduction to revenue. This compares to $2,562,000 of net SANCTURA promotion and advertising costs due to us from PLIVA in fiscal 2004 reflected as revenue.

Cost of product revenue relates primarily to SANCTURA and includes cost of product sold and royalties we owe to Madaus. Cost of product revenue increased $643,000, or 8%, to $8,593,000 in fiscal 2005 from $7,950,000 in fiscal 2004. Cost of SANCTURA sold decreased $1,312,000 or 18%, to $5,967,000 in fiscal 2005 from $7,279,000 in fiscal 2004. We sell SANCTURA to our marketing partner at cost and this decrease is commensurate with the decreased sales of product as described above. Royalties to Madaus increased $1,765,000 to $1,789,000 in fiscal 2005 from $24,000 in fiscal 2004 commensurate with increased SANCTURA royalty revenue as described above. Pursuant to the SANCTURA Agreement, we are reimbursed the royalties we owe to Madaus on sales of SANCTURA. Royalties due to the Massachusetts Institute of Technology for their portion of the Sarafem royalties decreased to $337,000 in fiscal 2005 from $452,000 in fiscal 2004 commensurate with the decrease in royalties we received from Lilly.

Research and development expense increased $7,294,000, or 31%, to $30,597,000 in fiscal 2005 from $23,303,000 in fiscal 2004. Research and development expense related to milestones and up front payments pursuant to license arrangements increased $6,500,000, including the $7,500,000 up front payment made to Schering for the in-license of NEBIDO. Additionally contributing to increased research and development expense was approximately $1,300,000 of increased staffing and related support costs. Partially offsetting these increases was a noncash charge of approximately $1,000,000 incurred in fiscal 2004 relating to the extension of expiration dates of certain stock option grants to an officer. External costs related to the development of our product and product candidates was approximately $17,200,000 in fiscal 2005 compared to approximately $17,500,000 in fiscal 2004. Decreased external development costs related to SANCTURA, and due primarily to twice-a-day development in fiscal 2004, were offset primarily by increased external development costs related to aminocandin. Total research and development expense for fiscal 2005 substantially relates to our major compounds being developed as follows: SANCTURA and SANCTURA XR $13,662,000, NEBIDO $7,576,000, PRO 2000 $1,157,000, pagoclone $2,575,000, IP 751 $525,000, and aminocandin $5,006,000. We also incurred research and development expenses for fiscal 2005 of $99,000 related to other compounds.

Marketing, general and administrative expense decreased $9,933,000, or 19%, to $41,983,000 in fiscal 2005 from $51,916,000 in fiscal 2004 primarily due to decreased marketing costs related to SANCTURA.

Marketing expenses decreased $9,975,000, or 26%, to $28,273,000 in fiscal 2005 from $38,248,000 in fiscal 2004. Promotion and advertising costs related to SANCTURA decreased approximately $15,500,000 as significant expenses were incurred in fiscal 2004 to launch SANCTURA. Subsequent to the Conversion, PLIVA was, and Esprit is now, responsible for such costs. Partially offsetting the decreased promotion and advertising costs are approximately $6,100,000 of increased sales force and sales operations-related costs. This increase reflects increased costs related to our approximately 85 person specialty sales force and related infrastructure which was in place for all of fiscal 2005 compared to approximately five months in fiscal 2004. Partially offsetting the increased costs related to our approximately 85 person specialty sales force and related infrastructure are decreased costs related to the approximately 200 person primary care sales force which was in place for only the first two months of fiscal 2005 compared to approximately five months in fiscal 2004.

General and administrative expense remained relatively constant at approximately $13,700,000 in fiscal 2005 and fiscal 2004. Certain nonrecurring expenses incurred in fiscal 2004 were offset by other increased costs incurred in fiscal 2005. In fiscal 2004, we extended the expiration dates of certain stock option grants to directors and officers and reflected a noncash charge of approximately $3,000,000 in general and administrative expense for these extensions. In fiscal 2004 we also incurred approximately $1,000,000 of expense for consulting services related to the SANCTURA Agreement. Fiscal 2005 included approximately $1,000,000 of increased personnel expense related to increased staffing to support the expanded company. Fiscal 2005 also included an increase of approximately $1,400,000 for consulting, accounting and other professional fees related to our implementation of Sarbanes-Oxley-required accounting and reporting control systems, tax compliance and other costs related to our expanded business activities. Also included in fiscal 2005 general and administrative expense is approximately $1,300,000 related to the nonutilization of our former facilities.

Investment income increased $1,746,000, or 125%, to $3,142,000 in fiscal 2005 from $1,396,000 in fiscal 2004. While weighted average invested balances in fiscal 2005 were somewhat lower than weighted average invested balances in fiscal 2004, the increase in investment income is primarily the result of higher interest rates.

Interest expense relates to our $72,000,000 of 6.25% Convertible Senior Notes due 2008 (the Convertible Notes). Annual interest expense is approximately $5,200,000 and includes approximately $700,000 of amortization of debt issuance costs.

The provision for income taxes of $3,171,000 in fiscal 2005 relates to U.S. federal alternative minimum tax and state income tax. Tax recognition of the initial and milestone payments received pursuant to the SANCTURA Agreement in fiscal 2004 were deferred to fiscal 2005 when they were recognized in full. Utilization of tax loss carryforwards is limited for use against the U.S. federal alternative tax and by certain states resulting in federal and state tax obligations in fiscal 2005.

Fiscal Year Ended September 30, 2004 Compared to Fiscal Year Ended September 30, 2003

Our net loss increased $36,400,000 to $(68,212,000), or $(1.43) per share, basic, in fiscal 2004 from $(31,812,000), or $(0.68) per share, basic, in fiscal 2003. This increased net loss is primarily the result of our product launch and marketing of SANCTURA.

Total revenues increased $13,481,000, or 257%, to $18,726,000 in fiscal 2004 from $5,245,000 in fiscal 2003. This increase is primarily attributable to $16,214,000 of revenues pursuant to the SANCTURA Agreement offset by $2,758,000 of reduced revenues from Lilly for Sarafem.

Product revenue increased $5,424,000, or 126%, to $9,740,000 in fiscal 2004 from $4,316,000 in fiscal 2003. This increase is primarily attributable to sales of SANCTURA to PLIVA in fiscal 2004 which were $7,279,000, including $3,952,000 related to sales of samples. This increase was partially offset by royalty revenue from Lilly which decreased $1,981,000, or 46%, to $2,335,000 in fiscal 2004 from $4,316,000 in fiscal 2003, which included $2,184,000 of accelerated sales milestones which were one-time payments.

Contract and license fee revenue increased $8,057,000, or 867%, to $8,986,000 in fiscal 2004 from $929,000 in fiscal 2003. Contract and license fees in fiscal 2004 relate almost entirely to the SANCTURA Agreement and include $6,250,000 from amortization of deferred revenue using the contingency-adjusted method from PLIVA and $2,562,000 net reimbursement due to us comprised of $5,664,000 of PLIVA s share of SANCTURA promotion and advertising costs incurred by us less $3,102,000 owed by us to PLIVA for our share of SANCTURA promotion and advertising costs incurred by PLIVA. Fiscal 2003 contract and license fees consist primarily of $777,000 from an initial payment received from Lilly related to the renegotiated agreement for Sarafem.

Cost of product revenue increased $6,977,000, or 641%, to $7,950,000 in fiscal 2004 from $1,073,000 in fiscal 2003. Fiscal 2004 cost of product revenue relates primarily to sales of SANCTURA which we sold to PLIVA at our

cost. Also included in cost of product revenue in fiscal 2004 is approximately $452,000 of royalties we owe to MIT for their portion of the royalties and contractual payments received from Lilly. This is a decrease of $567,000, or 56%, from $1,019,000 included in fiscal 2003 cost of product revenue resulting from the reduction of revenue from Lilly as described above.

Research and development expense decreased $1,163,000, or 5%, to $23,303,000 in fiscal 2004 from $24,466,000 in fiscal 2003. Development costs related to SANCTURA decreased approximately $1,600,000 due to decreased costs related to SANCTURA and other development costs partially offset by increased development costs for SANCTURA XR, including $1,750,000 of milestone payments in fiscal 2004 to Shire which is developing once-a-day formulations of SANCTURA. Further contributing to the decrease were license fees in fiscal 2003 of $1,500,000 paid to Aventis for aminocandin and $1,060,000 related to the transactions that resulted in our licensing IP 751 directly from the owner of the intellectual property rights. In fiscal 2004, we extended the expiration dates of certain stock option grants to an officer which resulted in a noncash charge of approximately $1,000,000 to research and development expense. Increased staffing in fiscal 2004 resulted in approximately $800,000 of additional personnel costs. Increased development activities related primarily to aminocandin, IP 751, PRO 2000 and other products resulted in approximately $1,300,000 of increased development costs. Total research and development expenses for fiscal 2004 substantially relate to our major compounds being developed as follows: SANCTURA $17,711,000, pagoclone $1,571,000, IP 751 $929,000, aminocandin $958,000 and PRO 2000 $1,601,000. We also incurred research and development expenses for fiscal 2004 of $533,000 related to other compounds and initiatives.

Marketing, general and administrative expense increased $40,811,000, or 368%, to $51,916,000 in fiscal 2004 from $11,105,000 in fiscal 2003. Marketing expenses increased $34,304,000 to $38,248,000 in fiscal 2004 from $3,944,000 in fiscal 2003. Fiscal 2004 included significantly increased promotion and advertising expenses related to SANCTURA and the build-up of the sales force infrastructure related to the launch and continued marketing of SANCTURA.

General and administrative expenses increased $6,507,000, or 91%, to $13,668,000 in fiscal 2004 from $7,161,000 in fiscal 2003. In fiscal 2004, we extended the expiration dates of certain stock option grants to directors and officers and reflected a noncash charge of approximately $3,000,000 in general and administrative expense for these extensions. In fiscal 2004 we also incurred approximately $1,000,000 of expense for consulting services related to the SANCTURA Agreement. Additionally in fiscal 2004, we incurred approximately $1,000,000 of personnel-related expense related to increased staffing to provide support services to the expanded company and approximately $900,000 of other costs related to the expansion of the company and other increased business activities.

Investment income increased $732,000, or 110%, to $1,396,000 in fiscal 2004 from $664,000 in fiscal 2003. This increase is due to higher weighted average invested balances, offset somewhat by lower interest rates. Market interest rates substantially decreased in fiscal 2004 from fiscal 2003; however, due to the receipt of $150,000,000 in the three month period ended June 30, 2004 pursuant to the SANCTURA Agreement, weighted average invested balances were substantially higher resulting in an increase in investment income.

Interest expense of $5,170,000 and $1,077,000 in fiscal 2004 and 2003, respectively, results from our July 2003 issuance of the Convertible Notes. Annual interest expense includes approximately $700,000 of amortization of debt issuance costs.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At September 30, 2005 we had consolidated cash, cash equivalents and marketable securities of $101,217,000 compared to $157,008,000 at September 30, 2004. This decrease of $55,791,000 was primarily the result of net cash used in operating activities of $55,757,000 (see Analysis of Cash Flows).

We are continuing to invest substantial amounts in the ongoing development and sales activities related to SANCTURA and our other product candidates. We believe we have sufficient cash for currently planned expenditures for at least the next twelve months.

We will require additional funds or corporate collaborations for the development and commercialization of our other product candidates, as well as any new businesses, products or technologies acquired or developed in the future. We have no commitments to obtain such funds. There can such be no assurance that we will be able to obtain additional financing to satisfy future cash requirements on acceptable terms, or at all. If such additional funds are not obtained, we may be required to delay product development and business development activities.

