INDEVUS PHARMACEUTICALS INC
Form 10-K
December 15, 2004

# 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, 2004**

**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**<br>**(State or other jurisdiction of incorporation or organization)** | **04-3047911**<br>**(I.RS. Employer Identification Number)** |
| **One Ledgemont Center**<br>**99 Hayden Avenue**<br>**Lexington, MA**<br>**(Address of principal executive offices)** | **02421-7966**<br>**(Zip Code)** |

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity (excluding preferred stock convertible into and having voting rights on certain matters equivalent to 622,000 shares of Common Stock) held by non-affiliates of the registrant was approximately $284,000,000, based on the last sales price of the Common Stock as of March 31, 2004. 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 13, 2004, 46,955,561 shares of Common Stock, $.001 par value per share, of the registrant were issued and outstanding.

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**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, 2004 to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 and the Exhibit Index beginning on page number 50 hereto.

**PART I**

***Note Regarding Forward Looking Statements***

Statements in this Form 10-K that are not statements or descriptions of historical facts are forward looking statements under Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA (trospium chloride tablets) and SANCTURA XR (once-a-day SANCTURA); our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux-related litigation. The words believe, expect, anticipate, intend, plan, estimate or other expressions which predict or indicate future events and trends and do not relate to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, this Form 10-K. These factors include, but are not limited to: dependence on the success of SANCTURA and SANCTURA XR; the early stage of products under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA and SANCTURA XR; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR; dependence on third parties for manufacturing and marketing; 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; 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. SANCTURA and SANCTURA XR are registered trademarks of Indevus.

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

**(a) General Description of Business**

Indevus is a biopharmaceutical company engaged in the acquisition, development and commercialization of a diversified portfolio of pharmaceutical product candidates, including multiple compounds in late-stage clinical development. We currently market SANCTURA for overactive bladder ( OAB ), and we have four compounds in clinical development: pagoclone for anxiety disorders, IP 751 for pain and

inflammatory disorders, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and aminocandin for systemic fungal infections.

We seek to acquire, develop and commercialize a portfolio of pharmaceutical products for a range of therapeutic indications, with a primary focus in urology, gynecology and infectious diseases. The key elements of our business strategy include: (1) identifying product candidates with differentiating features and defined specialty markets, (2) acquiring clinical and late pre-clinical stage compounds, including products with clinical data or market experience outside the U.S., (3) defining strategies to take these compounds through clinical testing and to market, (4) adding value to acquired products through pre-clinical development, clinical testing and regulatory review activities, and (5) commercializing products independently or in collaboration with corporate partners in order to help ensure the penetration of target specialty markets. Our strategy encompasses a range of products and therapeutic areas arising from our relationships with a diverse range of partners including biopharmaceutical, regional pharmaceutical, and multi-national pharmaceutical firms, as well as academic and government institutions. Our rights with respect to our current product candidates have been licensed from third parties. We believe our increased capabilities in sales and marketing, including our specialty sales force which we hired during fiscal year 2004 strengthen our overall ability to acquire later-stage clinical compounds and marketed products and to collaborate with partners seeking both development and commercialization capabilities.

In August 2004, we launched our lead product, SANCTURA, a muscarinic receptor antagonist for the treatment of OAB. In advance of the market launch of SANCTURA, we entered into a co-promotion and licensing agreement for the U.S. commercialization of SANCTURA with PLIVA d.d. ( PLIVA ) through its specialty branded subsidiary, Odyssey Pharmaceuticals, Inc. ( Odyssey ). Under this agreement, we have received $150 million in up-front and milestone payments, and we are entitled to receive an additional $65 million upon the achievement of certain milestones, as well as royalties on net sales of SANCTURA. In addition, PLIVA is funding, for three years, our specialty sales force that is marketing SANCTURA to urology specialists, obstetricians and gynecologists, and other high prescribers who treat this condition.

It is estimated that more than 33 million Americans suffer from OAB. In 2003, the market for drugs to treat OAB was approximately $1.1 billion in the U.S. The currently marketed SANCTURA is a twice-a-day formulation, and we are currently developing a once-a-day formulation, SANCTURA XR, under an agreement with Shire Laboratories, Inc. ( Shire ).

Pagoclone is a GABA (gamma amino butyric acid) receptor agonist for the treatment of anxiety disorders. To date, there have been three Phase II clinical trials of pagoclone that demonstrated statistically significant efficacy, two in panic disorder and one in generalized anxiety disorder ( GAD ), as well as three other clinical trials that did not demonstrate statistically significant efficacy. Results from these clinical trials suggest the potential of pagoclone as a novel anti-anxiety agent that is free from the sedative effects and withdrawal or rebound-anxiety symptoms seen with other anti-anxiety agents. We have been granted a U.S. patent for the use of pagoclone to treat stuttering. We are currently analyzing the clinical and the commercial opportunities associated with the drug treatment of stuttering, and we are contemplating a Phase II trial of pagoclone in stuttering in 2005. We have exclusive, worldwide rights to develop and market pagoclone.

IP 751 is a non-psychoactive synthetic derivative of tetrahydrocannabinol (THC). Pre-clinical studies have shown that this novel anti-inflammatory and analgesic compound appears to inhibit inflammatory cytokines, including IL 1-beta and matrix metalloproteinases (MMPs) through a peroxisome proliferators-activated receptor (PPAR)-mediated mechanism. Results of a Phase II clinical trial conducted in Germany and published in the Journal of the American Medical Association in October 2003 showed that treatment with IP 751 significantly reduced neuropathic pain among 21 patients and was well-tolerated, without causing psychoactive adverse events. 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 psychoactive properties. An Investigational New Drug Application ( IND ) for IP 751 has been filed with the FDA. We have exclusive, worldwide rights to develop and market IP 751. We will focus our internal resources on certain specialty indications, such as interstitial cystitis, a painful bladder disease, and seek a corporate partner for larger indications such as pain and arthritis.

PRO 2000 is a topical microbicide in development for the prevention of the sexual transmission of HIV and other sexually transmitted diseases ( STDs ). A number of pre-clinical and early clinical studies with PRO 2000 have been completed under the sponsorship of government agencies and research organizations in the U.S.,

Europe, Africa and India. Government-sponsored Phase I and Phase I/II clinical trials in both healthy and HIV-positive women have shown PRO 2000 to be well-tolerated. In September 2004, the Microbicide Development Program, funded by the United Kingdom Department for International Development, selected PRO 2000 as the sole agent to be tested in a Phase III clinical trial due to start in 2005 in a number of African countries. In addition, an NIH-sponsored Phase II/III clinical trial to assess the safety and effectiveness of PRO 2000 is planned to begin by early 2005 at sites in Africa and the U.S. Enrollment was recently completed in an ongoing Phase II clinical trial in Uganda funded by the European Commission to assess the safety of PRO 2000. We have exclusive, worldwide rights to develop and market PRO 2000.

Aminocandin is an echinocandin, a new class of anti-fungal compounds in development for the treatment of a broad spectrum of systemic, invasive fungal infections. Aminocandin has shown in vitro and in vivo activity against a number of candida and aspergillus fungal species. Results of a Phase I trial we conducted with intravenously administered aminocandin showed that it was well tolerated and demonstrated a prolonged duration of anti-fungal activity following single-dose therapy. Data from this trial also indicate that intravenous aminocandin may be amenable to a less frequent dosing regimen, unlike the other echinocandins, which generally must be administered every day. Pending the successful completion of an ongoing multiple-dose Phase I trial of this drug, we plan to initiate Phase II trials in 2005. We plan to pursue technological solutions related to an oral formulation in parallel with an intravenous clinical program. We have exclusive, worldwide rights to develop and market aminocandin.

In addition to our product candidates in development, we are receiving royalties under a patent we licensed to Eli Lilly & Company ( Lilly ) based on net sales of Sarafem® in the U.S. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual syndrome.

Our in-licensing and product acquisition strategy is focused on compounds for the medical specialist. We are seeking development-stage and marketed compounds primarily in urology, gynecology and infectious diseases.

Indevus Pharmaceuticals, Inc. is a Delaware corporation. Our principal office is at 99 Hayden Avenue, Suite 200, Lexington, Massachusetts 02421-7966 and our main telephone number is (781) 861-8444. Reports, proxy statements and other information concerning us may be accessed and reviewed through our website: http://www.indevus.com.

**(b) Financial Information about Industry Segments**

We operate in only one business segment.

**(c) Narrative Description of Business**

**PRODUCTS**

The following table summarizes the status of our products and product candidates.

| Product Name | Indication/Use | Status* | Commercial Rights |
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|---|---|---|---|
| SANCTURA | Overactive bladder | Launched August 2004 | U.S. |
| Pagoclone | Anxiety disorders/Stuttering | Phase III in panic disorder; Phase II in GAD | Worldwide |
| IP 751 | Pain/inflammation | Phase I/II | Worldwide |
| PRO 2000 | Prevention of HIV and other sexually-transmitted diseases | Phase II/III | Worldwide |
| Aminocandin | Systemic fungal infections | Phase I | Worldwide |

* See Government Regulation.

***SANCTURA***

*General.* We launched our lead product, SANCTURA (trospium chloride tablets), a muscarinic receptor antagonist for the treatment of OAB, on August 23, 2004, in conjunction with Odyssey, PLIVA s U.S. specialty branded subsidiary. SANCTURA was approved by the FDA on May 28, 2004 and is indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency and urinary frequency. An estimated 33 million Americans suffer from OAB (Urology, Vol. 63. No. 3, March 2004). In 2003, the market for drugs to treat OAB was approximately $1.1 billion in the U.S. (IMS data). SANCTURA has been extensively studied and is currently marketed in most European countries where it is one of the leading treatments for OAB.

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

*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. A total of 523 patients were studied at 51 sites in the first of these trials, believed to be the first study in the OAB category to pre-specify and to achieve dual primary endpoints, comparing the reduction in the frequency of urination and the reduction in urge urinary incontinence episodes among drug-treated patients versus placebo patients. The three-month trial measured the effects of 20 milligrams (mg) of SANCTURA versus placebo, twice daily, on symptoms of OAB. Patients treated with SANCTURA experienced statistically significantly fewer toilet voids per day at the end of the three-month trial than did patients on placebo. The improvement (decrease) in number of toilet voids for the SANCTURA group compared with the placebo group was observed at each measurement date during the trial (weeks 1, 4 and 12). At week 12, SANCTURA-treated patients had 2.37 ($p<0.0001$) fewer toilet voids per day, compared to baseline, and placebo patients had 1.29 fewer toilet voids per day compared to baseline. 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. This improvement (decrease) in incontinence episodes for the SANCTURA group was observed beginning at week 1 and continued throughout the study. SANCTURA patients had 59 percent ($p<0.0001$) fewer incontinence episodes per day at the end of the study, compared to baseline, and placebo patients had 44 percent fewer incontinence episodes at the end of the study, compared to baseline. SANCTURA-treated patients increased their volume voided per void beginning at week 1 and continuing through three months ($p<0.0001$), with an increase of 32.1 milliliters (mL) at week 12, compared to an increase of 7.7 mL in placebo patients. Treatment with SANCTURA also led to a significant improvement (decrease) in average urgency severity, another key symptom of OAB, beginning at week 1 and continuing through three months ($p=0.0001$). These findings are consistent with the expected pharmacodynamic effects of SANCTURA and the increase of maximum bladder capacity caused by anticholinergic relaxation of the detrusor muscle. Data from this first U.S. Phase III trial were presented at the annual meeting of the American Urological Association annual meeting in April 2003 and published in the *Journal of Urology*, May 2004.

A nine-month open label period followed the conclusion of this three-month trial. A total of 407 of the original 523 patients opted to continue treatment into the open-label phase of this trial. Two hundred and four patients originally randomized to placebo in the double-blind phase were switched to SANCTURA, while 203 patients continued with SANCTURA treatment. After treatment for up to one year, patients continuing on SANCTURA treatment maintained comparable and sustained efficacy for the entire treatment period. Patients who crossed over from placebo to SANCTURA rapidly experienced a similar degree of efficacy which was also sustained for the entire nine-month period. Regardless of initial treatment, at 12 months the mean reduction in frequency of urination for all patients ranged from 18 to 21 voids per week, and the mean reduction in urge incontinence episodes for patients who switched from placebo to SANCTURA was 72 percent and for patients

who continued on SANCTURA was 64 percent, compared to baseline. All patients experienced an average increase of 27 to 28 ml in volume voided per void at the end of the study. Treatment with SANCTURA was also well tolerated, and the most frequently reported adverse events were dry mouth at 11.3 percent and constipation at 8.8 percent. Data from this trial were presented at the annual meeting of the American Urogynecological Society in July 2004.

Additional data analyses from this trial presented at the International Continence Society Meeting in October 2003 showed that treatment with SANCTURA reduced urgency severity ($p<0.0001$) and was associated with onset of action beginning as early as three days after initiation of therapy ($p=0.05$). Additional data from this trial presented at a sectional meeting of the American Urology Association in October 2003 demonstrated that early patient response to treatment with SANCTURA is an accurate predictor of long-term therapeutic success. Urgency severity is not yet approved in any labeling. Indevus plans to submit a supplemental NDA to provide for inclusion of these data in the SANCTURA package insert.

Our second Phase III trial included a total of 658 patients studied at 52 sites in the U.S. The trial measured the effects of 20 mg of SANCTURA given twice daily versus placebo on symptoms of OAB. Patients treated with SANCTURA experienced statistically significantly fewer toilet voids per day at the end of the 12-week trial than did patients on placebo. The improvement (decrease) in number of toilet voids for the SANCTURA group compared with the placebo group was observed at each follow-up visit during the trial (weeks 1, 4 and 12). SANCTURA-treated patients had fewer toilet voids at week 1 and continuing through three months, with an average of 2.67 ($p<0.0001$) fewer toilet voids per day at three months compared to baseline, while placebo patients had an average of 1.76 fewer toilet voids per day compared to baseline. SANCTURA-treated patients also experienced statistically significantly fewer episodes of urge urinary incontinence per day at the end of the 12-week trial than did patients on placebo. This improvement (decrease) in incontinence episodes for the SANCTURA group was observed beginning at week 1 and continued throughout the study. Using median percent change, SANCTURA-treated patients had 83 percent ($p<0.0001$) fewer incontinence episodes per day at the end of the study compared to baseline, and placebo patients had 50 percent fewer incontinence episodes per day compared to baseline. SANCTURA-treated patients increased their volume voided per void beginning at week 1 and continuing through week 12 ($p<0.0001$), with an increase of 35.6 mL at week 12, compared to an increase of 9.4 mL in placebo patients. In addition to these endpoints, the trial assessed the effect of SANCTURA on daytime sleepiness using the Stanford Sleepiness Scale (SSS). The changes in average SSS scores were minimal and comparable for the SANCTURA and placebo treatment groups at weeks 1, 4 and 12. SANCTURA was well tolerated in this trial as well, as evidenced by its adverse event profile that included the most common adverse events associated with the antimuscarinic class of drugs, dry mouth and constipation. Data from this second U.S. Phase III trial were presented at the annual meeting of the International Continence Society in August 2004.

Across the two U.S. Phase III trials, the most common adverse events considered possibly related to treatment were dry mouth (20.1 percent for SANCTURA vs. 5.8 percent for placebo), constipation (9.6 percent for SANCTURA vs. 4.6 percent for placebo) and headache (4.2 percent for SANCTURA vs. 2.0 percent 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.

In February 2004, we announced a 90-day extension to the original FDA Prescription Drug User Fee Act (PDUFA) action date based on our submission of a second clinical trial to determine if SANCTURA has any clinically significant effect on cardiac electrophysiology, as measured by the QT interval of cardiac muscle contractility. Our previously submitted NDA contained a placebo-controlled study, designed with FDA input and considered the current standard at the time, concluding that SANCTURA did not prolong the QT interval.

In November 2002, the FDA issued a preliminary concept paper concerning the clinical evaluation of QT interval prolongation for non-antiarrhythmia drugs which stipulated that QT interval studies should have larger sample sizes than previously required, should include a greater number of ECG readings than previously

required, and should include a positive control, such as the drug moxifloxacin, which causes a predictable increase in the QT interval. In late 2003, we became aware that a competitive OAB product with a pending NDA received an approvable letter, requiring the sponsor to perform a QT study. A second competitive OAB product also received an approvable letter with a requirement to perform additional unspecified clinical studies. Although we believe that our first QT study of SANCTURA, completed in 2001, demonstrated no effect on the QT interval, we decided to perform a second QT study with the new standard as described in the November 2002 FDA concept paper. FDA was consulted on the study design, the study was completed in late 2003, and the final study report was submitted to FDA. The study demonstrated that both SANCTURA and placebo had no significant effect on the QT interval while moxifloxacin, the positive comparator, had an expected increase in QT interval. Thus, the study concluded that SANCTURA has no significant effect on the QT interval. There was an incidental finding of more non-specific T-wave inversion in the SANCTURA treatment group than the placebo and active comparator group. These findings were asymptomatic, of unknown clinical significance and were not observed in the two U.S. Phase III trials involving 591 OAB patients receiving SANCTURA. As a result of the submission of this new QT study, the FDA established a 90-day extension to the original PDUFA date of February 27, 2004, moving that date to May 28, 2004, on which the FDA approved the SANCTURA NDA.

Our current formulation of SANCTURA is twice-a-day. In March 2003, we signed an exclusive agreement with Shire under which Shire is developing extended release formulations of SANCTURA. We have completed pharmacokinetic and safety studies with several once-a-day formulations, and we expect to begin Phase II clinical trials with a lead formulation, to be known as SANCTURA XR, in the first half of calendar year 2005, to be followed by the initiation of a Phase III clinical program with this formulation planned later in 2005.

Madaus currently manufactures SANCTURA in Germany. In order to manufacture the product for sale in the U.S., Madaus manufacturing must comply with U.S. current Good Manufacturing Practices, ( cGMP ). The FDA conducted a pre-approval inspection at the Madaus manufacturing facility in early February 2004. No significant issues were noted by the inspector, and as a result, Madaus initiated and continues manufacturing of SANCTURA for use in the U.S.

*Commercialization*. On April 6, 2004, we entered a co-promotion and licensing agreement with PLIVA through its specialty branded subsidiary, Odyssey, for the U.S. commercialization of SANCTURA. The agreement provides for payments to Indevus from PLIVA that include $30 million received by us upon signing and $120 million received by us upon the approval of SANCTURA by the FDA on May 28, 2004. In addition, we could receive up to $45 million in future payments contingent upon the achievement of certain milestones related to the development of SANCTURA XR, as well as a payment of $20 million related to the achievement of a long-term commercialization milestone in 2013.

