INDEVUS PHARMACEUTICALS INC
Form 10-K
December 07, 2006

# 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, 2006**

**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** | **04-3047911** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |

**33 Hayden Avenue**
**Lexington, MA** **02421-7966**
**(Address of principal executive offices)** **(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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ¨ NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ¨ NO x

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

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 $289,000,000, based on the last sales price of the Common Stock as of March 31, 2006. 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 1, 2006, 56,065,456 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, 2006 to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 and the Exhibit Index beginning on page number 59 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), SANCTURA XR (once-daily SANCTURA) and NEBIDO® (testosterone undecanoate); 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 tre 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, SANCTURA XR, and NEBIDO; the early stage of product candidates under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR and NEBIDO; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO; 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, Inc. (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. DELATESTRYL is our registered trademark for our DELATESTRYL® product. 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.

**Where You Can Find More Information**

We are subject to the information and reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, under which we file periodic reports, proxy and information statements and other information with the SEC. Copies of the reports, proxy statements and other information may be examined without charge at

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the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, or on the Internet at http://www.sec.gov. Copies of all or a portion of such materials can be obtained from the Public Reference Room of the SEC upon payment of prescribed fees. Please call the SEC at 1-800-SEC-0330 for further information about the Public Reference Room.

Financial and other information about Indevus is available on our website (http://www.indevus.com). We make available on our website, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. Copies are available in print to any Indevus shareholder by completing an on-line request in the Investor section of our website or by request in writing to Investor Relations, Indevus Pharmaceuticals, Inc., 33 Hayden Ave., Lexington, MA 02421.

**ITEM 1.** ***Business***

**Overview**

Indevus is a biopharmaceutical company engaged in the acquisition, development and commercialization of products to treat urological, gynecological and men s health conditions. We currently market two products through our approximately 85 person specialty sales force and we have six products in development. Our marketed products include SANCTURA for overactive bladder ( OAB ), which we co-promote with our partner Esprit Pharma, Inc. ( Esprit ), and DELATESTRYL (testosterone enanthate) for the treatment of male hypogonadism.

Our core urology, gynecology and men s health portfolio contains four compounds in development in addition to our marketed products SANCTURA and DELATESTRYL. Our most advanced compound is SANCTURA XR, the once-daily formulation of SANCTURA. In October 2006, we submitted a New Drug Application ( NDA ) to the U.S. Food and Drug Administration ( FDA ) seeking approval for SANCTURA XR. NEBIDO, for male hypogonadism, is currently in a fully-enrolled, Phase III pharmacokinetic study and we expect to submit an NDA for NEBIDO in mid-2007. PRO 2000, a topical microbicide for the prevention of infection by HIV and other sexually-transmitted diseases ( STDs ), is in two ongoing Phase III trials. IP 751 is for pain and inflammatory disorders, including interstitial cystitis.

In addition to our core urology, gynecology and men s health portfolio, we are preparing to begin a Phase III development program for pagoclone, a GABA (gamma amino butyric acid) receptor modulator which we are developing for the treatment of persistent developmental stuttering. Our product portfolio also contains aminocandin, an echinocandin for systemic fungal infections for which we recently licensed worldwide rights to Novexel S.A. ( Novexel ). We also 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 corporate headquarters is located at 33 Hayden Avenue, Lexington, Massachusetts 02421-7971, and our main telephone number is (781) 861-8444.

**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, product candidates, or products that have 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 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 approximately 85 person specialty sales force.

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[1] | Commercial Rights |
|---|---|---|---|
| SANCTURA | Overactive bladder | Marketed | U.S.[2] |
| SANCTURA XR | Overactive bladder | NDA submitted | Worldwide[3] |
| DELATESTRYL | Hypogonadism | Marketed | U.S. |
| NEBIDO | Hypogonadism | Phase III | U.S. |
| PRO 2000 | HIV and STD prevention | Phase III | Worldwide |
| IP 751 | Interstitial cystitis/pain | Phase I | Worldwide |

[1] See Government Regulation.
[2] Licensed to Esprit.
[3] Licensed to Esprit in the U.S.; certain territories outside the U.S. licensed to Madaus GmbH.

***SANCTURA***

*General.* In August 2004, we launched SANCTURA, 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 therapeutic class as SANCTURA.

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

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 2005, the market for drugs to treat OAB was approximately $1.4 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 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. The first trial included 523 patients who were studied at 51 sites. The second trial included 658 patients who were studied at 52 sites. Both trials were three-month trials and 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.

Across the two 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 as a platform for future growth, we have a sales and marketing infrastructure which includes a 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.* We are developing SANCTURA XR 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 therapeutic class as SANCTURA XR.

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

Our formulation of SANCTURA XR was developed under a development and license agreement with Supernus Pharmaceuticals, Inc. ( Supernus ), formerly Shire Laboratories, Inc. signed in March 2003. We completed pharmacokinetic and safety studies with several once-daily formulations, including our lead formulation that was used in our Phase II trial and our Phase III program.

*Development Program.* In October 2006, we submitted an NDA to the FDA seeking approval for SANCTURA XR to treat patients with OAB. As a result of the submission of the NDA, we received a $10,000,000 milestone payment from Esprit, our co-promotion partner for SANCTURA and SANCTURA XR in the United States.

Our development program for SANCTURA XR included two randomized, double-blind, placebo-controlled Phase III trials conducted in the U.S. that were submitted in the NDA. We announced positive data from the first Phase III trial in June 2006 and positive data from the second Phase III trial in July 2006. The first trial included 601 patients who were studied at 55 sites. The second trial included 564 patients who were studied at 62 sites. Both trials were 12-week trials and measured the effects of 60 mg of SANCTURA XR versus placebo, once-daily, on symptoms of OAB. Patients treated with SANCTURA XR experienced statistically significantly fewer

toilet voids per day at the end of the 12-week trial than did patients on placebo. SANCTURA XR treated patients also experienced statistically significantly fewer episodes of urge urinary incontinence per day at the end of the 12-week trial than did placebo patients. Treatment with SANCTURA XR also led to a statistically significant improvement (decrease) in average urgency severity, another key symptom of OAB. Additionally, SANCTURA XR had a rapid onset of action and achieved a statistically significant difference from placebo as early as Week 1 of therapy for key efficacy endpoints. The most common anticholinergic side effects were dry mouth (10.7% of the SANCTURA XR treated patients compared to 3.7% of the placebo treated patients) and constipation (8.5% of the SANCTURA XR treated patients compared to 1.5% of the placebo treated patients).

In June 2005, we announced results from a pilot Phase II trial of SANCTURA XR. The trial was a two-week, multi-center, placebo-controlled, double-blind study designed to evaluate the efficacy and safety of 60 mg SANCTURA XR versus placebo, once-daily, in 148 patients with OAB. The common symptoms of overactive bladder, such as urgency, frequency and incontinence episodes were measured daily. SANCTURA XR was found to improve all of the symptoms and signs of overactive bladder. The magnitude of improvement compared to placebo was very similar to that 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 (12% of the SANCTURA XR treated patients compared to 8% of the placebo treated patients) and constipation (2% of the SANCTURA XR treated patients vs. none reported in the placebo treated patients).

***NEBIDO***

*General.* In July 2005, we licensed the exclusive U.S. rights for NEBIDO from Schering AG, Germany ( Schering ). Currently under development as a testosterone replacement therapy for male patients with hypogonadism, NEBIDO is an intramuscular depot injection which was designed to provide replacement testosterone in hypogonadal men for up to three months before requiring the next injection. NEBIDO has been approved and launched in Europe and a number of other countries outside of the U.S. 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 differing severity which include sexual dysfunction, fatigue, 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 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.

*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, this formulation of testosterone undecanoate depot injection has been approved in over 80 countries under the trade names NEBIDO and Reandron.

As part of our development program we are conducting a pharmacokinetic study following a minimum of 100 hypogonadal men for 48 weeks to supplement the existing Schering clinical database. We completed enrollment in the trial in June 2006 and expect to complete the trial in the second quarter of calendar 2007. Assuming positive results, we anticipate submitting an NDA in mid-2007. The existing database from Schering s clinical development program contains over 300 patients that have been treated for up to eight years in five 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 two injections of 6-8 weeks provides effective testosterone replacement in patients with

hypogonadism. The Company may conduct additional trials for marketing purposes. If approved, we intend to commercialize NEBIDO in the U.S. utilizing our specialty sales force.

***DELATESTRYL***

*General.* In January 2006, we acquired DELATESTRYL, a marketed injectable testosterone preparation for the treatment of male hypogonadism from Savient Pharmaceuticals, Inc. ( Savient ). DELATESTRYL provides testosterone enanthate, a derivative of the primary endogenous androgen testosterone, for intramuscular injection. Suggested dosing of DELATESTRYL is once every 2 to 4 weeks. Dosage and duration of therapy will depend on age, sex, diagnosis and patient s response to treatment. DELATESTRYL has been shown to reduce symptoms and prevent consequences associated with testosterone deficiency. We market DELATESTRYL through our specialty sales force primarily to urologists and endocrinologists.

***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 susceptible 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 over four million new adult HIV infections will occur worldwide in 2006 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.* PRO 2000 is being studied, as the only agent, in a 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 $22,700,000 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. This trial commenced in October 2005, and is designed to examine the safety and efficacy of PRO 2000 in preventing HIV infection and transmission of other STDs in women. An estimated 10,000 women will be enrolled in this trial that is expected to last approximately three to four years and include interim analyses of safety and efficacy data conducted by an independent data safety monitoring board. As of September 30, 2006, approximately 2,600 women have been enrolled in the trial.

PRO 2000 is also being studied, as one of two investigational topical microbicides, in 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, which commenced in February 2005, is designed to examine the safety and effectiveness of two candidate topical microbicides, including PRO 2000, in preventing HIV infection and transmission of other STDs 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. As of September 30, 2006, approximately 1,700 women have been enrolled in the trial.

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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 one each in the 2% and 4% groups became infected and developed disease.

The Company is currently considering strategic partners for future development and commercialization of PRO 2000.

***IP 751***

*General.* IP 751 is believed to be a non-psychoactive synthetic derivative of tetrahydrocannabinol (THC) and is in pre-clinical development to treat interstitial cystitis. IP 751 appears to suppress various inflammatory cytokines 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 one 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 appeared to have no effect on the normal voiding mechanism of the bladder. We have now completed additional studies confirming these results.

We also believe that IP 751 will have significant applications in multiple areas of chronic and acute pain, including neuropathic and inflammatory pain. An Investigational New Drug Application ( 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.