Product Development

We expect to continue to expend substantial additional amounts for the development of our products. In particular, we are continuing to expend substantial funds for SANCTURA, SANCTURA XR, and other related development efforts. We are responsible for conducting and funding the development of SANCTURA XR. We could receive approximately $45 million in future payments contingent upon the filing and approval of an NDA for SANCTURA XR. Esprit will not have an obligation to pay the development milestone of approximately $35.0 million related to the FDA approval of the NDA for SANCRURA XR or the $20.0 million long-term commercialization milestone and the rights to SANCTURA XR will revert to us if Esprit provides notice to us no later than the approval date that it does not intend to proceed with the launch of SANCTURA XR.

Additionally, after November 28, 2004 and pursuant to the Conversion, PLIVA had been, and Esprit is now, responsible for funding certain Phase IV studies that may be conducted. There can be no assurance that results of any ongoing or future pre-clinical or clinical trials will be successful, that additional trials will not be required, that any drug or product under development will receive FDA approval in a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with cGMP, or successfully marketed in a timely manner, or at all, or that we will have sufficient funds to develop or commercialize any of our products.

We have entered into an agreement with Madaus for the manufacture of SANCTURA. In order to manufacture SANCTURA for sale in the United States, Madaus manufacturing facility must comply with cGMP requirements. Failure to meet or maintain compliance with cGMP requirements could cause a material disruption of, or cessation in, the commercialization of SANCTURA. We may seek a second source for SANCTURA if Madaus is unable to continue to meet all regulatory requirements or provide the necessary quantities of SANCTURA in a timely manner; this alternate source would require FDA approval which may or may not be obtained.

Total research and development expenses incurred by us through September 30, 2005 on the major compounds currently being developed or marketed, including allocation of corporate general and administrative expenses, are approximately as follows: $98,900,000 for SANCTURA and SANCTURA XR, $7,700,000 for NEBIDO, $14,400,000 for PRO 2000, $3,900,000 for IP 751, $23,700,000 for pagoclone, and $10,400,000 for aminocandin. In June 2002, we re-acquired rights to pagoclone from Pfizer Inc. During the period Pfizer had rights to pagoclone, Pfizer conducted and funded all development activities for pagoclone. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA. Given these uncertainties and other

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risks, variables and considerations related to each compound and regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from September 30, 2005 through the preparation of an NDA for our major compounds currently being developed as follows: approximately $38,000,000 for SANCTURA XR, $8,000,000 for NEBIDO, $16,000,000 for PRO 2000, approximately $25,000,000 for IP 751, approximately $93,000,000 for aminocandin, and approximately $51,000,000 for pagoclone. Actual costs to complete any of our products may differ significantly from the estimates. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development.

Analysis of Cash Flows

Cash used in operating activities in fiscal 2005 of $55,757,000 consisted primarily of the net loss of $53,218,000. The net decrease in deferred revenue of $1,442,000 is the result of $12,433,000 milestone payments and product prepayments received from PLIVA and Esprit and $13,875,000 of amortization into contract and license fee revenue. A use of cash resulted from a $4,064,000 reduction of accounts payable primarily due to reduced operating expenses from the cessation of SANCTURA-related promotion and advertising activities pursuant to the Conversion and general timing of payments. A further use of cash of $3,542,000 resulted from a reduction of accrued expenses and other liabilities primarily from reduced inventory due to a reduced rate of production of SANCTURA and the cessation of promotion and advertising costs pursuant to the Conversion, partially offset by increased accruals related to research and development activities and other operating activities. A $4,505,000 source of cash resulted from a net reduction of accounts receivable due to collections from PLIVA.

Net cash provided by investing activities of $36,845,000 is primarily due to maturities and sales of marketable securities of $37,780,000 less $957,000 of capital expenditures.

Net cash provided from financing activities of $911,000 resulted from net proceeds from the issuance of treasury stock pursuant to our stock option and employee stock purchase plans. We cannot predict if or when stock options will be exercised in the future.

Contractual Obligations and Off-Balance Sheet Arrangements

The following chart summarizes our contractual payment obligations as of September 30, 2005. The Convertible Notes and license fees are reflected as liabilities on our Balance Sheet as of September 30, 2005. Operating leases are accrued and paid pursuant to the lease arrangement. Purchase obligations relate to research and development agreements and arrangements; portions of these amounts are reflected as accrued expenses on our Balance Sheet as of September 30, 2005.

	Payments due by Period				
Contractual Obligations	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**Greater than 5 Years**	**Total**
Convertible Notes (1)	$	$ 72,000,000	$	$	$ 72,000,000
Interest on Convertible Notes (1)	4,500,000	8,100,000			12,600,000
Purchase obligations (2)	16,379,000	4,176,000	35,000		20,590,000
Operating leases (3)	1,463,000	2,457,000	2,226,000	188,000	6,334,000
License fees	100,000				100,000

Total	$ 22,442,000	$ 86,733,000	$ 2,261,000	$ 188,000	$ 111,624,000

(1) See Note H of Notes to Consolidated Financial Statements.
(2) Relates primarily to agreements and purchase orders with contractors for the conduct of clinical trials and other research and development activities.
(3) See Note G of Notes to Consolidated Financial Statements.

Pursuant to certain of our in-licensing arrangements, we will owe payments to our licensors upon achievement of certain development, regulatory and licensing milestones. We cannot predict if or when such events will occur.

Pursuant to the Madaus Agreement, we are committed to purchase from Madaus significant minimum quantities of bulk SANCTURA tablets during fiscal 2006 aggregating approximately $9,700,000. If we do not satisfy this minimum purchase requirement, we would be subject to a minimum supply fee of a portion of the value of the unpurchased minimum quantities. Pursuant to the SANCTURA Agreement, Esprit agreed to purchase the same quantities of SANCTURA and to be responsible for commercial product procurement costs, including costs to manufacture SANCTURA and the minimum supply fee.

We lease approximately 90 automobiles for our field sales force. The lease requires a minimum term of 12 months per automobile. We expect monthly lease expense related to this operating lease to be approximately $50,000. We are responsible for certain disposal costs in case of termination.

In December 2004, we entered into a lease agreement for our new corporate headquarters in Lexington, MA. This lease for approximately 45,000 square feet, provides for an initial term of 66 months commencing upon occupancy. Lease payments commence six months after occupancy and the aggregate minimum rental commitment is approximately $5,400,000 for the initial term. The initial term of the lease expires in December 2010. Additionally, we have provided a $500,000 letter of credit to the landlord as a security deposit. The expiration of the letter of credit coincides with the initial term of the lease. We occupied our new facility in June 2005, prior to the April 2007 expiration of the lease period of our prior facility. As a result, we recorded a charge of approximately $1,310,000 in fiscal 2005 related to the nonutilization of our prior facility.

Pursuant to agreements we have with Les Laboratoires Servier, from whom we in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., the manufacturer of Redux, and other parties, we may be required to indemnify such parties for Redux-related liabilities.

Other

In December 2004, the Financial Accounting Standards Board (FASB) issued its Statement of Financial Accounting No. 123 (revised 2004), Share-Based Payments (SFAS No. 123R), which revises Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation and requires companies to expense the fair value of employee stock options and other forms of stock-based compensation. Under SFAS 123R, the most significant change in practice would be treating the fair value of stock-based payment awards that are within its scope as compensation expense in the income statement beginning on the date that a company grants the awards to employees. We are required to implement SFAS 123(R) for our 2006 fiscal year. SFAS 123(R) will apply to all awards granted after the implementation date and to previously-granted awards unvested as of the implementation date. The effect of adoption of SFAS 123(R) is currently estimated to result in approximately $3,100,000 of noncash expense in fiscal 2006. However, our actual share-based compensation expense in fiscal 2006 depends on numerous factors, including fair value of awards at the time of grant.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections. SFAS No. 154 is a replacement of Accounting Principles Board Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application as the required method for reporting a change in accounting principle. SFAS No. 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS No. 154. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company will adopt this pronouncement beginning October 1, 2006.

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ITEM 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

We own financial instruments that are sensitive to market risks as part of our investment portfolio. The investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We do not own derivative financial instruments in our investment portfolio.

Interest Rate Risk related to Cash, Cash Equivalents and Marketable Securities

We invest our cash in a variety of financial instruments, primarily in short-term bank deposits, money market funds, and domestic and foreign commercial paper and government securities. These investments are denominated in U.S. dollars and are subject to interest rate risk, and could decline in value if interest rates fluctuate. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity and we have implemented guidelines limiting the duration of investments. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

Risk related to the Convertible Notes

The fair value of our Convertible Notes is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Convertible Notes are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, a decrease of 10% of the market value of our Common Stock could reduce the value of a $1,000 Note by approximately $94. An increase in market interest rates could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, an interest rate increase of 1% could reduce the value of a $1,000 Convertible Note by approximately $50 . The two examples provided above are only hypothetical and actual changes in the value of the Convertible Notes due to fluctuations in market value of our Common Stock or interest rates could vary substantially from these examples.

ITEM 8. ***Financial Statements and Supplementary Data***

The response to this item is included in a separate section of this Report. See Index to Consolidated Financial Statements on Page F-1.

ITEM 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

ITEM 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of September 30, 2005, of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2005 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions

about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

Management s Report on Internal Control Over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principals in the United States. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based upon that evaluation, management has concluded that our internal control over financial reporting was effective as of September 30, 2005.

Our assessment of the effectiveness of our internal control over financial reporting as of September 30, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears on page F-2.

Due to inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that compliance with the policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***Other Information***

None.

PART III

The information required by Item 10: Directors and Executive Officers of the Registrant; Item 11: Executive Compensation; Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters; Item 13: Certain Relationships and Related Transactions; and Item 14: Principal Accounting Fees and Services will be included in and is incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation l4A within 120 days after the close of our fiscal year except the information required by Regulation S-K, Item 201(d) which is reflected in Part II, Item 5. Market for Registrant s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities.

PART IV

ITEM 15. ***Exhibits, Financial Statement Schedules***

(a)1. Financial Statements

An index to Consolidated Financial Statements appears on page F-1.

2. Schedules

All financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.