For the first six months following the approval of SANCTURA, we received a commission based on net sales of SANCTURA. During this period, we were responsible for funding our own sales force and certain advertising and promotional costs and PLIVA and Indevus co-promoted SANCTURA 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. Pursuant to the terms of our agreement, we have exercised our right to convert the agreement into a royalty-bearing structure. The conversion became effective on November 29, 2004.

Under the royalty-bearing structure, we receive royalties from PLIVA based on net sales of SANCTURA, and PLIVA is responsible for promotional, advertising and sales-force related costs. We also transferred to PLIVA approximately 200 of our sales representatives who were promoting SANCTURA to primary care physicians and certain other specialists. We have retained a specialty sales force of approximately 85 sales representatives who continue to promote SANCTURA to urology specialists, obstetricians and gynecologists, and other high prescribers. This specialty sales force is subsidized by PLIVA for three years.

Under our agreement with PLIVA, we are responsible for funding the development of the once-a-day formulation of SANCTURA. We purchase commercial quantities of SANCTURA in bulk form from Madaus and

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supply the finished product to PLIVA, who is responsible for product distribution and records revenue for sales of the product.

***Pagoclone***

*General.* Pagoclone is under development as a treatment for anxiety disorders. Clinical targets to date have included panic and generalized anxiety disorders. Panic disorder is a severe anxiety condition characterized by panic attacks, a discrete period in which there is the sudden onset of intense apprehension, fearfulness or terror. During these attacks, symptoms such as breathing difficulty, sweating, heart palpitations, dizziness or fainting, and fear of losing control are present. GAD is characterized by excessive anxiety and worry most days for at least six months about a variety of events or activities, such as work or family. Patients with GAD experience persistent diffuse anxiety without the specific symptoms that characterize phobic disorders, panic disorders or obsessive-compulsive disorders. There are estimated to be approximately 20 million people in the U.S. (*Drug and Market Development, October 2001*) and approximately 60 million worldwide with anxiety disorders (*In Vivo, September 2001*).

Anxiety disorders are believed to be associated with excessive neuronal activity resulting from a decrease in the function of the major inhibitory neurotransmitter called GABA. We believe that pagoclone, a novel GABA modulator and a member of the cyclopyrrolone class of compounds, increases the action of GABA, thus alleviating symptoms of panic and anxiety.

Current pharmacological treatments for panic and anxiety disorders commonly include benzodiazepines, selective serotonin reuptake inhibitors, serotonin/norepinephrine reuptake inhibitors and serotonin agonists. Traditional side effects seen with these classes of anti-anxiety drugs include sedation, lack of mental acuity, withdrawal and rebound anxiety related to the benzodiazepine class of drugs, and agitation, insomnia, nausea, dry mouth, other central nervous system effects and sexual dysfunction related to serotonin and norepinephrine reuptake inhibitors and serotonin agonists. Pre-clinical and clinical data suggest that treatment with pagoclone may have advantages over these treatments because pagoclone appears to be free from these common side effects.

*Development Program*. To date, a total of six clinical trials have been conducted with pagoclone in GAD and panic disorder, including three Phase II clinical trials that demonstrated statistically significant efficacy, two in panic disorder conducted by us and one in GAD conducted by Pfizer Inc. ( Pfizer ), then our licensee. Pfizer s most recent data in two Phase II GAD trials and one Phase III panic disorder trial did not show statistically significant efficacy. In all of the clinical trials, pagoclone was well-tolerated, with no clinically significant differences with respect to adverse events, such as sedation and withdrawal effects as compared with placebo. We believe that the complete data package from the trials, combined with extensive clinical pharmacology, manufacturing process and commercial formulation work completed to date, suggest the potential of pagoclone as a novel anti-anxiety agent which lacks the sedative effects and withdrawal or rebound-anxiety symptoms seen with existing classes of such agents. We are planning additional clinical development with pagoclone to begin in 2005.

In November 1997, we announced that data from a Phase II clinical trial with 16 patients suffering from panic attacks showed that those who were treated with 0.3 milligrams per day of pagoclone experienced a reduction in the number of their panic attacks compared to those who received placebo. This double-blind, placebo controlled crossover study was conducted by a team of researchers in the United Kingdom. Pagoclone produced a significant reduction (40%, p=0.012) in the total number of panic attacks over a two-week treatment period and a reduction (40%, p=0.006) in the average number of panic attacks per day compared to the pre-treatment period. No significant change in the total number of panic attacks was observed during placebo treatment.

In August 1998, we announced results of our Phase II clinical trial showing that treatment with pagoclone statistically significantly reduced the frequency of panic attacks among patients suffering from panic disorder. In

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addition, pagoclone was well-tolerated by these patients, with no evidence of sedation and no apparent withdrawal symptoms in this study. This double-blind, placebo-controlled, Phase II clinical trial involved 277 patients at six clinical sites in the U.S. Patients were enrolled in the study following confirmed diagnoses of panic disorder. The number of attacks experienced by each patient during a two-week screening period prior to enrollment represented the baseline for subsequent comparison of panic attack frequency. Following the screening period, patients were randomized to receive one of three doses of pagoclone orally (.15 milligrams/day, .30 milligrams/day or .60 milligrams/day) or placebo for eight weeks. The primary outcome measurement was the change from baseline in the number of panic attacks seen at the eight week time point. This primary analysis showed that patients in the .15 milligrams/day group experienced a 43% reduction in the number of panic attacks relative to patients on placebo (p=0.141), that patients in the .30 milligrams/day group experienced a 70% reduction relative to patients on placebo (p=0.021), and that patients in the .60 milligrams/day group experienced a 52% reduction (p=0.098) relative to patients on placebo.

Pagoclone was well-tolerated with no clinically significant differences from placebo. Sedation, a major side effect of benzodiazepine drugs, was evaluated by use of the Stanford Sleepiness Scale. There were no differences observed between pagoclone and placebo using this scale. In addition, there were no evident withdrawal effects seen at the end of the study as determined by the Rickels Withdrawal Scale. Other common side effects seen with existing classes of anti-anxiety drugs were not significantly different between pagoclone patients and patients receiving placebo in this trial. These traditional side effects include lack of mental acuity and rebound anxiety related to the benzodiazepine class of drugs, and agitation, insomnia, nausea, dry mouth, other central nervous system effects and sexual dysfunction related to serotonin and norepinephrine reuptake inhibitors and serotonin agonists.

In December 2001, Pfizer reported that patients treated with pagoclone experienced a statistically significant improvement in symptoms of GAD, compared to patients treated with placebo. In addition, pagoclone was well-tolerated, with no difference from placebo in sedation and no evidence of withdrawal effects. This six-week Phase II clinical trial conducted by Pfizer among 200 patients involved a flexible dose regimen ranging from 0.3 milligrams of pagoclone per day to 1.2 milligrams per day. Entry criteria for patients included Hamilton Anxiety Scale (HAM-A) scores of 20 or higher. Pagoclone patients had a mean 2.3 point lower HAM-A score than placebo patients at week three (p=.033), a mean 3.3 point lower score at week four (p=.006) and a mean 3.2 point lower score at week six (p=.012). At week six, the mean reduction in HAM-A score among pagoclone patients was 11.7 versus 8.5 for placebo. There were no statistically significant differences between pagoclone-treated and placebo-treated patients with respect to side effects, such as sleepiness, as measured by the Stanford Sleepiness Scale, and withdrawal symptoms, as measured by the Rickel s Withdrawal Symptom Checklist. In addition, there were no clinically significant or laboratory adverse events among patients treated with pagoclone.

Pfizer also conducted two additional GAD trials utilizing a fixed dose paradigm. Pagoclone was given to patients twice a day (n=353) in one study and once a day (n=339) in the second study. Doses of up to 1.2 mg per day were compared to placebo and each study included approximately 80-90 patients per treatment group. No statistically significant difference was observed between any of the doses of pagoclone and placebo in these trials, although there was a trend for the lowest doses of pagoclone to reduce HAM-A scores. We believe that this lack of a dose response is not uncommon with psychiatric agents. We believe that higher doses of many of these agents often do not add benefits and may be harmful. Pagoclone was well-tolerated in these trials. Pfizer also conducted a study with pagoclone in panic disorder. We believe that the lack of efficacy found in this trial may have resulted from the inclusion of patients whose disorder was too mild to demonstrate a statistically significant drug effect. Based on these findings, Pfizer subsequently elected not to pursue further development of the compound and returned to us exclusive, worldwide development and commercialization rights to pagoclone.

We have been carefully analyzing clinical and regulatory strategies to maximize the commercial potential of pagoclone. Although GAD is a large potential commercial opportunity, there are several mitigating factors that we have been considering: (1) additional Phase III trials in GAD are large and expensive; (2) it will be necessary

to out-license pagoclone to a larger company with a substantial primary care sales force to successfully launch the product; and (3) the available patent coverage for GAD is limited to 2012 assuming a Waxman-Hatch extension. These factors limit the commercial possibilities for pagoclone in GAD. We have recently been 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 children and adults in the U.S. The therapy of stuttering consists mainly of behavioral modification and speech therapy. There are currently no drugs approved in the U.S. for the therapy of stuttering.

In the course of clinical trials for GAD and panic with pagoclone, we observed three patients who entered these trials with a secondary diagnosis of stuttering. These patients were noted to have a dramatic reduction in stuttering while receiving pagoclone. On discontinuation of study drug, stuttering returned to positive levels. These patients represented a small sample of the study and additional testing is necessary to determine whether pagoclone would be effective among a larger group of patients who stutter.

We are currently evaluating the clinical and regulatory pathway to study pagoclone in stuttering and the commercial opportunity in the U.S., where full-term pagoclone patent coverage exists, and in Europe, where patents were not filed but where ten years of data exclusivity is usually granted for the approval of a new chemical entity. We are contemplating initiating a Phase II study in stuttering during 2005 pending future evaluation of clinical and commercial factors. Given the substantial preclinical, clinical and manufacturing database that has been generated by us, our licensor, Aventis, and our former partners, Warner-Lambert and Pfizer, we believe pagoclone is a highly leveraged commercial opportunity. Should it be demonstrated to be safe and effective in stuttering, we believe we could form a specialty sales force that could successfully introduce the product to pediatric and adult neurologists in the U.S. We expect to seek a partner to commercialize the product outside the U.S.

***IP 751***

*General.* IP 751 is a non-psychoactive synthetic derivative of tetrahydrocannabinol (THC) in early clinical development to treat pain and inflammatory disorders. IP 751 appears to suppress inflammatory cytokines, including IL-1 beta and matrix metalloproteinases (MMPs) through a peroxisome proliferators-activated receptor (PPAR)-gamma-mediated mechanism, which are implicated in pain and inflammation. 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 COX-2 (cyclooxygenase-2) inhibitors. We believe IP 751 has a broad potential to treat painful 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.

*Development Program.* Pre-clinical development of IP 751 has demonstrated that it is active in multiple pre-clinical models of pain and inflammation. An initial Phase I clinical trial designed to assess its safety showed that it was well-tolerated, with no clinically significant adverse events and no evidence of psychoactive effects.

In December 2002, we announced results of a Phase II clinical trial showing that patients treated with IP 751 experienced a significant reduction in neuropathic pain. Investigators at the Hannover Medical School in Hannover, Germany reported that patients experienced significantly less pain when treated with IP 751 compared with placebo during the two-week, crossover design trial among 21 patients. In addition, the drug was well-tolerated, with no major adverse psychological or physical effects observed. These results were subsequently published in the Journal of the American Medical Association (JAMA 2003; 290 (13); 1757-1762). Patients in this trial had chronic pain syndromes as a result of previous spinal or peripheral nerve injuries, despite the continuation of standard pain medications. For inclusion in the trial, they had to have experienced pain for at least six months, although the average duration of their pain syndromes was greater than ten years. Patients were randomized to two 7-day treatment periods in a crossover design. They received one of two doses of IP 751 (20

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milligrams or 40 milligrams) or placebo twice a day during the first week, then were switched to the other regimen during the second week. The degree of pain measured by visual analog scores (VAS) decreased significantly during treatment with IP 751 when compared with placebo (p=0.02). Additional preclinical, Phase I and Phase II clinical trials are currently being planned for IP 751.

An IND for IP 751 was filed in March, 2000. We are currently completing manufacturing process activities related to IP 751 in advance of future clinical trials. The broad scope of therapeutic targets for IP 751 offers the potential for corporate partnering activities focused on those indications requiring large trials and significant financial resources. While we believe that larger clinical indications may ultimately represent significant value for the product, consistent with our business model we are focusing our internal efforts on specialty disease states, such as interstitial cystitis, a painful bladder disease, that can be targeted for commercialization with a specialty sales force. We are currently defining the optimal preclinical and clinical proof of principle pathways for this and other specialty indications which we would seek to retain for self-marketing in the U.S. In parallel, we are seeking a partner to maximize the overall potential of IP 751 for the larger clinical indications.

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

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

*Development Program.* A number of pre-clinical and early clinical studies with PRO 2000 have 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 (SHIV), and went on to develop AIDS symptoms. Of the treated animals, none in the 0.5% group, and only one each in the 2% and 4% groups became infected and developed disease. Results of this study were presented in February 2001 at the 8th Conference on Retroviruses and Opportunistic Infections (*Lewis et al., Efficacy of PRO 2000 Gel in a Macaque Model for Vaginal HIV Transmission*).

In October 2000, dosing and follow-up for a Phase I/II clinical trial of PRO 2000 was completed by the NIH at sites in the U.S. and South Africa. This study was designed to assess safety and acceptability in healthy, sexually active women and HIV-infected, sexually abstinent women. The results were presented at the International Congress of Sexually Transmitted Infections in June 2001 (*Mayer et al., The Safety and Tolerability of PRO 2000 Gel, a Novel Topical Microbicide, in Sexually Active HIV- and Abstinent HIV+ Women*). No serious side effects were reported in this trial, and the investigators concluded that PRO 2000 was safe and

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well-tolerated in both groups of women. Previous Phase I clinical trials conducted in Europe with support from the Medical Research Council of the United Kingdom showed a promising safety and acceptability profile for the drug in healthy, sexually abstinent women. Other Phase I clinical trials, to evaluate the safety of male exposure to PRO 2000, showed that it was safe and well-tolerated.

In September 2001, we were awarded a grant by the CONRAD Program under its Global Microbicide Project to subsidize two toxicity studies performed by us with PRO 2000. These animal studies have been completed and will support the ongoing PRO 2000 clinical program.

In June 2003, we announced the initiation of a Phase II clinical trial in Uganda funded by the European Commission. This trial is designed to assess the safety of PRO 2000 in approximately 200 sexually active female volunteers. Enrollment in this trial is completed.

An NIH-sponsored Phase II/III clinical trial to assess the safety and effectiveness of PRO 2000 in blocking male to female HIV transmission is planned to begin in late 2004 at sites in Africa and the U.S. The study is expected to involve approximately 3,200 HIV-uninfected women, most of whom are at risk for acquiring HIV by virtue of living in regions where the infection rate is high. The trial will also evaluate effectiveness against other STDs. In connection with this trial, the HIV Prevention Trials Network (HPTN) provided funding through Family Health International (FHI) to reimburse certain costs related to supplies of PRO 2000.

PRO 2000 is also being tested by the Microbicides Development Programme (MDP), an international partnership to develop and test vaginal microbicides. MDP was established in February 2002 with funding of approximately $22.7 million from the United Kingdom s Department for International Development (DFID). The program is administered by 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. In September 2004, the MDP selected PRO 2000 as the sole agent to be tested in a Phase III clinical trial due to start in 2005 in a number of African countries. An estimated 12,000 women will be recruited and supported for nine months or longer in connection with these trials. In a statement, the MDP explained that PRO 2000 had been shown in laboratory studies to be substantially more effective in blocking HIV infection than another microbicide known as Emmelle. Two doses of PRO 2000 (0.5 percent and 2 percent) are to be tested in order to provide information about the relationship between dose and protection.

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

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

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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 (visiongain, 2004 report).

*Development Program*. Results of a Phase I clinical trial of the intravenous formulation of aminocandin completed in June 2004 showed that it was well tolerated among healthy volunteers and demonstrated a prolonged duration of anti-fungal activity following single-dose administration. The trial was designed to test the safety and tolerance of rising single doses of intravenously administered aminocandin among approximately 40 healthy volunteers. Secondary objectives included the pharmacokinetic assessment of aminocandin in plasma and urine, and the determination of in vitro fungicidal activity of the serum collected from the volunteers.

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

A multi-dose Phase I trial of aminocandin was initiated in October 2004 to test the safety, tolerability and pharmacokinetics of rising multiple doses among 32 healthy volunteers. In this trial, the in vitro activity of aminocandin will be evaluated in serum samples from trial subjects challenged with certain species of the fungi candida and aspergillus. Ascending rising doses of the drug will be tested, and escalation to the next higher dose will be based on safety as well as systemic and local tolerance. Results of this trial will help optimize the dosing level and regimen for further clinical testing, including Phase II clinical trials expected to begin in 2005.

We believe that aminocandin may have the potential to be delivered orally, unlike the currently approved drugs or those under development in its class that can be delivered only intravenously. We plan to pursue technological solutions and feasibility studies related to an oral formulation in parallel with an intravenous clinical program. An oral fungicidal agent would be useful in preventing serious fungal infections in patients at risk and would allow for convenient and extended outpatient therapy.

**AGREEMENTS**

*SANCTURA*. In November 1999, we entered into an agreement with Madaus under which we licensed exclusive rights to develop and market SANCTURA in the U.S. In exchange for these rights, we have agreed to pay Madaus potential regulatory and sales milestone payments and royalties on net sales or, if sublicensed by us, we would pay to Madaus a portion of royalties on net sales received from the sublicencee, in lieu of royalty payments. We are responsible for all clinical development and regulatory activities and costs related to the compound in the U.S. In December 2002, we entered into a manufacturing agreement with Madaus whereby Madaus will produce and sell to us commercial quantities in bulk form.

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

On April 6, 2004, we entered into a co-promotion and licensing agreement with PLIVA through its specialty branded subsidiary, Odyssey, for the U.S. commercialization of SANCTURA for OAB. The agreement provides for payments to Indevus from PLIVA that include $30 million received by us upon signing and $120 million received by us upon the approval of SANCTURA by the FDA in May 2004. In addition, we could receive up to $45 million in future payments contingent upon the achievement of certain milestones related to the development of SANCTURA XR, as well as a payment of $20 million related to the achievement of a long-term commercialization milestone in 2013.

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 are 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.

