INDEVUS PHARMACEUTICALS INC
Form 10-K
December 22, 2003
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended September 30, 2003

or

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

for the transition period from to

Commission File No. 0-18728

Indevus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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Indicate by check mark 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 $278,000,000, based on the last sales price of the Common Stock as of December 19, 2003. 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. This determination of affiliate status may not be conclusive for other purposes.

As of December 19, 2003, 47,260,661 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, 2003 to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 and the Exhibit Index beginning on page number 45 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 trospium; 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 indica 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 trospium; the early stage of products under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly trospium; risks associated with contractual agreements; dependence on third parties for manufacturing and marketing; competition; need for additional funds and corporate partners, including for the commercialization of trospium and for the development of pagoclone and citicoline; 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.

ITEM 1. ***Business***

(a) General Description of Business

Indevus is a biopharmaceutical company engaged in the development and commercialization of a diversified portfolio of pharmaceutical product candidates, including multiple compounds in late-stage clinical development. We currently have six compounds in development: trospium for

overactive bladder, pagoclone for panic and generalized anxiety disorders, citicoline for ischemic stroke, 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.

We seek to acquire, develop and commercialize a portfolio of pharmaceutical products for a range of therapeutic indications. The key elements of our business strategy include: (1) identifying product candidates with broad applications and large, unsatisfied markets, (2) acquiring clinical and late pre-clinical stage compounds, including products with clinical data or market experience outside the United States, (3) defining

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strategies to take these compounds through clinical testing and to market, (4) adding value to acquired products through clinical testing and regulatory review activities, and (5) commercializing products in collaboration or combination with corporate partners in order to help ensure the timely penetration of target 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.

Our lead product candidate is trospium chloride (trospium), a muscarinic receptor antagonist in development as a treatment for overactive bladder. On April 28, 2003, we submitted our New Drug Application (NDA) for trospium for filing with the U.S. Food and Drug Administration (FDA). The NDA for trospium includes data from 34 clinical studies involving over 2,800 subjects and patients, including 12 double-blind, placebo-controlled or active-controlled studies, 14 clinical pharmacology and pharmacokinetic studies and 8 uncontrolled studies. Results from previous clinical trials and our 523-patient Phase III trial demonstrated that treatment with trospium significantly reduced the frequency of both urination and incontinence episodes in patients with overactive bladder. In addition to the twice-a-day formulation of trospium which is the subject of the filed NDA, we have entered into an agreement with Shire Laboratories, Inc. (Shire) to develop extended release, once-a-day formulations. We are currently evaluating commercial opportunities for trospium, including co-promotion and licensing arrangements, strategic combinations, and other partnering opportunities. It is estimated that more than 17 million Americans suffer from overactive bladder in the United States. According to a recent *SCRIP* Report, only 20 percent of overactive bladder patients are currently treated with pharmacotherapy. In 2002, the market for drugs to treat overactive bladder was approximately $1 billion in the United States. We have exclusive rights to develop and market trospium in the United States. Trospium is currently marketed in Europe, where it is one of the leading treatments for overactive bladder.

Pagoclone is a GABA (gamma amino butyric acid) receptor agonist for the treatment of anxiety disorders. Pagoclone is in Phase III clinical stage development for panic disorder and Phase II for generalized anxiety disorder (GAD). To date, there have been three Phase II clinical trials of pagoclone that demonstrated statistically significant efficacy, two in panic disorder and one in 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 are pursuing new development and commercialization partnerships for pagoclone, and we are planning to initiate an additional clinical trial with pagoclone in 2004. We have exclusive, worldwide rights to develop and market pagoclone.