(b) Exhibits

3.4	-	Restated Certificate of Incorporation of Registrant, as amended (63)
3.5	-	By-Laws of Registrant (50)
4.1	-	Indenture dated as of July 16, 2003 between the Registrant, Lehman Brothers Inc. and Wachovia Capital Markets, LLC (51)
4.2	-	Registration Rights Agreement dated as of July 16, 2003 between the Registrant, Lehman Brothers Inc. and Wachovia Capital Markets, LLC (51)
4.8	-	1997 Equity Incentive Plan and Form of Restricted Stock Award Agreement thereunder (25)
10.6	-	Assignment of Invention and Agreement between Richard Wurtman, M.D., Judith Wurtman and the Registrant (1)
10.9	-	Restated and Amended 1989 Stock Option Plan (4)
10.11	-	Restated Amendment to MIT Option Agreement (1)
10.12(a)	-	Patent and Know-How License Agreement between the Registrant and Les Laboratoires Servier (Servier) dated February 7, 1990 with Revised Appendix A (1)
10.12(b)	-	Amendment Agreement between Registrant and Servier, Orsem and Oril Produits Chimiques dated November 19, 1992 (2) (6)
10.12(c)	-	Amendment Agreement dated April 28, 1993 between Registrant and Servier (9)
10.12(d)	-	Consent and Amendment Agreement among Servier, American Home Products Corp. and Registrant (17)
10.13	-	Trademark License Agreement between the Registrant and Orsem dated February 7, 1990 (1)
10.14	-	Supply Agreement between the Registrant and Oril Produits Chimiques dated February 7, 1990 (1) (2)
10.16	-	Assignment of Invention by Richard Wurtman, M.D. (1)
10.25	-	License Agreement between the Registrant and the Massachusetts Institute of Technology (3)
10.37	-	License Agreement dated as of February 15, 1992 between the Registrant and Massachusetts Institute of Technology (5)
10.40	-	Patent and Know-How Sublicense and Supply Agreement between Registrant and American Cyanamid Company dated November 19, 1992 (2) (6)
10.41	-	Equity Investment Agreement between Registrant and American Cyanamid Company dated November 19, 1992 (6)
10.42	-	Trademark License Agreement between Registrant and American Cyanamid Company dated November 19, 1992 (6)
10.44	-	Consent Agreement between Registrant and Servier dated November 19, 1992 (12)
10.45	-	Agreement between Registrant and PAREXEL International Corporation dated October 22, 1992 (as of July 21, 1992) (2) (7)
10.46	-	License Agreement dated February 9, 1993 between the Registrant and Massachusetts Institute of Technology (2) (8)
10.52	-	License Agreement dated February 18, 1994 between Registrant and Rhone-Poulenc Rorer, S.A. (11)

10.55	-	Patent License Agreement between Registrant and Massachusetts Institute of Technology dated March 1, 1994 (11)
10.59	-	Exhibit D to Agreement between Registrant and Parexel International Corporation dated as of March 15, 1994 (2) (12)
10.60(a)	-	Acquisition Agreement dated as of May 13, 1994 among the Registrant, Intercardia, Inc., Cardiovascular Pharmacology Engineering Consultants, Inc. (CPEC), Myocor, Inc. and the sellers named therein (13)
10.60(b)	-	Amendment dated June 15, 1994 to Acquisition Agreement referenced in Exhibit 10.60(a) (13)
10.61	-	License Agreement dated December 6, 1991 between Bristol-Myers Squibb and CPEC, as amended (2) (13)
10.61(a)	-	Letter Agreement dated November 18, 1994 between CPEC and Bristol-Myers Squibb (4)
10.65(a)	-	1994 Long-Term Incentive Plan, as amended (23)
10.68(a)	-	Interneuron Pharmaceuticals, Inc. 1995 Employee Stock Purchase Plan, as amended (19) (58)
10.78	-	Contract Manufacturing Agreement dated November 20, 1995 between Registrant and Boehringer Ingelheim Pharmaceuticals, Inc. (2) (l7)
10.83	-	Co-promotion Agreement effective June 1, 1996 between Wyeth-Ayerst Laboratories and Interneuron Pharmaceuticals, Inc. (2) (18)
10.87	-	Lease dated February 5, 1997 between Registrant and Ledgemont Realty Trust (21)
10.93	-	Form of Indemnification Agreement between Registrant and each director, executive officer and certain officers of the Registrant entered into as of October 6, 1997 (26)
10.94	-	1998 Employee Stock Option Plan (27)
10.96	-	Assignment and Assumption and Royalty Agreement between Intercardia and Registrant dated May 8, 1998 (29)
10.102	-	Employment Agreement between Interneuron Pharmaceuticals, Inc. and Michael W. Rogers dated and effective as of February 23, 1999 (34)
10.103	-	Employment Agreement between Interneuron Pharmaceuticals, Inc. and Bobby W. Sandage, Jr. dated and effective as of March 15, 1999 (34)
10.104	-	Employment Agreement between Interneuron Pharmaceuticals, Inc. and Mark S. Butler dated and effective as of March 15, 1999 (34)
10.105	-	Employment Agreement between Intemeuron Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated and effective as of May 1, 1999 (34)
10.108	-	Exchange Agreement dated July 15, 1999 between Intercardia, Inc. and Interneuron Pharmaceuticals, Inc. (35)
10.109	-	Amended and Restated Limited Liability Company Agreement of CPEC LLC dated July 15, 1999 among CPEC LLC, Interneuron Pharmaceuticals, Inc. and Intercardia, Inc. (35)
10.110	-	Assignment, Assumption and License Agreement dated July 15, 1999 by and between CPEC LLC and Intercardia, Inc. (35)
10.113	-	License Agreement effective as of November 26, 1999 between Madaus AG and Interneuron Pharmaceuticals, Inc. (37) (2)
10.116(a)	-	2000 Stock Option Plan (39)

10.119	-	License Agreement by and between Charles S. Lieber, M.D. and Interneuron Pharmaceuticals, Inc. dated December 26, 2000 (42) (2)
10.120	-	Indemnity and Release Agreement between American Home Products Corporation and Interneuron Pharmaceuticals, Inc. dated as of May 30, 2001 (43) (2)
10.124	-	Form of Stock Purchase Agreement dated December 20, 2001 between Indevus Pharmaceuticals, Inc. and the Investors named on Schedule A attached thereto (45)
10.127	-	Employment Agreement dated and effective as of October 1, 2002 by and between Indevus Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. (47)
10.128	-	Amendment No. 1 to Licensing Agreement by and between Registrant and Eli Lilly and Company and Eli Lilly S.A. (48) (2)
10.129	-	Supply Agreement between Registrant and Madaus AG dated December 16, 2003 (48) (2)
10.130	-	Development and License Agreement between Registrant and Shire Laboratories Inc. dated March 11, 2003 (49) (2)
10.131	-	Amendment to the License Agreement by and between Registrant and Paligent Inc. dated April 10, 2003 (49)
10.132	-	License Agreement by and between Registrant and Aventis Pharma SA dated April 18, 2003 (51) (2)
10.133	-	License Agreement by and between Registrant and Sumner Burstein dated August 22, 2003 (52) (2)
10.134	-	Assignment and Termination Agreement by and between Registrant and Manhattan Pharmaceuticals, Inc. dated August 22, 2003 (52) (2)
10.135	-	Fiscal 2004 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 25, 2003 (52)
10.136	-	Agreement by and between the Registrant and Ferrer Internacional S.A. dated January 22, 2004 (53)(2)
10.138	-	2004 Equity Incentive Plan (54)
10.139	-	License, Commercialization and Supply Agreement dated April 6, 2004 between the Registrant and Odyssey Pharmaceuticals Inc. (55)(2)
10.140	-	Fiscal 2005 CEO Bonus Plan, as adopted by the Board of Directors on December 7, 2004 (56)
10.141	-	Fiscal 2005 Senior Executive Bonus Plan, as adopted by the Board of Directors on December 7, 2004 (56)
10.142	-	Indenture of Lease dated December 20, 2004 between the Registrant and Mortimer B. Zuckerman and Edward H. Linde, Trustees of Hayden Office Trust (57)
10.143	-	Amendment No. 1 to License, Commercialization and Supply Agreement dated April 30, 2005 between the Registrant and Odyssey Pharmaceuticals, Inc. (59)
10.144	-	Amendment and Consent Agreement dated May 14, 2005 between the Registrant, Odyssey Pharmaceuticals, Inc., and Saturn Pharmaceuticals, Inc (60)
10.145	-	License Agreement dated July 28, 2005 between the Registrant and Schering Aktiengesellschaft (61)
10.146	-	Fiscal 2006 CEO Bonus Plan, as adopted by the Board of Directors on September 20, 2005 (62)

10.147	-	Fiscal 2006 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 20, 2005 (62)
10.148	-	Collaborative Research and Licensing Agreement dated July 26, 2005 between the Registrant and Medical Research Counsel (63) (2)
10.149	-	Form of Indemnification Agreement between Registrant and certain directors, executive officers and officers of the Registrant (63)
21	-	List of Subsidiaries (63)
23	-	Consent of PricewaterhouseCoopers LLP (63)
31.1	-	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (63)
31.2	-	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (63)
32.1	-	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer (63)
32.2	-	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Michael W. Rogers, Chief Financial Officer (63)

(1) Incorporated by reference to the Registrant s Registration Statement on Form S-1 (File No. 33-32408) declared effective on March 8, 1990.
(2) Confidential Treatment requested for a portion of this Exhibit.
(3) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the year ended September 30, 1990.
(4) Incorporated by reference to Post-Effective Amendment No. 2 to the Registrant s Registration Statement on Form S-1 (File No. 33-32408) filed December 18, 1991.
(5) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1992.
(6) Incorporated by reference to the Registrant s Form 8-K dated November 30, 1992.
(6a) Incorporated by reference to Post-Effective Amendment No. 5 to the Registrant s Registration Statement on Form S-1 (File No. 33-32408) filed on December 21, 1992.
(7) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1992.
(8) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 1992.
(9) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1993.
(10) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 1993.
(11) Incorporated by reference to the Registrant s Registration Statement on Form S-3 or Amendment No. I (File no. 33-75826).
(12) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1994.
(13) Incorporated by reference to the Registrant s Form 8-K dated June 20, 1994.
(14) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1994.
(15) Incorporated by reference to the Registrant s Report on Form 8-K dated June 2, 1995.

(16) Incorporated by reference to the Registrant s Report on Form 8-K dated August 16, 1995.
(17) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1995.
(18) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q or 10-Q/A for the period ended June 30. 1996.
(19) Incorporated by reference to Amendment No. 1 to Registrant s Registration Statement on Form S-3 (File No. 333-1273) filed March 15, 1996.
(20) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1996.
(21) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 1996.
(22) Incorporated by reference to Exhibit 3.5 of the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1997.
(25) Incorporated by reference to the Registrant s Form S-8 (File No. 333-40315) filed November 14, 1997.
(26) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1997.
(27) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 1997.
(28) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1998.
(29) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 1998.
(30) Incorporated by reference as to Exhibit 99.1 of Registrant s Form 8-K dated September 3, 1998.
(31) Incorporated by reference as to Exhibit 99.2 of Registrant s From 8-K dated September 28, 1998.
(32) Incorporated by reference as to Exhibit 99.3 of Registrant s Form 8-K dated September 28, 1998.
(34) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1999.
(35) Incorporated by reference to Registrant s Form 8-K dated July 27, 1999.
(37) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1999.
(38) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 1999.
(39) Incorporated by reference to Registrant s Definitive Proxy Statement filed January 28, 2000.
(40) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 2000.
(41) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2000.
(42) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 2000.
(43) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 2001.
(44) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2001.
(45) Incorporated by reference to Exhibit 10.124 of Registrant s Form 8-K dated December 21, 2001.
(46) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 1998.
(47) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2002.
(48) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 2003.
(49) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2003.

(50) Incorporated by reference to Registrant s Form 8-K filed July 3, 2003.
(51) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 2003.
(52) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2003.
(53) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2004.
(54) Incorporated by reference to Registrant s Definitive Proxy Statement filed January 28, 2004.
(55) Incorporated by reference to Registrant s Form 8-K filed April 19, 2004.
(56) Incorporated by reference to Registrant s Form 8-K filed December 13, 2004.
(57) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 2004.
(58) Incorporated by reference to Registrant s Definitive Proxy Statement filed January 28, 2005.
(59) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2005.
(60) Incorporated by reference to Registrant s Form 8-K filed May 17, 2005.
(61) Incorporated by reference to Registrant s Form 8-K filed August 2, 2005.
(62) Incorporated by reference to Registrant s Form 8-K filed October 28, 2005.
(63) Filed with this report.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 14, 2005

INDEVUS PHARMACEUTICALS, INC.

By: /s/ GLENN L. COOPER
Glenn L. Cooper, M.D. President, Chief Executive Officer and Chairman

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons in the capacity and as of the date indicated.