Under our agreement with PLIVA, at any time beginning six months after the approval of SANCTURA, each company had the right to convert the agreement into a royalty-bearing structure, whereby we would receive royalties from PLIVA based on net sales of SANCTURA, and PLIVA would be responsible for promotional, advertising and sales force-related costs. On September 27, 2004, we formally notified PLIVA of our election to terminate the initial six-month co-promotion period of the agreement, thereby converting the agreement into a royalty-bearing structure. The conversion became effective on November 29, 2004. We transferred to PLIVA approximately 200 of our sales representatives who were promoting SANCTURA to primary care physicians and certain other specialists. We have retained a specialty sales force of approximately 85 sales representatives who continue to promote SANCTURA to urology specialists, obstetricians and gynecologists, and other high prescribers. This specialty sales force is subsidized by PLIVA for three years.

Under our agreement with PLIVA, we supply the finished SANCTURA product to PLIVA, who is responsible for product distribution. We are responsible for funding the development of SANCTURA XR under our agreement with PLIVA.

*Pagoclone.* In February 1994, we licensed from 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 or, 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.

In December 1999, we entered into an agreement with Pfizer under which we licensed to Pfizer exclusive, worldwide rights to develop and commercialize pagoclone. Under the Pfizer agreement we received $16,750,000, including an up-front payment of $13,750,000, and were entitled to receive additional payments contingent upon the achievement of clinical and regulatory milestones, as well as royalties on net sales. In addition, under the Pfizer agreement, Pfizer was responsible for conducting and funding all further clinical development, regulatory review, manufacturing and marketing of pagoclone on a worldwide basis. In June 2002, Pfizer elected not to pursue further development of the compound and returned to us exclusive, worldwide development and commercialization rights to pagoclone.

*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 also entered into an agreement with Sumner Burstein, Ph.D., the individual owner of certain intellectual property rights related to IP 751 under which this individual granted to us an exclusive, worldwide license to these rights in exchange for up-front, milestone and royalty payments. In August 2003, we also entered into a renegotiated agreement with Manhattan whereby we acquired all remaining intellectual property rights to IP 751 and our potential financial obligations to Manhattan related to IP 751, in exchange for a combination of cash and equity payments from us to Manhattan. We are responsible for the clinical development, regulatory review activities and commercialization of this compound.

*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 by us. 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.

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

*Citicoline.* In January 1993, we entered into an agreement with Ferrer Internacional, S.A. ( Ferrer ), subsequently amended, granting us the exclusive right to make, use and sell any products or processes developed under patent rights relating to certain uses of citicoline in exchange for an up-front license fee and royalties based on sales.

Effective January 22, 2004, we entered into a new agreement with Ferrer superseding our January 1993 agreement and covering the development, manufacture, and marketing of citicoline in the U.S. and Canada. Under the terms of the new agreement, we have granted Ferrer exclusive rights to our patents and know-how related to citicoline. In exchange, Ferrer agreed to assume all future development, manufacturing, and commercialization costs of citicoline. Indevus will receive 50% of all milestone payments made to Ferrer by a third party and royalties on net sales of the product. On October 26, 2004, IVAX Corporation announced a licensing agreement between Grupo 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 U.S.

*Sarafem.* In June 1997, we entered into an agreement with Lilly, under which we sublicensed to Lilly exclusive, worldwide rights under an 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 to treat a severe form of PMS which is marketed under the trade name Sarafem. Lilly s composition of matter patent on fluoxetine expired in July 2001. The Lilly agreement provided for milestone payments and royalties based on net sales of fluoxetine attributable to the approved indication in the U.S. up to an annual maximum limit. In December 2002, we entered into a renegotiated licensing agreement with Lilly providing us an initial payment upon the signing of the agreement and future royalty payments from Lilly based on net sales of Sarafem in the U.S. from October 1, 2002 until the expiration of our patent related to Sarafem. 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.

**MANUFACTURING AND MARKETING**

*General.* Our ability to conduct clinical trials on a timely basis, to obtain regulatory approvals and to commercialize our products will depend in part upon our ability to manufacture our products, either directly or through third parties, at a competitive cost and in accordance with applicable FDA and other regulatory requirements, including cGMP regulations. We have no manufacturing facilities and limited marketing capabilities. In general, we intend to seek corporate collaborations in which a third party assumes responsibility and funding for manufacturing and, in some cases, for marketing products.

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. There can be no assurance we will be able to obtain or retain third-party manufacturing and marketing collaborations on acceptable terms, or at all, which may delay or prevent the commercialization of products under development. Such collaborative arrangements could result in lower revenues and profit margins than if we marketed a product ourself. In the event we determine to establish our own manufacturing or additional marketing capabilities, we may require substantial additional funds.

*SANCTURA.* Pursuant to our April 6, 2004 agreement with PLIVA, we and PLIVA are co-promoting SANCTURA through a joint sales force of approximately 500 sales representatives. For the six months following the approval of SANCTURA on May 28, 2004, we established a sales force initially numbering approximately 280 representatives promoting SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians. During that period, we were responsible for funding our sales force and certain advertising and promotional costs.

Pursuant to the terms of our agreement, we exercised our right to convert the agreement into a royalty-bearing structure effective November 29, 2004. Under this royalty-bearing structure, PLIVA is responsible for all advertising and promotional costs. We transferred to PLIVA a majority of our sales force who are promoting SANCTURA to primary care physicians and certain other specialists. We have retained a specialty sales force of approximately 85 sales representatives who continue to promote SANCTURA to urology specialists, obstetricians and gynecologists, and other high prescribers. This specialty sales force is subsidized by PLIVA for three years.

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 PLIVA, and under our agreement with PLIVA, PLIVA is responsible for product distribution.

*Pagoclone.* We are responsible for the clinical development, regulatory review activities, manufacturing and marketing of pagoclone, either independently or through a corporate partner.

*IP 751.* We are responsible for the clinical development, regulatory review activities, manufacturing and marketing of this compound, either independently or through a corporate partner.

*PRO 2000.* We are responsible for providing adequate amounts of 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.

*Aminocandin.* 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.

**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.

There can be no assurance that currently marketed products, or products under development or introduced by others, will not adversely affect sales of any products developed by us, render our products or potential products obsolete or uneconomical, or result in treatments or cures superior to any therapy developed by us, or that any therapy developed by us will be preferred to any existing or newly developed products or technologies. Other companies may succeed in developing and commercializing competing products earlier than we may or products which are safer and more effective than those we have or are developing. Advances in current treatment methods may also adversely affect the market for such products. The approval and introduction of therapeutic or other products that compete with products being developed by us could also adversely affect our ability to attract and maintain patients in clinical trials for the same indication or otherwise to complete our clinical trials successfully or on a timely basis. Further, certain of our agreements eliminate or provide for reduced royalties in the event of generic competition. We expect technological developments in our fields of product development to occur at a rapid rate and expect competition to intensify as advances in these fields are made.

*SANCTURA.* Current therapy for OAB includes anticholinergics, such as Detrol and Detrol LA (tolterodine) by Pfizer, Ditropan and Ditropan XL (oxybutynin) by Johnson & Johnson, Inc., Oxytrol (oxybutynin transdermal patch) by Watson Pharmaceuticals, and generic oxybutynin. Vesicare® (solifenacin) by Yamanouchi Pharma America and Glaxo Smith Kline was approved by the FDA in November 2004. We are aware of other companies evaluating specific antimuscaranics and antispasmodics in pre-clinical and clinical development or under regulatory review for

OAB, including Enablex® (darifenacin) by Novartis AG. Certain products currently on the market for the treatment of OAB are available in once-a-day formulations, unlike our currently marketed twice-a-day formulation of SANCTURA. We are currently developing SANCTURA XR, a once-a-day formulation of SANCTURA, under an agreement with Shire Laboratories.

*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.

Current pharmacological treatments for anxiety and panic disorders generally include benzodiazepines, such as Valium® (diazepam, Roche) and Xanax® (alprazolam, Pharmacia and Upjohn), serotonin agonists such as BuSpar, serotonin/norepinephrine reuptake inhibitors such as Effexor (venlafaxine, Wyeth) and selective serotonin reuptake inhibitors such as Paxil® (paroxetine, Glaxo SmithKline), Zoloft® (sertraline, Pfizer), Lexapro (escitalopram, Forest) and Prozac® (fluoxetine, Eli Lilly). Traditional side effects seen with these classes of anti-anxiety drugs include sedation, lack of mental acuity, withdrawal and rebound anxiety related to the benzodiazepine class of drugs, and agitation, insomnia, nausea, dry mouth, other central nervous system effects and sexual dysfunction related to serotonin and norepinephrine reuptake inhibitors. We are aware of competitors which market certain prescription drugs for indications other than anxiety and which are planning to seek an expansion of labeling to include anxiety as an indication. In addition, we are aware that other companies are developing compounds for anxiety that are in pre-clinical or clinical development.

*IP 751.* Current treatments for interstitial cystitis are aimed at relieving symptoms and include Elmiron (pentosan polysulfate sodium), approved by the FDA in 1996. 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 (non-steroidal anti-inflammatories), 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), promoted by Pfizer, and Bextra® (valdecoxib), promoted by Pfizer. The principal marketed opioids include oxycontin and morphine. A key unmet need in the area of pain management is the reduction of side effects experienced with existing treatments, including gastrointestinal bleeding, ulceration, cardiovascular effects, tolerance and physical or psychological dependence. Pre-clinical studies suggest that IP 751 may lack the gastrointestinal ulceration seen with NSAIDs and the cardiovascular effects seen with COX-2 inhibitors. We believe IP 751 has a broad potential to treat painful inflammatory conditions such as arthritis, post-operative pain, and musculoskeletal injuries.

*PRO 2000.* We are not aware of any comparable product to prevent sexually-transmitted infections having been approved for use anywhere in the world. Approximately 60 new substances are being evaluated for this indication, but we believe only a few have reached the stage of development of PRO 2000. These include BufferGel by Reprotect, LLC, Savvy by Biosyn, Inc., Emmelle by ML Laboratories, PLC, Carraguard by The Population Council, and cellulose sulfate gel by the Contraceptive Research and Development Program.

*Aminocandin.* There are several new echinocandins approved or under development for the treatment of any or all of esophageal candidiasis, invasive candidemia/candidiasis, or aspergillosis. Cancidas® (caspofungin, 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. Fujisawa filed an NDA for micafungin in 2002 for a range of indications. Vicuron Pharmaceuticals received an approvable letter in May 2004 from the FDA for anidulafungin and is pursuing the approval of this compound for both esophageal candidiasis and invasive candidemia/candidiasis.

**PATENTS AND PROPRIETARY RIGHTS**

The products being developed by us may conflict with patents which have been or may be granted to competitors, universities or others. Third parties could bring legal actions against us or our sublicensees claiming patent infringement and seeking damages or to enjoin manufacturing and marketing of the affected product or the use of a process for the manufacture of such products. If any such actions are successful, in addition to any potential liability for indemnification, damages and attorneys fees in certain cases, we could be required to

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obtain a license, which may not be available, in order to continue to manufacture or market the affected product or use the affected process. 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.

There can be no assurance that patent applications filed by us or others, in which we have an interest as assignee, licensee or prospective licensee, will result in patents being granted or that, if granted, any of such patents will afford protection against competitors with similar technology or products, or could not be circumvented or challenged. In addition, certain products we are developing are not covered by any patents and, accordingly, we will be dependent on obtaining market exclusively under the Waxman-Hatch Act for such products. If we are unable to obtain strong proprietary rights protection of our products after obtaining regulatory clearance, competitors may be able to market competing generic products by obtaining regulatory clearance, by demonstrating equivalency to our product, without being required to conduct the lengthy clinical tests required of us. Certain of our agreements provide for reduced royalties, or forego royalties altogether, in the event of generic competition.

*SANCTURA.* There are no existing U.S. composition of matter patents covering the use of orally-administered SANCTURA to treat OAB. 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 SANCTURA through the development of SANCTURA XR, the once-a-day formulation of the drug. We expect to seek patent protection with respect to SANCTURA XR, which if granted, is likely to include a term of up to twenty years. However, we cannot provide any assurance that any patent on such once-a-day formulations, if granted, can or will preclude eventual market erosion from new technologies or competing products.

*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. A Notice of Allowance was issued in November 2004 for a pagoclone patent covering methods and compositions for alleviating stuttering.

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

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

*Aminocandin.* We hold an exclusive, worldwide license from Aventis to patents and patent applications related to aminocandin. The patent portfolio for aminocandin includes five sets of patents and patent applications that cover composition of matter, methods and processes of manufacture and compounds related to aminocandin.

U.S. patents were issued to us in September and October 1998 and in February 1999 relating to use of citicoline in the protection of brain tissue from cerebral infarction following ischemic stroke. We licensed worldwide rights to these patents to Ferrer in 1997, except in the U.S. and Canada, in exchange for which we will be entitled to royalties from Ferrer on certain exports and sales of the solid oral form of citicoline in certain countries upon its approval in each country. Foreign counterpart patent applications were filed and are being pursued by us.

In May 2000, we were awarded a U.S. patent, including claims directed to a composition of matter, for a hyperhydrated form of citicoline. It is believed that solid forms of citicoline, including tablets, have greater stability when this hyperhydrated form of citicoline is present.

**GOVERNMENT REGULATION**

*Therapeutic.* Prior to commercialization, our products will require regulatory clearance by the FDA and by comparable agencies in most foreign countries. The nature and extent of regulation differs with respect to different products. In order to test, produce and market certain therapeutic products in the U.S., mandatory procedures and safety standards, approval processes, and manufacturing and marketing practices established by the FDA must be satisfied.

An IND is required before human clinical use in the U.S. of a new drug compound or biological product can commence. The IND includes results of pre-clinical (animal) studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations 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 to gather additional information on safety and effectiveness needed to clarify the product s benefit-risk relationship, discover less common side effects and adverse reactions, and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase IV, or post-marketing, studies to be conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit an NDA for approval of a drug. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. There can be no assurance that the FDA or any foreign health authority will grant an approval on a timely basis, or at all. The FDA may deny an NDA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer s quality control and manufacturing procedures conform to cGMP regulations. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase IV, or post-marketing studies, may be required to provide additional data on safety and will be required to

gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes may be required to be submitted to the FDA or foreign regulatory authority.

*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 various periods of time following approval of a drug during which the FDA may not approve, or in certain cases even accept, applications for certain similar or identical drugs from other sponsors unless those sponsors provide their own safety and effectiveness data. Under the Waxman-Hatch 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 Waxman-Hatch 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.

SANCTURA has been granted five years of market exclusivity under the Waxman-Hatch Act. Other products we develop may be entitled to patent extension under the Waxman-Hatch Act. However, there can be no assurance that we will be able to take advantage of 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.

*Other.* The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Federal Trade Commission 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, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The Federal Trade Commission may assess civil penalties for violations of the requirement to rely upon a reasonable basis for advertising claims for non-prescription and food products.

## EMPLOYEES

As of September 30, 2004, we had 356 full-time employees. Pursuant to our agreement with PLIVA, we have since transferred to PLIVA approximately 200 of our sales representatives and have retained a specialty sales force of approximately 85 sales representatives. Consequently, as of December 1, 2004, we had 153 full-time employees. None of our employees is represented by a labor union and we believe our employee relations are satisfactory. We are highly dependent upon certain key personnel and believe our future success will depend in large part on our ability to retain such individuals and attract other highly skilled management, marketing and scientific personnel.

**ITEM 2.** ***Properties***

We lease an aggregate of approximately 22,800 square feet of office space in Lexington, MA. The lease expires in April 2007 and provides for annual rent of approximately $550,000. We are currently negotiating to lease additional corporate office space to support the growth in employees.

**ITEM 3.** ***Legal Proceedings***

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

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

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

Pursuant to agreements we have with Les 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.

*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 | 51 | President, Chief Executive Officer and Chairman |
| Noah D. Beerman | 42 | Executive Vice President, Chief Business Officer |
| Mark S. Butler | 58 | Executive Vice President, Chief Administrative Officer and General Counsel |
| Michael W. Rogers | 44 | Executive Vice President, Chief Financial Officer and Treasurer |
| Bobby W. Sandage, Jr., Ph.D | 51 | Executive Vice President, Research and Development and Chief Scientific Officer |
| John H. Tucker | 41 | Executive Vice President, Chief Sales and Marketing Officer |

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

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

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

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

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

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

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

## 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 will depend on the success of SANCTURA.***

Our future success will depend in large part on the success of SANCTURA. There are many risks associated with the successful development, manufacturing and commercialization of SANCTURA.

***Risks related to the commercialization of SANCTURA***

We will be highly dependent on PLIVA, pursuant to our co-promotion and licensing agreement with PLIVA for the commercialization of SANCTURA and we, in combination or collaboration with PLIVA, may not be successful in commercializing SANCTURA. We would be materially adversely affected if SANCTURA did not achieve or maintain market acceptance. We will also be dependent on Madaus AG ( Madaus ), the licensor of SANCTURA to us and the current manufacturer of SANCTURA, to manufacture SANCTURA for us. If Madaus 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 delay the commercialization or create disruptions in the supply of SANCTURA. Our approved NDA relates to an immediate release, twice-a-day formulation of SANCTURA. We have entered into an agreement with Shire Laboratories, Inc. ( Shire ) to develop extended release, once-a-day formulations of SANCTURA, called SANCTURA XR. Our long-term success will be highly dependent on our ability to successfully develop, manufacture and commercialize SANCTURA XR. If efforts to develop a once-a-day formulation are unsuccessful, we will rely on sales solely from the twice-a-day formulation which may suffer from generic penetration after the expiration of any market exclusivity period and from competition with once-a-day and other formulations of competing products.

***Risks related to competition in the overactive bladder market***

Competition in the overactive bladder market is intense and expected to increase. 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 will compete with drugs from large, multinational companies who have substantially greater marketing and financial resources and experience than us. SANCTURA will compete with other therapies for overactive bladder, including anticholinergics currently on the market. In addition, antimuscarinic and antispasmodics for overactive bladder are the subject of testing or commercialization efforts by other companies, including certain treatments for which NDAs have already been filed. Launches of other competitive products are expected to occur in the near future and we cannot predict with accuracy the timing or impact of the introduction of competitive products or their possible effect on our sales.

***Lack of Patent Protection***

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. Under the Waxman-Hatch 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 that has not been the subject of an approved NDA in the past. 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.

We expect to seek patent protection for SANCTURA XR, an extended release, once-a-day formulation of SANCTURA. Such patents may not be granted. If granted, there can be no assurance that these patents can or will preclude eventual market erosion from new technologies or competing products. If we were unable to obtain a patent on such formulation we would have to rely solely on market exclusivity for this formulation.

***Regulatory risks***

On May 28, 2004, the FDA approved SANCTURA. The FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of SANCTURA. In addition, although SANCTURA has thus far demonstrated an acceptable safety profile in clinical trials, there can be no assurance that the safety profile of the drug would not change when taken in future trials or by a larger population of users.