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**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[1] | Commercial Rights |
|---|---|---|---|
| Sarafem | Premenstrual Dysphoric Disorder | Marketed | Worldwide[2] |
| Pagoclone | Stuttering | Phase III | Worldwide |
| Aminocandin | Systemic fungal infections | Phase I | Worldwide[3] |

[1] See Government Regulation.
[2] Licensed to Lilly
[3] Know-how licensed to Novexel

***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 ( PMS ). 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, stuttering is defined as a communication disorder involving disruptions, 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 May 2006, we announced results of our Phase II trial for pagoclone in persistent developmental stuttering. The trial, know as the EXPRESS study, was an eight-week, randomized, double-blind, placebo-controlled trial, with an open-label extension. There were a total of 132 patients randomized in the study at 16 sites in the United States. Results from the trial showed that pagoclone produces a statistically

significant benefit in multiple primary and secondary endpoints compared to placebo. Additionally, pagoclone produced either numerically superior improvements or trends for significant improvement on virtually all other primary and secondary endpoints when compared to placebo. Pagoclone was also shown to be well-tolerated and not associated with any serious adverse events.

The primary endpoints evaluated in the double-blind phase of the study were the Frequency and Duration Subscale of the Stuttering Severity Instrument Version 3 (SSI-3), the Stuttering Severity Scale (SEV) and the Subjective Screening of Stuttering (SSS) Severity Subscore. The secondary endpoints evaluated in the study included the Clinician Global Impression-Improvement (CGI-I), the Liebowitz Social Anxiety Scale (LSAS) and the Speech Naturalness Scale (SNS). Given that this was an exploratory study, pre-specified analyses utilized 1-tailed tests of significance.

In September 2006, we announced that following an End of Phase II meeting with the FDA, we had established a clinical plan towards regulatory approval of pagoclone for the treatment of persistent developmental stuttering. Specifically, the FDA advised us to: 1) pursue pediatric studies in parallel with adult studies so that if pagoclone is effective and safe in both populations, the NDA could be approvable for the broadest possible stuttering population; 2) conduct the next adult and pediatric placebo-controlled trials as fixed dose-response studies to determine the minimally-effective dose; and 3) pursue Phase III trials under special protocol assessments ( SPA ) to allow the FDA to formally sign-off on trial designs.

We are planning to submit a request for an SPA to the FDA for the Phase III pagoclone protocol in December 2006. We also intend to initiate a pediatric pharmacokinetic study in December 2006 to estimate the dose proportionality of pagoclone in pediatric patients compared to adults. We anticipate beginning a Phase II/III trial in a pediatric population in the second half of 2007.

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 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 then conducted two Phase II GAD trials and one Phase III panic disorder trial that 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, we have an extensive database for pagoclone including toxicology, pharmacology and manufacturing packages. We are currently evaluating commercialization options for pagoclone in parallel with our ongoing development program and preliminary market development activities.

In June 2006, we initiated a Phase II proof of concept trial designed to evaluate the efficacy of various doses of pagoclone versus placebo in delaying the ejaculatory response in male patients with primary premature ejaculation ( PE ). The trial was expected to enroll approximately 100 patients at multiple sites in the United States. Patients were to be evaluated for a total of nine weeks including a four-week screening phase and a five-week treatment phase. In September 2006, we elected to perform an interim analysis following a publication in the journal *Lancet* of studies of the investigational drug dapoxetine in PE. Based on the high placebo response in the dapoxetine trials, we believed that the pagoclone PE trial might have an inadequate sample size to detect an effect when compared to placebo, and therefore might need to be increased. The interim analysis revealed only a slight effect at the highest dose tested. Given the modest effect, it was unlikely that the completed trial would meet its clinical and statistical objectives. Accordingly, the study was discontinued and no further work on pagoclone for PE is currently planned.

***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 anti-fungals, 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

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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 have developed new formulations which we believe address these issues.

Results of a Phase I trial of the intravenous formulation of aminocandin, completed in June 2004, showed that aminocandin 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. In December 2006, we outlicensed the know-how relating to aminocandin to Novexel.

**AGREEMENTS**

*SANCTURA and SANCTURA XR*. 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 under which Madaus produces and sells to us commercial quantities of SANCTURA in bulk form.

In March 2003, we signed a development and license agreement with Supernus under which Supernus developed once-daily, extended release formulations of SANCTURA (SANCTURA XR) and granted us exclusive worldwide rights under Supernus related patents and know-how. The agreement includes potential future development and commercialization milestone payments from us to Supernus, as well as royalties based on potential future sales of SANCTURA XR. We are responsible for all development costs and the commercialization of SANCTURA XR 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 $5,600,000, $7,900,000, 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 $8,800,000 from $7,700,000 through December 31, 2007, and extended for one additional year at an annual rate of $4,400,000. Further, Esprit is not subject to minimum detail and sales force requirements. 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 $30,000,000 upon the initial signing, $120,000,000 upon the approval of SANCTURA by the FDA in May 2004, $10,000,000 upon initiation of the SANCTURA XR Phase III clinical trial program in September 2005, and $10,000,000 upon submission of the NDA in October 2006. In addition, we are eligible to receive an approximately $35,000,000 future payment contingent upon the approval of the 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 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 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.

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.

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.

In November 2006, we entered into (i) a License and Supply Agreement, and (ii) an amendment to our original licensing agreement with Madaus (the Madaus Agreements ). Under the Madaus Agreements, we agreed to (a) purchase from Madaus all required trospium active pharmaceutical ingredient through November 2007 (b) license Madaus the rights to sell SANCTURA XR in all countries outside of the United States (the Madaus Territory ) except Canada, Japan, Korea and China (the Joint Territory ), (c) pay to Madaus a fee based on the number of capsules of SANCTURA XR sold by us in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share, (d) supply SANCTURA XR to Madaus for a specified period of time (e) provide development committee support for a defined period and (f) provide future know-how to Madaus. In exchange, Madaus (a) waived all rights to manufacture SANCTURA XR, (b) will purchase SANCTURA XR from us at cost plus a fee based on the number of SANCTURA XR capsules sold in the Madaus Territory, and (c) will make payments upon the achievement of certain commercial milestones and royalties based on future sales of SANCTURA XR in the Madaus Territory. Certain of the milestone and royalty payments we will receive represent royalty and milestone payments due to Supernus from Indevus under the Supernus Agreement. We and Madaus will share the economics of development and commercialization in the countries in the Joint Territory. If either party decides not to pursue development and commercialization of SANCTURA XR in any country in the Joint Territory, the other party has the right to develop and commercialize SANCTURA XR in that country.

In November 2006, we entered into the API Supply Agreement with Helsinn Chemicals SA and Helsinn Advanced Synthesis SA ( Helsinn ) (the Helsinn Agreement ) whereby Helsinn agreed to supply trospium active pharmaceutical ingredient to us. Trospium active pharmaceutical ingredient is used in the production of SANCTURA XR. The term of the Helsinn Agreement is seven years and contains certain minimum purchase requirements.

*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 us with finished product. We agreed to pay to Schering up to $30,000,000 in up-front, regulatory milestone, and commercialization milestone payments, including a $7,500,000 up-front payment paid in August 2005 and a $5,000,000 payment due upon approval by the FDA to market the product. We also agreed to pay to Schering 25% of net sales of NEBIDO to cover both the cost of finished product and royalties.

In October 2006, we entered into an agreement with Schering under which we finalized terms of our July 2005 license for the manufacture and the supply of NEBIDO from Schering. Pursuant to the terms of this agreement, Schering agreed to manufacture and supply us with all of our requirements for NEBIDO for a supply price based on net sales of NEBIDO. In addition, we are obligated to purchase certain minimum quantities from Schering during the term of this agreement, which expires at the same time as the Schering Agreement.

*DELATESTRYL.* In January 2006, we acquired DELATESTRYL, an injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient, for a total purchase price of $6,800,000 and accounted for the transaction as the purchase of an asset. Upon closing, we paid Savient $5,600,000 and we owe Savient an additional $1,300,000 which is payable in two installments of approximately $644,000 on the first and second anniversary of the closing. Additionally, we assumed Savient s previous obligation to purchase approximately $1,100,000 of additional DELATESTRYL inventory. We believe the supplier defaulted on its

obligation to provide DELATESTRYL in the time required and we believe we are no longer obligated to purchase this inventory. However, in the event the supplier was able to demonstrate compliance with the agreement and we were obligated to purchase such inventory, we may be required to provide a reserve for at least a portion of the value of this inventory.

Under the terms of the acquisition, we are obligated to pay royalties to Savient for three years following the closing based upon the cumulative net sales of DELATESTRYL. The royalty rate will be 5% on the first $5,000,000 of cumulative net sales, increasing to 10% on cumulative net sales between $5,000,000 and $10,000,000. The royalty rate on cumulative net sales above $10,000,000 will be 25%, subject to a minimum annual payment of $200,000 following the quarter in which cumulative net sales reach $10,000,000. Additionally, until March 2007, we are obligated to pay a Savient licensor 6% of net sales.

*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 $500,000 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 $500,000 payment and an optional buyout payment. In September 2004, we exercised this option and made a $500,000 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 in developing countries with high need under a license agreement to be negotiated in good faith, or to supply to the MRC PRO 2000 to be distributed in these 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 (the Aminocandin Agreement ). 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 Aminocandin 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.

In December 2006, we licensed our know how related to aminocandin to Novexel, SA ( Novexel ) for an upfront payment of $1,500,000 and potential future development milestones and royalties on net sales (the Novexel Agreement ). The Novexel Agreement also contains customary provisions regarding reporting, insurance, indemnification and termination under certain circumstances. Immediately prior to the execution of the Novexel Agreement, Aventis assigned the Aminocandin Agreement to Novexel. Effective as of the date of the Novexel Agreement, we entered into a termination agreement with Novexel terminating the Aminocandin Agreement, thereby alleviating us from any further development or financial obligation relating to aminocandin. Pursuant to the Novexel Agreement, Novexel now is responsible for all future development, manufacturing, marketing and financial obligations relating to aminocandin.

*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 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 2004, we entered into a new agreement with Ferrer International, S.A. ( 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 direct 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, Esprit is responsible for all advertising and promotional costs and for subsidizing our sales force at specified annual amounts through 2008. We are co-promoting SANCTURA and expect to co-promote SANCTURA XR with our sales force consisting of approximately 85 sales representatives through 2008. The combined sales forces of Indevus and Esprit are promoting SANCTURA and intend to co-promote SANCTURA XR to urology specialists, obstetricians and gynecologists, and primary care physicians.

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.

In November 2006, we entered into an agreement with Madaus under which Madaus has agreed to waive its rights under our original licensing agreement to manufacture SANCTURA XR in the United States. In return, Madaus will receive a fixed fee based on the number of capsules of SANCTURA XR sold by the Company in the United States.

We currently plan to manufacture SANCTURA XR though a partner. We intend to sell SANCTURA XR to Esprit for the U.S. market. We rely on third party manufacturing to produce SANCTURA XR, including the manufacture of the active pharmaceutical ingredient as well as finishing and packaging the product. We expect to be the exclusive supplier of SANCTURA XR to Esprit and Madaus.

*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. Schering is exclusively responsible for the manufacture and supply of finished product to us. 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 ).