Name	Title	Date
/s/ GLENN L. COOPER **Glenn L. Cooper, M.D.**	President, Chief Executive Officer and Chairman (Principal Executive Officer)	December 14, 2005
/s/ HARRY GRAY **Harry Gray**	Director	December 14, 2005
/s/ MICHAEL E. HANSON **Michael E. Hanson**	Director	December 14, 2005
/s/ STEPHEN C. MCCLUSKI **Stephen C. McCluski**	Director	December 14, 2005
/s/ MALCOLM MORVILLE **Malcolm Morville**	Director	December 14, 2005
/s/ CHERYL P. MORLEY **Cheryl P. Morley**	Director	December 14, 2005
/s/ DAVID B. SHARROCK **David B. Sharrock**	Director	December 14, 2005

/s/ Michael W. Rogers **Michael W. Rogers**	Executive Vice President, Chief Financial Officer, and Treasurer (Principal Financial Officer)	December 14, 2005
/s/ Dale Ritter **Dale Ritter**	Senior Vice President, Finance, (Principal Accounting Officer)	December 14, 2005

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Indevus Pharmaceuticals, Inc.:

We have completed an integrated audit of Indevus Pharmaceuticals, Inc. s 2005 consolidated financial statements and of its internal control over financial reporting as of September 30, 2005 and audits of its 2004 and 2003 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)1, present fairly, in all material respects, the financial position of Indevus Pharmaceuticals, Inc. and its subsidiaries at September 30, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Internal control over financial reporting

Also, in our opinion, management s assessment, included in Management s Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of September 30, 2005 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2005, based on criteria established in *Internal Control Integrated Framework* issued by the COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and on the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and

directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers, LLP

Boston, Massachusetts

December 14, 2005

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands except share data)

	September 30, 2005	September 30, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 85,098	$ 103,099
Marketable securities	16,119	50,423
Accounts receivable	2,537	7,042
Inventories	971	1,160
Prepaid and other current assets	2,516	3,082
Total current assets	107,241	164,806
Marketable securities		3,486
Property and equipment, net	1,103	546
Insurance claim receivable	1,258	1,258
Prepaid debt issuance costs	1,843	2,503
Other assets	1,086	1,239
Total assets	$ 112,531	$ 173,838
LIABILITIES		
Current liabilities:		
Accounts payable	$ 2,297	$ 6,361
Accrued expenses	9,910	13,707
Accrued interest	950	950
Deferred revenue	14,851	12,500
Total current liabilities	28,008	33,518
Convertible notes	72,000	72,000
License fees payable		100
Deferred revenue	127,457	131,250
Other	202	
Minority interest	6	8
Commitments and contingencies (Notes G and I)		
STOCKHOLDERS DEFICIT		
Convertible preferred stock $.001 par value, 5,000,000 shares authorized:		
Series B, 239,425 shares issued and outstanding (liquidation preference September 30, 2005 $3,026)	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference September 30, 2005 $502)	500	500
Common stock, $.001 par value 120,000,000 shares authorized; 47,825,896 shares issued at September 30, 2005 and 2004	48	48
Additional paid-in-capital	307,435	309,050
Accumulated deficit	(422,121)	(368,903)
Accumulated other comprehensive loss	(4)	(131)
Treasury stock, at cost, 660,607 and 1,057,125 shares at September 30, 2005 and 2004, respectively	(4,000)	(6,602)

Total stockholders deficit	(115,142)	(63,038)
Total liabilities and stockholders deficit	$ 112,531	$ 173,838

The accompanying notes are an integral part of the consolidated financial statements

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands except per share data)

	For the years ended September 30,		
	2005	**2004**	**2003**
Revenues:			
Product revenue	$ 14,269	$ 9,740	$ 4,316
Contract and license fees	19,067	8,986	929
Total revenues	33,336	18,726	5,245
Costs and expenses:			
Cost of product revenue	8,593	7,950	1,073
Research and development	30,597	23,303	24,466
Marketing, general and administrative	41,983	51,916	11,105
Total costs and expenses	81,173	83,169	36,644
Loss from operations	(47,837)	(64,443)	(31,399)
Investment income	3,142	1,396	664
Interest expense	(5,170)	(5,170)	(1,077)
Other	(182)	5	
Loss before income taxes	(50,047)	(68,212)	(31,812)
Provision for income taxes	(3,171)		
Net loss	$ (53,218)	$ (68,212)	$ (31,812)
Net loss per common share, basic and diluted	$ (1.13)	$ (1.43)	$ (0.68)
Weighted average common shares outstanding, basic and diluted	46,977	47,542	46,930

The accompanying notes are an integral part of the consolidated financial statements

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(Dollar amounts in thousands)

	Common Stock		Preferred Stock		Additional
	Number of Shares	Par Value Amount	Number of Shares	Amount	Paid-In Capital
Balance at September 30, 2002	46,875,885	$ 47	244,425	$ 3,500	$ 302,678
Proceeds from exercise of stock options	150,000				254
Proceeds from offering of Employee Stock Purchase Plan	75,452				160
Dividends on preferred stock					(35)
Stock-based compensation and other	74,324				395
Comprehensive loss:					
Net loss					
Unrealized net gain on marketable and equity securities					
Total comprehensive loss					
Balance at September 30, 2003	47,175,661	47	244,425	3,500	303,452
Purchase of treasury stock					
Proceeds from exercise of stock options	576,332	1			1,407
Proceeds from offering of Employee Stock Purchase Plan	68,120				145
Dividends on preferred stock					(35)
Stock-based compensation and other	5,783				4,081
Comprehensive loss:					
Net loss					
Unrealized net loss on marketable and equity securities					
Total comprehensive loss					
Balance at September 30, 2004	47,825,896	48	244,425	3,500	309,050
Proceeds from exercise of stock options					(1,036)
Proceeds from offering of Employee Stock Purchase Plan					(580)
Dividends on preferred stock					(35)
Stock-based compensation and other					36
Comprehensive loss:					
Net loss					
Unrealized net gain on marketable and equity securities					
Total comprehensive loss					
Balance at September 30, 2005	47,825,896	$ 48	244,425	$ 3,500	$ 307,435

The accompanying notes are an integral part of the consolidated financial statements.

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(Dollar amounts in thousands)

	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Shares		Total Equity (Deficit)	Comprehensive Loss
			Number of Shares	Amount		
Balance at September 30, 2002	$ (268,879)	$ (128)			$ 37,218	
Proceeds from exercise of stock options					254	
Proceeds from offering of Employee Stock Purchase Plan					160	
Dividends on preferred stock					(35)	
Stock-based compensation and other					395	
Comprehensive loss:						
Net loss	(31,812)				(31,812)	$ (31,812)
Unrealized net gain on marketable and equity securities		61			61	61
Total comprehensive loss						$ (31,751)
Balance at September 30, 2003	(300,691)	(67)			6,241	
Purchase of treasury stock			1,166,200	(7,319)	(7,319)	
Proceeds from exercise of stock options			(84,751)	582	1,990	
Proceeds from offering of Employee Stock Purchase Plan			(17,838)	92	237	
Dividends on preferred stock					(35)	
Stock-based compensation and other			(6,486)	43	4,124	
Comprehensive loss:						
Net loss	(68,212)				(68,212)	$ (68,212)
Unrealized net loss on marketable and equity securities		(64)			(64)	(64)
Total comprehensive loss						$ (68,276)
Balance at September 30, 2004	(368,903)	(131)	1,057,125	(6,602)	(63,038)	
Proceeds from exercise of stock options			(246,791)	1,620	584	
Proceeds from offering of Employee Stock Purchase Plan			(138,364)	908	328	
Dividends on preferred stock					(35)	
Stock-based compensation and other			(11,363)	74	110	
Comprehensive loss:						
Net loss	(53,218)				(53,218)	$ (53,218)
Unrealized net gain on marketable and equity securities		127			127	127
Total comprehensive loss						$ (53,091)
Balance at September 30, 2005	$ (422,121)	$ (4)	660,607	$ (4,000)	$ (115,142)	

The accompanying notes are an integral part of the consolidated financial statements.

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands)

	For the years ended September 30,		
	2005	**2004**	**2003**
Cash flows from operating activities:			
Net loss	$ (53,218)	$ (68,212)	$ (31,812)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	403	122	16
Amortization of convertible note issuance costs	660	660	138
Impairment and loss on equity securities	185		
Noncash compensation	75	4,089	
Noncash license fee			360
Lease abandonment	1,310		
Changes in assets and liabilities:			
Accounts receivable	4,505	(6,887)	395
Inventories	189	(1,160)	
Prepaid and other assets	652	(3,013)	(708)
Accounts payable	(4,064)	4,353	1,610
Deferred revenue	(1,442)	143,750	(24)
Accrued expenses and other liabilities	(5,012)	4,945	3,530
Net cash (used in) provided by operating activities	(55,757)	78,647	(26,495)
Cash flows from investing activities:			
Purchases of property and equipment	(957)	(636)	(33)
Purchases of marketable securities		(61,208)	(56,836)
Proceeds from maturities and sales of marketable securities	37,780	63,671	21,991
Proceeds from sale of Aeolus	22		
Net cash (used in) provided by investing activities	36,845	1,827	(34,878)
Cash flows from financing activities:			
Net proceeds from issuance of common and treasury stock	911	2,227	414
Proceeds from issuance of convertible notes			72,000
Costs related to issuance of convertible notes			(3,301)
Purchase of treasury stock		(7,319)	
Net cash (used in) provided by financing activities	911	(5,092)	69,113
Net change in cash and cash equivalents	(18,001)	75,382	7,740
Cash and cash equivalents at beginning of period	103,099	27,717	19,977
Cash and cash equivalents at end of period	$ 85,098	$ 103,099	$ 27,717

The accompanying notes are an integral part of the consolidated financial statements.

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. Nature of the Business

Indevus Pharmaceuticals, Inc. (Indevus or the Company) 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. The Company currently markets SANCTURA for overactive bladder (see Note N) and has six compounds in clinical development: SANCTURA XR, a once-daily formulation of SANCTURA, NEBIDO for male hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted diseases, IP 751 for pain and inflammatory disorders, including interstitial cystitis, pagoclone for the treatment of stuttering, and aminocandin for systemic fungal infections.

The Company is subject to risks and uncertainties common to companies in the biopharmaceuticals industry and specific risks. Such risks 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.

B. Summary of Significant Accounting Policies

Basis of Presentation: The consolidated financial statements include the accounts of the Company and its majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. Investments in subsidiaries which are less than majority but greater than 20% owned are reflected using the equity method of accounting. For an entity that is not a variable interest entity under FIN 46, Consolidation of Variable Interest Entities, the Company s policy is to consolidate a subsidiary when the Company owns greater than 50% of the voting interest in the subsidiary and/or controls it. Certain prior year amounts have been reclassified to conform to fiscal 2005 classifications. In connection with preparation of the accompanying consolidated financial statements, the Company concluded that it was appropriate to classify its investments in auction rate securities as short-term available-for-sale investments. Previously, such investments were classified as cash and cash equivalents. Accordingly, the Company has revised the classification to exclude from cash and cash equivalents $24.0 million and $30.0 million of auction rate securities at September 30, 2004 and 2003, respectively, and to include such amounts as short-term available-for-sale investments. In addition, the Company has made corresponding revisions to the accompanying consolidated statements of cash flows to reflect the gross purchases and sales of these securities as investing activities. As a result, cash used in investing activities decreased $6.0 million in fiscal 2004 and cash used in investing activities increased $30.0 million in fiscal 2003. This revision in classification does not affect previously reported cash flows from operations or from financing activities.

Use of Estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Actual results could differ from those estimates.