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

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

In addition to SANCTURA, we currently have four other compounds which are in various stages of development and have not been approved by the FDA. These product candidates are subject to the risk that any or all of them are found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances. We are unable to predict whether any of these other product candidates will receive regulatory clearances or 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 other product candidates receive regulatory clearance, our products may not achieve or maintain market acceptance.

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

Before obtaining regulatory approval for the commercial sale of any of the pharmaceutical products we are developing, we or our licensees must demonstrate that the product is safe and efficacious for use in each target indication. The process of obtaining FDA and other regulatory approvals is lengthy and expensive. If clinical trials do not demonstrate the safety and efficacy of certain products under development, we will be materially adversely affected. The results of pre-clinical studies and early clinical trials may not predict results that will be obtained in large-scale testing or use. Clinical trials of products we are developing may not demonstrate the safety and efficacy of such products. Regardless of clinical trial results, the FDA may not approve marketing of the product. The costs to obtain regulatory approvals could be considerable and the failure to obtain, or delays in obtaining, regulatory approval could have a significant negative effect on our business performance and financial results. Even if pre-market 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 Inc. ( Pfizer ) to elect not to pursue further development of the compound and to return to us exclusive, worldwide development and commercialization rights to pagoclone.

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

We have limited sales and marketing capabilities to market our products. Substantial additional funds will be required to complete development and commercialization of our products and, accordingly, we expect to seek

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

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

We currently contract with third parties for all of our manufacturing needs and do not manufacture any of our own products or product candidates. 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 out-source 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 U.S. current Good Manufacturing Practices, so-called cGMP , requirements. 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. This 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.

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

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

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

Our existing cash resources will be insufficient to commercialize any of our product candidates on our own. In addition, we continue to expend substantial funds for research and development, marketing, general and administrative, and manufacturing. We expect to continue to use substantial cash for operating activities in fiscal 2005 as we continue to fund our development activities, as well as marketing activities related to SANCTURA. We may seek additional funding through corporate collaborations, strategic combinations or public or private equity and debt financing options. Any such corporate collaboration, strategic combination or financial transactions could result in material changes to the capitalization, operations, management and prospects for our business and no assurance can be given that the terms of a strategic transaction would be favorable to us or our security holders. If we raise additional funds by issuing equity securities, existing stockholders will be diluted and future investors may be granted rights superior to those of existing stockholders. There can be no assurance that additional financing will be available on terms acceptable to us or at all. If we sell securities in a private offering, we may have to sell such shares at a discount from the market price of our stock which could have a depressive effect on our stock price.

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In addition, future resales of shares in the public market sold in a private offering could negatively affect our stock price. Our cash requirements and cash resources will vary significantly depending upon the following principal factors:

- marketing success of SANCTURA;
- the costs and expenses of manufacturing SANCTURA with our partner, PLIVA;
- the costs and progress of research and development programs;
- the timing and cost of obtaining regulatory approvals; and
- whether we are successful in either in-licensing or out-licensing products.

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

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

We have incurred substantial net losses over the past four fiscal years including net losses of approximately $1,500,000, $17,600,000, $31,800,000 and $68,200,000 for fiscal years 2001, 2002, 2003 and 2004 respectively. At September 30, 2004 we had an accumulated deficit of approximately $369,000,000.

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

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

We may never achieve or sustain profitability in the future. We expect to continue to experience fluctuations in revenue as a result of the timing of regulatory filings or approvals, product launches, license fees, royalties, product shipments, and milestone payments.

***The outcome of the Redux litigation could materially harm us.***

On September 15, 1997, we announced a market withdrawal of our first commercial prescription product, the weight loss medication Redux, which had been launched by American Home Products Corp. ( AHP ), now Wyeth, our licensee, in June 1996. Following the withdrawal, we

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

On May 30, 2001, we entered into an indemnity and release agreement with AHP, now Wyeth, which provides for indemnification of Redux-related claims brought by plaintiffs who initially elected not to stay in the

AHP national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension, a serious disease involving the blood vessels in the lungs. This agreement also provides for funding of all defense costs related to all Redux-related claims and provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. However, Redux-related judgments that are not covered by the AHP indemnity and release agreement may be insufficiently insured or uninsured. Such claims, if successful, could have a material adverse effect on our business, results of operations and financial condition. We are unable to predict whether the existence of such litigation may adversely affect our business.

***We 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.

Our patents may not afford any competitive advantages and may be challenged or circumvented by third parties. Further, patents may not issue on pending patent applications. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing any advantage of the patent.

Our license for SANCTURA, a compound approved for use in the treatment of overactive bladder, does not include any patents that we expect to use in the commercialization of the product for overactive bladder.

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

- to enforce any of our patents;
- to determine the scope and validity of the patent rights of others; or
- in response to legal action against us claiming damages for infringement of patent rights or other proprietary rights or seeking to enjoin commercial activities relating to the affected product or process.

The outcome of any litigation may be uncertain. Any litigation may also result in significant use of management and financial resources.

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 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 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 filing of the earliest non-provisional patent application directed to the product, its use or method of manufacture. We are relying on market exclusivity under the Waxman-Hatch Act for the twice-a-day formulation of SANCTURA.

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

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

Many of the other companies who market or are expected to market competitive drugs or other products are large, multinational companies who have substantially greater marketing and financial resources and experience than us. We may not be able to develop products that are more effective or achieve greater market acceptance than competitive products. In addition, our competitors may develop products that are safer or more effective or less expensive than those we are developing or that would render our products less competitive or obsolete. As a result, our products may not be able to compete successfully. In addition, royalties payable to us under certain conditions may be reduced or eliminated if there is generic competition.

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

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

Our agreements with licensors and licensees generally provide the other party with rights to terminate the agreement, in whole or in part, under certain circumstances. Many of our agreements require us to diligently pursue development of the underlying product or risk loss of the license or incur penalties. Depending upon the importance to us of the product that is subject to any such agreement, this could materially adversely affect our business. In particular, termination of our agreements with Madaus or PLIVA, related to SANCTURA, or our agreements with Aventis, S.A. ( Aventis ), under which we license pagoclone and aminocandin, could substantially reduce the likelihood of successful commercialization of our product candidates which would materially harm us. The agreements with PLIVA, Madaus or Aventis may be terminated by any of them if we are in material breach of our agreements with them or if we become insolvent or file for bankruptcy protection.

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

We have a small number of employees and are dependent on certain executive officers and scientific personnel, including Glenn L. Cooper, our chief executive officer, Noah D. Beerman, our chief business officer, Mark S. Butler, our chief administrative officer and general counsel, Michael W. Rogers, our chief financial officer, Bobby W. Sandage, Jr., our chief scientific officer, and John H. Tucker, our chief sales and marketing officer. Our business could be adversely affected by the loss of any of these individuals. In addition, we rely on the assistance of independent consultants to design and supervise clinical trials and prepare FDA submissions.

Competition for qualified employees among pharmaceutical and biotechnology companies is intense, and the loss of any qualified employees, or an inability to attract, retain and motivate highly skilled employees, could adversely affect our business and prospects. Competition to attract and retain pharmaceutical sales people is intense. We may not be able to attract additional qualified employees or retain our existing personnel.

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

The use of products in clinical trials and the marketing of products may expose us to substantial product liability claims and adverse publicity. Certain of our agreements require us to obtain specified levels of insurance coverage, naming the other party as an additional insured. We currently maintain product liability and clinical trial insurance in the amount of $40,000,000. We may obtain additional coverage for products that may be marketed in the future, including SANCTURA. 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.

**Risks Related to Our Common Stock and Other Securities**

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

Our board of directors has the authority, without further approval of our stockholders, to fix the rights and preferences, and to issue up to 5,000,000 shares of preferred stock, 244,425 of which are currently issued and outstanding. In addition, vesting of shares of our common stock subject to stock awards under our 1997 Equity Incentive Plan accelerates and outstanding options under our stock option plans become immediately exercisable upon certain changes in control of the Company, except under certain conditions. In addition, Delaware corporate law imposes limitations on certain business combinations. These provisions could, under certain circumstances, delay or prevent a change in control of the Company and, accordingly, could adversely affect the price of our common stock. Also, our license agreement for citicoline contains change of control provisions that may have the effect of discouraging or delaying a change of control of the Company.

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

market success of SANCTURA;

results of clinical studies and regulatory reviews;

partnerships, corporate collaborations, and strategic corporate transactions;

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

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

market conditions in the pharmaceutical and biotechnology industries;

competitive products;

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

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

proprietary rights;

Redux-related litigation developments;

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

general economic conditions.

The high and low sales prices of our common stock as reported by Nasdaq Stock Market were: $8.75 and $1.34 for fiscal 2000, $10.00 and $1.16 for fiscal 2001, $12.83 and $0.85 for fiscal 2002, $6.90 and $1.32 for fiscal 2003 and $10.25 and $4.86 for fiscal 2004 through September 30, 2004. 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 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, 2004, we had 46,768,771 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, 2004, we had reserved the following shares of our common stock for issuance:

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

10,941,792 shares issuable upon exercise of outstanding options and warrants, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option and warrant holders if we issue additional securities below certain prices;

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

1,764,264 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, 2004, we had $72,000,000 of outstanding debt reflected in our balance sheet relating to our outstanding Convertible Notes. We may incur additional indebtedness in the future and the Convertible Notes do not restrict our future issuance of indebtedness. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

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

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

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

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

to seek additional financing in the debt or equity markets;

to refinance or restructure all or a portion of our indebtedness, including the Convertible Notes;

to sell selected assets; or

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

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

**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, 2004: | | |
| July 1 through September 30, 2004 | $ 7.98 | $ 4.86 |
| April 1 through June 30, 2004 | 10.25 | 5.95 |
| January 1 through March 31, 2004 | 7.74 | 5.74 |
| October 1 through December 31, 2003 | 6.34 | 5.20 |
| Fiscal Year Ended September 30, 2003 | | |
| July 1 through September 30, 2003 | $ 6.90 | $ 5.05 |
| April 1 through June 30, 2003 | 6.85 | 2.38 |
| January 1 through March 31, 2003 | 2.59 | 1.80 |
| October 1 through December 31, 2002 | 2.83 | 1.32 |

**Approximate Number of Equity Security Holders**

The number of holders of record of our Common Stock as of September 30, 2004 was approximately 551.

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

**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, 2004:

| Plan category | Number of Securities to be issued upon exercise of outstanding options and warrants (a) | Weighted-average exercise price of outstanding options and warrants (b) | Number of securities remaining available for future issuance under equity compensation plans (Excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders | 12,556,624 | $ 4.57 | 1,751,182 |
| Equity compensation plans or arrangements not approved by security holders | 10,000(1) | $ 6.19 | 12,082(2) |
| Total | 12,566,624 | $ 4.57 | 1,763,264 |

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

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

**Issuer Purchases of Equity Securities**

| Period | (a) Total Number of Shares (or Units) Purchased | (b) Average Price Paid per Share (or Unit) | (c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs | (d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| Ju1y 1 through July 31 | 1,166,200 | $ 6.28 | 1,166,200 | 1,333,800 |
| August 1 through August 31 | | | | |
| September 1 through September 30 | | | | |

On July 1, 2004 we announced that our board of directors had authorized the repurchase from time to time of up to 2,500,000 shares of our common stock in open market transactions. We did not set an expiration or termination date for the repurchase program.

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

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

| | Fiscal Years Ended September 30, | | | | |
|---|---|---|---|---|---|
| | 2004 | 2003 | 2002 | 2001 | 2000 |
| | (Amounts in thousands except per share) | | | | |
| **Statement of Operations Data:** | | | | | |
| Revenues: | | | | | |
| Product revenue | $ 9,740 | $ 4,316 | $ 3,439 | $ 1,952 | $ |
| Contract and license fees | 8,986 | 929 | 968 | 13,281 | 27,754 |
| Total revenues | 18,726 | 5,245 | 4,407 | 15,233 | 27,754 |
| Cost of product revenue | 7,950 | 1,073 | 733 | 417 | 3,000 |
| Research and development | 23,303 | 24,466 | 13,614 | 5,582 | 3,182 |
| Marketing, general and administrative | 51,916 | 11,105 | 8,090 | 7,238 | 6,823 |
| Product withdrawal (1) | | | | (5,582) | (1,757) |
| Income (loss) from operations | (64,443) | (31,399) | (18,030) | 7,578 | 16,506 |
| Investment income | 1,396 | 664 | 987 | 1,811 | 1,868 |
| Interest expense | 5,170 | 1,077 | | | |
| Income (loss) from continuing operations | (68,212) | (31,812) | (17,586) | 8,509 | 19,956 |
| Cumulative effect of change in accounting principle (2) | | | | (10,000) | |
| Net income (loss) | (68,212) | (31,812) | $ (17,586) | $ (1,491) | $ 19,956 |
| Preferred stock dividends | 35 | 35 | 35 | 35 | 35 |
| Net income (loss) attributable to common stockholders | (68,247) | (31,847) | (17,621) | (1,526) | 19,921 |
| Income (loss) per common share from continuing operations-diluted | $ (1.43) | $ (0.68) | $ (0.38) | $ 0.19 | $ 0.46 |
| Loss per common share from cumulative effect of change in accounting principle-basic and diluted | | | | $ (0.22) | |
| Net income (loss) per common share-basic and diluted | $ (1.43) | $ (0.68) | $ (0.38) | $ (0.03) | $ 0.46 |
| Weighted average common shares-diluted | 47,542 | 46,930 | 45,896 | 45,628 | 43,838 |
| Proforma amounts assuming the 2001 accounting change relating to revenue recognition is applied retroactively (2): | | | | $ 8,509 | $ 9,956 |
| Preferred stock dividends | | | | 35 | 35 |
| Net income attributable to common stockholders | | | | 8,474 | 9,921 |
| Net income per common share: | | | | | |
| Basic | | | | $ 0.19 | $ 0.23 |
| Diluted | | | | $ 0.19 | $ 0.23 |

| | September 30, | | | | |
|---|---|---|---|---|---|
| | 2004 | 2003 | 2002 | 2001 | 2000 |
| | (Amounts in thousands) | | | | |
| **Balance Sheet Data:** | | | | | |
| Working capital | $ 131,288 | $ 73,866 | $ 34,876 | $ 23,970 | $ 26,325 |
| Total assets | 173,838 | 90,071 | 43,931 | 34,917 | 46,826 |
| Convertible notes, long-term | 72,000 | 72,000 | | | |

| | | | | | |
|---|---|---|---|---|---|
| Total liabilities | 236,868 | 83,817 | 6,700 | 6,160 | 18,728 |
| Accumulated deficit | (368,903) | (300,691) | (268,879) | (251,293) | (249,802) |
| Total stockholders equity (deficit) | (63,038) | 6,241 | 37,218 | 28,660 | 27,766 |

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

(2) Relates to the adoption in fiscal 2001 of the provisions of SAB 101. As a result of the adoption of SAB 101, the Company recorded a noncash charge of $10,000,000 in fiscal 2001 for the cumulative effect of a change in accounting principle to defer license fee revenue previously recognized in fiscal 2000 related to a license agreement which provided the licensee with an option to license an alternative compound. The impact of the adoption of SAB 101 was to defer revenue recognized for such license agreement from fiscal 2000 to the fourth quarter of fiscal 2001 when the option lapsed.

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

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

**Description of the Company**

We are a biopharmaceutical company engaged in the development and commercialization of a diversified portfolio of product candidates, including multiple compounds in late-stage clinical development. We currently market SANCTURA for OAB, and have four compounds in clinical development: pagoclone for anxiety disorders, IP 751 for pain and inflammatory disorders, PRO 2000 for the prevention of infection by HIV and other sexually transmitted pathogens, and aminocandin for treatment of systemic fungal infections. Our primary therapeutic focus is in urology, gynecology and infectious diseases.

**Significant Product Developments in Fiscal 2004**

***SANCTURA***

On May 28, 2004, our NDA for SANCTURA was approved by the FDA for the treatment of OAB.

On April 6, 2004, we entered into the PLIVA Agreement for the U.S. commercialization of SANCTURA. We granted PLIVA an exclusive right and license to co-promote and sell SANCTURA in the United States. The PLIVA Agreement provides for payments to us from PLIVA, including $150 million received in fiscal 2004, $30 million upon signing and $120 million upon FDA approval of SANCTURA twice daily. In addition, we could receive up to $45 million in future payments contingent upon the achievement of certain milestones related to the development of a once-a-day formulation of SANCTURA, as well as a payment of $20 million related to the achievement of a long-term commercialization milestone in 2013.

For the first six months following the approval of SANCTURA, we received a commission based on net sales of SANCTURA. During this period, we were responsible for funding our own sales force and certain advertising and promotional costs, and PLIVA and we co-promoted SANCTURA 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.

On September 27, 2004, we made formal notification to PLIVA with respect to the termination of the co-promotion period of the Agreement, thereby converting the Agreement into a royalty-bearing structure. The conversion became effective on November 29, 2004. Under this royalty-bearing structure, we receive royalties from PLIVA based on net sales of SANCTURA, and PLIVA is responsible for promotional and advertising costs. Additionally, our specialty sales force consisting of approximately 85 sales representatives will be subsidized by PLIVA for the three years commencing November 29, 2004 and is continuing to promote SANCTURA to urology specialists, obstetricians and gynecologists, and other high prescribers.

Pursuant to the NDA, the SANCTURA finished product is being manufactured by our licensor, Madaus AG ( Madaus ), at their manufacturing facility in Germany. We launched SANCTURA in August 2004.

Under the PLIVA Agreement, we are responsible for funding the development of the once-a-day formulation of SANCTURA. While we are responsible for the manufacture of SANCTURA and sell it to PLIVA at cost, PLIVA is responsible for product inventory management and sales order fulfillment including billing and collecting of customer receivables. The PLIVA Agreement is subject to termination by PLIVA under certain circumstances. Under the PLIVA Agreement, we granted a security interest to PLIVA in our FDA marketing authorizations or approvals relating to SANCTURA and agreed to indemnify PLIVA under certain circumstances.

Our current formulation of SANCTURA is twice-a-day. In March 2003, we signed an exclusive agreement with Shire under which Shire is developing extended release formulations of SANCTURA. We have completed pharmacokinetic and safety studies with several once-a-day formulations, and we expect to begin Phase II clinical trials with a lead formulation, to be known as SANCTURA XR, in the first half of calendar year 2005, to be followed by the initiation of a Phase III clinical program with this formulation planned later in 2005.