*DELATESTRYL.* We are responsible for manufacturing and marketing of DELATESTRYL. We currently market DELATESTRYL directly through our sales force. We purchased DELATESTRYL inventory from Savient. Additional inventory may be obtained through a contract manufacturer.

*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. We are currently considering strategic partners for the commercialization of IP 751.

*Pagoclone.* We are responsible for manufacturing and marketing of pagoclone. We are currently evaluating commercialization options for pagoclone in parallel with our ongoing development program and preliminary market development activities.

*Aminocandin.* In December 2006, we licensed the know-how related to aminocandin to Novexel. Novexel is responsible for all future manufacturing and marketing of aminocandin.

**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 and SANCTURA XR.* 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., generic oxybutynin, and generic oxybutynin extended release. Many of the products on the market for the treatment of OAB are available in once daily formulations, whereas SANCTURA is currently available as a twice daily formulation. We believe there are other products in various stages of development for the treatment of OAB, which may lead to further competition.

*NEBIDO.* Current preferred methods for treating male hypogonadism are topical and injectable treatments. Topical 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., including DELATESTRYL, 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.

*DELATESTRYL.* Current preferred methods for treating male hypogonadism are topical and injectable treatments. Topical 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., in addition to DELATESTRYL. The majority of the injectable treatments are generic. 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. We believe there are 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., 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 Bayer Pharmaceuticals, 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. In addition there are auditory feedback devices that are currently used by some people who stutter. 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. ERAXIS (anidulafungin), by Pfizer Inc., was approved by the FDA in June 2006 to treat candidemia and other forms of candidiasis, including esophageal 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 and SANCTURA XR*. 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-daily formulation of the drug. Our licensor, Supernus, has filed three patent applications directed to various aspects of the once-a-day formulation, including but not limited to the use of bioavailability enhancers, elements of extended release matrices and drug release characteristics. These patent applications have been published but have not yet been examined by the United States Patent and Trademark Office. Once granted the corresponding patents would have identical patent terms extending into late 2024. Foreign counterparts are also being pursued in major markets outside the United States, such as Europe and Japan. We have also filed patent applications directed to additional uses of trospium chloride, the active ingredient in SANCTURA. These pending patent applications, which cover the use of trospium chloride for promoting uninterrupted sleep and treating interstitial cystitis, if granted, would enjoy patent terms ending in early 2024 and early 2026, respectively. Foreign counterparts of the former patent application are being pursued in Canada, Europe and Japan.

*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. If granted, the corresponding U.S. patent would have a patent term extending into early 2024.

*DELATESTRYL.* We do not have any unexpired patent protection for DELATESTRYL.

*PRO 2000.* We own intellectual property relating to PRO 2000, including five issued U.S. patents: two covering compositions of matter issued in June 2000 and April 2002, two covering the use of PRO 2000 to inhibit, treat, or prevent HIV infection, which were issued in April and October 1997, respectively, and one covering the use of PRO 2000 to prevent pregnancy issued in September 1999. These U.S. patents are slated to expire as early as November 2013 to as late as June 2017. Foreign counterpart patents to the domestic composition and methods involving HIV patents have been granted in Japan and in numerous countries across Europe. A Canadian patent application remains pending. Foreign counterpart patents to the domestic method patent for the prevention of pregnancy have been granted in Australia, China, Hong Kong, Mexico, New Zealand, Russian Federation, South Africa, and South Korea. Patent applications remain pending in Brazil, Canada, and Japan.

*IP 751.* We own certain patent rights to compounds, compositions, and methods of use (e.g., inhibition, treatment and prevention of pain or inflammation; also, inhibition of cell proliferation) relating to IP 751 and its analogs. These rights, which were purchased from Dr. Sumner Burstein and Manhattan Pharmaceuticals, Inc., include four issued U.S. patents and numerous foreign counterpart patents and patent applications. The issued U.S. patents are slated to expire as early as July 2012 to as late as April 2021. The company also owns rights under domestic patent applications directed to the anti-emetic uses of IP 751 and its analogs. These applications were filed in September 2006. If granted, the corresponding patents would have a patent term extending until 2026.

*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 own certain patent rights, which were assigned to us by Warner Lambert, which are directed to many uses of pagoclone, including the treatment of obsessive compulsive disorder and social anxiety disorder, and certain methods of manufacture of racemic pagoclone and an enantiomer of pagoclone. The patent rights assigned to us by Warner Lambert are set to expire as early as April 2022 to as late as March 2023. We have also filed a patent application that covers a transdermal patch including pagoclone, which, if granted, would enjoy a patent term extending into early 2025. The Company also owns U.S. Patent No. 6,855,721, which covers a method of alleviating stuttering by the administration of a therapeutically effective dose of pagoclone or a pharmaceutically acceptable salt thereof. This last patent is set to expire no earlier than July 2020.

*Aminocandin*. We hold an exclusive, worldwide license from Aventis to patents and patent applications directed to echinocandin compounds, their antifungal compositions, processes of manufacture, and methods of inhibiting the proliferation of fungi or of treating fungal infections. The aminocandin patent portfolio includes four issued U.S. patents and at least one pending patent application. These issued patents and pending patent applications are accorded patent terms that will expire as early as December 2018 and as late as December 2022. Foreign counterpart patents and patent applications exist or are being pursued in a long list of foreign countries.

*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 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 U.S., 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 ), however 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 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 to the FDA an NDA, being an application for approval to market a new drug. The process of completing the clinical trials for the 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 discretion, if it determines that its regulatory criteria have not been satisfied, or it 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 current cGMP regulations. In order to comply with the standards set forth in these regulations, manufacturers must continuously expend time and resources in production quality control and quality assurance, and to demonstrate responsiveness to the findings of audits or inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies. In addition, clinical trials must be conducted in compliance with Good Clinical Practice regulations, and clinical trial sites and manufacturing facilities, both foreign and domestic, also are subject to such inspections and responsiveness to findings.

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 a foreign regulatory authority may require post-marketing reporting to monitor the side effects or ongoing safety of a drug. Results of such post-marketing programs may limit the further marketing of these products. Also, if there are modifications to an approved drug, including changes in manufacturing process or in manufacturing facility, an application seeking approval of such changes may be required to be submitted to and prior approved by the FDA or a foreign regulatory authority, and this review 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 Waxman-Hatch 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, 2006, we had 158 full-time employees. None of our employees are 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 a substantial portion of our revenue from Esprit under the SANCTURA Agreement. We believe that revenues derived under the SANCTURA Agreement will continue to account for a substantial portion 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, or to market SANCTURA, 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. Esprit is not obligated to purchase any minimum amount of SANCTURA from us. SANCTURA may suffer from generic penetration after the expiration of the market exclusivity period in May 2009, and competes with many once-daily 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. Further, our sales force subsidy for our co-promotion of SANCTURA and SANCTURA XR in the U.S. expires on December 31, 2008.

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 all of 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 may not compete successfully in the overactive bladder market.***

Competition in the overactive bladder market is intense and has increased since the launch of SANCTURA in August 2004 and two other competitive products in early 2005. 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, antimuscarinics and antispasmodics for overactive bladder are the subject of testing or commercialization efforts by other companies, including

certain treatments for which approval may be sought in the future. Launches of other competitive products may occur in the near future and we cannot predict with accuracy the timing or impact of the introduction of competitive products or their possible effect on our sales.

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 that have been filed for SANCTURA XR, an extended release, once-daily 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 will have to rely solely on market exclusivity for this formulation, which will be shorter than five years.

***Our product candidates including SANCTURA XR and NEBIDO may not be successfully developed or achieve market acceptance.***

We currently have six compounds which are in various stages of development and have not been approved by the FDA, including SANCTURA XR and NEBIDO. 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 including SANCTURA XR and NEBIDO.***

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 are considerable and the failure to obtain, or delays in obtaining, regulatory approval could have a significant negative effect on our business performance and financial results. Even if pre-launch approval of a product is obtained, the FDA is authorized to impose post-marketing requirements. A number of companies in the pharmaceutical industry, including 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 (our previous licensee of this compound) to elect not to pursue further development of the compound and to return to us all rights to pagoclone.

***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 assessed in future trials or when used by a larger patient population.

If SANCTURA becomes 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 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.

***We are dependent on third parties to manufacture SANCTURA and SANCTURA XR.***

We are currently dependent on Madaus to manufacture SANCTURA and will be dependent on a third party for the manufacture of SANCTURA XR. We are also dependent on third parties in the supply chain, for the manufacture of trospium chloride, the active pharmaceutical ingredient in SANCTURA and SANCTURA XR. 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 or SANCTURA XR.

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***We 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 enter into any collaborative arrangements, we will depend on the efforts of these collaborative partners and we will have limited or no control over the development, manufacture and commercialization of the products subject to the collaboration. If certain of our collaborative partners terminate the related agreements or fail to develop, manufacture or commercialize products, we would be materially adversely affected. Because we expect generally to retain a royalty interest in sales of products licensed to third parties, our revenues may be less than if we marketed products directly.

We 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 current good manufacturing practices, or 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 and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us.

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

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

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

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

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

***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 2007 as we continue to fund our development activities, as well as marketing activities related to SANCTURA and DELATESTRYL. 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;
- marketing success of DELATESTRYL, sales of which may be negatively impacted if NEBIDO is introduced to the market;
- the costs and progress of our 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 $17,600,000, $31,800,000, $68,200,000, $53,200,000 and $50,600,000 for fiscal years 2002, 2003, 2004, 2005, and 2006, respectively. At September 30, 2006 we had an accumulated deficit of approximately $472,700,000.

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. We also continue to expect fluctuations in expense from the timing of clinical trials, payments to licensors for development milestones, and in licensing fees for new product candidates.

***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, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the AHP indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. We are unable to predict whether the existence of such litigation may adversely affect our business.

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

***We 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 or selling are not covered by any patents and, accordingly, we will be dependent on obtaining market exclusively under the Waxman-Hatch Act for such products. If we are unable to obtain strong proprietary rights protection of our products after obtaining regulatory clearance, competitors may be able to market competing generic products by obtaining regulatory clearance, by demonstrating equivalency to our product, without being required to conduct the lengthy and expensive clinical trials required of us. Certain of our agreements provide for reduced royalties, or forgo royalties altogether, in the event of generic competition.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a 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. We do not otherwise currently own or have a license to issued patents that cover our SANCTURA product.

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

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

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

***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 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. In the event our products were unable to be sold at the rate we currently anticipate, we could potentially have excess inventory, resulting in an impairment charge that could have material effect on our financial statements.

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

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

Our product candidates, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept or utilize the associated products. The product candidates that we are attempting to develop differ from established treatment methods and will compete with a number of more established drugs and therapies manufactured and marketed by major pharmaceutical companies.