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Cash, Cash Equivalents and Marketable Securities: The Company invests available cash primarily in short- term bank deposits, money market funds, repurchase agreements, domestic and foreign commercial paper and government securities. Cash and cash equivalents includes investments with maturities of three months or less at date of purchase. Marketable securities consist of investments purchased with maturities greater than three months and are classified as noncurrent if they mature one year or more beyond the balance sheet date and not considered available to fund current operations. The Company classifies its investments in debt securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time the investments are purchased. At September 30, 2005 and 2004, all investments held were classified as available-for-sale. Investments are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income or loss until realized. The fair value of these securities is based on quoted market prices.

Accounts Receivable: Trade accounts receivable are recorded at the invoiced amount and do not bear interest. At September 30, 2005 and 2004, the Company had not recorded an allowance for doubtful accounts as the Company believes all balances to be fully collectible.

Concentration of Credit Risk: Financial instruments that potentially subject the Company to concentration of credit risk consist principally of money market funds and marketable securities. The Company places these investments in highly rated financial institutions. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in these accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no foreign exchange contracts, option contracts or other foreign exchange hedging arrangements.

To date, the Company s revenues have been generated from a limited number of sources. In fiscal 2005, the Company s revenue was primarily generated pursuant to the SANCTURA Agreement (see Note N). Total revenues generated in accordance with these agreements was $31,650,000, or 95%, of total revenue in fiscal 2005 and $16,214,000, or 87%, of total revenue in fiscal 2004. Esprit also represented approximately 99% of accounts receivable at September 30, 2005. The Company believes credit risk associated with Esprit is not significant.

Inventory: Inventory is stated at the lower or cost or market determined under the first in, first out (FIFO) method.

Property and Equipment: Property and equipment are stated at cost. The Company provides for depreciation using the straight-line method based upon the following estimated useful lives:

Office and other equipment	2 to 5 years
Leasehold improvements	Shorter of lease term or estimated useful life

Expenses for repairs and maintenance are charged to operations as incurred. Upon retirement or sale, the cost of the assets disposed and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged, respectively, to operations.

Impairment of Long-Lived Assets: The Company evaluates the recoverability of its long-lived assets when the facts and circumstances suggest that these assets may be impaired. When the Company conducts an evaluation they consider several factors, including operating results, business plans, economic projections, strategic plans and market emphasis. Unrealizable long-lived asset values are charged to operations if the Company s evaluations indicate that the value of these assets is impaired.

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue Recognition: Product revenue consists of revenues from sales of products, commissions and royalties and reimbursements for royalties owed by the Company to Madaus GmbH (Madaus) pursuant to the SANCTURA Agreement (See Note N). Contract and license fee revenue consists of revenue stemming from contractual initial and milestone payments received from customers, including amortization of deferred revenue from contractual payments, reimbursements from PLIVA for their share of SANCTURA promotion and advertising costs incurred by the Company less an amount owed by the Company to PLIVA for the Company s share of SANCTURA promotion and advertising costs incurred by PLIVA, sales force subsidies, and grants from agencies supporting research and development activities.

The Company records sales of product as product revenue upon the later of shipment or as title passes to its customer.

Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize the Company s licensed technologies and are generally reported to the Company in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based. If the royalty report for such period is received subsequent to the time the Company is required to report its results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, in which case the Company recognizes such royalty revenue in the subsequent accounting period when it receives the royalty report and when the amount of and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

The Company s business strategy includes entering into collaborative license and development or co-promotion agreements with strategic partners for the development and commercialization of the Company s products or product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones and royalties on net product sales. Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. In multiple element arrangements where the Company has continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as the Company completes its performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement. The Company records such revenue as contract and license fee revenue.

Revenues from milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. Determination as to whether a milestone meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations. Revenues from milestone payments related to arrangements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone. The Company records such revenue as contract and license fee revenue.

Under the SANCTURA Agreement, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue using the contingency-adjusted performance model. Under this

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

model, when a milestone is earned, revenue is immediately recognized on a pro-rata basis in the period the Company achieves the milestone based on the time elapsed from inception of the SANCTURA Agreement to the time the milestone is earned over the estimated duration of the SANCTURA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the SANCTURA Agreement.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force (EITF) Issue Number 00-21, Accounting Revenue Arrangements with Multiple Deliverables (EITF 00-21). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104 (SAB 104), unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements. In particular relating to the SANCTURA Agreement, the Company and PLIVA were contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by the Company, reimbursements from PLIVA for PLIVA s share are reflected in contract and license fee revenue. For promotion and advertising costs incurred by PLIVA, reimbursements to PLIVA for the Company s share were reflected as a reduction of contract and license fee revenue.

Cash received in advance of revenue recognition is recorded as deferred revenue.

Research and Development: Research and development costs are expensed in the period incurred. Included in research and development costs are wages, benefits and other operational costs related to the Company s research and development department and employees, allocations of facilities costs, external costs of outside contractors engaged to conduct clinical trials and other clinical studies, and costs of consultants.

Income Taxes: Deferred tax liabilities and assets are recognized based on temporary differences between the financial statement basis and tax basis of assets and liabilities using current statutory tax rates. A valuation allowance against net deferred tax assets is established if, based on the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounting for Stock-Based Compensation: The Company applies Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), and related interpretations, in accounting for its stock-based compensation plans. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment SFAS No. 123 (SFAS No. 148). Had compensation expense for the Company s stock option plans been determined based on the fair value at the grant date for awards under these plans using a Black-Scholes option pricing model consistent with the methodology prescribed under SFAS No. 148, the Company s net loss and net loss per share would have approximated the pro forma amounts indicated below:

	Fiscal year ended September 30,		
	2005	2004	2003
As reported net loss	$ (53,218,000)	$ (68,212,000)	$ (31,812,000)
Noncash compensation expense included in reported net loss	$ 75,000	$ 4,089,000	$
Compensation expense determined under the fair-value method for all awards	$ (3,247,000)	$ (1,903,000)	$ (1,231,000)
Pro forma net loss	$ (56,390,000)	$ (66,026,000)	$ (33,043,000)
As reported net loss per common share:			
Basic	$ (1.13)	$ (1.43)	$ (0.68)
Diluted	$ (1.13)	$ (1.43)	$ (0.68)
Pro forma net loss per common share:			
Basic	$ (1.20)	$ (1.39)	$ (0.70)
Diluted	$ (1.20)	$ (1.39)	$ (0.70)

All stock-based awards to non-employees are accounted for at their fair value in accordance with SFAS No. 123 and EITF No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with, Selling, Goods or Services.

Pro forma information regarding net loss shown above was determined as if the Company and its consolidated subsidiaries had accounted for employee stock options and shares purchased under stock purchase plans under the fair value method of SFAS No. 123. The fair value of each option grant is estimated on the date of the grant using a Black-Scholes option-pricing model with the following weighted-average assumptions used for grants:

	2005	2004	2003
Dividend yield	0%	0%	0%
Expected volatility	60%	90%	90%
Risk free interest rate	3.95%-4.15%	1.9%-3.1%	1.7%-3.5%
Expected option life	4 years	4 years	4 years
Weighted average grant date fair value:			
Options granted at fair market value	$ 3.84	$ 6.62	$ 3.64

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options. The Company s employee stock options have characteristics significantly different from those of traded options such as vesting restrictions and extremely limited transferability. In addition, the assumptions used in option valuation models are highly subjective, particularly the assumption of expected stock price volatility of the underlying stock. Changes in these subjective assumptions can materially affect the fair value estimate. See Recent Accounting Pronouncements for further discussion of stock-based compensation.

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Comprehensive Income or Loss: Components of comprehensive income or loss include net income or loss and all other non-owner changes in equity such as the change in the cumulative gain or loss on marketable securities. The Company presents comprehensive income or loss in its consolidated statements of stockholders equity (deficit).

Segment Information: The Company operates in one business segment, drug development and commercialization. The Company follows the requirements of SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information.

Recent Accounting Pronouncements:

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), Share-Based Payments (SFAS No. 123R), which revises SFAS No. 123, Accounting for Stock-Based Compensation and requires companies to expense the fair value of employee stock options and other forms of stock-based compensation. Under SFAS 123R, the most significant change in practice would be treating the fair value of stock-based payment awards that are within its scope as compensation expense in the income statement beginning on the date that a company grants the awards to employees. The Company is required to implement SFAS 123(R) for fiscal 2006. SFAS 123(R) will apply to all awards granted after the implementation date. The Company expects to incur a noncash charge to operations of approximately $3,100,000 in fiscal 2006 related to the adoption of SFAS 123(R). However, the actual share-based compensation expense in fiscal 2006 depends on numerous factors, including fair value of awards at the time of grant.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections. SFAS No. 154 is a replacement of APB No. 20 and FASB Statement No. 3. SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application as the required method for reporting a change in accounting principle. SFAS No. 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS No. 154. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company will adopt this pronouncement beginning October 1, 2006. The Company does not expect the adoption of SFAS No. 154 will have a material impact on the Company s financial position or results of operations.

C. Marketable Securities

Investments in marketable securities consisted of the following at September 30, 2005 and 2004:

	2005		2004	
	Cost	Market Value	Cost	Market Value

State government obligations	$ 15,000,000	$ 15,000,000	$ 24,000,000	$ 24,000,000
U.S. corporate notes	1,123,000	1,119,000	29,903,000	29,909,000
	$16,123,000	$ 16,119,000	$ 53,903,000	$ 53,909,000

At September 30, 2005, there were no gross unrealized gains and gross unrealized losses on marketable securities were $4,000. At September 30, 2004, gross unrealized gains and losses on marketable securities were $15,000 and $9,000 respectively. At September 30, 2005 and 2004, state government obligations consisted of auction rate securities having stated maturities between 27 and 40 years from the respective balance sheet dates. These securities are readily liquid, available to fund current operations and classified as available-for sale and are therefore classified as current marketable securities. At September 30, 2005, U.S. corporate notes of $1,119,000 mature within one year of the balance sheet date. At September 30, 2004, U.S. corporate notes of $26,423,000

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

mature within one year of the balance sheet date and $3,486,000 mature beyond one year but within two years from the balance sheet date. At September 30, 2005 and 2004, respectively, the Company had no investments in an unrealized loss position for which other-than-temporary impairments have not been recognized.

D. Inventories

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out (FIFO) method.

The components of inventory at September 30, 2005 and 2004 are as follows:

	2005	2004
Raw materials	$ 971,000	$ 488,000
Finished goods		672,000
	$ 971,000	$ 1,160,000

Inventories consist solely of SANCTURA. Raw materials consist of tablets of SANCTURA in bulk form purchased from the Company s supplier, Madaus. Finished goods consist of SANCTURA tablets packaged in bottles for resale and blister packages for distribution as samples.

E. Property and Equipment

At September 30, 2005 and 2004, property and equipment consisted of the following:

	2005	2004
Office and other equipment	$ 1,911,000	$ 1,418,000
Leasehold improvements	317,000	362,000
	2,228,000	1,780,000
Less: accumulated depreciation and amortization	(1,125,000)	(1,234,000)

$ 1,103,000	$ 546,000

There were no assets under capital leases at September 30, 2005 and 2004, respectively.

Depreciation and amortization expenses for the years ended September 30, 2005, 2004, and 2003 were $403,000, $122,000, and $16,000, respectively.

F. Accrued Expenses

At September 30, 2005 and 2004, accrued expenses consisted of the following:

	2005	2004
Clinical and sponsored research	$ 3,020,000	$ 2,399,000
Compensation related	2,547,000	4,132,000
Lease abandonment	849,000	
Professional fees	1,074,000	2,701,000
Income taxes	802,000	
Redux related	578,000	654,000
Manufacturing and production costs		3,139,000
Other	1,040,000	682,000
	$ 9,910,000	$ 13,707,000

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

G. Commitments

The Company leases its facilities, as well as certain office equipment and furniture under non-cancelable operating leases. Rent expense under these leases was approximately $940,000, $600,000, and $557,000, for the years ended September 30, 2005, 2004, and 2003, respectively.