Aminocandin

In June 2004, we announced that aminocandin, under development as a treatment for systemic fungal infections, was well tolerated among healthy volunteers in a Phase I clinical trial and demonstrated a prolonged duration of antifungal 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 serum fungicidal activity. 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.

On October 6, 2004, we announced the initiation of a multi-dose Phase I trial of aminocandin. This trial tests the safety, tolerability and pharmacokinetics of raising multiple doses of aminocandin among healthy volunteers. In addition, the in vitro activity of aminocandin will be evaluated in serum samples from trial subjects. The study is ongoing and results of this trial will help optimize the dosing level and regimen for further clinical testing, including Phase II clinical trials expected to begin in 2005.

Citicoline

Effective January 22, 2004, we entered into a new agreement with Ferrer covering the development, manufacture, and marketing of citicoline in the U.S. and Canada. Under the terms of the new agreement, 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. We will receive 50% of all milestone payments made to Ferrer by a third party and royalties on net sales of the product. This new agreement allows us to retain significant participation in the future economics of citicoline, should the product be approved and marketed in the U.S. and Canada, without incurring any further costs.

In October 2004, IVAX Corporation announced a licensing arrangement with Ferrer for citicoline. Under the terms of this arrangement, IVAX will be responsible for fulfilling the requirements for FDA approval of citicoline for acute stroke and for commercializing citicoline in the U.S.

**Significant Judgments 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 U.S. 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 PLIVA Agreement and Deferred Revenue*

The initial $30 million payment received from PLIVA and the $120 million payment received from PLIVA upon receipt of FDA approval to market SANCTURA are significant and we are recording the initial and milestone payments received from PLIVA as deferred revenue and amortizing each of these components into revenue under the contingency-adjusted method over the estimated remaining duration of the PLIVA Agreement commencing on the date earned. We believe the estimated term of the PLIVA 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 PLIVA Agreement below.

The Pliva Agreement expires on the later of (i) the twelfth (12th) anniversary of the Launch Date of SANCTURA Twice-Daily or (ii) the expiration of the last to expire patent included in the Indevus Patent Rights covering SANCTURA Once-Daily. 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 Pliva Agreement:

- SANCTURA Twice-daily 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 Once-Daily including the filing of an NDA and ultimate approval by the FDA to market SANCTURA Once-Daily;
- The potential of success in obtaining approval of patents covering SANCTURA Once-Daily and the protection such patents may afford;
- If protection from patents was not obtained for SANCTURA Once-Daily, 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 from large pharmaceutical companies.

After considering all of the above, we estimated the expected term of the PLIVA 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 Once-Daily 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 Once-Daily 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 Once-Daily, the term of the arrangement may extend beyond the estimated twelve years.

We amortized $6,250,000 of deferred revenue into contract and license fee revenue in fiscal 2004 and the balance of deferred revenue at September 30, 2004 is $143,750,000. We will reevaluate our estimate of the expected term of the PLIVA Agreement when new information is known that could affect this estimate. If we change our estimate of the duration of the PLIVA Agreement in the future and extend or reduce our estimate of its duration, we would decrease or increase, respectively, the amount of periodic revenue to be recognized from the amortization of remaining deferred revenue.

*Insurance Claim Receivable*

As of September 30, 2004, 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, 2004 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*

In the fourth quarter of fiscal 2003, we reduced our estimate of the amount of Redux-related expenses, including legal expenses, remaining due, in part, to a decline in the amount of actual payments during 2003. As a result, we reduced our accrued liability for Redux-related expenses by approximately $600,000 and reflected this reduction as a credit in marketing, general and administrative expense. At September 30, 2003, we have an accrued liability of approximately $700,000 for such Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ significantly from the amount currently accrued at September 30, 2003. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

**Significant Accounting Policy**

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

The Company records sales of product as product revenue upon the later of shipment or as title passes to its customer. In fiscal 2004, the Company commenced selling SANCTURA to PLIVA in bottles for resale and blister packs for distribution as samples (see Note N of Notes to Consolidated Financial Statements).

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 unless the royalty report for such period is received subsequent to the time the Company is required to report its results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, in which case the Company recognizes such royalty revenue in the subsequent accounting period when it receives the royalty report and when the amount of and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

The Company s business strategy includes entering into collaborative license and development or co-promotion agreements with strategic partners for the development and commercialization of the Company s products or product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones and royalties on net product sales. Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. In multiple element arrangements where the Company has continuing performance obligations,

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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. Contractual subsidies of ongoing expenses are recorded as contract and license fee revenue.

Under the PLIVA 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 agreement to the time the milestone is earned over the estimated duration of the PLIVA Agreement. Going forward, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the PLIVA Agreement.

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

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

**Results of Operations**

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

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

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

Product revenue increased $5,424,000, or 126%, to $9,740,000 in fiscal 2004 from $4,316,000 in fiscal 2003. This increase is primarily attributable to sales of SANCTURA to PLIVA in fiscal 2004 which were $7,279,000, including $3,952,000 related to sales of samples. This increase was partially offset by royalty revenue from Lilly which decreased $1,981,000, or 46%, to $2,335,000 in fiscal 2004 from $4,316,000 in fiscal 2003, which included $2,184,000 of accelerated sales milestones which were one-time payments and did not recur.

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

Cost of product revenue increased substantially in fiscal 2004 to $7,950,000 from $1,073,000 in fiscal 2003. Fiscal 2004 cost of product revenue relates primarily to sales of SANCTURA which we sell to PLIVA at our cost. Also included in cost of product revenue in fiscal 2004 is approximately $452,000 of royalties we owe to Massachusetts Institute of Technology for their portion of the royalties and contractual payments received from Lilly. This is a decrease of $567,000, or 56%, from $1,019,000 included in fiscal 2003 cost of product revenue resulting from the reduction of revenue from Lilly as described above.

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

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

General and administrative expenses increased $6,507,000, or 91%, to $13,668,000 in fiscal 2004 from $7,161,000 in fiscal 2003. In fiscal 2004, we extended the expiration dates of certain stock option grants to directors and officers and reflected a noncash charge of $3,020,000 in general and administrative expense for

these extensions. In fiscal 2004 we also incurred approximately $1,023,000 of expense for a consultant which performed services related to the PLIVA Agreement. Additionally in fiscal 2004, we incurred approximately $1,000,000 of personnel-related expense related to increased staffing to provide support services to the expanded company and approximately $900,000 of other costs related to the expansion of the company and other increased business activities.

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

Interest expense of $5,170,000 and $1,077,000 in fiscal 2004 and 2003, respectively, results from our July 2003 issuance of $72,000,000 of 6.25% Convertible Senior Notes due 2008 (the Notes ). Annual interest expense includes approximately $700,000 of amortization of debt issuance costs.

In fiscal 2005, the $145,000,000 of initial and milestone payments received from PLIVA in fiscal 2004 will be recognized as income for tax purposes, but will continue to be amortized into revenue for financial statement purposes over the expected term of the PLIVA Agreement. We expect to offset any net taxable income in fiscal 2005 with a portion of net operating loss carryforwards. However due to limitations on the use of net operating loss for federal alternative minimum tax and state taxes we will incur alternative minimum tax and state tax expense in fiscal 2005.

As a result of the conversion of the PLIVA Agreement into a royalty bearing structure, we expect a reduction in our sales and marketing cost structure effective November 29, 2004. On that date approximately 200 of our sales representatives who have been detailing SANCTURA to primary care physicians became PLIVA employees who will continue to detail SANCTURA to primary care physicians. We retained approximately 85 sales representatives who will continue detailing SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians. Additionally, on November 29, 2004, PLIVA became financially responsible for all promotion and advertising services related to brand support provided by third parties. Commencing November 29, 2004, PLIVA will provide us a subsidy for our sales force of approximately $7,700,000 annually. We will record this subsidy in contract and license fee revenue as earned. We expect losses in fiscal 2005 will decrease as a result of these changes.

Fiscal Year Ended September 30, 2003 Compared to Fiscal Year Ended September 30, 2002

Our net loss increased $14,226,000 to $(31,812,000), or $(0.68) per share, basic, in fiscal 2003 from $(17,586,000), or $(0.38) per share, basic, in fiscal 2002. This increased net loss is primarily the result of our continued efforts to develop SANCTURA, including clinical trials, filing of an NDA, and development of a once-a-day formulation, and premarketing activities related to trospium.

Total revenues increased $838,000, or 19%, to $5,245,000 in fiscal 2003 from $4,407,000 in fiscal 2002. Product revenue, which comprises 97% of total revenue, relates to royalties and other payments received from Lilly for Sarafem and increased $1,654,000, or 48%, to $5,093,000 in fiscal 2003 from $3,439,000 in fiscal 2002. Royalty revenue in fiscal 2003 was recognized pursuant to our renegotiated agreement with Lilly (see Note N of Notes to Consolidated Financial Statements) and includes $777,000 from an initial payment received from Lilly related to the renegotiated agreement for Sarafem and $2,184,000 of accelerated milestone payments received from Lilly. Royalty revenue in fiscal 2002 was recognized pursuant to our original agreement with Lilly and included approximately $3,199,000 of royalty revenue in the three month period ended December 31, 2001 which resulted from sales of Sarafem in a higher royalty payment bracket. Contract and license fee revenue of

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$152,000 in fiscal 2003 consisted of a research grant related to funding of certain PRO 2000 development. Contract and license fee revenue of $968,000 in fiscal 2002 consisted of a $500,000 milestone payment from Amgen Inc. ( Amgen ) related to continuation of development of leptin receptor technology which we licensed to Amgen, funding of certain PRO 2000 development from CONRAD and other revenue.

Cost of revenues of $1,073,000 and $733,000 in fiscal 2003 and 2002, respectively, consisted primarily of amounts due or paid to MIT for their portion of the contractual payments and royalties received from Lilly.

Research and development expenses increased $10,852,000, or 80%, to $24,466,000 in fiscal 2003 from $13,614,000 in fiscal 2002. This increase is primarily related to SANCTURA and includes increased clinical costs, including costs for the ongoing clinical trial, continuing development of extended release formulations of SANCTURA, and costs related to the preparation of the NDA. Fiscal 2003 research and development expenses also include license and contractual payments aggregating $2,000,000 related to aminocandin and PRO 2000 and increased costs related to the development of pagoclone and IP 751. Partially offsetting these increased costs is a decrease in noncash expense related to a stock option grant and modifications of stock option grants to an executive officer of the Company in fiscal 2002, a decrease in development expense related to dersalazine due our cessation of development of the compound, and a license fee of $500,000 related to IP 751 in fiscal 2002. Total research and development expenses for fiscal 2003 substantially relate to our major compounds being developed as follows: SANCTURA $17,045,000, pagoclone $1,571,000, IP 751 $929,000, aminocandin $958,000, and PRO 2000 $1,601,000. We also incurred research and development expenses for fiscal 2004 of $527,000 related to other compounds and initiatives.

Marketing, general and administrative expense increased $3,015,000, or 37%, to $11,105,000 in fiscal 2003 from $8,090,000 in fiscal 2002. These increases are primarily due to continuing pre-marketing activities for SANCTURA, and also include costs related to our attendance at the American Urological Association convention in April 2003. In connection with the filing and FDA acceptance of the NDA for SANCTURA, we have increased our rate of expenditure for SANCTURA pre-marketing activities. Also contributing to increased marketing, general and administrative expense is higher legal, insurance and other administrative expenses. Partially offsetting these increases is a decrease in noncash expense related to modifications of stock option grants to directors and executive officers of the Company in fiscal 2002 and other stock option grants to consultants and a reduction of approximately $600,000 of our accrued liability for Redux-related expenses.

Investment income decreased $323,000, or 33%, to $664,000 in fiscal 2003 from $987,000 in fiscal 2002. These decreases resulted primarily from reduced market interest rates.

Interest expense of $1,077,000 in fiscal 2003 results from our July 2003 issuance of $72,000,000 of Notes. Annual interest expense is expected to be approximately $5,200,000, which includes approximately $700,000 of amortization of debt issuance costs.

Included in other is impairment of equity securities of $487,000 in fiscal 2002 reflects the write down of our investment in Incara, Inc. ( Incara ) to fair value as the decline in Incara common stock was deemed other than temporary.

**Liquidity and Capital Resources**

Cash, Cash Equivalents and Marketable Securities

At September 30, 2004, we had consolidated cash, cash equivalents and marketable securities of $157,008,000 compared to $84,087,000 at September 30, 2003. This increase of $72,921,000 was primarily the result of net cash provided by operating activities of $78,647,000 which included the receipt of $150,000,000 pursuant to the PLIVA Agreement, less $7,319,000 expended on purchases of treasury stock.

We are continuing to invest substantial amounts in the ongoing development and sales and marketing activities related to SANCTURA. We are investing in the production of inventories of SANCTURA and are selling the final product to PLIVA at cost. We believe the funds received from PLIVA under the PLIVA Agreement will be sufficient to meet our obligations for the commercialization of SANCTURA. We believe we have sufficient cash for currently planned expenditures for at least the next twelve months.

We may require additional funds or corporate collaborations for the development and commercialization of our other compounds in development, 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, if such funds are required, we will be able to obtain additional financing to satisfy future cash requirements on acceptable terms, or at all. If such additional funds are not obtained, we may be required to delay product development and business development activities.

Product Development

We expect to continue to expend substantial additional amounts for the development of our products. In particular, we are continuing to expend substantial funds for SANCTURA, SANCTURA XR, and other related development efforts. We could receive up to $45 million in future payments contingent upon the achievement of certain milestones related to the development of SANCTURA XR. Additionally, after November 28, 2004, PLIVA is responsible for funding certain Phase IV studies that may be conducted. There can be no assurance that results of any ongoing or future pre-clinical or clinical trials will be successful, that additional trials will not be required, that any drug or product under development will receive FDA approval in a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with cGMP or successfully marketed in a timely manner, or at all, or that we will have sufficient funds to develop or commercialize any of our products.

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

Total research and development expenses incurred by us through September 30, 2004 on the major compounds currently being developed or marketed, including allocation of corporate general and administrative expenses, are approximately as follows: $77,300,000 for SANCTURA, $19,400,000 for pagoclone, $12,303,000 for PRO 2000, $3,500,000 for aminocandin and $3,100,000 for IP 751. In June 2002, we re-acquired rights to pagoclone from Pfizer Inc. During the period Pfizer had rights to pagoclone, Pfizer conducted and funded all development activities for pagoclone. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA. Given these uncertainties and other 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, 2004 through the preparation of an NDA for

our major compounds currently being developed as follows: approximately $15,000,000 for PRO 2000, approximately $60,000,000 for IP 751, approximately $30,000,000 for aminocandin, and approximately $38,000,000 for pagoclone. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to the uncertainty of the number of required trials and size of such trials and the duration of development. We are unable to estimate the date of development completion for citicoline because Ferrer is now responsible for its development. We are unable to estimate the date of development completion for pagoclone due to the scope complexity and cost of the type of clinical trials necessary which may require the financial assistance of a partner to complete. Actual costs and time to complete any of our products may differ significantly from the estimates.

Analysis of Cash Flows

Cash provided by operating activities for fiscal 2004 of $78,647,000 consisted primarily of the $150,000,000 received from PLIVA pursuant to the PLIVA Agreement, of which $143,750,000 was classified as deferred revenue, and the net loss of $68,212,000. We paid $4,500,000 of interest on our convertible notes in fiscal 2004. Increase in accounts receivable is primarily due to purchases of SANCTURA by PLIVA. Accrued expenses and other liabilities increased primarily due to increased marketing and production activities related to SANCTURA.

Net cash used in investing activities of $4,173,000 is primarily due to $3,591,000 of net purchases of marketable securities. Marketable securities are purchased and mature during our normal investment activities related to available funds.

Net cash used in financing activities of $5,092,000 is comprised of $7,319,000 used to purchase treasury stock and $2,227,000 net proceeds from the issuance of common stock and treasury stock upon the exercise of stock options and warrant and vestings of grants of common stock pursuant to our employee stock purchase plan. We cannot predict if or when stock options will be exercised in the future.

**Other**

Repurchase of Common Stock

On July 1, 2004, we announced that our board of directors had authorized the repurchase from time to time of up to 2,500,000 shares of its common stock in open market transactions. Through September 30, 2004 and the date of this report, we repurchased 1,166,000 shares at an average price of approximately $6.28 per share.

Contractual Obligations and Off-Balance Sheet Arrangements

The following chart summarizes our contractual payment obligations as of September 30, 2004. The Notes and license fees are reflected as liabilities on our Balance Sheet as of September 30, 2004. Operating leases are accrued and paid on a monthly basis. Purchase obligations relate to research and development agreements and arrangements and SANCTURA premarketing agreements and arrangements; portions of these amounts are reflected as accrued expenses on our Balance Sheet as of September 30, 2004.

| | Payments due by Period | | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Less than 1 Year** | **1-3 Years** | **3-5 Years** | **Greater than 5 Years** | **Total** |
| Notes (1) | $ | $ | $ 72,000,000 | $ | $ 72,000,000 |
| Operating leases (2) | 573,000 | 904,000 | | | 1,477,000 |
| Interest on Notes (1) | 4,500,000 | 9,000,000 | 9,000,000 | | 22,500,000 |
| License fees | 100,000 | 200,000 | | | 300,000 |
| Purchase obligations (3) | 15,115,000 | 308,000 | 2,000 | | 15,425,000 |
| Total | $ 20,288,000 | $ 10,412,000 | $ 81,002,000 | $ | $ 111,702,000 |

(1) See Note H of Notes to Consolidated Financial Statements.

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

Pursuant to certain of our in-licensing arrangements, we will owe payments to our licensors upon achievement of certain development, regulatory and licensing milestones. While we cannot predict if or when such events will occur, depending on the successful achievement of certain development, regulatory and licensing milestones, we may owe up to approximately $4,000,000 in fiscal 2005.

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.

In addition to purchases of bulk SANCTURA tablets aggregating approximately $6,700,000 in fiscal 2004, we are committed to purchase from Madaus significant additional quantities during the initial launch year of SANCTURA aggregating approximately $6,400,000. PLIVA agreed to purchase from us commercial quantities of SANCTURA and to be responsible for commercial product procurement costs, including costs to manufacture SANCTURA.

We have an agreement to lease automobiles for our sales force, including sales representatives and field district managers. As of September 30, 2004, no automobiles had been leased. We expect to have approximately 90 automobiles leased pursuant to this arrangement by December 31, 2004. Under this operating lease arrangement, we expect our annual lease rental costs to be approximately $550,000. In addition, due to a substantial increase in employees, we are negotiating to lease additional office space in Lexington, MA that would increase our future annual lease commitments.