***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 and SANCTURA XR, our agreement with Aventis, under which we license pagoclone, or our agreements 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, Thomas F. Farb, our President and Chief Operating Officer, Noah D. Beerman, our Chief Business Officer, Mark S. Butler, our Chief Administrative Officer and General Counsel, Michael W. Rogers, our Chief Financial Officer, 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 $40,000,000. We may obtain additional coverage for products that may be marketed in the future, including SANCTURA XR and NEBIDO. 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, 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 awards under our 2004 Equity Incentive Plan accelerates and outstanding options under our stock option plans become immediately exercisable upon certain changes in control of 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, among others, include:

market success of SANCTURA;

results of clinical studies and regulatory reviews;

the marketing approval of SANCTURA XR;

results of our NEBIDO Phase III pharmacokinetic study;

partnerships, corporate collaborations and company acquisitions;

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

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

market conditions in the pharmaceutical and biotechnology industries;

competitive products;

sales, the possibility of sales, or buybacks of 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, regulatory progress and delays and timing and recognition of certain expenses;

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

Redux-related litigation developments;

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

general economic conditions.

The high and low sales prices of our common stock as reported by NASDAQ Stock Market were: $12.83 and $0.85 for fiscal 2002, $6.90 and $1.32 for fiscal 2003, $10.25 and $4.86 for fiscal 2004, $7.45 and $2.41 for fiscal 2005, and $6.62 and $2.52 for fiscal 2006. 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, 2006, we had 56,040,456 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, 2006, 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;
- 12,132,778 shares issuable upon exercise of outstanding options and Performance Stock Awards, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if we issue additional securities below certain prices;
- 622,222 shares upon conversion of preferred stock owned by Wyeth, subject to anti-dilution provisions; and
- 2,414,618 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, 2006, we had $72,000,000 of outstanding debt reflected in our balance sheet relating to our outstanding Convertible Notes. If the price of our common stock at the time of convertible debt is due does not exceed 150% of conversion price then in effect for a specified period, then the company may not be able to redeem the notes to cause a conversion, then the company may be obligated to repay the note holders in cash on the July 2008 due date. 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 or other sources in the future to service our debt, we may be required, among other things:

- to seek additional financing in the debt or equity markets;
- to refinance or restructure all or a portion of our indebtedness, including the 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 $1,100,000. The initial term of this lease expires in December 2010.

**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 (formerly American Home Products Corporation), 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. After the withdrawal of Redux, we were named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purported 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.

On May 30, 2001, we entered into an indemnity and release agreement with Wyeth pursuant to which Wyeth agreed to indemnify us against certain classes of product liability cases filed against us involving 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 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.

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.

On January 18, 2005, Wyeth announced that they had developed a proposed process by which large numbers of cases involving claimants, who opted out of Wyeth s national class action settlement and who have named both Wyeth and Indevus as defendants, might be negotiated and settled. Since that date a significant number of cases in which Indevus has been named as a defendant have been dismissed or resolved.

*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 | 53 | Chief Executive Officer and Chairman |
| Thomas F. Farb | 50 | President and Chief Operating Officer |
| Noah D. Beerman | 44 | Executive Vice President, Chief Business Officer |
| Mark S. Butler | 60 | Executive Vice President, Chief Administrative Officer and General Counsel |
| Michael W. Rogers | 46 | Executive Vice President, Chief Financial Officer and Treasurer |
| Bobby W. Sandage, Jr., Ph.D. | 53 | Executive Vice President, Research and Development and Chief Scientific Officer |
| John H. Tucker | 43 | Executive Vice President, Chief Sales and Marketing Officer |

*Glenn L. Cooper, M.D.* is the Chairman and Chief Executive Officer of Indevus. Dr. Cooper has been Chairman since January 2000, Chief Executive Officer since May 1993, and was President until Thomas F. Farb s election as President in 2006. Dr. Cooper joined the Company in May 1993 as President, Chief Executive Officer and a member of the Board of Directors. In January 2000, Dr. Cooper was appointed Chairman of the Board of Directors. From September 1992 to June 1994, Dr. Cooper was also President and Chief Executive Officer of Progenitor, Inc. Prior to joining Progenitor, Dr. Cooper was Executive Vice President and Chief Operating Officer of Sphinx Pharmaceuticals Corporation from August 1990. Prior to Sphinx, Dr. Cooper had been associated with Eli Lilly since 1985, 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 a B.A. from Harvard College.

*Thomas F. Farb* is the President and Chief Operating Officer of Indevus, a position he has held since re-joining the Company in October 2006. Mr. Farb had previously served as the Company s Executive Vice President and Chief Financial Officer from April 1994 to August 1998. From September 2003 to October 2006, Mr. Farb was Managing Director of New America Partners, an investment management and merchant bank firm which he co-founded. Prior to New America Partners, Mr. Farb was a General Partner and Chief Financial Officer of Summit Partners from September 1998 to September 2003. From October 1992 to March 1994, Mr. Farb was Vice President, Corporate Development and Strategic Planning and Chief Financial Officer for Cytyc Corporation, a publicly-held medical device and diagnostics company. Mr. Farb received a B.A. from Harvard College**.**

*Noah D. Beerman* is the Executive Vice President, Chief Business Officer of Indevus, a position he has held since September 2004. Mr. Beerman joined the Company in June 1997 as Director of Business Development and subsequently was appointed Executive Director in June 1998, Vice President in January 2000, and Senior Vice

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President in August 2000. 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* is the Executive Vice President, Chief Administrative Officer and General Counsel, a position he has held since December 1995. Mr. Butler joined the Company in December 1993 as Senior 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* is the Executive Vice President, Chief Financial Officer and Treasurer of Indevus, a position he has held since joining the Company in February 1999. 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.* is the Executive Vice President, Research and Development and Chief Scientific Officer of Indevus, a position he has held since December 1995. Dr. Sandage joined the Company in November 1991 as Vice President-Medical and Scientific Affairs and was appointed Vice President, Research and Development in February 1992 and, Senior Vice President, Research and Development in February 1994. From February 1989 to November 1991, Dr. Sandage 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* is the Executive Vice President, Chief Sales and Marketing Officer of Indevus, a position he has held since September 2004. Mr. Tucker joined the Company in April 2002 as Vice President, Sales and Marketing and was appointed Senior Vice President in December 2003. 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. Mr. Tucker 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, 2006: | | |
| July 1 through September 30, 2006 | $ 6.39 | $ 5.03 |
| April 1 through June 30, 2006 | 6.22 | 4.40 |
| January 1 through March 31, 2006 | 6.62 | 5.04 |
| October 1 through December 31, 2005 | 5.41 | 2.52 |
| 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 |

**Approximate Number of Equity Security Holders**

The number of holders of record of our Common Stock as of September 30, 2006 was approximately 664.

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, 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 that we may issue.

**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, 2006:

| Plan category | Number of Securities | Weighted-average exercise price of | Number of securities remaining available |
|---|---|---|---|

| | to be issued upon exercise of outstanding options (a) | outstanding options (b) | for future issuance under equity compensation plans (Excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders | 11,781,378 | $ 4.55 | 2,402,536 |
| Equity compensation plans or arrangements not approved by security holders | | | 12,082(1) |
| Total | 11,781,378 | $ 4.55 | 2,414,618 |

(1) 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 registered public 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, | | | | |
|---|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2003 | 2002 |
| | (Amounts in thousands except per share) | | | | |
| **Statement of Operations Data:** | | | | | |
| Revenues: | | | | | |
| Product revenue | $ 26,738 | $ 14,269 | $ 9,740 | $ 4,316 | $ 3,439 |
| Contract and license fees | 23,714 | 19,067 | 8,986 | 929 | 968 |
| Total revenues | 50,452 | 33,336 | 18,726 | 5,245 | 4,407 |
| Cost of product revenue | 19,692 | 8,593 | 7,950 | 1,073 | 733 |
| Research and development | 43,203 | 30,597 | 23,303 | 24,466 | 13,614 |
| Marketing, general and administrative | 36,009 | 41,983 | 51,916 | 11,105 | 8,090 |
| Loss from operations | (48,452) | (47,837) | (64,443) | (31,399) | (18,030) |
| Investment income | 3,505 | 3,142 | 1,396 | 664 | 987 |
| Interest expense | 5,170 | 5,170 | 5,170 | 1,077 | |
| Loss before income taxes | (50,554) | (50,047) | (68,212) | (31,812) | (17,586) |
| Provision for income taxes | | (3,171) | | | |
| Net loss[1] | (50,554) | (53,218) | (68,212) | (31,812) | (17,586) |
| Preferred stock dividends | 35 | 35 | 35 | 35 | 35 |
| Net loss attributable to common stockholders | (50,589) | (53,253) | (68,247) | (31,847) | (17,621) |
| Loss per common share from operations- diluted | (1.02) | (1.13) | (1.43) | (0.68) | (0.38) |
| Net loss per common share-basic and diluted | $ (1.02) | $ (1.13) | $ (1.43) | $ (0.68) | $ (0.38) |
| Weighted average common shares-diluted | 49,411 | 46,977 | 47,542 | 46,930 | 45,896 |

| | September 30, | | | | |
|---|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2003 | 2002 |
| | (Amounts in thousands ) | | | | |
| **Balance Sheet Data:** | | | | | |
| Working capital | $ 54,876 | $ 79,233 | $ 131,288 | $ 73,866 | $ 34,876 |
| Total assets | 92,307 | 112,531 | 173,838 | 90,071 | 43,931 |
| Convertible Notes, long-term | 72,000 | 72,000 | 72,000 | 72,000 | |
| Total liabilities including deferred revenue | 216,511 | 227,667 | 236,868 | 83,817 | 6,700 |
| Accumulated deficit | (472,675) | (422,121) | (368,903) | (300,691) | (268,879) |
| Total stockholders equity (deficit) | (124,330) | (115,142) | (63,038) | 6,241 | 37,218 |

(1) The Company adopted SFAS 123R on a prospective basis beginning in fiscal 2006. See Note L of the Notes to Consolidated Financial Statements.

**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**

Indevus is a biopharmaceutical company engaged in the acquisition, development and commercialization of products to treat urological, gynecological and men s health conditions. We currently market two products through our approximately 85 person specialty sales force and we have six products in development. Our marketed products include SANCTURA for overactive bladder, which we co-promote with our partner Esprit, and DELATESTRYL for the treatment of male hypogonadism.

Our core urology, gynecology and men s health portfolio contains four compounds in development in addition to SANCTURA and DELATESTRYL. Our most advanced compound is SANCTURA XR, the once-daily formulation of SANCTURA. In October 2006, we submitted an NDA to the FDA seeking approval for SANCTURA XR. NEBIDO, for male hypogonadism, is currently in a fully-enrolled Phase III pharmacokinetic study and we expect to submit an NDA for NEBIDO in mid-2007. PRO 2000, a topical microbicide for the prevention of infection by HIV and other sexually-transmitted diseases, is in two ongoing Phase III trials. IP 751 is for pain and inflammatory disorders, including interstitial cystitis.