At September 30, 2005, the Company s future minimum payments under non-cancelable lease arrangements are as follows:

Fiscal year	Operating Leases
2006	$ 1,463,000
2007	1,377,000
2008	1,079,000
2009	1,102,000
2010	1,125,000
Thereafter	188,000
Total lease payments	$ 6,334,000

Pursuant to certain of our in-licensing arrangements, the Company will owe payments to our licensors upon achievement of certain development, regulatory and licensing milestones. The Company cannot predict if or when such events will occur.

Pursuant to the Agreement with Madaus, the Company is committed to purchase from Madaus significant minimum quantities of bulk SANCTURA tablets during fiscal 2006 aggregating approximately $9,700,000. If this minimum purchase requirement is not satisfied, the Company would be subject to a minimum supply fee of a portion of the value of the unpurchased minimum quantities. Pursuant to the SANCTURA Agreement, Esprit agreed to purchase the same quantities of SANCTURA and to be responsible for commercial product procurement costs, including costs to manufacture SANCTURA and the minimum supply fee.

The Company leases approximately 90 automobiles for its field sales force. The lease requires a minimum term of 12 months per automobile. The Company expects monthly lease expense related to this operating lease to be approximately $50,000. The Company is responsible for certain disposal costs in case of termination.

In December 2004, the Company entered into a lease agreement for its new corporate headquarters in Lexington, MA. This lease, for approximately 45,000 square feet, provides for an initial term of 66 months commencing upon occupancy. Lease payments commence six months after occupancy and the aggregate minimum rental commitment is approximately $5,400,000 for the initial term. The initial term of this

lease expires in December 2010. Additionally, the Company has provided a $500,000 letter of credit to the landlord as a security deposit. The expiration of the letter of credit coincides with the initial term of the facility lease. The Company occupied its new facility in June 2005, prior to the April 2007 expiration of the lease period of our prior facility. As a result, the Company recorded a charge of approximately $1,310,000 to marketing, general and administrative expense in fiscal 2005 related to the nonutilization of its prior facility. This charge was recorded pursuant to SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities, and incorporates management s best estimate of future rental obligations offset by potential sublease income. Approximately $259,000 of the initial liability was paid in fiscal 2005 and at September 30, 2005, the remaining liability was $1,051,000, of which $202,000 was classified as noncurrent.

Guarantees

Our charter provides for indemnification, to the fullest extent permitted under Delaware law, of any person who is made a party to any action or threatened with any action as a result of such person s serving or having served as one of our officers or directors. We have separate indemnification agreements with certain of our

officers and directors. The indemnification obligation survives termination of the indemnified party s involvement with us but only as to those claims arising from such person s role as an officer or director. The maximum potential amount of future payments that we could be required to make under the charter provision and the corresponding indemnification agreements is unlimited; however, we have director and officer insurance policies that, in most cases, would limit our exposure and enable us to recover a portion of any future amounts paid.

We also enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, and clinical sites. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. However, other than costs and claims related to the market withdrawal of Redux (see Note I), to date there have been no claims to defend or settle related to these indemnification provisions.

H. Convertible Notes

In July 2003, the Company received net proceeds of approximately $68,700,000 from the sale of $72,000,000 aggregate principal amount of 6.25% Convertible Senior Notes due 2008 (the Convertible Notes) to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The Convertible Notes are convertible at anytime prior to the July 15, 2008 maturity date into the Company s Common Stock at an initial conversion price of $6.656 per share, subject to adjustment for certain events; the Company has reserved approximately 10,800,000 shares of Common Stock for issuance pursuant to such a conversion and has registered with the SEC the Convertible Notes and Common Stock for resale. Additionally, all or a portion of the Convertible Notes are redeemable by the Company for cash at any time after July 20, 2006 provided the Company s Common Stock equals or exceeds 150% of the conversion price then in effect for a specified period and all of the Convertible Notes are subject to repurchase by the Company at the option of the Convertible Note holders if a change in control occurs. Interest is payable semiannually in arrears on January 15 and July 15 through the maturity date. Prepaid debt issuance costs related to the Convertible Notes were $3,301,000 and are being amortized to interest expense on a straight-line basis over the five year term of the Convertible Notes. At September 30, 2005, the market value of a $1,000 Convertible Note was approximately $940.

I. Withdrawal of Redux, Legal Proceedings, Insurance Claims, and Related Contingencies

In May 2001, the Company entered into the AHP Indemnity and Release Agreement pursuant to which Wyeth agreed to indemnify the Company against certain classes of product liability cases filed against the Company related to Redux (dexfenfluramine hydrocloride capsules) C-IV, a prescription anti-obesity compound withdrawn from the market in September 1997. This indemnification covers plaintiffs who initially opted out of Wyeth s national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth has agreed to fund all future legal costs related to the Company s defense of Redux-related product liability cases. Also, pursuant to the agreement, Wyeth has funded additional insurance coverage to supplement the Company s existing product liability insurance. The Company believes this total insurance coverage is sufficient to address its potential remaining Redux product liability exposure. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which the Company is not otherwise indemnified or covered under the AHP Indemnity and Release Agreement will not have a material adverse effect on the Company s future business, results of operations or financial condition or that the potential of any such claims would not adversely affect the Company s ability to obtain sufficient financing to fund operations. Up to the date of the AHP Indemnity and Release Agreement, the

INDEVUS PHARMACEUTICALS, INC.

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Company s defense costs were paid by, or subject to reimbursement to the Company from, the Company s product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to Indevus by Wyeth, the Company agreed to dismiss its suit against Wyeth filed in January 2000, its appeal from the order approving Wyeth s national class action settlement of diet drug claims, and its cross-claims against Wyeth related to Redux product liability legal actions.

At September 30, 2005, the Company has an accrued liability of approximately $600,000 for Redux-related expenses, including legal expenses. In fiscal 2003, the Company reduced its estimate of the amount of Redux-related expenses, including legal expenses, remaining due, in part, to a decline in the amount of actual payments during fiscal 2003. As a result, the Company reduced its accrued liability for Redux-related expenses by approximately $600,000 and reflected this reduction as a credit in marketing, general and administrative expense. The amounts the Company ultimately pays could differ significantly from the amount currently accrued at September 30, 2005. To the extent the amounts paid differ from the amounts accrued, the Company will record a charge or credit to the statement of operations.

As of September 30, 2005, the Company had an outstanding insurance claim of approximately $3,700,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company s current outstanding insurance claim is made pursuant to the Company s product liability policy issued to the Company by Reliance Insurance Company (Reliance). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $1,258,000 reflecting the Company s best estimate given the available facts and circumstances. The amount the Company collects could differ from the $1,258,000 reflected as a noncurrent insurance claim receivable at September 30, 2005. It is uncertain when, if ever, the Company will collect any of its $3,700,000 of estimated claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the $5,000,000 limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

J. Stockholders Equity

Preferred Stock: The Certificate of Incorporation of the Company authorizes the issuance of 5,000,000 shares of preferred stock. The Board of Directors has the authority to issue preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions, including the dividend, conversion, voting, redemption (including sinking fund provisions), and other rights, liquidation preferences, and the number of shares constituting any series and the designations of such series, without any further vote or action by the stockholders of the Company. In fiscal 1993, the Company issued shares of Series B and Series C Convertible Preferred Stock in connection with an agreement with Wyeth (see Note N).

Stock Options and Warrants: The Company s 1989 Stock Option Plan (the 1989 Plan) expired in 1999 and the Company s 1994 Long-Term Incentive Plan (the 1994 Plan) expired in 2004, however incentive and non-qualified options granted to employees, officers, directors and consultants pursuant to the 1989 and 1994 Plans which were outstanding as of the date of the 1989 and 1994 Plans expiration may be exercised until cancelled or expired. Under the 1998 Stock Option Plan (the 1998 Plan), incentive and non-qualified options to purchase 1,500,000 shares may be granted. Under the Company s 2000 Stock Option Plan (the 2000 Plan),

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

incentive and non-qualified options to purchase 3,500,000 shares may be granted. Under the Company s 2004 Equity Incentive Plan (the 2004 Plan), incentive and non-qualified options to purchase 3,000,000 shares may be granted. Under the 1998 Plan, the 2000 Plan, the 2004 Plan, and under the 1989 and 1994 Plans prior to their expiration (collectively the Option Plans), employees and officers may be granted incentive and nonqualified options and directors and consultants may be granted non-qualified options. Persons who were executive officers or directors of the Company as of the date of adoption of the 1998 Plan are not eligible to receive grants under the 1998 Plan. The duration of each Option Plan is ten years. The term of each grant under the 1989, 1994, 2000, and 2004 Plans cannot exceed ten years and the term of each grant under the 1998 Plan cannot exceed seven years.

Presented below under the caption Stock Options is all Plan and Non-Plan option activity and under the caption Warrants is all warrant activity:

	Stock Options		Warrants	
	Shares	Weighted Average Exercise Price	Shares	Exercise Price
Outstanding at September 30, 2002	10,119,377	$ 4.21	105,000	$ 5.00-$7.13
Granted	1,206,000	$ 3.64		
Exercised	(150,000)	$ 5.02		
Cancelled	(912,207)	$ 4.37		
Outstanding at September 30, 2003	10,263,170	$ 4.17	105,000	$ 5.00-$7.13
Granted	1,661,500	$ 6.62		
Exercised	(661,083)	$ 3.01	(20,000)	$ 5.25
Cancelled	(331,795)	$ 5.55	(75,000)	$ 5.00-$7.13
Outstanding at September 30, 2004	10,931,792	$ 4.57	10,000	$ 6.19
Granted	1,433,500	$ 3.84		
Exercised	(245,791)	$ 2.37		
Cancelled	(271,206)	$ 6.25		
Outstanding at September 30, 2005	11,848,295	$ 4.49	10,000	$ 6.19

At September 30, 2005, stock options were outstanding and exercisable as follows:

	Outstanding			Exercisable	
Range of Exercise Price	Number	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number	Weighted Average Exercise Price

$1.22-$ 2.38	3,051,544	4.5 years	$	2.26	3,039,877	$ 2.26
$2.45-$ 4.16	3,669,917	6.0 years	$	3.65	2,281,745	$ 3.89
$4.26-$ 6.19	3,509,834	4.6 years	$	5.95	2,994,522	$ 5.97
$6.21-$20.13	1,617,000	7.8 years	$	7.42	796,500	$ 7.83
$1.22-$20.13	11,848,295	5.5 years	$	4.49	9,112,644	$ 4.38

All outstanding options vest at various rates over periods up to four years and expire at various dates from December 14, 2005 to September 12, 2015. At September 30, 2004, 8,585,491 options were exercisable at a weighted average exercise price of $4.23. At September 30, 2003, 8,772,963 options were exercisable at a weighted average exercise price of $4.21.

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All outstanding warrants expire on July 17, 2006.

In fiscal 2004, the Company extended the exercise date of certain stock options granted to certain officers, directors and vice presidents and incurred a noncash charge of approximately $4,081,000.

Restricted Stock Awards: The Company s 1997 Equity Incentive Plan (the 1997 Plan) provides for the grant of restricted stock awards which entitle the plan participants to receive up to an aggregate of 1,750,000 shares of the Company s Common Stock upon satisfaction of specified vesting periods. As of September 30, 2005, restricted stock awards to acquire an aggregate of 1,737,918 shares had been granted, net of forfeitures, to employees of the Company primarily in consideration of services rendered by the employee to the Company and payment of the par value of the shares. As of September 30, 2005, 1,737,918 shares have vested and been issued and there were 12,082 restricted stock awards available for grant by the Company under the 1997 Plan.