Recent Accounting Pronouncements

In January 2003, the FASB issued FIN 46. FIN 46 requires that if an entity has a controlling financial interest in a VIE, the assets, liabilities and results of activities of the VIE should be included in the consolidated financial statements of the entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. For those arrangements entered into prior to January 31, 2003, FIN 46 requires its provisions, as amended by FIN 46R which was issued by the FASB in December 2003, be adopted by us in the second quarter of fiscal 2004. The adoption of FIN 46R did not have a material impact on our financial position or results of operations.

EITF 03-6 was issued in March 2004 and is intended to clarify what is a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-6 is effective for reporting periods beginning after March 31, 2004. The adoption of this pronouncement did not have an impact on our consolidated financial position, results of operations or cash flows.

**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 Notes

The fair value of our Notes is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Notes are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the 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 $1000 Note by approximately $57. An increase in market interest rates could result in a decrease in the fair value of the Notes. For example on a very simplified basis, an interest rate increase of 1% could reduce the value of a $1000 Note by approximately $25. The two examples provided above are only hypothetical and actual changes in the value of the 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***

Prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2004. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective for the purpose of timely alerting the appropriate individuals of the material information required to be included in our periodic SEC reports. 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.

In addition, we reviewed our internal controls, and there have been no significant changes in our internal controls that has materially affected or is reasonably likely to materially affect those controls subsequent to the date of our last evaluation.

**PART III**

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

**PART IV**

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

(a)1. Financial Statements

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

2. Schedules

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

(b) Exhibits

| | | |
|---|---|---|
| 3.4 | - | Restated Certificate of Incorporation of Registrant, as amended (22) (50) |
| 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) |
| 4.4 | - | Certificate of Designation establishing Series C Preferred Stock, as amended (10) (50) |
| 4.8 | - | 1997 Equity Incentive Plan and Form of Restricted Stock Award Agreement thereunder (25) |
| 10.5 | - | Consultant and Non-competition Agreement between the Registrant, Richard Wurtman, M.D. (17) |
| 10.6 | - | Assignment of Invention and Agreement between Richard Wurtman, M.D., Judith Wurtman and the Registrant (1) |
| 10.7 | - | Management Agreement between the Registrant and Lindsay Rosenwald, M.D. (1) |
| 10.9(a) | - | 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 ( License Agreement ) (1) |
| 10.12(b) | - | Revised Appendix A to License Agreement (1) |
| 10.12(c) | - | Amendment Agreement between Registrant and Servier, Orsem and Oril Produits Chimiques dated November 19, 1992 (2) (6) |
| 10.12(d) | - | Amendment Agreement dated April 28, 1993 between Registrant and Servier (9) |
| 10.12(e) | - | 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) |
| 10.22(a) | - | License Agreement dated January 15, 1993, as amended, between the Registrant and Grupo Ferrer (2) (9) |
| 10.22(b) | - | Addendum and Second Amendment to License Agreement between the Registrant and Ferrer Internacional S.A., dated June 1, 1998 (29) |
| 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 the Acquisition Agreement (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) |
| 10.71 | - | Securities Purchase Agreement dated June 2, 1995 between the Registrant and Reliance Insurance Company, including Warrant and exhibits (15) |
| 10.74 | - | Securities Purchase Agreement dated as of August 16, 1995 between the Registrant and BT Holdings (New York), Inc., including Warrant issued to Momint (nominee of BT Holdings) (16) |
| 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) |
| 10.84 | - | Master Consulting Agreement between Interneuron Pharmaceuticals, Inc. and Quintiles, Inc. dated July 12, 1996 (18) |
| 10.85 | - | Amendment No. 1 dated July 3, 1996 to Master Consulting Agreement between Interneuron Pharmaceuticals, Inc. and Quintiles, Inc. dated July 12, 1996 (2) (18) |
| 10.86 | - | Lease Agreement between Transcell Technologies, Inc. and Cedar Brook Corporate Center, L.P., dated September 19, 1996, with Registrant guaranty (20) |
| 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) |
| 10.95 | - | Agreement and Plan of Merger dated March 2, 1998 by and among Registrant, Intercardia, Inc. and Transcell Technologies, Inc. (28) |

| | | |
|---|---|---|
| 10.95(a) | - | Waiver and Consent Agreement dated May 8, 1998 by and among Registrant, Intercardia and Transcell (28) |
| 10.96 | - | Assignment and Assumption and Royalty Agreement between Intercardia and Registrant dated May 8, 1998 (29) |
| 10.97 | - | License Agreement between Registrant and the Administrators of the Tulane Educational Fund dated April 29, 1998 (29) |
| 10.98 | - | Letter of Understanding between the Registrant and the Plaintiffs Management Committee dated September 3, 1998 (30) |
| 10.99 | - | Agreement of Compromise and Settlement, including Appendices, dated September 21, 1998, between the Registrant and the Plaintiffs Management Committee (31) |
| 10.100 | - | Royalty Agreement between the Registrant and the Plaintiffs Management Committee effective as of September 21, 1998 (32) |
| 10.102 | - | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Michael W. Rogers dated and effective as of February 23, 1999 (34) |
| 10.103 | - | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Bobby W. Sandage, Jr. dated and effective as of March 15, 1999 (34) |
| 10.104 | - | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Mark S. Butler dated and effective as of March 15, 1999 (34) |
| 10.105 | - | Employment Agreement between Intemeuron Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated and effective as of May 1, 1999 (34) |
| 10.108 | - | Exchange Agreement dated July 15, 1999 between Intercardia, Inc. and Interneuron Pharmaceuticals, Inc. (35) |
| 10.109 | - | Amended and Restated Limited Liability Company Agreement of CPEC LLC dated July 15, 1999 among CPEC LLC, Interneuron Pharmaceuticals, Inc. and Intercardia, Inc. (35) |
| 10.110 | - | Assignment, Assumption and License Agreement dated July 15, 1999 by and between CPEC LLC and Intercardia, Inc. (35) |
| 10.113 | - | License Agreement effective as of November 26, 1999 between Madaus AG and Interneuron Pharmaceuticals, Inc. (37) (2) |
| 10.114 | - | License Agreement effective as of December 2, 1999 by and between Interneuron Pharmaceuticals, Inc. and Takeda Chemical Industries, Ltd. (37) (2) |
| 10.116 | - | License Agreement between Intemeuron Pharmaceuticals, Inc. and Warner-Lambert Company effective as of December 23, 1999 (38) (2) |
| 10.116(a) | - | 2000 Stock Option Plan (39) |
| 10.117 | - | License Agreement by and between HeavenlyDoor.com, Inc. and Intemeuron Pharmaceuticals, Inc. dated June 14, 2000 (40) (2) |
| 10.118 | - | Fiscal 2001 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 13, 2000 (41) |
| 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) |

| | | |
|---|---|---|
| 10.121 | - | Amendment dated June 22, 2001 to License Agreement dated December 23, 1999 between Interneuron Pharmaceuticals, Inc. and Warner-Lambert Company (44) (2) |
| 10.122 | - | Agreement by and between J. Uriach & Cia., S.A. and Interneuron Pharmaceuticals, Inc. dated September 28, 2001 (44) (2) |
| 10.123 | - | Fiscal 2002 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 26, 2001 (44) |
| 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) |
| 10.125 | - | License Agreement by and between Atlantic Technology Ventures, Inc. and Indevus Pharmaceuticals, Inc. dated June 28, 2002 (46) (2) |
| 10.126 | - | Fiscal 2003 Senior Executive Bonus Plan, as adopted by the Board of Directors on December 10, 2002 (47) |
| 10.127 | - | Employment Agreement dated and effective as of October 1, 2002 by and between Indevus Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. (47) |
| 10.128 | - | Amendment No. 1 to Licensing Agreement by and between Registrant and Eli Lilly and Company and Eli Lilly S.A. (48) (2) |
| 10.129 | - | Supply Agreement between Registrant and Madaus AG dated December 16, 2003 (48) (2) |
| 10.130 | - | Development and License Agreement between Registrant and Shire Laboratories Inc. dated March 11, 2003 (49) (2) |
| 10.131 | - | Amendment to the License Agreement by and between Registrant and Paligent Inc. dated April 10, 2003 (49) |
| 10.132 | - | License Agreement by and between Registrant and Aventis Pharma SA dated April 18, 2003 (51) (2) |
| 10.133 | - | License Agreement by and between Registrant and Sumner Burstein dated August 22, 2003 (52) (2) |
| 10.134 | - | Assignment and Termination Agreement by and between Registrant and Manhattan Pharmaceuticals, Inc. dated August 22, 2003 (52) (2) |
| 10.135 | - | Fiscal 2004 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 25, 2003 (52) |
| 10.136 | - | Agreement by and between the Registrant and Ferrer Internacional S.A. dated January 22, 2004 (53)(2) |
| 10.138 | - | 2004 Equity Incentive Plan (54) |
| 10.139 | - | License, Commercialization and Supply Agreement dated April 6, 2004 between the Registrant and Odyssey Pharmaceuticals Inc. (55)(2) |
| 10.140 | - | Fiscal 2005 CEO Bonus Plan, as adopted by the Board of Directors on December 7, 2004 (56) |
| 10.141 | - | Fiscal 2005 Senior Executive Bonus Plan, as adopted by the Board of Directors on December 7, 2004 (56) |
| 21 | - | List of Subsidiaries (57) |
| 23 | - | Consent of PricewaterhouseCoopers LLP (57) |
| 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 (57) |

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 (57)

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 (57)

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 (57)

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(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 granted 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) Filed with this report.

**SIGNATURES**

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

Date: December 14, 2004

INDEVUS PHARMACEUTICALS, INC.

By: /s/ GLENN L. COOPER

**Glenn L. Cooper, M.D. President,**

**Chief Executive Officer and Chairman**

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

| Name | Title | Date |
|---|---|---|
| /s/ GLENN L. COOPER<br>**Glenn L. Cooper, M.D.** | President, Chief Executive Officer and Chairman (Principal Executive Officer) | December 14, 2004 |
| /s/ HARRY GRAY<br>**Harry Gray** | Director | December 14, 2004 |
| /s/ STEPHEN C. MCCLUSKI<br>**Stephen C. McCluski** | Director | December 14, 2004 |
| /s/ MALCOLM MORVILLE<br>**Malcolm Morville** | Director | December 14, 2004 |
| /s/ CHERYL P. MORLEY<br>**Cheryl P. Morley** | Director | December 14, 2004 |
| /s/ LEE J. SCHROEDER<br>**Lee J. Schroeder** | Director | December 14, 2004 |
| /s/ DAVID B. SHARROCK<br>**David B. Sharrock** | Director | December 14, 2004 |

| | | |
|---|---|---|
| /s/ MICHAEL W. ROGERS<br>**Michael W. Rogers** | Executive Vice President, Chief Financial Officer, and Treasurer (Principal Financial Officer) | December 14, 2004 |
| /s/ DALE RITTER<br>**Dale Ritter** | Senior Vice President, Finance, (Principal Accounting Officer) | December 14, 2004 |

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**REPORT OF INDEP ENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Indevus Pharmaceuticals, Inc. and its subsidiaries at September 30, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2004 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 an audit to obtain reasonable assurance about whether the financial statements are free from material misstatement. An audit 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.

/s/ PRICEWATERHOUSECOOPERS LLP

Boston, Massachusetts

December 13, 2004

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED BALANCE SHEETS**

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

| | September 30, 2004 | September 30, 2003 |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 127,099 | $ 57,717 |
| Marketable securities | 26,423 | 26,370 |
| Accounts receivable | 7,042 | 155 |
| Inventories | 1,160 | |
| Prepaids and other current assets | 3,082 | 1,241 |
| Total current assets | 164,806 | 85,483 |
| Marketable securities | 3,486 | |
| Property and equipment, net | 546 | 33 |
| Insurance claim receivable | 1,258 | 1,258 |
| Prepaid debt issuance costs | 2,503 | 3,163 |
| Other assets | 1,239 | 134 |
| Total assets | $ 173,838 | $ 90,071 |
| **LIABILITIES** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 6,361 | $ 2,008 |
| Accrued expenses | 13,707 | 8,671 |
| Accrued interest | 950 | 938 |
| Deferred revenue | 12,500 | |
| Total current liabilities | 33,518 | 11,617 |
| Convertible Notes | 72,000 | 72,000 |
| License fees payable | 100 | 200 |
| Deferred revenue | 131,250 | |
| Minority interest | 8 | 13 |
| Commitments and contingencies (Notes G and I) | | |
| **STOCKHOLDERS EQUITY (DEFICIT)** | | |
| Convertible preferred stock, $.001 par value, 5,000,000 shares authorized: | | |
| Series B, 239,425 shares issued and outstanding (liquidation preference at September 30, 2004 $3,026) | 3,000 | 3,000 |
| Series C, 5,000 shares issued and outstanding (liquidation preference at September 30, 2004 $502) | 500 | 500 |
| Common stock, $.001 par value, 80,000,000 shares authorized; 47,825,896 shares issued and 47,175,661 shares issued and outstanding at September 30, 2004 and 2003, respectively | 48 | 47 |
| Additional paid-in capital | 309,050 | 303,452 |
| Accumulated deficit | (368,903) | (300,691) |
| Accumulated other comprehensive loss | (131) | (67) |
| Treasury stock, at cost, 1,057,125 shares at September 30, 2004 | (6,602) | |

| | | |
|---|---|---|
| Total stockholders equity (deficit) | (63,038) | 6,241 |
| Total liabilities and stockholders equity (deficit) | $ 173,838 | $ 90,071 |

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, | | |
|---|---|---|---|
| | **2004** | **2003** | **2002** |
| Revenues: | | | |
| Product revenue | $ 9,740 | $ 4,316 | $ 3,439 |
| Contract and license fees | 8,986 | 929 | 968 |
| Total revenues | 18,726 | 5,245 | 4,407 |
| Costs and expenses: | | | |
| Cost of product revenue | 7,950 | 1,073 | 733 |
| Research and development | 23,303 | 24,466 | 13,614 |
| Marketing, general and administrative | 51,916 | 11,105 | 8,090 |
| Total costs and expenses | 83,169 | 36,644 | 22,437 |
| Loss from operations | (64,443) | (31,399) | (18,030) |
| Investment income | 1,396 | 664 | 987 |
| Interest expense | (5,170) | (1,077) | |
| Other | 5 | | (543) |
| Net loss | $ (68,212) | $ (31,812) | $ (17,586) |
| Loss per common share, basic and diluted | $ (1.43) | $ (0.68) | $ (0.38) |
| Weighted average common shares outstanding, basic and diluted | 47,542 | 46,930 | 45,896 |

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

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

**(Dollar amounts in thousands)**

| | Common Stock | | Preferred Stock | | |
|---|---|---|---|---|---|
| | Number of Shares | Par Value Amount | Number of Shares | Amount | Additional Paid-In Capital |
| Balance at September 30, 2001 | 43,283,016 | $ 43 | 244,425 | $ 3,500 | $ 276,399 |
| Private placement of common stock, net of issuance costs of $1,688 | 3,125,000 | 4 | | | 23,309 |
| Proceeds from exercise of stock options and warrants | 161,301 | | | | 620 |
| Proceeds from offering of Employee Stock Purchase Plan | 77,478 | | | | 162 |
| Dividends on preferred stock | | | | | (35) |
| Stock-based compensation and other | 229,090 | | | | 2,223 |
| Comprehensive loss: | | | | | |
| Net loss | | | | | |
| Unrealized net loss on marketable and equity securities | | | | | |
| Total comprehensive loss | | | | | |
| Balance at September 30, 2002 | 46,875,885 | 47 | 244,425 | 3,500 | 302,678 |
| Proceeds from exercise of stock options | 150,000 | | | | 254 |
| Proceeds from offering of Employee Stock Purchase Plan | 75,452 | | | | 160 |
| Dividends on preferred stock | | | | | (35) |
| Stock-based compensation and other | 74,324 | | | | 395 |
| Comprehensive loss: | | | | | |
| Net loss | | | | | |
| Unrealized net loss on marketable and equity securities | | | | | |
| Total comprehensive loss | | | | | |
| Balance at September 30, 2003 | 47,175,661 | 47 | 244,425 | 3,500 | 303,452 |
| Purchase of treasury stock | | | | | |
| Proceeds from exercise of stock options | 576,332 | 1 | | | 1,407 |
| Proceeds from offering of Employee Stock Purchase Plan | 68,120 | | | | 145 |
| Dividends on preferred stock | | | | | (35) |
| Stock-based compensation and other | 5,783 | | | | 4,081 |
| Comprehensive loss: | | | | | |
| Net loss | | | | | |
| Unrealized net loss on marketable and equity securities | | | | | |
| Total comprehensive loss | | | | | |
| Balance at September 30, 2004 | 47,825,896 | $ 48 | 244,425 | $ 3,500 | $ 309,050 |

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

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

**(Dollar amounts in thousands)**

| | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Treasury Stock | | Total Equity (Deficit) | Comprehensive Loss |
|---|---|---|---|---|---|---|
| | | | Number of Shares | Amount | | |
| Balance at September 30, 2001 | $ (251,293) | $ 11 | | | $ 28,660 | |
| Private placement of common stock, net of issuance costs of $1,699 | | | | | 23,313 | |
| Proceeds from exercise of stock options and warrants | | | | | 620 | |
| Proceeds from offering of Employee Stock Purchase Plan | | | | | 162 | |
| Dividends on preferred stock | | | | | (35) | |
| Stock-based compensation and other | | | | | 2,223 | |
| Comprehensive loss: | | | | | | |
| Net loss | (17,586) | | | | (17,586) | $ (17,586) |
| Unrealized net loss on marketable and equity securities | | (139) | | | (139) | (139) |
| Total comprehensive loss | | | | | | $ (17,725) |
| Balance at September 30, 2002 | (268,879) | (128) | | | 37,218 | |
| Proceeds from exercise of stock options | | | | | 254 | |
| Proceeds from offering of Employee Stock Purchase Plan | | | | | 160 | |
| Dividends on preferred stock | | | | | (35) | |
| Stock-based compensation and other | | | | | 395 | |
| Comprehensive loss: | | | | | | |
| Net loss | (31,812) | | | | (31,812) | $ (31,812) |
| Unrealized net loss on marketable and equity securities | | 61 | | | 61 | 61 |
| Total comprehensive loss | | | | | | $ (31,751) |
| Balance at September 30, 2003 | (300,691) | (67) | | | 6,241 | |
| Purchase of treasury stock | | | 1,166,200 | (7,319) | (7,319) | |
| Proceeds from exercise of stock options | | | (84,751) | 582 | 1,990 | |
| Proceeds from offering of Employee Stock Purchase Plan | | | (17,838) | 92 | 237 | |
| Dividends on preferred stock | | | | | (35) | |
| Stock-based compensation and other | | | (6,486) | 43 | 4,124 | |
| Comprehensive loss: | | | | | | |
| Net loss | (68,212) | | | | (68,212) | $ (68,212) |
| Unrealized net loss on marketable and equity securities | | (64) | | | (64) | (64) |

| | | | | | | |
|---|---|---|---|---|---|---|
| Total comprehensive loss | | | | | | $ (68,276) |
| Balance at September 30, 2004 | $ (368,903) | $ (131) | 1,057,125 | $ (6,602) | $ (63,038) | |