In addition to our core urology, gynecology and men s health portfolio we are preparing to begin a Phase III development program for pagoclone which we are developing for the treatment of persistent developmental stuttering. Our product portfolio also contains aminocandin, an echinocandin for systemic fungal infections for which we recently licensed worldwide rights to Novexel. We also are receiving royalties under a patent we licensed to Eli Lilly & Company 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.

**Recent Product Developments**

***SANCTURA XR***

In October 2006, we submitted an NDA to the FDA seeking approval for SANCTURA XR to treat patients with overactive bladder. As a result of the submission of the NDA, we received a $10,000,000 milestone payment from Esprit, our co-promotion partner for SANCTURA and SANCTURA XR in the United States.

Our development program for SANCTURA XR has included two randomized, double-blind, placebo-controlled Phase III trials conducted in the U.S. that were submitted in the NDA. We announced positive data from the first Phase III trial in June 2006 and positive data from the second Phase III trial in July 2006. The first trial included 601 patients who were studied at 55 sites. The second trial included 564 patients who were studied at 62 sites. Both trials were 12-week trials and measured the effects of 60mg of SANCTURA XR versus placebo, once daily, on symptoms of OAB. Patients treated with SANCTURA XR experienced statistically significantly fewer toilet voids per day at the end of the 12-week trial than did patients on placebo. SANCTURA XR treated patients also experienced statistically significantly fewer episodes of urge urinary incontinence per day at the end of the 12-week trial than did placebo patients. Treatment with SANCTURA XR also led to a statistically

significant improvement (decrease) in average urgency severity, another key symptom of OAB. Additionally, SANCTURA XR had a rapid onset of action and achieved a statistically significant difference from placebo as early as Week 1 of therapy for key efficacy endpoints. The most common anticholinergic side effects were dry mouth (10.7% of the SANCTURA XR treated patients compared to 3.7% of the placebo treated patients) and constipation (8.5% of the SANCTURA XR treated patients compared to 1.5% of the placebo treated patients).

In November 2006, we entered into (i) a License and Supply Agreement and (ii) an amendment to an original licensing agreement with Madaus (the Madaus Agreements ). Under the Madaus Agreements, we agreed to

(a) purchase from Madaus all required trospium active pharmaceutical ingredient through November 2007 (b) license to Madaus the rights to sell SANCTURA XR in all countries outside of the United States (the Madaus Territory ) except Canada, Japan, Korea and China (the Joint Territory ), (c) pay to Madaus a fixed fee based on the number of capsules of SANCTURA XR sold by us in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share, (d) supply SANCTURA XR to Madaus for a specified period of time (e) provide development committee support for a defined period and (f) provide future know-how to Madaus. In exchange, Madaus (a) waived all rights to manufacture SANCTURA XR, (b) will purchase SANCTURA XR from us at cost plus a fee based on the number of SANCTURA XR capsules sold in the Madaus Territory, and (c) will make payments upon the achievement of certain commercial milestones and royalties based on future sales of SANCTURA XR in the Madaus Territory. Certain of the milestone and royalty payments we will receive represent royalty and milestone payments due to Supernus from Indevus under the Supernus Agreement. We and Madaus will share the economics of development and commercialization in the countries in the Joint Territory. If either party decides not to pursue development and commercialization of SANCTURA XR in any country in the Joint Territory, the other party has the right to develop and commercialize SANCTURA XR in that country.

In November 2006, we entered into the Helsinn Agreement whereby Helsinn agreed to supply trospium active pharmaceutical ingredient to us. Trospium active pharmaceutical ingredient is used in the production of SANCTURA XR. The term of the Helsinn Agreement is seven years and contains certain minimum purchase requirements.

NEBIDO

In June 2006, we completed enrollment in a Phase III pharmacokinetic trial to supplement the existing clinical database for NEBIDO. If successful, we anticipate filing an NDA for NEBIDO in mid-2007. We intend to commercialize NEBIDO in the U.S. utilizing our specialty sales force.

In October 2006, we entered into an agreement with Schering under which we finalized terms of our July 2005 license for the manufacture and the supply of NEBIDO from Schering. Pursuant to the terms of this agreement, Schering agreed to manufacture and supply us with all of our requirements for NEBIDO. In addition, we are obligated to purchase certain minimum quantities from Schering during the term of this agreement, which expires at the same time as the Schering Agreement.

Pagoclone

In May 2006, we announced results of our Phase II clinical trial for pagoclone in persistent developmental stuttering. The trial, know as the EXPRESS study, was an 8-week, randomized, double-blind, placebo-controlled trial, with an open-label extension. Results from the 132-patient trial showed that pagoclone produces a statistically significant benefit in multiple primary and secondary endpoints compared to placebo. Additionally, pagoclone produced either numerically superior improvements or trends for significant improvement on virtually all other primary and secondary endpoints when compared to placebo. Pagoclone was also shown to be well tolerated and not associated with any serious adverse events.

In September 2006, we announced that following an End of Phase II meeting with the FDA, we had established a clinical plan towards regulatory approval of pagoclone for the treatment of persistent developmental stuttering and will initiate a Phase III trial in the first half of 2007. Specifically, the FDA advised us to: 1) pursue pediatric studies in parallel with adult studies so that if pagoclone is effective and safe in both populations, the NDA could be approvable for the broadest possible stuttering population; 2) conduct the next adult and pediatric placebo-controlled trials as fixed dose-response studies to determine the minimally-effective dose; and 3) pursue Phase III trials under special protocol assessments to allow the FDA to formally sign off on trial designs.

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In June 2006, we initiated a Phase II proof of concept trial designed to evaluate the efficacy of various doses of pagoclone versus placebo in delaying the ejaculatory response in male patients with primary premature ejaculation. In September 2006, we elected to perform an interim analysis which revealed only a slight effect at the highest dose tested. Given the modest effect, it was unlikely that the completed trial would meet its clinical and statistical objectives. Accordingly, the study was discontinued and no further work on pagoclone for PE is currently planned.

Aminocandin

In April 2003, we licensed exclusive, worldwide rights from Aventis to aminocandin (the Aminocandin Agreement ). In December 2006, we licensed our know how related to aminocandin to Novexel for an upfront payment of $1,500,000 and potential future development milestones and royalties on net sales (the Novexel Agreement ). Immediately prior to the execution of the Novexel Agreement, Aventis assigned the Aminocandin Agreement to Novexel. Effective as of the date of the Novexel Agreement, we entered into a termination agreement with Novexel terminating the Aminocandin Agreement, thereby alleviating us from any further development or financial obligation relating to aminocandin. Pursuant to the Novexel Agreement, Novexel now is responsible for all future development, manufacturing, marketing and financial obligations relating to aminocandin.

**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 initial and milestone payments received from PLIVA and 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. Through September 30, 2006, we have received $161,000,000 of such payments. Additionally, as a result of the October 2006 submission of the NDA, we received a $10,000,000 milestone payment from Esprit.

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 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 $13,417,000, $13,875,000 and $6,250,000 of deferred revenue into contract and license fee revenue in fiscal 2006, 2005 and 2004, respectively, and the balance of deferred revenue related to the initial and the subsequent milestone payments at September 30, 2006 is $127,457,000. 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.

*Revenue Recognition Policy*

Product revenue consists primarily 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 O of Notes to Consolidated Financial Statements). Product revenue also includes revenue earned from shipments of DELATESTRYL, acquired in January 2006 from Savient Pharmaceuticals, Inc. ( Savient ). 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 when 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, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received 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 records sales of product as product revenue upon the later of shipment or as title passes to its customer. Sales of DELATESTRYL are reflected net of reserves for returns and allowances.

Contract and license fee revenue consists of revenue from contractual initial and milestone payments received from partners, including amortization of deferred revenue from contractual payments, sales force subsidies, and grants from agencies supporting research and development activities. In addition, during fiscal years 2004 and 2005, contract and license fee revenue also included reimbursements from our SANCTURA marketing partner for their share of SANCTURA promotion and advertising costs incurred by the Company less an amount owed by the Company to our SANCTURA marketing partner for the Company s share of SANCTURA promotion and advertising costs incurred by our SANCTURA marketing partner.

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The Company s business strategy includes entering into collaborative license, 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 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 the Company completes its 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 d.d. ( 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.

*Insurance Claim Receivable*

As of September 30, 2006, 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, 2006 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, 2006, we have an accrued liability of approximately $559,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ materially from the amount currently accrued at September 30, 2006. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

*Accounting for Stock-Based Compensation*

We have several stock-based employee compensation plans. On October 1, 2005, we adopted Statement of Financial Accounting Standards No. 123R Accounting for Stock-Based Compensation ( SFAS 123R ) using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. The fair value of options at grant date was estimated using the Black-Scholes option-pricing model. Stock-based employee compensation expense related to option grant activity was $3,331,000, before tax, for the twelve month period ended September 30, 2006. Previously, we had followed Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, which resulted in the accounting for employee share options at their intrinsic value in the consolidated financial statements.

We were required to make significant estimates related to the adoption of SFAS 123R. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the twelve month period ended September 30, 2006, we used a weighted-average expected stock-price volatility of 65%. For stock option grants to executives during the twelve month periods ended September 30, 2006, we used a weighted average expected stock-price volatility of 73%. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. We also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the twelve month period ended September 30, 2006, we used a weighted-average expected option life assumption of 6.25 years for non-executives and 8.0 years for executives. A shorter expected term would result in a lower compensation expense.

Additionally, during the twelve months ended September 30, 2006 the Board of Directors adopted a modification to our stock option plans relating to the retirement of employees and directors who are also reporting persons pursuant to Section 16 of the Securities Exchange Act of 1934. This modification stipulates that awards to

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such persons who retire after meeting certain age and service requirements may have an extended period of time after retirement to exercise options that were vested at the date of retirement. Pursuant to SFAS 123R, we are required to record the value of this modification to existing stock options. In the twelve month period ended September 30, 2006, we recorded $300,000 of noncash compensation expense related to this modification. Also, during the twelve months ended September 30, 2006, we amended certain provisions of outstanding stock options and recorded $472,000 of noncash compensation expense related to these modifications.

During the twelve month period ended September 30, 2006, we granted 215,900 shares of restricted common stock with service-based vesting criteria and from 210,750 to 351,400 of contingently issuable shares of other unvested awards with service and market-based vesting criteria. Service-based stock awards granted during the period have a weighted average grant date fair value of $6.36, the closing price of the common stock on the date of the grant. Service and market based awards were valued using a lattice model. Service and market based stock awards granted during the period have a weighted average grant date fair value of $4.13. During the twelve month period ended September 30, 2006, $432,000 of noncash compensation expense related to these awards was recognized. As of September 30, 2006, there remained approximately $1,900,000 of compensation expense related to such stock awards remained to be recognized as expense over approximately 2.4 years. As of September 30, 2006, there remained approximately $5,738,000 of compensation costs related to non-vested stock options to be recognized as expense over a weighted average period of approximately 1.3 years.