Citicoline is cytidine-5 diphosphate choline, a precursor for the biosynthesis of phosphatidylcholine, a major building block of nerve cell membranes, and has been under development as a neuroprotective treatment for ischemic stroke. We have completed three Phase III clinical trials and one Phase II/III clinical trial with citicoline in North America. We believe that these studies may indicate the effectiveness of citicoline in reducing the disability associated with ischemic stroke utilizing various outcome measures. However, only one of these trials has successfully met its primary outcome objective. Two meta-analyses of clinical trials presented at the 27th International Stroke Conference in February 2002 and a recently published analysis of pooled data from various controlled trials suggest that treatment with citicoline may reduce infarct growth after stroke and reduce rates of death or disability over the long term. We believe that additional clinical testing of citicoline is required before an NDA can be submitted. We have defined the design and clinical endpoints of our next stroke trial based on discussions with the FDA, and we continue to have discussions with the FDA regarding the number of additional trials that may be necessary to complete the development of citicoline sufficient for filing an NDA. We are seeking a development partnership for the commercialization of citicoline. We have exclusive rights to develop and market citicoline in the United States and Canada.

IP 751 is a non-psychoactive synthetic derivative of tetrahydrocannabinol (THC). Pre-clinical studies have shown that this novel anti-inflammatory and analgesic compound inhibits inflammatory cytokines, particularly interleukin 1-beta and TNF-alpha. In addition, results of a Phase II clinical trial conducted in Germany and published in the Journal of the Medical Association in September 2003 showed that treatment with IP 751

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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. Additional Phase I and Phase II clinical trials are currently being planned for IP 751. We have exclusive, worldwide rights to develop and market IP 751.

PRO 2000 is a topical microbicide in development for the prevention of the sexual transmission of HIV and other sexually-transmitted diseases (STDs). 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 February 2002, PRO 2000 was selected for a broad, five-year testing program of vaginal microbicides by an international collaboration of research groups in the United Kingdom and Africa under a grant from the United Kingdom Department for International Development (DFID). A Phase II clinical trial in Africa, funded by the European Commission, is currently underway to assess the safety of PRO 2000. It is expected that in 2004 a National Institutes of Health (NIH)-sponsored Phase II clinical trial will begin and may extend to a Phase III clinical trial to determine its safety and efficacy in preventing male and female HIV transmission. 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. We expect aminocandin will be ready for Phase I clinical testing in early 2004 as an intravenous agent. We believe that aminocandin also has 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 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 United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual syndrome.

Indevus Pharmaceuticals, Inc. is a Delaware corporation. Our principal office is at One Ledgemont Center, 99 Hayden Avenue, 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.

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(c) Narrative Description of Business

PRODUCTS

The following table summarizes, in order of current development stage, our product candidates.

Product Name	Indication/Use	Regulatory Status*	Commercial Rights
Trospium	Overactive bladder	NDA filed	United States
Pagoclone	Panic and GAD	Phase III in panic disorder; Phase II in GAD	Worldwide
Citicoline	Ischemic stroke	Phase III	United States and Canada
IP 751	Pain/inflammation	Phase I/II	Worldwide
PRO 2000	Prevention of HIV and sexually-transmitted diseases	Phase II	Worldwide
Aminocandin	Treatment of fungal infections	Phase I planned	Worldwide

* See Government Regulation.

Trospium

General. Trospium chloride is our lead product candidate and is under development as a drug to treat overactive bladder, defined as urinary frequency and urgency that may be coupled with urge incontinence. According to the American Foundation for Urological Disorders, an estimated 17 million Americans suffer from overactive bladder, and approximately 85 percent of these sufferers are women. According to a recent *SCRIP* Report, only 20 percent of overactive bladder patients are currently treated with pharmacotherapy. In 2002, the market for drugs to treat overactive bladder was approximately $1 billion in the United States. Trospium is currently marketed in most European countries where it is one of the leading treatments for overactive bladder.

Trospium 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 overactive bladder symptoms.