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(Amounts in thousands)**

| | For the years ended September 30, | | |
|---|---|---|---|
| | **2004** | **2003** | **2002** |
| Cash flows from operating activities: | | | |
| Net loss | $ (68,212) | $ (31,812) | $ (17,586) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | | |
| Depreciation and amortization | 122 | 16 | 59 |
| Amortization of convertible note issuance costs | 660 | 138 | |
| Noncash compensation | 4,089 | | 2,188 |
| Noncash license fee | | 360 | |
| Impairment of equity securities | | | 487 |
| Changes in assets and liabilities: | | | |
| Accounts receivable | (6,887) | 395 | (219) |
| Inventories | (1,160) | | |
| Prepaid and other assets | (3,013) | (708) | (136) |
| Accounts payable | 4,353 | 1,610 | 345 |
| Deferred revenue | 143,750 | (24) | 24 |
| Accrued expenses and other liabilities | 4,945 | 3,530 | 229 |
| Net cash provided by (used in) operating activities | 78,647 | (26,495) | (14,609) |
| Cash flows from investing activities: | | | |
| Capital expenditures | (636) | (33) | (10) |
| Purchase of marketable securities | (37,008) | (26,836) | (26,297) |
| Proceeds from maturities and sales of marketable securities | 33,471 | 21,991 | 12,015 |
| Net cash used in investing activities | (4,173) | (4,878) | (14,292) |
| Cash flows from financing activities: | | | |
| Net proceeds from issuance of common and treasury stock | 2,227 | 414 | 24,095 |
| Proceeds from issuance of convertible notes | | 72,000 | |
| Costs related to issuance of convertible notes | | (3,301) | |
| Distribution to minority interest stockholder | | | (140) |
| Purchase of treasury stock | (7,319) | | |
| Net cash provided by (used in) financing activities | (5,092) | 69,113 | 23,955 |
| Net change in cash and cash equivalents | 69,382 | 37,740 | (4,946) |
| Cash and cash equivalents at beginning of period | 57,717 | 19,977 | 24,923 |
| Cash and cash equivalents at end of period | $ 127,099 | $ 57,717 | $ 19,977 |
| Supplemental information: | | | |
| Interest paid | $ 4,500 | $ | $ |

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

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**A. Nature of the Business**

Indevus Pharmaceuticals, Inc. ( Indevus or the Company ) is a biopharmaceutical company engaged in the acquisition, development and commercialization of a diversified portfolio of product candidates, including multiple compounds in late-stage clinical development. The Company currently markets SANCTURA for overactive bladder (see Note N) and has four compounds in clinical development: pagoclone for anxiety disorders, IP 751 for pain and inflammatory disorders, PRO 2000 for the prevention of infection by the human immunodeficiency virus ( HIV ) and other sexually transmitted pathogens, and aminocandin for systemic fungal infections.

The Company is subject to risks and uncertainties common to companies in the biopharmaceuticals industry and specific risks. Such risks include but are not limited to dependence on the success of SANCTURA and SANCTURA XR; the early stage of products under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA and SANCTURA XR; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR; dependence on third parties for manufacturing and marketing; 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; limited patent and proprietary rights; dependence on market exclusivity; valuation of our Common Stock; risks related to repayment of debts; and risks related to increased leverage.

**B. Summary of Significant Accounting Policies**

*Basis of Presentation:* The consolidated financial statements include the accounts of the Company and its majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. Investments in subsidiaries which are less than majority but greater than 20% owned are reflected using the equity method of accounting. For an entity that is not a variable interest entity under FIN 46, *Consolidation of Variable Interest Entities,* the Company s policy is to consolidate a subsidiary when the Company owns greater than 50% of the voting interest in the subsidiary and/or controls it. Certain prior year amounts have been reclassified to conform to fiscal 2004 classifications.

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

*Cash, Cash Equivalents and Marketable Securities:* The Company invests available cash primarily in short-term bank deposits, money market funds, domestic and foreign commercial paper and government securities. Cash and cash equivalents includes investments with maturities of three months or less at date of purchase. Marketable securities consist of investments purchased with maturities greater than three months and are classified as noncurrent if they mature one year or more beyond the balance sheet date. The Company classifies its investments in debt securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time the investments are purchased. At September 30, 2004 and 2003, all investments held were classified as available-for-sale. Investments are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income or loss until realized. The fair value of these securities is based on quoted market prices.

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

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

To date, the Company s revenues have been generated from a limited number of sources. In fiscal 2004, the Company entered into the PLIVA Agreement (see Note N of Notes to Consolidated Financial Statements) which generated $16,214,000, or 87%, of total revenue in fiscal 2004. PLIVA also represented approximately 99% of accounts receivable at September 30, 2004. The Company believes credit risk associated with PLIVA is not significant.

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

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

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

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

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

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

The Company records sales of product as product revenue upon the later of shipment or as title passes to its customer. In fiscal 2004, the Company commenced selling SANCTURA to PLIVA in bottles for resale and blister packs for distribution as samples (see Note N of Notes to Consolidated Financial Statements).

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 unless the royalty report for such period is received subsequent to the time the Company is required to report its results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, in which case the Company recognizes such royalty revenue in the

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

subsequent accounting period when it receives the royalty report and when the amount of and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

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

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

Under the PLIVA 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 agreement to the time the milestone is earned over the estimated duration of the PLIVA Agreement. Going forward, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the PLIVA Agreement.

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

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 fur the Company s share ware reflected as a reduction of contract and license fee revenue.

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

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

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

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

| | Fiscal year ended September 30, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| As reported net loss | $ (68,212,000) | $ (31,812,000) | $ (17,586,000) |
| Noncash compensation expense included in reported net income, net of tax | $ 4,089,000 | $ | $ 2,188,000 |
| Compensation expense determined under the fair-value method for all awards, net of tax | $ (1,903,000) | $ (1,231,000) | $ (2,306,000) |
| Pro forma net loss | $ (66,026,000) | $ (33,043,000) | $ (17,704,000) |
| As reported net loss per common share: | | | |
| Basic | $ (1.43) | $ (0.68) | $ (0.38) |
| Diluted | $ (1.43) | $ (0.68) | $ (0.38) |
| Pro forma net loss per common share: | | | |
| Basic | $ (1.39) | $ (0.70) | $ (0.39) |
| Diluted | $ (1.39) | $ (0.70) | $ (0.39) |

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

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

| | 2004 | 2003 | 2002 |
|---|---|---|---|
| Dividend yield | 0% | 0% | 0% |
| Expected volatility | 90% | 90% | 90% |
| Risk-free interest rate | 1.9%-3.1% | 1.7%-3.5% | 1.8%-4.6% |
| Expected option life | 4 years | 4 years | 3 years |
| Weighted average grant date fair value: | | | |
| Options granted at fair market value | $ 6.62 | $ 3.64 | $ 3.10 |
| Options granted at less than fair market value | | | $ 3.48 |

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

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

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

*Recent Accounting Pronouncements:*

In January 2003, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, ( FIN 46 ). FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity ( VIE ), the assets, liabilities and results of activities of the VIE should be included in the consolidated financial statements of the entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. For those arrangements entered into prior to January 31, 2003, FIN 46 requires its provisions, as amended by FIN 46R which was issued by the FASB in December 2003, be adopted by the Company in the second quarter of fiscal 2004. The Company s adoption of FIN 46R in the second quarter of fiscal 2004 did not have a material impact on the Company s financial position or results of operations.

Emerging issues Task Force ( EITF ) 03-6, *Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings per Share* ( EITF 03-6 ), was issued in March 2004. EITF 03-6 is intended to clarify what is a participating security and how to apply the two-class method of computing earnings per share

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-6 is effective for reporting periods beginning after March 31, 2004. The adoption of this pronouncement did not have an impact on the Company s consolidated financial position, results of operations or cash flows due to the net loss reported. In the event the Company reports net income, the Company will allocate undistributed earnings and report earnings per share accordingly.

**C. Marketable Securities**

Investments in marketable securities consisted of the following at September 30, 2004 and 2003:

| | 2004 | | 2003 | |
|---|---|---|---|---|
| | Cost | Market Value | Cost | Market Value |
| U.S. corporate notes | $ 29,903,000 | $ 29,909,000 | $ 9,666,000 | $ 9,669,000 |
| U.S. government obligations | | | 14,944,000 | 14,944,000 |
| Foreign corporate obligations | | | 1,055,000 | 1,056,000 |
| State government obligations | | | 700,000 | 701,000 |
| | $ 29,903,000 | $ 29,909,000 | $ 26,365,000 | $ 26,370,000 |

At September 30, 2004, gross unrealized gains and losses on marketable securities were $15,000 and $9,000, respectively. At September 30, 2003, gross unrealized gains and losses were $6,000 and $1,000 respectively. At September 30, 2004, $26,423,000 of marketable securities mature within one year and $3,486,000 mature beyond one year but within two years from the balance sheet date. At September 30, 2003, all marketable securities mature within one year from the balance sheet date. At September 30, 2004 and 2003, respectively, the Company had no investments in an unrealized loss position for which other-than-temporary impairments have not been recognized.

**D. Inventories**

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

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

| | 2004 |
|---|---|
| Raw materials | $ 488,000 |
| Finished goods | 672,000 |
| | $ 1,160,000 |

Inventories consist solely of SANCTURA. There was no inventory at September 30, 2003. Raw materials consist of tablets of SANCTURA in bulk form purchased from the Company s supplier, Madaus A.G. Finished goods consist of SANCTURA tablets packaged in bottles for resale and blister packages for distribution as samples.

**E. Property and Equipment**

At September 30, 2004 and 2003, property and equipment consisted of the following:

| | 2004 | 2003 |
|---|---|---|
| Office and other equipment | $ 1,418,000 | $ 788,000 |
| Leasehold improvements | 362,000 | 362,000 |
| | 1,780,000 | 1,150,000 |
| Less: accumulated depreciation and amortization | (1,234,000) | (1,117,000) |
| | $ 546,000 | $ 33,000 |

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

There were no assets under capital leases at September 30, 2004 and 2003, respectively.

Depreciation and amortization expenses for the years ended September 30, 2004, 2003, and 2002 were $122,000, $16,000, and $59,000, respectively.

**F. Accrued Expenses**

At September 30, 2004 and 2003, accrued expenses consisted of the following:

| | 2004 | 2003 |
|---|---|---|
| Clinical and sponsored research | $ 2,399,000 | $ 4,799,000 |
| Compensation related | 4,132,000 | 1,228,000 |
| Manufacturing and production costs | 3,139,000 | |
| Professional fees | 2,701,000 | 1,121,000 |
| Redux related | 654,000 | 717,000 |
| Other | 682,000 | 806,000 |
| | $ 13,707,000 | $ 8,671,000 |

**G. Commitments**

The Company leases its facilities, as well as certain office equipment and furniture under non-cancelable operating leases. Rent expense under these leases was approximately $600,000, $557,000, and $484,000, for the years ended September 30, 2004, 2003, and 2002, respectively.

At September 30, 2004, the Company s future minimum payments under non-cancelable lease arrangements are as follows:

| Fiscal Year | Operating Leases |
|---|---|
| 2005 | $ 573,000 |

| | |
|---|---|
| 2006 | 584,000 |
| 2007 | 320,000 |
| Thereafter | |
| Total lease payments | $ 1,477,000 |

During August of 2004, the Company entered into a long-term lease agreement with a fleet management company. Under the terms of this agreement, the Company will provide vehicles for its sales force subject to the minimum commitment for each vehicle of twelve months.

Pursuant to certain of the Company s in-licensing arrangements, the Company will owe payments to its licensors upon achievement of certain development and regulatory milestones; the Company cannot predict if or when such events will occur. (See Note N.)

*Guarantees*

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

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

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

**H. Convertible Notes**

In July 2003, the Company received net proceeds of approximately $68,700,000 from the sale of $72,000,000 aggregate principal amount of 6.25% Convertible Senior Notes due 2008 (the Notes ) to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The Notes are convertible at anytime prior to the July 15, 2008 maturity date into the Company s Common Stock at an initial conversion price of $6.656 per share, subject to adjustment for certain events; the Company has reserved approximately 10,800,000 shares of Common Stock for issuance pursuant to such a conversion and has registered with the SEC the Notes and Common Stock for resale. Additionally, all or a portion of the Notes are redeemable by the Company for cash at any time after July 20, 2006 provided the Company s Common Stock equals or exceeds 150% of the conversion price then in effect for a specified period and all of the Notes are subject to repurchase by the Company at the option of the Note holders if a change in control occurs. Interest is payable semiannually in arrears on January 15 and July 15 through the maturity date. Prepaid debt issuance costs related to the Notes was $3,301,000 and is being amortized to interest expense on a straight-line basis over the five year term of the Notes. At September 30, 2004, the market value of a $1000 Note was approximately $1,314.

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

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

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

At September 30, 2004, the Company has an accrued liability of approximately $700,000 for Redux-related expenses, including legal expenses. In fiscal 2003, the Company reduced our estimate of the amount of Redux-related expenses, including legal expenses, remaining due, in part, to a decline in the amount of actual payments during fiscal 2003. As a result, the Company reduced our accrued liability for Redux-related expenses by approximately $600,000 and reflected this reduction as a credit in marketing, general and administrative expense. The amounts the Company ultimately pay could differ significantly from the amount currently accrued at September 30, 2004. To the extent the amounts paid differ from the amounts accrued, the Company will record a charge or credit to the statement of operations.

As of September 30, 2004, the Company had an outstanding insurance claim of $3,735,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company s current outstanding insurance claim is made pursuant to the Company s product liability policy issued to the Company by Reliance Insurance Company ( Reliance ). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $1,258,000 reflecting the Company s best estimate given the available facts and circumstances. The amount the Company collects could differ from the $1,258,000 reflected as a noncurrent insurance claim receivable at September 30, 2004. It is uncertain when, if ever, the Company will collect any of its $3,735,000 of estimated claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the $5,000,000 limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

**J. Stockholders Equity**

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

*Stock Options and Warrants:* The Company s 1989 Stock Option Plan (the 1989 Plan ) expired in 1999, however incentive and non-qualified options granted to employees, officers, directors and consultants pursuant to the 1989 Plan which were outstanding as of the date of the 1989 Plan s expiration may be exercised until cancelled or expired. Under the Company s 1994 Long-Term Incentive Plan (the 1994 Plan ), incentive and non-qualified options to purchase 6,000,000 shares may be granted. Under the 1998 Stock Option Plan (the 1998 Plan ), incentive and non-qualified options to purchase 1,500,000 shares may be granted. Under the Company s 2000 Stock Option Plan (the 2000 Plan ), incentive and non-qualified options to purchase 3,500,000

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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

| | Stock Options | | Warrants | |
|---|---|---|---|---|
| | Shares | Weighted Average Exercise Price | Shares | Exercise Price |
| Outstanding at September 30, 2001 | 9,590,958 | $4.15 | 705,000 | $5.00-$10.00 |
| Granted | 796,917 | $4.95 | | |
| Exercised | (155,166) | $5.66 | (25,000) | $6.19 |
| Cancelled | (113,332) | $4.07 | (575,000) | $6.19-$9.44 |
| Outstanding at September 30, 2002 | 10,119,377 | $4.21 | 105,000 | $5.00-$7.13 |
| Granted | 1,206,000 | $3.64 | | |
| Exercised | (150,000) | $5.02 | | |
| Cancelled | (912,207) | $4.37 | | |
| Outstanding at September 30, 2003 | 10,263,170 | $4.17 | 105,000 | $5.00-$7.13 |
| Granted | 1,661,500 | $6.62 | | |
| Exercised | (661,083) | $3.01 | (20,000) | $5.25 |
| Cancelled | (331,795) | $5.55 | (75,000) | $5.13-$7.13 |
| Outstanding at September 30, 2004 | 10,931,792 | $4.57 | 10,000 | $6.19 |

At September 30, 2004, 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 |
| $1.22-$ 3.58 | 4,363,250 | 6.2 years | $ 2.57 | 3,825,203 | $ 2.48 |

| | | | | | | |
|---|---|---|---|---|---|---|
| $3.63-$ 6.00 | 2,810,667 | 5.1 years | $ | 4.78 | 2,139,835 | $ 4.47 |
| $6.05-$ 7.60 | 3,359,000 | 6.1 years | $ | 6.44 | 2,397,751 | $ 6.26 |
| $7.64-$20.13 | 398,875 | 7.3 years | $ | 9.19 | 222,702 | $ 10.05 |
| $1.22-$20.13 | 10,931,792 | 5.9 years | $ | 4.57 | 8,585,491 | $ 4.23 |

All outstanding options vest at various rates over periods up to four years and expire at various dates from January 21, 2005 to September 28, 2014. At September 30, 2003, 8,772,963 options were exercisable at a weighted average exercise price of $4.21. At September 30, 2002, 9,301,144 options were exercisable at a weighted average exercise price of $4.20.

All outstanding warrants expire on July 17, 2006.

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In fiscal 2004, the Company extended the exercise date of certain stock options granted to certain officers, directors and vice presidents and incurred a noncash charge of approximately $4,081,000. In fiscal 2002, the Company (i) granted a fully-vested option to purchase 100,000 shares of Common Stock to an executive officer of the Company at an exercise price less than the fair market value of the Common Stock at the time of the grant and incurred a noncash charge to operations of approximately $262,000 and (ii) extended the exercise date of certain stock options granted to certain executive officers and a director and incurred a noncash charge of approximately $1,475,000. The Company has granted stock options to consultants to the Company and has incurred a noncash charge to operations of approximately $317,000 in fiscal 2002.

*Restricted Stock Awards:* As an integral component of a management and employee retention program designed to motivate, retain and provide incentive to the Company s management and other employees, the Company s Board of Directors adopted the 1997 Equity Incentive Plan in October 1997 (the 1997 Plan ). The 1997 Plan provides for the grant of restricted stock awards which entitle the plan participants to receive up to an aggregate of 1,750,000 shares of the Company s Common Stock upon satisfaction of specified vesting periods. As of September 30, 2004, restricted stock awards to acquire an aggregate of 1,737,918 shares had been granted, net of forfeitures, to employees of the Company primarily in consideration of services rendered by the employee to the Company and payment of the par value of the shares. The shares subject to the awards have been registered under the Securities Act of 1933 on a registration statement on Form S-8 and, accordingly, may be sold by the 1997 Plan participants immediately upon vesting of the shares. As of September 30, 2004, 1,737,918 shares have vested and been issued, one grant of 1,000 shares was outstanding and vests on November 18, 2004, and there were 12,082 restricted stock awards available for grant by the Company under the 1997 Plan.