We recognized the full impact of our share-based payment plans, including the impact of the charges related to the modifications and restricted stock explained above, in the consolidated statement of income for the twelve month period ended September 30, 2006 under SFAS 123R and did not capitalize any such costs on the consolidated balance sheets, as such costs that qualified for capitalization were not material. We allocated these noncash expenses of $4,535,000 in the twelve month period ended September 30, 2006 as follows: $851,000 to research and development and $3,684,000 to marketing, general and administrative expense.

Presented below is the Company s stock option activity:

| | Stock Options | | Warrants | |
|---|---|---|---|---|
| | Shares | Weighted Average Exercise Price | Shares | Exercise Price |
| 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 |
| Granted | 606,250 | $ 4.87 | | |
| Exercised | (409,938) | $ 2.83 | | |
| Cancelled | (263,229) | $ 4.99 | (10,000) | $ 6.19 |
| Outstanding at September 30, 2006 | 11,781,378 | $ 4.55 | | |
| Options exercisable at end of period | 9,579,206 | $ 4.48 | | |
| Weighted average fair value of options granted during fiscal 2006 | $ 3.25 | | | |

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At September 30, 2006, 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 |
| $1.22-$ 2.71 | 3,021,002 | 3.9 years | $ 2.31 | 2,847,440 | $ 2.29 |
| $2.77-$ 4.16 | 3,407,251 | 5.3 years | $ 3.67 | 2,583,361 | $ 3.81 |
| $4.26-$ 6.19 | 3,671,750 | 4.1 years | $ 5.94 | 3,098,958 | $ 6.01 |
| $6.21-$20.13 | 1,681,375 | 7.0 years | $ 7.33 | 1,049,447 | $ 7.60 |
| $1.22-$20.13 | 11,781,378 | 4.8 years | $ 4.55 | 9,579,206 | $ 4.48 |

The aggregate intrinsic value of outstanding options as of September 30, 2006 was $19,100,000, of which $16,100,000 was related to exercisable options. The intrinsic value of options exercised during the twelve months ended September 30, 2006 and 2005 was $1,431,000 and $960,000, respectively. The intrinsic value of options vested during the twelve months ended September 30, 2006 was $1,327,000. The weighted average contractual life for total options exercisable at September 30, 2006 was approximately 3.9 years.

The aggregate intrinsic value of restricted stock awards outstanding at September 30, 2006 was $1,278,000 for awards with service-based vesting criteria and from $1,248,000 to $2,079,000 for awards with service and market based vesting criteria.

**Results of Operations**

Fiscal Year Ended September 30, 2006 Compared to Fiscal Year Ended September 30, 2005

Our net loss decreased $2,664,000 to $(50,554,000), or $(1.02) per share, basic, in fiscal 2006 from $(53,218,000), or $(1.13) per share, basic, in fiscal 2005. This reduced loss is primarily the result of increased revenues related to SANCTURA and decreased sales and marketing expenses, partially offset by increased research and development and general and administrative expenses.

Total revenues increased $17,116,000, or 51%, to $50,452,000 in fiscal 2006 from $33,336,000 in fiscal 2005. Product revenue, which includes royalties and sales of product, increased $12,469,000, or 87%, to $26,738,000 in fiscal 2006 from $14,269,000 in fiscal 2005. Sales of SANCTURA to our marketing partner increased $9,136,000 to $14,975,000 in fiscal 2006 from $5,839,000 in fiscal 2005. Sales of SANCTURA to our marketing partner are dependent upon the timing of our partner s orders which can vary from period to period; past sales are not indicative of future sales. Royalties from SANCTURA increased $992,000 to $7,734,000 in fiscal 2006 from $6,742,000 in fiscal 2005. Royalties in fiscal 2006 reflected the minimum royalties due pursuant to the SANCTURA Agreement. We expect royalty revenue from SANCTURA will continue to reflect such contractual minimum royalties, which are $1,969,000 per quarter from July 1, 2006 through June 30, 2007. Minimum royalties will increase to $2,625,000 per quarter beginning with our fourth quarter of fiscal 2007. Minimum royalties will cease after June 30, 2008. Additionally, product revenue in fiscal 2006 included $2,709,000 of net sales of DELATESTRYL and royalties from Lilly on sales of Sarafem decreased $369,000, or 22%, to $1,318,000 in fiscal 2006 from $1,687,000 in fiscal 2005. We will not receive royalties on Sarafem after November 2007, unless additional patent extensions are applicable.

Contract and license fee revenue related almost entirely to the SANCTURA Agreement and increased $4,647,000, or 24%, to $23,714,000 in fiscal year 2006 from $19,067,000 in fiscal 2005. Sales force subsidy pursuant to the SANCTURA Agreement increased $2,122,000, or 32%, to $8,811,000 in fiscal 2006 from $6,689,000 in fiscal 2005. Fiscal 2006 reflected a slightly higher average subsidy rate than fiscal 2005 as well as a full year of subsidy compared to only ten months of subsidy in fiscal 2005. Sales force subsidies for the fiscal year ended September 30, 2007 are expected to approximate $8,750,000. Fiscal 2005 included a $1,490,000

reduction to contract and license fee revenue for net reimbursement due to PLIVA for SANCTURA promotion and advertising costs; the absence of a similar reimbursement in fiscal 2006 resulted in an increase in contract and license fee revenue. After the co-promotion period ended November 28, 2004, PLIVA became responsible for promotion and advertising costs. The fiscal year ended September 30, 2006 included $1,266,000 of contract and license fee revenue, $1,000,000 of which was received in cash, from the amended bucindolol license agreement. Also included in contract and license fee revenue was $13,417,000 and $13,875,000 from amortization of deferred revenue during fiscal 2006 and 2005, respectively.

Cost of product revenue increased $11,099,000, or 129%, to $19,692,000 in fiscal 2006 from $8,593,000 in fiscal 2005. The increase is primarily due to the increases in sales of SANCTURA product sold to our marketing partner at our cost to manufacture and the cost of DELATESTRYL sold of $2,417,000.

Research and development expense increased $12,606,000, or 41%, to $43,203,000 in fiscal 2006 from $30,597,000 in fiscal 2005. The increase is primarily due to a net increase in external product development costs of approximately $10,700,000 during fiscal 2006. External development costs related to trospium increased approximately $12,100,000 in fiscal 2006, and related primarily to our Phase III clinical development program for SANCTURA XR initiated in September 2005. Pagoclone external development costs increased by approximately $3,000,000 in fiscal 2006, of which $1,800,000 related to our Phase II clinical trial for stuttering and $1,200,000 related to our Phase II trial for premature ejaculation which was discontinued in September 2006. NEBIDO clinical external development costs increased approximately $4,300,000 in fiscal 2006 and related to our pharmacokinetic trial initiated in fiscal 2006. We also incurred increased external research and development expenses of $1,500,000 and $1,000,000 during fiscal 2006 for our IP 751 and PRO 2000 products, respectively. Partially offsetting these increases is decreased external development costs related to aminocandin of approximately $3,700,000 in fiscal 2006. Our fiscal 2005 research and development expense also included a $7,500,000 up front payment made to Schering for the in-license of NEBIDO. Additionally, employee and compensation related expense increased approximately $1,700,000 in fiscal 2006, related to additional staffing and noncash stock-based compensation expense from the adoption of SFAS 123R. Total research and development expense for fiscal 2006 substantially relates to our major compounds being developed as follows: SANCTURA and SANCTURA XR $25,523,000, NEBIDO $6,129,000, PRO 2000 $2,304,000, pagoclone $6,308,000, IP 571 $2,211,000 and aminocandin $681,000.

Marketing, general and administrative expense decreased $5,974,000, or 14%, to $36,009,000 in fiscal 2006 from $41,983,000 in fiscal 2005 primarily due to decreased marketing costs related to SANCTURA.

Marketing expenses decreased $7,742,000, or 27%, to $20,531,000 in fiscal 2006 from $28,273,000 in fiscal 2005. The decrease in marketing expense in fiscal 2006 reflected approximately $7,100,000 of decreased promotion and advertising expense related to SANCTURA and approximately $3,100,000 of decreased sales force-related expense. As noted above, after the co-promotion period ended November 29, 2004 pursuant to the Conversion, PLIVA became responsible for promotion and advertising costs and we transferred approximately 200 primary care sales representatives to PLIVA. Partially offsetting these decreases were increased expenses primarily related to the marketing of DELATESTRYL, noncash stock-based compensation expense from the adoption of SFAS 123R and other marketing and sales related activities. In January 2006, the sales force commenced promoting DELATESTRYL in addition to SANCTURA.

General and administrative expense increased $1,768,000, or 13%, to $15,478,000 in fiscal 2006 from $13,710,000 in fiscal 2005. Included in the fiscal 2006 general and administrative expense were charges of approximately $2,800,000 for noncash stock-based compensation expense related to the adoption of SFAS 123R, increases in legal fees of approximately $400,000 and increased compensation expense of approximately $800,000 related primarily to higher staffing levels. Partially offsetting these increases was a decrease of $300,000 for Sarbanes-Oxley Section 404 compliance. In addition, in fiscal 2005 we incurred a charge of $1,300,000 related to the non-utilization of our former facilities. During the fiscal year ended September 30,

2006, we settled the remaining lease obligations relating to our former facility for a payment of $500,000 and reflected a credit of approximately $300,000 in marketing, general, and administrative expense related to the extinguishment of the remaining accrued liability.

Investment income increased $363,000, or 12%, to $3,505,000 in fiscal 2006 from $3,142,000 in fiscal 2005. While weighted average invested balances in fiscal 2006 were somewhat lower than weighted average invested balances in fiscal 2005, the increase in investment income is primarily the result of higher interest rates.

Interest expense relates to our $72,000,000 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, 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 non-utilization 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.

**Liquidity and Capital Resources**

Cash, Cash Equivalents and Marketable Securities

At September 30, 2006 we had consolidated cash, cash equivalents and marketable securities of $76,125,000 compared to $101,217,000 at September 30, 2005. This decrease of $25,092,000 was primarily the result of net cash used in operating activities of $61,699,000 partially offset by $36,827,000 of net proceeds from the issuance of common and treasury stock. In July 2006, we issued 8,050,000 shares of common stock pursuant to an underwritten public offering at a price to the public of $4.65 per share resulting in net proceeds of $35,028,000.

We are continuing to invest substantial amounts in the ongoing development of our product candidates and sales activities related to SANCTURA and DELATESTRYL. In particular, we are investing in the development of NEBIDO and will invest in regulatory activities related to a NEBIDO NDA if the currently ongoing pharmacokinetic study is successful. In January 2006, we paid approximately $5,600,000 to Savient related to our purchase of DELATESTRYL and will pay an additional $1,289,000 in two installments of approximately $644,000 on the first and second anniversary of the closing. Additionally, we assumed Savient s previous obligation to purchase $1,100,000 of additional DELATESTRYL inventory. However, we believe the supplier defaulted on its obligation to provide DELATESTRYL in the time required and we believe we are no longer obligated to purchase this inventory. In the event the supplier was able to demonstrate compliance with the agreement and we are obligated to purchase such inventory, we may be required to provide a reserve for at least a portion of the value of this inventory. 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 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.