Employee Stock Purchase Plan: The Company s 1995 Employee Stock Purchase Plan (the 1995 Plan) covers an aggregate of 800,000 shares of Common Stock which is offered in one-year offerings (an Offering). Each Offering is divided into two six-month Purchase Periods (the Purchase Periods). Stock is purchased at the end of each Purchase Period with employee contributions at the lower of 85% of the closing sale price of the Company s Common Stock on the first day of an Offering or the last day of the related Purchase Period. At September 30, 2005, there were 287,986 shares remaining to be purchased under the 1995 Plan.

Treasury Stock: In fiscal 2004, the Company s Board of Directors approved the repurchase from time to time by the Company of up to 2,500,000 shares of Indevus Common Stock in the open market and the Company repurchased an aggregate of 1,166,000 shares for $7,319,000. The Company reissued 506,000 of those shares primarily pursuant to its employee stock option and purchase plans.

Other: In addition to the 47,826,000 shares of Common Stock outstanding at September 30, 2005, there were approximately 28,669,000 shares of Common Stock reserved for issuance (Reserved Common Shares). Included in the number of Reserved Common Shares are the following: (i) 10,817,000 shares reserved for issuance upon conversion of the Convertible Notes; (ii) 12,164,000 shares reserved for issuance under the Option Plans; (iii) 4,756,000 shares of Common Stock reserved for issuance upon conversion of the Company s authorized but unissued Preferred Stock; (iv) 622,000 shares of Common Stock issuable upon conversion of issued and outstanding Preferred Stock; (v) 300,000 shares reserved for issuance under the 1995 and 1997 Plans; and (vi) 10,000 shares reserved for issuance from exercise of outstanding warrants.

K. Weighted Average Common Shares

During the year ended September 30, 2005, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were as follows: (i) the Convertible Notes which are convertible into 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008; (ii) options to purchase 5,200,925 shares of Common Stock at prices ranging from $4.26 to $20.13 with expiration dates ranging up to March 1, 2015 and (iii) a warrant to purchase 10,000 shares of Common Stock with an exercise price of $6.19 and with an expiration date of July 17, 2006. Additionally, during the

year ended September 30, 2005, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 6,114,889 shares of Common Stock at prices ranging from $1.22 to $4.16 with expiration dates ranging up to September 12, 2015 and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

During the year ended September 30, 2004, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were as follows: (i) the Convertible Notes which are convertible into 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008; (ii) options to purchase 671,121 shares of Common Stock at prices ranging from $6.50 to $20.13 with expiration dates ranging up to September 28, 2014 and (iii) a warrant to purchase 10,000 shares of Common Stock with an exercise price of $6.19 and with an expiration date of July 17, 2006. Additionally, during the year ended September 30, 2004, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 9,538,920 shares of Common Stock at prices ranging from $1.22 to $6.36 with expiration dates ranging up to August 17, 2014 and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

During the year ended September 30, 2003, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were as follows: (i) the Convertible Notes which are convertible into 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008; (ii) options to purchase 5,920,822 shares of Common Stock at prices ranging from $3.63 to $20.13 with expiration dates ranging up to June 3, 2013 and (iii) warrants to purchase 105,000 shares of Common Stock with exercise prices ranging from $5.00 to $7.13 and with expiration dates ranging up to July 17, 2006. Additionally, during the year ended September 30, 2003, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 4,380,139 shares of Common Stock at prices ranging from $1.22 to $3.58 with expiration dates ranging up to April 23, 2013 and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

L. Income Taxes

The provision for income taxes for the year ended September 30, 2005 consists of the following:

	2005
Current tax expense:	
Federal	$ 1,665,000
State	1,506,000
Deferred tax expense:	
Federal	17,564,000
State	(900,000)
Change in Valuation Allowance	(16,664,000)
	$ 3,171,000

The Company s effective tax rate for the years ended September 30, 2005 varies from the statutory rate as follows:

	2005	2004	2003
U.S. statutory rate	(34.0)%	(34.0)%	(34.0)%
State taxes	4.8	(6.0)	(6.0)
Permanent differences	0.7		
Credit generation	(1.2)		
Expiration of credit	2.8		
Valuation allowance	33.2	40.0	40.0
	(6.3)%	%	%

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Significant components of the Company s deferred tax assets as of September 30, 2005, 2004 and 2003 are shown below. As required by SFAS No. 109, the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss and research credit carryforwards and deferred income. The Company has determined that, at this time, it is more likely than not that the Company will not realize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance has been established at September 30, 2005.

At September 30, 2005, 2004 and 2003, the significant components of the Company s deferred tax asset consisted of the following:

	2005	2004	2003
Federal and state net operating loss carryforwards	$ 65,020,000	$ 101,085,000	$ 75,105,000
Federal and state tax credit carryforwards	9,589,000	7,091,000	5,787,000
Capital loss carryforwards	2,133,000	1,733,000	3,257,000
Accrued expenses	8,691,000	8,700,000	6,923,000
Investment in CPEC LLC	6,287,000	6,918,000	7,557,000
Investment in unconsolidated subsidiaries	11,726,000	13,755,000	13,756,000
Deferred revenue	52,500,000		
Total deferred tax asset before valuation allowance	155,946,000	139,282,000	112,385,000
Valuation allowance against total deferred tax asset	(155,946,000)	(139,282,000)	(112,385,000)
Net deferred tax asset	$	$	$

As of September 30, 2005, the Company had net operating loss carryforwards for federal income tax purposes of approximately $187,000,000 which expire at various dates from 2006 through 2024. In addition, the Company had approximately $6,210,000 of tax credit carryforwards for federal income tax purposes expiring at various dates through 2025 and capital loss carryforwards of approximately $5,334,000 for federal income tax purposes expiring at various dates through 2010. Approximately $17,300,000 of the net operating loss carryforwards available for federal income tax purposes relate to exercises on non-qualified stock options and disqualifying dispositions of incentive stock options, the tax benefit from which, if realized, will be credited to additional paid-in capital. Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, use of the Company s net operating loss and tax credit carryforwards may be subject to annual limitations due to a change in ownership of more than 50%.

M. Related Party Transactions

The Company has or had agreements with certain directors, an officer who is not an employee and the spouse of an officer of the Company, to provide technical and other consulting services. Total amounts due or paid pursuant to such agreements were approximately $400,000, $310,000 and $324,000 in fiscal 2005, 2004, and 2003, respectively.

N. Product Agreements

Madaus. In November 1999, the Company entered into an agreement with Madaus under which we licensed exclusive rights to develop and market SANCTURA in the United States. In exchange for these rights, we have agreed to pay Madaus potential regulatory and sales milestone payments and royalties on net sales or, if

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

sublicensed by us, we would pay to Madaus a portion of royalties on net sales received from the sublicensee, in lieu of royalty payments. The Company is responsible for all clinical development and regulatory activities and costs related to the compound in the United States. In December 2002, we entered into a manufacturing agreement with Madaus whereby Madaus will produce and sell to us commercial quantities in bulk form.

Esprit and PLIVA. In April 2004, the Company entered into a license, commercialization and supply agreement with PLIVA d.d. (PLIVA) through its specialty-branded subsidiary, Odyssey Pharmaceuticals, Inc. for the U.S. commercialization of SANCTURA for overactive bladder (the SANCTURA Agreement). In May 2005, the Company, PLIVA and Esprit entered into an Amendment and Consent Agreement (the Amendment and Consent), which became effective as of July 1, 2005, pursuant to which the Company amended certain provisions of the SANCTURA Agreement and consented to the acquisition by Esprit of the rights to market SANCTURA in the U.S. from PLIVA and the assumption by Esprit of PLIVA s obligations under the SANCTURA Agreement. Upon the effectiveness of the Amendment and Consent Agreement, the effective royalty rates increased and the Company became entitled to annual minimum royalties of $5,625,000, $7,875,000, and $10,500,000 for the first three years of the Amendment and Consent Agreement, respectively. Additionally, the annual sales force subsidy was increased to $8,750,000 through December 31, 2007 and extended for one additional year at an annual rate of $4,375,000. Further, Esprit is not subject to minimum detail and sales force requirements. Esprit granted Indevus the right to co-promote one of Esprit s future products on terms to be negotiated. Except if the context indicates otherwise, all references to the SANCTURA Agreement shall mean the agreement as amended by the Amendment and Consent.

Under the SANCTURA Agreement, the Company received $30,000,000 upon the initial signing, $120,000,000 upon the approval of SANCTURA by the FDA in May 2004 and $10,000,000 upon initiation of the SANCTURA XR Phase III clinical trial program in September 2005. In addition, the Company is eligible to receive approximately $45,000,000 in future payments contingent upon the filing and approval of an NDA for SANCTURA XR, as well as a payment of $20,000,000 related to the achievement of a long-term commercialization milestone in 2013. Esprit will not have an obligation to pay the development milestone of approximately $35,000,000 related to the FDA approval of the NDA for SANCTURA XR or the $20,000,000 long-term commercialization milestone and the rights to SANCTURA XR will revert to the Company if Esprit provides notice to the Company no later than the approval date that it does not intend to proceed with the launch of SANCTUA XR.

For the six months following the approval of SANCTURA, called the co-promotion period, the Company received a commission based on net sales of SANCTURA, a portion of which funded the Company s sales force and certain advertising and promotional costs. The Company was co-promoting SANCTURA with PLIVA through a joint sales force of approximately 500 sales representatives. The Company established a sales force initially numbering approximately 280 representatives promoting SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians.

The Company exercised its right to convert the SANCTURA Agreement into a royalty-bearing structure effective November 29, 2004 (the Conversion). Upon the Conversion, approximately 200 of the Company s primary care sales representatives became PLIVA employees and PLIVA became responsible for promotional, advertising and sales force-related costs. Effective upon the Conversion, the Company began receiving royalties on net sales of SANCTURA and a sales force subsidy at an annual rate of approximately $7,700,000.

Under the SANCTURA Agreement, we supply SANCTURA to our marketing partner, which is responsible for product distribution. We are responsible for funding the development of SANCTURA XR and we are eligible to receive additional payments upon achievement of regulatory

milestones.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Shire: In March 2003, the Company signed an exclusive development agreement with Shire Laboratories Inc. (Shire) under which Shire is developing extended release formulations of SANCTURA. The agreement includes potential future development and commercialization milestone payments from Indevus to Shire, as well as royalties based on potential future sales of extended release SANCTURA. Indevus will be responsible for all development costs and the commercialization of extended release formulations of SANCTURA under this agreement. In fiscal 2004, the company paid $1,750,000 in milestone payments relating to the development of the once-a-day formulation.

Schering: In July 2005, the Company licensed exclusive U.S. rights from Schering AG, Germany (Schering) to market NEBIDO, a long-acting injectable testosterone preparation for the treatment of male hypogonadism (the Schering Agreement). Pursuant to the terms of the Schering Agreement, the Company will be responsible for the development and commercialization of NEBIDO in the United States and Schering will be responsible for manufacturing and supplying finished product to the Company. The Company agreed to pay to Schering up to $30,000,000 in up-front, regulatory milestone, and commercialization milestone payments. In fiscal 2005, the Company paid $7,500,000 as an up-front milestone payment which was charged to research and development expense. Upon approval by the FDA to market the product, the Company will pay Schering $5,000,000 regulatory milestone payment. When commercialization of the product commences, the Company will pay Schering 25% of net sales of NEBIDO to cover both the cost of finished product and royalties.