The Company has incurred compensation expense from the date of grant of awards through the vesting period of shares subject to restricted stock awards. The Company incurred charges related to restricted stock awards of approximately $8,000 and $134,000 in fiscal 2004 and 2002, respectively, which reflected the fair market value of the shares at the time of the grant. Such expense has been allocated to research and development and marketing, general and administrative expense over the vesting period of the restricted stock awards.

*Employee Stock Purchase Plan:* The Company s 1995 Employee Stock Purchase Plan (the 1995 Plan ) covers an aggregate of 500,000 shares of Common Stock which is offered in one-year offerings (an Offering ). Each Offering is divided into two six-month Purchase Periods (the Purchase Periods ). Stock is purchased at the end of each Purchase Period with employee contributions at the lower of 85% of the last sale price of the Company s Common Stock on the first day of an Offering or the last day of the related Purchase Period. At September 30, 2004, 126,350 shares remain to be purchased under the 1995 Plan.

*Treasury Stock:* In July 2004, the Company s Board of Directors approved the repurchase from time to time by the Company of up to 2,500,000 shares of Indevus Common Stock in the open market and through September 30, 2004 the Company repurchased an aggregate of 1,166,000 shares for $7,319,000 and reissued 109,000 of those shares pursuant to exercises of 85,000 stock options, 6,000 warrants, and 18,000 shares issued under the 1995 Plan.

*Other:* In addition to the 47,826,000 shares of Common Stock outstanding at September 30, 2004, there were approximately 28,900,000 shares of Common Stock reserved for issuance ( Reserved Common Shares ). Included in the number of Reserved Common Shares are the following: (i) 10,817,000 shares reserved for issuance upon conversion of the Notes; (ii) 12,557,000 shares reserved for issuance under the Option Plans; (iii) 4,756,000 shares of Common Stock reserved for issuance upon conversion of the Company s authorized but unissued Preferred Stock; (iv) 622,000 shares of Common Stock issuable upon conversion of issued and outstanding Preferred Stock; (v) 138,000 shares reserved for issuance under the 1995 and 1997 Plans; and (vi) approximately 10,000 shares reserved for issuance from exercise of outstanding warrants and Non-Plan

Options.

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**K. Weighted Average Common Shares**

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

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

During the year ended September 30, 2002, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were as follows: (i) options to purchase 3,236,792 shares of Common Stock at prices ranging from $6.00 to $20.13 with expiration dates ranging up to May 13, 2012 and (ii) warrants to purchase 105,000 shares of Common Stock with exercise prices ranging from $5.00 to $7.13 and with expiration dates ranging up to July 17, 2006. Additionally, during the year ended September 30, 2002, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 6,882,585 shares of Common Stock at prices ranging from $1.22 to $5.00 with expiration dates ranging up to September 10, 2012 and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**L. Income Taxes**

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

| | 2004 | 2003 |
|---|---|---|
| Federal and state net operating loss carryforwards | $ 101,085,000 | $ 75,105,000 |
| Federal and state tax credit carryforwards | 7,091,000 | 5,788,000 |
| Capital loss carryforwards | 1,733,000 | 3,257,000 |
| Accrued expenses | 8,700,000 | 6,922,000 |
| Investment in CPEC LLC | 6,918,000 | 7,558,000 |
| Investment in unconsolidated subsidiaries | 13,755,000 | 13,755,000 |
| Total deferred tax asset before valuation allowance | 139,282,000 | 112,385,000 |
| Valuation allowance against total deferred tax asset | (139,282,000) | (112,385,000) |
| Net deferred tax asset | $ | $ |

At September 30, 2004, the Company had net operating loss carryforwards available for federal income tax purposes of approximately $266,000,000 which expire at various dates from 2005 to 2024. In addition, the Company had approximately $5,600,000 of tax credit carryforwards for federal income tax purposes expiring at various dates through 2024 and capital loss carryforwards of approximately $4,300,000 for federal income tax purposes expiring at various dates though 2006. The Company s ability to use the net operating loss carryforwards may be subject to limitations resulting from ownership changes as defined in the U.S. Internal Revenue Code. Approximately $17,300,000 of the net operating loss carryforwards available for federal income tax purposes relate to exercises of non-qualified stock options and disqualifying dispositions of incentive stock options, the tax benefit from which, if realized, will be credited to additional paid-in capital.

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

**M. Related Party Transactions**

The Company has or had agreements with certain directors, an officer who is not an employee and the spouse of an officer of the Company to provide technical and other consulting services. Total amounts due or paid pursuant to such agreements were approximately $310,000, $324,000 and $198,000 in fiscal 2004, 2003, and 2002, respectively. In June 2002, the Company entered into a licensing agreement with Manhattan Pharmaceuticals, Inc. (formerly Atlantic Technology Ventures, Inc.) ( Manhattan ). A former director of the Company was a shareholder of

Manhattan at the time the transaction was approved by all of the disinterested directors of Indevus.

**N. Product Agreements**

*PLIVA:* In April 2004, the Company entered into a co-promotion and licensing agreement with Odyssey Pharmaceuticals, Inc., a specialty branded subsidiary of PLIVA d.d. ( PLIVA ) (the PLIVA Agreement ) for the U.S. commercialization of SANCTURA (trospium chloride), approved for marketing on May 28, 2004 by

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

the U.S. Food and Drug Administration ( FDA ) as a treatment for overactive bladder. Under the terms of this agreement, the Company granted PLIVA an exclusive right and license to co-promote and sell SANCTURA in the United States. Pursuant to the PLIVA Agreement the Company received $150 million, $30 million upon the execution of the agreement in April 2004 and $120 million in May 2004 upon receipt of the FDA approval of SANCTURA twice daily. In addition, Indevus could receive up to $45 million in future payments contingent upon the achievement of certain milestones related to the development of a once-a-day formulation of SANCTURA, as well as a payment of $20 million related to the achievement of a long-term commercialization milestone in 2013.

For the first six months following the approval of SANCTURA, Indevus is receiving a commission based on net sales of SANCTURA, adjusted by a fixed percentage of the aggregate advertising and promotion costs incurred by PLIVA and Indevus. During this period, Indevus has been responsible for funding its own sales force and certain advertising and promotional costs. PLIVA and Indevus have co-promoted SANCTURA through a joint sales force of approximately 500 sales representatives. Indevus established a sales force initially numbering approximately 280 representatives promoting SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians.

At any time beginning six months after the approval of SANCTURA, each company had the right to convert the PLIVA Agreement into a royalty-bearing structure, whereby Indevus will receive royalties from PLIVA based on net sales of SANCTURA, and PLIVA would be responsible for promotional and advertising costs. Should this right be exercised, Indevus specialty sales force would be subsidized by PLIVA for the first three years commencing on the effective date of the conversion and would continue to promote SANCTURA to urology specialists, obstetricians and gynecologists, and high prescribers during this period.

The Pliva Agreement contains certain obligations to PLIVA to be performed by the Company and gives the Company certain rights resulting from PLIVA s performance and obligations under the PLIVA Agreement. The Company s obligations to Pliva, over the term of the PLIVA Agreement, are to: (i) grant an exclusive right to PLIVA to all of our the Company s technology and know how related to SANCTURA in the U.S.; (ii) conduct and fund all development activities, on a best-efforts basis, to achieve FDA approval of SANCTURA Twice-daily and Once-Daily; (iii) participate equally with PLIVA on steering, development, and marketing committees; (iv) establish and train a sales force during the Copromotion Period and maintain a trained sales force during the first three years of the License Period; (v) provide to PLIVA at cost all product to be used for sale and all samples for distribution; (vi) engage and manage third-party promotion and advertising services related to the launch of SANCTURA Twice-Daily, as directed by the marketing committee during the Copromotion Period; and (vii) share with PLIVA at a predetermined percentage certain costs related to the launch of SANCTURA Twice-Daily. Our rights pursuant to the PLIVA Agreement, in addition to the initial and milestone payments, are to: (i) receive commissions on sales of SANCTURA during the Copromotion Period and royalties on sales of SANCTURA during the License Period; (ii) receive a subsidy for our sales force for the first three years of the License Period; (iii) receive reimbursement for a predetermined percentage of promotional and advertising costs incurred; and (iv) convert the PLIVA Agreement from the copromotion structure to the license structure after six months from FDA approval of SANCTURA.

Multiple element arrangements are evaluated pursuant to EITF 00-21, Accounting Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104 ( SAB 104 ) in service arrangements, provided all other revenue recognition criteria are met, service revenue should be recognized on a straight-line basis, unless evidence suggests otherwise, revenue from consideration received should be recognized on a straight-line basis over the expected term of the arrangement.

Under the PLIVA 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 agreement to the time the milestone is earned over the estimated duration of the PLIVA Agreement. Going forward, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the PLIVA Agreement.

Also, the Company and PLIVA are 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 of promotion and advertising costs incurred by PLIVA reflected as a reduction of contract and license fee revenue.

Additionally, the Company is recognizing commission and royalty payments, including PLIVA s reimbursement to the Company of its royalty obligation to Madaus, as product revenue when earned and shipments to PLIVA of product and samples as product revenue upon shipment, as such activities are reimbursed on a transaction by transaction basis as incurred over the expected term of the Pliva Agreement. Similarly, the subsidy from PLIVA for the Company s sales force will be recognized as contract and license fee revenue ratably over the three year period of expected receipt during the license period of the arrangement.

The Company estimated the expected twelve year duration of the PLIVA Agreement by assessing several factors. In addition to the contractual duration of the PLIVA Agreement, later of (i) the twelfth (12th) anniversary of the Launch Date of SANCTURA Twice-Daily or (ii) the expiration of the last to expire patent included in the Indevus Patent Rights covering SANCTURA Once-Daily, the Company considered: the absence of patent protection for SANCTURA Twice-Daily, the current reliance upon Waxman-Hatch market exclusivity, the potential for success of developing SANCTURA Once-Daily and obtaining patents for SANCTURA Once-Daily, strong competition in the OAB market.

PLIVA will be responsible for product inventory management and sales order fulfillment including billing and collection of customer receivables. The PLIVA Agreement is subject to termination by PLIVA under certain circumstances. Under the PLIVA Agreement, Indevus granted a security interest to PLIVA in Indevus FDA marketing authorizations or approvals relating to SANCTURA and agreed to indemnify PLIVA under certain circumstances.

The Company recorded the $150,000,000 received from PLIVA as deferred revenue and is amortizing the deferred revenue into contract and license fee revenue over the estimated twelve year duration of the PLIVA Agreement. For fiscal 2004, the Company recognized as contract and license fee revenue $6,250,000 from amortization of the deferred revenue under the contingency-adjusted method, $2,562,000 net reimbursement due to the Company comprised of $5,664,000 of PLIVA s share of SANCTURA promotion and advertising costs incurred by Indevus less $3,102,000 owed by the Company to PLIVA for Indevus share of SANCTURA promotion and advertising costs incurred by

PLIVA.

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Madaus:* In November 1999, the Company licensed exclusive U.S. rights from Madaus AG ( Madaus ) to trospium chloride, an orally-administered product for treatment for overactive bladder (urinary incontinence). In exchange, the Company has agreed to pay Madaus potential regulatory milestone, royalty and sales milestone payments. The Company is responsible for all clinical development and regulatory activities and costs related to the compound in the U.S. In December 2002, the Company entered into a manufacturing agreement with Madaus whereby Madaus will produce and sell to the Company commercial quantities of trospium in bulk form. In fiscal 2004, the Company s purchases of SANCTURA in bulk form aggregated approximately $6,700,000.

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

*Aventis:*

A. Pagoclone. In February 1994, the Company entered into a license agreement with Rhone-Poulenc Rorer, S.A. now Aventis S.A. ( Aventis ), granting the Company an exclusive worldwide license (subject to Aventis option to obtain a sublicense in France) under Aventis patent rights and know-how to manufacture, use and sell pagoclone (the Aventis Pagoclone Agreement ). In exchange, the Company paid a license fee and agreed to pay Aventis potential milestone payments and royalties based on potential net sales or, if sublicensed by the Company, the Company would pay to Aventis a portion of receipts from the sublicensee in lieu of milestone and royalty payments. Indevus also assumed responsibility for all clinical trials and regulatory submissions relating to pagoclone.

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

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

In June 1998, the Company licensed to Ferrer, on a worldwide basis except for the U.S. and Canada, the use of Indevus patent rights relating to the use of citicoline in the protection of brain tissue from cerebral infarction following ischemic stroke. In exchange for the license to Ferrer,

Indevus will be entitled to royalties from Ferrer

on certain exports and sales of the solid form of citicoline in certain countries upon its approval in each relevant country.

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

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

*CONRAD:* In September 2001, the Company was awarded a $535,000 grant by the Contraceptive Research and Development ( CONRAD ) Program under its Global Microbicide Project. This grant supports two toxicity studies currently being performed by the Company with PRO 2000. In fiscal 2002, the Company recorded approximately $254,000 of the remaining revenue pursuant to this grant.

*Lilly:* In June 1997, the Company licensed to Eli Lilly & Company ( Lilly ) worldwide, exclusive rights to Indevus patent covering the use of fluoxetine to treat certain conditions and symptoms associated with premenstrual syndrome ( PMS ). Lilly has received approval for fluoxetine to treat premenstrual dysphoric disorder, a severe form of PMS. The drug has been marketed under the trade name Sarafem by Lilly and its sublicense, Galen Holdings, Inc., respectively. In December 2002, the Company entered into a renegotiated agreement with Lilly providing for Lilly to pay the Company (i) an initial payment of approximately $777,000, (ii) royalties on net sales of Sarafem commencing October 1, 2002 through the expiration of the Company s patent related to Sarafem, and (iii) milestones based on Lilly s achievement of certain levels of Sarafem sales in each quarter commencing January 1, 2003, subject to an aggregate cap and immediate acceleration upon Lilly s sublicense of its rights related to Sarafem. The Company recognized the $777,000 initial payment as revenue upon signing the renegotiated agreement because the Company had no continuing performance obligations under the contract. The patent rights to the use of fluoxetine in treating PMS are licensed by the Company from the Massachusetts Institute of Technology, which is entitled to a portion of all payments, including royalties, made to Indevus by Lilly. The Company earned royalties of approximately $2,335,000, $4,319,000 (including $2,184,000 of accelerated milestone payments) and $3,437,000 in fiscal 2004, 2003 and 2002, respectively, on Lilly s sales of Sarafem.

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Uriach:* In September 2001, the Company licensed exclusive, worldwide rights to dersalazine, a compound for the treatment of inflammatory bowel disease, from J. Uriach & Cia., S.A. ( Uriach ), in exchange for an up-front licensing payment and potential development milestone and royalty payments to Uriach. Indevus was responsible for the clinical development, regulatory activities and commercialization of dersalazine. The Company is no longer developing dersalazine.

*IP 501:* During 1997, the Company obtained an option to negotiate an exclusive license to a compound designated by the Company as IP 501 for the treatment and prevention of cirrhosis of the liver caused by alcohol and hepatitis viruses. In January 2001, the Company exercised its option and entered into an agreement with Charles S. Lieber, M.D. to license IP 501. In fiscal 2003, the Company terminated this agreement.

*Wyeth:* In November 1992, the Company entered into an agreement with American Cyanamid Company (which subsequently was acquired by Wyeth) for the development and marketing in the U.S. of Redux. In connection with this agreement, Wyeth purchased from the Company the Series B and C Preferred Stock which is outstanding at September 30, 2004 and 2003. Holders of Series B and C Preferred Stock are entitled to receive mandatory dividends of $.13 and $1.00 per share, respectively, payable at the election of the Company in cash or Common Stock. Such dividends are payable annually on April 1 of each year, accrue on a daily basis and are cumulative. Holders of Series B and C Preferred Stock are also entitled to a liquidation preference of $12.53 and $100.00 per share, respectively, plus accumulated and unpaid dividends. Holders of Series B and C Preferred Stock are entitled to convert such shares into an aggregate of 622,222 shares of Common Stock (a conversion price of $5.63 per share) subject to anti-dilution adjustments. Holders of the Series B and C Preferred Stock are entitled to vote on all matters submitted to a vote of stockholders other than the election of directors, generally holding the number of votes equal to the number of shares of Common Stock into which such shares of Preferred Stock are convertible.

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

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

**O. Subsidiary and Investment in Aeolus**

Subsidiary

CPEC LLC is owned 65% by the Company and 35% by Aeolus and was developing bucindolol, a nonselective beta-blocker for treatment of congestive heart failure. Pursuant to the agreement under which bucindolol was acquired, the Company could have a maximum potential liability of approximately $1,700,000 if an NDA were filed and approved for bucindolol to treat congestive heart failure. In October 2003, CPEC LLC

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

licensed its bucindolol development and marketing rights to ARCA Discovery, Inc. in exchange for potential future milestone and royalty payments. The accounts of CPEC LLC are included in the Company s consolidated financial statements.

Investment in Aeolus

At September 30, 2004 and 2003, the Company s investment in Aeolus Pharmaceuticals, Inc. ( Aeolus ) (formerly Incara Pharmaceuticals, Inc. ) was comprised of 44,718 shares, or approximately .3%, of Aeolus common stock valued at $68,000 and $134,000, respectively and is included in other assets. In fiscal 2002, the Company recorded a charge to operations of $487,000 to write down its investment in Aeolus to fair value as, the decline in the value of Aeolus common stock was deemed other than temporary. The Company classifies its investment in Aeolus as available for sale and as such states its investment at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income.

**P. Quarterly Financial Data (Unaudited)**

| | First Quarter | Second Quarter | As restated Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| **Fiscal 2004** | | | | |
| Total revenues | $ 927,000 | $ 876,000 | $ 4,461,000 | $ 12,461,000 |
| Net loss | (12,024,000) | (11,370,000) | (16,963,000) | (27,855,000) |
| Net loss per common share, basic and diluted | $ (0.25) | $ (0.24) | $ (0.36) | $ (0.58) |
| **Fiscal 2003** | | | | |
| Total revenues | $ 822,000 | $ 2,871,000 | $ 714,000 | $ 838,000 |
| Net loss | (5,431,000) | (2,966,000) | (12,050,000) | (11,365,000) |
| Net loss per common share, basic and diluted | $ (0.12) | $ (0.06) | $ (0.26) | $ (0.24) |