Our $72,000,000 Convertible Notes become due in July 2008. All or a portion of the Convertible Notes are redeemable by us for cash at any time provided the Company s Common Stock equals or exceeds 150% of the conversion price then in effect for a specified period, currently $6.656 per share, 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. If the Convertible Notes are not converted to Common Stock by July 2008, we will be required to redeem them for cash.

There remains 1,950,000 shares issuable pursuant to the shelf registration statement on Form S-3 we filed with the SEC in December 2005. The registration statement remains effective and the remaining shares of our

common stock may be offered from time to time through one or more methods of distribution, subject to market conditions and our capital needs. The terms of any offerings would be established at the time of the offering. Currently, we do not have any commitments to sell such shares remaining under the registration statement.

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 XR, NEBIDO and other development efforts. We are responsible for conducting and funding the development of SANCTURA XR. We could receive approximately $35,000,000 in a future payment contingent upon the approval of an NDA for SANCTURA XR. 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, the U.S. rights to SANCTURA XR will revert to us and 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.

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 U.S. current Good Manufacturing Practices, 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.

Total research and development expenses incurred by us through September 30, 2006 on the major compounds currently being developed or marketed, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: $130,900,000 for SANCTURA and SANCTURA XR, $17,800,000 for NEBIDO, $17,600,000 for PRO 2000, $6,800,000 for IP 751, $32,900,000 for pagoclone, and $11,300,000 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 the above uncertainties, and other 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, 2006 through the preparation of an NDA for our major compounds currently being developed as follows: approximately $13,000,000 for NEBIDO, $13,000,000 for PRO 2000, approximately $46,000,000 for IP 751, and approximately $55,000,000 for pagoclone for stuttering. As a result of our recently announced agreement to outlicense aminocandin to Novexel, we do not expect to incur any expenses for future development. 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. We are currently considering strategic partners for future development and commercialization of IP 751 and PRO 2000 and evaluating commercialization options for pagoclone in parallel with our ongoing development program and preliminary market development activities.

Analysis of Cash Flows

Net cash used in operating activities in the twelve month period ended September 30, 2006 of $61,699,000 consisted primarily of the net loss of $50,554,000. Contributing to cash used in operating activities is a $14,834,000 decrease of deferred revenue consisting primarily of $13,417,000 of amortization into contract and license fee revenue and $1,434,000 recognized as product revenue for shipments of SANCTURA to our marketing partner. Also contributing to cash used in operating activities is a $3,950,000 increase in inventories, consisting of $4,921,000 related to DELATESTRYL purchased in fiscal 2006, less $971,000 related to SANCTURA inventory sold in fiscal 2006. Partially offsetting these uses of cash in operating activities is noncash compensation of $4,535,000 related to stock compensation expense pursuant to our adoption of SFAS 123R.

Net cash provided by investing activities of $9,943,000 is primarily comprised of net proceeds from maturities and sales of marketable securities of $10,167,000.

Net cash provided by financing activities of $36,827,000 primarily resulted from our July 2006 public issuance of common stock described above.

Contractual Obligations and Off-Balance Sheet Arrangements

The following chart summarizes our contractual payment obligations as of September 30, 2006. The Convertible Notes and license fees are reflected as liabilities on our Balance Sheet as of September 30, 2006. 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, 2006.

| | 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 | 3,600,000 | | | 8,100,000 |
| Purchase obligations (2) | 15,434,000 | 7,343,000 | 1,789,000 | 1,000 | 24,567,000 |
| Operating leases (3) | 1,231,000 | 2,215,000 | 1,251,000 | | 4,697,000 |
| Total | $ 21,165,000 | $ 85,158,000 | $ 3,040,000 | $ 1,000 | $ 109,364,000 |

(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 generally cannot predict if or when such events will occur. In fiscal 2006, we recorded a license

payment obligation to Madaus and an intangible asset of $1,500,000 in recognition of expected achievement of a contingent cumulative net sales milestone related to SANCTURA. We commenced amortizing the intangible asset to cost of revenue over the remaining estimated term of the Madaus license agreement and we expect to pay the milestone when it is achieved.

Pursuant to the Madaus Agreement, we are committed to purchase from Madaus significant minimum quantities of bulk SANCTURA tablets during fiscal 2007 aggregating approximately $3,900,000. 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.

Pursuant to the DELATESTRYL Agreement, we assumed Savient s previous obligation to purchase approximately $1,100,000 of additional DELATESTRYL inventory. We believe the supplier defaulted on its obligation to provide DELATESTRYL in the time required and we believe we are no longer obligated to purchase this inventory. In the event the supplier was able to demonstrate compliance with the agreement and we were obligated to purchase such inventory, we may be required to provide a reserve for at least a portion of the value of this inventory.

We lease approximately 95 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 June 2005, the lease agreement for our new corporate headquarters commenced at an annual rent of approximately $1,100,000. The initial term of the lease expires in December 2010 and the Company has a right to extend for an additional five-year period at current market rates. We provided a $500,000 letter of credit to the landlord as a security deposit and the expiration of the letter of credit coincides with the initial term of the lease. We vacated our prior facility in June 2005, prior to the April 2007 expiration of that lease. As a result, we recorded a charge of approximately $1,310,000 in fiscal 2005 related to the non-utilization of our prior facility. During fiscal 2006, we settled the remaining lease obligations relating to our prior facility for a payment of $500,000 and reflected a credit of approximately $300,000 in marketing, general, and administrative expense related to the extinguishment of our accrued liability.

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 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. We will adopt this pronouncement beginning October 1, 2006. We do not expect the adoption of SFAS No. 154 will have a material impact on our consolidated results of operations and financial condition.

In February 2006, the FASB issued SFAS No. 155, Accounting for Certain Hybrid Instruments , which is an amendment to SFAS No. 133 and SFAS No. 140. SFAS No. 155 allows financial instruments which have embedded derivatives to be accounted for as a whole (eliminating the need to bifurcate the derivative from its host) if the holder elects to account for the instrument as a whole instrument on a fair value basis. This statement is effective for all financial instruments acquired or issued after the beginning of an entity s first fiscal year that begins after September 15, 2006. The Company does not believe the adoption of this statement will have a material impact on the financial statements.

In June 2006, the FASB ratified Emerging Issues Task Force ( EITF ) Issue No. 06-3, How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation) . This standard allows companies to present in their statements of income any taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer, such as sales, use, value-added, and some excise taxes,

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on either a gross (included in revenue and costs) or a net (excluded from revenue) basis. This standard is effective for interim and fiscal years beginning after December 15, 2006. The Company is currently evaluating the potential impact of this issue on the financial statements, but does not believe the impact of the adoption of this standard will be material.

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertain Tax Provisions, an Interpretation of SFAS Statement 109 ( FIN 48 ). FIN 48 clarifies the accounting for uncertain tax positions as described in SFAS No. 109, Accounting for Income Taxes, and requires a company to recognize, in its financial statements, the impact of a tax position only if that position is more likely than not of being sustained on an audit basis solely on the technical merit of the position. In addition, FIN 48 requires qualitative and quantitative disclosures including a discussion of reasonably possible changes that might occur in the recognized tax benefits over the next twelve months as well as a roll-forward of all unrecognized tax benefits. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company intends to adopt FIN 48 beginning October 2007 and is currently evaluating the impact FIN 48 might have on its consolidated results of operations and financial condition.

In September 2006, the SEC issued Staff Accounting Bulletin, or SAB, No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements , or SAB 108, which is effective for fiscal years ending after November 15, 2006. SAB 108 provides interpretive guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. We do not expect the adoption of SAB 108 to have a material impact on our consolidated financial statements.

On September 15 2006, the Board issued FAS 157, Fair Value Measurements , which addresses how companies should measure fair value when they are required to do so for recognition or disclosure purposes. The standard provides a common definition of fair value and is intended to make the measurement of fair value more consistent and comparable as well as improving disclosures about those measures. The standard is effective for financial statements for fiscal years beginning after November 15, 2007 or the Company s 2009 fiscal year. This standard formalizes the measurement principles to be utilized in determining fair value for purposes such as derivative valuation and impairment analysis. The Company is still evaluating the implications of this standard, but does not currently expect it to have a significant impact.

**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 $59. 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 $8. 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, 2006, 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, 2006 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, 2006.

Our assessment of the effectiveness of our internal control over financial reporting as of September 30, 2006 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, 2006 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, Executive Officers, and Corporate Governance; 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 Director Independence; 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) Documents filed as a part of this report:

(1) Financial Statements: An index to Consolidated Financial Statements appears on page F-1 of this Report and such financial statements are filed as part of the annual report.

(2) Financial Statement Schedule: 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.

(3) Exhibits. The following exhibits are filed as part of the annual report:

| | | |
|---|---|---|
| 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)(65) |
| 4.9 | - | Form of Notice of Grant of Stock Options issued under the Registrant s 2004 Equity Incentive Plan (65) |
| 4.10 | - | Form of Option Agreement relating to Incentive Stock Options issued under the Registrant s 2004 Equity Incentive Plan (65) |
| 4.11 | - | Form of Option Agreement relating to Non-Qualified Stock Options issued under the Registrant s 2004 Equity Incentive Plan (65) |
| 4.12 | - | Form of Restricted Stock Award issued under the Registrant s 2004 Equity Incentive Plan (65) |
| 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) (71) |
| 10.103 | - | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Bobby W. Sandage, Jr. dated and effective as of March 15, 1999 (34) (71) |
| 10.104 | - | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Mark S. Butler dated and effective as of March 15, 1999 (34) (71) |
| 10.105 | - | Employment Agreement between Internmeuron Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated and effective as of May 1, 1999 (34) (71) |
| 10.108 | - | Exchange Agreement dated July 15, 1999 between Intercardia, Inc. and Interneuron Pharmaceuticals, Inc. (35) |

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| 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) (71) |
| 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) |
| 10.136 | - | 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) (71) |
| 10.141 | - | Fiscal 2005 Senior Executive Bonus Plan, as adopted by the Board of Directors on December 7, 2004 (56) (71) |
| 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) |