Paligent, Inc.: In June 2000, the Company licensed exclusive, worldwide rights from Paligent, Inc. (formerly HeavenlyDoor.com and Procept, Inc.) (Paligent) to develop and market PRO 2000, a candidate topical microbicide used to prevent infection by HIV and other sexually transmitted pathogens, in exchange for an up front payment and potential future milestone payments and royalties on net sales. In April 2003, the Company amended the terms of the PRO 2000 licensing agreement with Paligent whereby Paligent agreed to relinquish a potential future $500,000 milestone payment and provide Indevus an option to acquire all rights to PRO 2000 by a certain future date in exchange for an immediate payment and an optional buyout payment by Indevus. In September 2004, the Company exercised this option and paid $500,000 to Paligent for all rights to PRO 2000.

Manhattan Pharmaceuticals, Inc. and Sumner Burstein, Ph.D.: In June 2002, the Company licensed exclusive, worldwide rights to IP 751 from Manhattan Pharmaceuticals, Inc. (Manhattan) in exchange for an up-front licensing payment, potential development milestones and royalty payments (the Manhattan Agreement). In August 2003, the Company simultaneously entered into a renegotiated agreement with Manhattan and an agreement with Sumner Burstein, Ph.D. (the Burstein Agreement), the individual owner of intellectual property rights related to IP 751, whereby the Manhattan Agreement was terminated in exchange for a combination of cash and equity payments from the Company to Manhattan and the Company acquired an exclusive, worldwide license to IP 751 intellectual property rights from Dr. Burstein pursuant to the Burstein agreement in exchange for an amount which was partially payable immediately and partially in the future and potential milestone and royalty payments. The Company reflected a charge of $1,060,000, including approximately $360,000 for approximately 60,000 shares of Common Stock issued to Manhattan, in research and development expense in the fiscal year ended September 30, 2003 related to these transactions. The Company remains responsible for the clinical development, regulatory review activities and commercialization of this compound.

Aventis:

A. Pagoclone. In February 1994, the Company entered into a license agreement with Rhone-Poulenc Rorer, S.A. now Aventis S.A. (Aventis), granting the Company an exclusive worldwide license (subject to Aventis option to obtain a sublicense in France) under Aventis patent rights and know-how to manufacture, use and sell

pagoclone. In exchange, the Company paid a license fee and agreed to pay Aventis potential milestone payments and royalties based on potential net sales or, if sublicensed by the Company, the Company would pay to Aventis a portion of receipts from the sublicensee in lieu of milestone and royalty payments. Indevus also assumed responsibility for all clinical trials and regulatory submissions relating to pagoclone.

B. Aminocandin. In April 2003, the Company licensed exclusive, worldwide rights from Aventis to aminocandin, an anti-fungal compound for the treatment of systemic, invasive fungal infections. In exchange for these rights and for Aventis inventory of aminocandin, Indevus made an up-front payment to Aventis, and is obligated to pay potential milestones and royalties on potential future sales. Under this agreement, Indevus is responsible for all development and commercialization activities for both intravenous and oral formulations of aminocandin. Aventis has agreed to manufacture the key component of aminocandin, using its proprietary fermentation technology. The Company charged $1,500,000 to research and development expense in fiscal 2003 for the up-front payment. Upon commencement of the multi-dose phase I trial of aminocandin in fiscal 2005, the Company made a $750,000 milestone payment to Aventis which was charged to research and development expense in fiscal 2005.

Lilly: In June 1997, the Company licensed to Eli Lilly & Company (Lilly) worldwide, exclusive rights to Indevus patent covering the use of fluoxetine to treat certain conditions and symptoms associated with premenstrual syndrome (PMS). Lilly has received approval for fluoxetine to treat premenstrual dysphoric disorder, a severe form of PMS. The drug has been marketed under the trade name Sarafem by Lilly and its sublicense, Galen Holdings, Inc., respectively. In December 2002, the Company entered into a renegotiated agreement with Lilly providing for Lilly to pay the Company (i) an initial payment of approximately $777,000, (ii) royalties on net sales of Sarafem commencing October 1, 2002 through the expiration of the Company s patent related to Sarafem, and (iii) milestones based on Lilly s achievement of certain levels of Sarafem sales in each quarter commencing January 1, 2003, subject to an aggregate cap and immediate acceleration upon Lilly s sublicense of its rights related to Sarafem. The Company recognized the $777,000 initial payment as revenue upon signing the renegotiated agreement because the Company had no continuing performance obligations under the contract. The patent rights to the use of fluoxetine in treating PMS are licensed by the Company from the Massachusetts Institute of Technology, which is entitled to a portion of all payments, including royalties, made to Indevus by Lilly. The Company earned royalties of approximately $1,686,000, $2,335,000 and $4,319,000 (including $2,184,000 of accelerated milestone payments) in fiscal 2005, 2004 and 2003, respectively, on Lilly s sales of Sarafem.

Ferrer: In January 1993, the Company licensed from Ferrer International, S.A. (Ferrer) exclusive rights in the U.S., Puerto Rico and Canada to certain uses of citicoline, a drug under development for potential treatment for ischemic stroke. In January 2004, the Company entered into a new agreement with Ferrer covering the development, manufacture and marketing of citicoline in the U.S. and Canada. Under the terms of the new agreement, the Company granted Ferrer exclusive rights to its patents and know-how related to citicoline. In exchange, Ferrer agreed to assume all future development, manufacturing and commercialization costs of citicoline. Indevus will receive 50% of all milestone payments made to Ferrer by a third party and royalties on net sales of the product.

In June 1998, the Company licensed to Ferrer, on a worldwide basis except for the U.S. and Canada, the use of Indevus patent rights relating to the use of citicoline in the protection of brain tissue from cerebral infarction following ischemic stroke. In exchange for the license to Ferrer, Indevus will be entitled to royalties from Ferrer on certain exports and sales of the solid form of citicoline in certain countries upon its approval in each relevant country.

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Medical Research Council: In July 2005, the Company entered into the Collaborative Research and Licensing Agreement with the Medical Research Council, an agency of the United Kingdom (the MRC). The Company agreed to grant the MRC a non-exclusive license to PRO 2000 solely for its use in the Phase III trial and also supply, at no cost to the MRC, all PRO 2000 and placebo required for the Phase III trial, in exchange for the right to have PRO 2000 included in the MRC s approximately 10,000 person Phase III clinical trial studying the prevention of the transmission of HIV and other sexually-transmitted diseases to be conducted primarily in Africa and India and the right to use the results of this trial. Under terms of this agreement the MRC will be responsible for all other trial costs. Additionally, the Company agreed to make PRO 2000 available to all communities in need of the product, including developing countries, and to supply to the MRC PRO 2000 to be distributed in developing countries at the Company s cost plus a markup pursuant to a supply agreement to be negotiated. The Company will pay the MRC a minimal royalty on sales of PRO 2000 in non-developing countries.

Wyeth: In November 1992, the Company entered into an agreement with American Cyanamid Company (which subsequently was acquired by Wyeth) for the development and marketing in the U.S. of Redux. In connection with this agreement, Wyeth purchased from the Company the Series B and C Preferred Stock which is outstanding at September 30, 2005 and 2004. Holders of Series B and C Preferred Stock are entitled to receive mandatory dividends of $0.13 and $1.00 per share, respectively, payable at the election of the Company in cash or Common Stock. Such dividends are payable annually on April 1 of each year, accrue on a daily basis and are cumulative. Holders of Series B and C Preferred Stock are also entitled to a liquidation preference of $12.53 and $100.00 per share, respectively, plus accumulated and unpaid dividends. Holders of Series B and C Preferred Stock are entitled to convert such shares into an aggregate of 622,222 shares of Common Stock (a conversion price of $5.63 per share) subject to anti-dilution adjustments. Holders of the Series B and C Preferred Stock are entitled to vote on all matters submitted to a vote of stockholders other than the election of directors, equivalent to 568,850 shares of Common Stock.

Servier: In February 1990, the Company entered into a series of agreements, subsequently amended, with Les Laboratoires Servier (Servier) under which the Company licensed U.S. marketing rights to Redux, in exchange for royalty payments on net product sales. Indevus agreed to indemnify Servier under certain circumstances and Indevus was required to name Servier as an additional insured on its product liability insurance policies, which are subject to ongoing claims by Servier. (See Note I.)

Boehringer: In November 1995, the Company entered into a manufacturing agreement with Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer) under which Boehringer agreed to supply, and the Company agreed to purchase, all of the Company s requirements for Redux capsules. The contract contained certain insurance and indemnification commitments by the Company and required conformance by Boehringer to the FDA s Good Manufacturing Practices regulations. Boehringer has made certain claims on the Company related to the Company s cancellation of the manufacturing agreement with Boehringer. The Company has disputed these claims and has accrued an amount with respect to such potential claims which is the Company s best estimate of the amount due to Boehringer. The amount accrued may differ from the amount, if any, paid by the Company to Boehringer in respect of these claims. (See Note I.)

O. Subsidiary and Investment in Aeolus

Subsidiary

CPEC LLC is owned 65% by the Company and 35% by Aeolus Pharmaceuticals, Inc. (Aeolus) (formerly Incara Pharmaceuticals, Inc.) and was developing bucindolol, a nonselective beta-blocker for treatment of congestive heart failure. Pursuant to the agreement under which bucindolol was acquired, the Company could

INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

have a maximum potential liability of approximately $1,700,000 if an NDA were filed and approved for bucindolol to treat congestive heart failure. In October 2003, CPEC LLC licensed its bucindolol development and marketing rights to ARCA Discovery, Inc. in exchange for potential future milestone and royalty payments. The accounts of CPEC LLC are included in the Company s consolidated financial statements.

Investment in Aeolus

In 2005, the Company liquidated its investment of 44,718 common shares of Aeolus and recorded a loss on equity securities of $185,000. At September 30, 2004, the value of this investment was $68,000. The Company classified its investment in Aeolus as available for sale and as such stated its investment at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income.

P. Quarterly Financial Data (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Fiscal 2005				
Total revenues	$ 5,763,000	$ 9,277,000	$ 8,193,000	$ 10,103,000
Net loss	(21,149,000)	(9,720,000)	(9,789,000)	(12,560,000)
Net loss per common share, basic and diluted	$ (0.44)	$ (0.21)	$ (0.21)	$ (0.27)
Fiscal 2004				
Total revenues	$ 927,000	$ 876,000	$ 4,461,000	$ 12,462,000
Net loss	(12,024,000)	(11,370,000)	(16,963,000)	(27,855,000)
Net loss per common share, basic and diluted	$ (0.25)	$ (0.24)	$ (0.36)	$ (0.58)

Q. Subsequent Event

In December 2005, the Company entered into an agreement to acquire Delatestryl®, (testosterone enanthate), a marketed injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient Pharmaceuticals, Inc. (Savient) (the Delatesrtyl Agreement). This Delatestryl Agreement is expected to close in January 2006 subject to certain contractual and financial conditions. Upon closing, the Company will make an initial cash payment to Savient of $5.0 million and will be committed to pay a total of approximately $3.3 million for Delatestryl inventory, including our assumption of Savient s previous obligation to purchase approximately $1.1 million of additional Delatestryl inventory. The Company expects to commence selling Delatestryl upon closing. Under the terms of the Delatestryl Agreement, the Company will pay royalties to Savient for three years following the closing of the transaction based upon the cumulative net sales of Delatestryl. The royalty rate will be 5% on the first $5 million of cumulative net sales following closing increasing to 10% on cumulative net sales between $5 million and $10 million. The royalty rate on cumulative net sales above $10 million will be 25%, subject to a minimum annual payment of $200,000 following the quarter in which cumulative net sales reach $10 million.