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| 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) (71) |
| 10.147 | - | Fiscal 2006 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 20, 2005 (62) (71) |
| 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) (71) |
| 10.150 | - | Asset Purchase Agreement dated December 12, 2005 by and between Saviant Pharmaceuticals, Inc. and the Registrant (2) (64) |
| 10.151 | - | Form of Employment Agreement by and between the Registrant and Noah D. Beerman, dated March 31, 2006 (66) (71) |
| 10.152 | - | Form of Employment Agreement by and between the Registrant and John H. Tucker, dated March 31, 2006 (66) (71) |
| 10.153 | - | Form of Underwriting Agreement, dated June 28, 2006; by and between the Registrant and UBS Securities LLC, as representative of the several underwriters named therein (67) |
| 10.154 | - | A copy of the Fiscal Year 2007 CEO Bonus Plan, as adopted by the Board of Directors on September 12, 2006 (68) (71) |
| 10.155 | - | A copy of the Fiscal Year 2007 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 12, 2006 (68) (71) |
| 10.156 | - | Form of Employment Agreement by and between the Registrant and Thomas Farb dated on or about October 16, 2006 (69) (71) |
| 10.157 | - | Form of Indemnification Agreement with Thomas Farb dated on or about October 16, 2006 (63) (71) |
| 10.158 | - | Manufacturing and Supply Agreement by and between the Registrant and Schering AG, Germany dated on or about October 20, 2006 (2) (70) |
| 10.159 | - | License and Supply Agreement by and between the Registrant and Madaus GmbH dated on or about November 3, 2006 (2) (70) |
| 10.160 | - | Amendment and Agreement by and between the Registrant and Madaus GmbH dated on or about November 3, 2006 (2) (70) |
| 10.161 | - | Know-How License Agreement by and between the Registrant and Novexel SA dated December 4, 2006 (2) (70) |
| 10.162 | - | API Supply Agreement by and between the Registrant and Helsinn Chemicals SA and Helsinn Advanced Synthesis SA dated on or about November 22, 2006 (2) (70) |
| 21 | - | List of Subsidiaries (70) |
| 23 | - | Consent of PricewaterhouseCoopers LLP (70) |
| 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 (70) |
| 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 (70) |

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|---|---|---|
| 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 (70) |
| 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 (70) |

(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) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2003.
(64) Incorporated by reference to Registrant s Form 8-K filed December 16, 2005.
(65) Incorporated by reference to Registrant s Form 8-K filed March 6, 2006.
(66) Incorporated by reference to Registrant s Form 8-K filed April 6, 2006.
(67) Incorporated by reference to Registrant s Form 8-K filed June 30, 2006.
(68) Incorporated by reference to Registrant s Form 8-K filed September 18, 2006.
(69) Incorporated by reference to Registrant s Form 8-K filed October 20, 2006.
(70) Filed with this report.
(71) Management contract or compensatory plan or arrangement.

**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 7, 2006

INDEVUS PHARMACEUTICALS, INC.

By: /s/ GLENN L. COOPER

**Glenn L. Cooper, M.D.**
**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<br>**Glenn L. Cooper, M.D.** | Chief Executive Officer and Chairman (Principal Executive Officer) | December 7, 2006 |
| /s/ ANDREW FERRARA<br>**Andrew Ferrara** | Director | December 7, 2006 |
| /s/ MICHAEL E. HANSON<br>**Michael E. Hanson** | Director | December 7, 2006 |
| /s/ STEPHEN C. MCCLUSKI<br>**Stephen C. McCluski** | Director | December 7, 2006 |
| /s/ MALCOLM MORVILLE<br>**Malcolm Morville** | Director | December 7, 2006 |
| /s/ CHERYL P. MORLEY<br>**Cheryl P. Morley** | Director | December 7, 2006 |
| /s/ DAVID B. SHARROCK<br>**David B. Sharrock** | Director | December 7, 2006 |

| | | |
|---|---|---|
| /s/ MICHAEL W. ROGERS<br>**Michael W. Rogers** | Executive Vice President, Chief Financial Officer, and Treasurer (Principal Financial Officer) | December 7, 2006 |
| /s/ DALE RITTER<br>**Dale Ritter** | Senior Vice President, Finance, (Principal Accounting Officer) | December 7, 2006 |

**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 integrated audits of Indevus Pharmaceuticals, Inc. s 2006 and 2005 consolidated financial statements and of its internal control over financial reporting as of September 30, 2006, and an audit of its 2004 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, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2006 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.

As discussed in Note L to the consolidated financial statements, the Company changed its method of accounting for stock-based payments in fiscal 2006.

*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, 2006 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, 2006, 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 7, 2006

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED BALANCE SHEETS**

**(Amounts in thousands except share data)**

| | September 30, 2006 | September 30, 2005 |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 70,169 | $ 85,098 |
| Marketable securities | 5,956 | 16,119 |
| Accounts receivable, net | 2,851 | 2,537 |
| Inventories | 1,628 | 971 |
| Prepaid and other current assets | 2,598 | 2,516 |
| Total current assets | 83,202 | 107,241 |
| Property and equipment, net | 880 | 1,103 |
| Insurance claim receivable | 1,258 | 1,258 |
| Prepaid debt issuance costs | 1,183 | 1,843 |
| Inventories | 3,293 | |
| Other assets | 2,491 | 1,086 |
| Total assets | $ 92,307 | $ 112,531 |
| **LIABILITIES** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 2,917 | $ 2,297 |
| Accrued expenses | 11,026 | 9,910 |
| Accrued interest | 950 | 950 |
| Deferred revenue | 13,433 | 14,851 |
| Total current liabilities | 28,326 | 28,008 |
| Convertible notes | 72,000 | 72,000 |
| Deferred revenue | 114,041 | 127,457 |
| Other | 2,144 | 202 |
| Minority interest | 126 | 6 |
| 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, 2006 $3,026) | 3,000 | 3,000 |
| Series C, 5,000 shares issued and outstanding (liquidation preference September 30, 2006 $502) | 500 | 500 |
| Common stock, $.001 par value, 120,000,000 shares authorized; 56,040,456 shares issued and outstanding at September 30, 2006 and 47,825,896 shares issued at September 30, 2005 | 56 | 48 |
| Additional paid-in-capital | 344,789 | 307,435 |
| Accumulated deficit | (472,675) | (422,121) |
| Accumulated other comprehensive loss | | (4) |
| Treasury stock, at cost, 660,607 shares at September 30, 2005 | | (4,000) |
| Total stockholders deficit | (124,330) | (115,142) |

| | | |
|---|---|---|
| Total liabilities and stockholders deficit | $ 92,307 | $ 112,531 |

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, | | |
|---|---|---|---|
| | **2006** | **2005** | **2004** |
| Revenues: | | | |
| Product revenue | $ 26,738 | $ 14,269 | $ 9,740 |
| Contract and license fees | 23,714 | 19,067 | 8,986 |
| Total revenues | 50,452 | 33,336 | 18,726 |
| Costs and expenses: | | | |
| Cost of product revenue | 19,692 | 8,593 | 7,950 |
| Research and development | 43,203 | 30,597 | 23,303 |
| Marketing, general and administrative | 36,009 | 41,983 | 51,916 |
| Total costs and expenses | 98,904 | 81,173 | 83,169 |
| Loss from operations | (48,452) | (47,837) | (64,443) |
| Investment income | 3,505 | 3,142 | 1,396 |
| Interest expense | (5,170) | (5,170) | (5,170) |
| Minority interest and other | (437) | (182) | 5 |
| Loss before income taxes | (50,554) | (50,047) | (68,212) |
| Provision for income taxes | | (3,171) | |
| Net loss | $ (50,554) | $ (53,218) | $ (68,212) |
| Net loss per common share, basic and diluted | $ (1.02) | $ (1.13) | $ (1.43) |
| Weighted average common shares outstanding, basic and diluted | 49,411 | 46,977 | 47,542 |

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

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT**

**(Dollar amounts in thousands)**

| | Common Stock | | Preferred Stock | | |
|---|---|---|---|---|---|
| | Number of Shares | Par Value Amount | Number of Shares | Amount | Additional Paid-In Capital |
| 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 |
| Public offering of common stock, net of issuance costs of $2,405 | 8,050,000 | 8 | | | 35,020 |
| Proceeds from exercise of stock options | 86,562 | | | | (923) |
| Proceeds from offering of Employee Stock Purchase Plan | 68,067 | | | | (114) |
| Dividends on preferred stock | | | | | (35) |
| Stock-based compensation and other | 9,931 | | | | 3,406 |
| Comprehensive loss: | | | | | |
| Net loss | | | | | |
| Unrealized net gain on marketable and equity securities | | | | | |
| Total comprehensive loss | | | | | |
| Balance at September 30, 2006 | 56,040,456 | $ 56 | 244,425 | $ 3,500 | $ 344,789 |

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

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS 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, 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) | |
| Public offering of common stock, net of issuance costs of $2,405 | | | | | 35,028 | |
| Proceeds from exercise of stock options | | | (323,376) | 2,082 | 1,159 | |
| Proceeds from offering of Employee Stock Purchase Plan | | | (125,666) | 754 | 640 | |
| Dividends on preferred stock | | | | | (35) | |
| Stock-based compensation and other | | | (211,565) | 1,164 | 4,570 | |
| Comprehensive loss: | | | | | | |
| Net loss | (50,554) | | | | (50,554) | $ (50,554) |
| Unrealized net gain on marketable and equity securities | | 4 | | | 4 | 4 |
| Total comprehensive loss | | | | | | $ (50,550) |

| | | | | | |
|---|---|---|---|---|---|
| Balance at September 30, 2006 | $ (472,675) | $ | $ | $ (124,330) | |

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, | | |
|---|---|---|---|
| | **2006** | **2005** | **2004** |
| Cash flows from operating activities: | | | |
| Net loss | $ (50,554) | $ (53,218) | $ (68,212) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | | | |
| Depreciation and amortization | 447 | 403 | 122 |
| Amortization of convertible note issuance costs | 660 | 660 | 660 |
| Minority interest in net income of consolidated subsidiary | 435 | | |
| Noncash consideration | (266) | | |
| Impairment and loss on equity securities | | 185 | |
| Noncash stock-based compensation | 4,535 | 75 | 4,089 |
| Lease abandonment | | 1,310 | |
| Changes in assets and liabilities: | | | |
| Accounts receivable | (314) | 4,505 | (6,887) |
| Inventories | (3,950) | 189 | (1,160) |
| Prepaid and other assets | (1,221) | 652 | (3,013) |
| Accounts payable | 620 | (4,064) | 4,353 |
| Deferred revenue | (14,834) | (1,442) | 143,750 |
| Accrued expenses and other liabilities | 2,743 | (5,012) | 4,945 |
| Net cash (used in) provided by operating activities | (61,699) | (55,757) | 78,647 |
| Cash flows from investing activities: | | | |
| Purchases of property and equipment | (224) | (957) | (636) |
| Purchases of marketable securities | (5,956) | | (61,208) |
| Proceeds from maturities and sales of marketable securities | 16,123 | 37,780 | 63,671 |
| Other | | 22 | |
| Net cash provided by investing activities | 9,943 | 36,845 | 1,827 |
| Cash flows from financing activities: | | | |
| Proceeds from sale of common stock, net | 35,028 | | |
| Proceeds from exercise of stock options and stock issued under employee stock purchase plan | 1,799 | 911 | 2,227 |
| Purchase of treasury stock | | &nbs | |