Current treatments in the United States for overactive bladder include compounds in the same class as trospium, such as Detrol and Detrol®LA (tolterodine), Ditropan® and Ditropan XL® (oxybutynin) and Oxytrol® (oxybutynin transdermal formulation). In contrast to trospium, these drugs have been shown to cross into the central nervous system. Based on pre-clinical findings to date, we believe that trospium does not enter into the central nervous system due to its distinct chemical structure, and as a result it may avoid central nervous system side effects. In addition, at therapeutic concentrations trospium is not an inhibitor of, or metabolized by, specific enzymes in the Cytochrome P450 system, a metabolic pathway commonly associated with drug-drug interactions. Since many of the patients who suffer from overactive bladder are also taking other medications, the potential lack of drug-drug interaction would be a significant distinguishing factor for this compound. Furthermore, trospium is not highly metabolized and is excreted largely unchanged in the urine.

Development Program. On April 28, 2003, we submitted an NDA for trospium with the FDA and on June 27, 2003 our NDA was accepted for filing by the FDA. In European and United States clinical trials, trospium has been shown to reduce symptoms associated with overactive bladder. The clinical database for trospium trials

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currently encompasses over 2,800 patients in 34 clinical trials, of which twelve are double-blind, controlled studies, including nine double-blind, placebo-controlled studies, and three are active-controlled trials. Many of these studies assessed the relative efficacy of trospium on urodynamic measurements such as bladder capacity and compliance, maximum detrusor pressure, and residual urine, in addition to urination and incontinence frequency diary data. One trial was a long-term comparative 52-week study on safety, tolerability, and efficacy. In addition to this clinical database, over 10,000 patients have been followed in post-marketing trials.

In September 2002, we announced results from a 523-patient, double-blind, placebo-controlled Phase III clinical trial with trospium that were subsequently presented at the annual meeting of the American Urology Association on April 28, 2003. The trial met both of its primary endpoints, achieving statistically significant reduced frequencies of urination ($p \leq 0.0001$) and urinary incontinence episodes ($p \leq 0.0001$) among patients treated with trospium (20 mg twice a day) compared with patients who received placebo. In addition, the trial met all overactive bladder secondary endpoints, including but not limited to, urgency, increased bladder capacity (volume voided) and quality of life. The drug was also well-tolerated, as the incidence of dry mouth and other adverse events observed in this trial suggest a favorable product profile for trospium. Over 400 patients from this trial elected to participate in an ongoing nine-month open label extension of the study. Additional data analyses from this trial presented at the International Continence Society Meeting (October 7-10, 2003) showed that treatment with trospium reduced urgency severity ($p<0.0001$) and was associated with onset of action beginning as early as three days after initiation of therapy ($p=0.05$). A presentation of additional data at a sectional meeting of the American Urology Association (October 14, 2003) demonstrated that early patient response to treatment with trospium is an accurate predictor of long-term therapeutic success. As part of our continuing development program, we are conducting additional clinical trials in the United States to explore further certain attributes of trospium.

Madaus AG (Madaus), the licensor of trospium, has conducted several trials comparing the safety and efficacy of trospium with its two principal competitors in Europe, tolterodine and oxybutynin. A double-blind, randomized efficacy trial, testing trospium and oxybutynin, was conducted with 358 patients, 268 of whom were treated with trospium (20 mg twice a day) and 90 with oxybutynin (5 mg twice a day) over a 52-week period. Halaska et al. (*World Journal of Urology, Vol. 20, 2003, 392-399*) reported that there was no significant difference between trospium and oxybutynin in the reduction in urinations and urge incontinence episodes. Among key safety measures, trospium had a statistically and clinically significantly lower incidence of dry mouth ($p<0.01$) than oxybutynin.

A second double-blind, placebo-controlled randomized efficacy trial, testing trospium and tolterodine, was conducted by Madaus with 180 patients, 57 of whom were treated with trospium (20 mg twice a day), 63 with tolterodine (2 mg twice a day) and 60 with placebo over a three-week period. Junemann et al. (*Neurourol Urodyn 19, 2000, 488-90*) reported that trospium-treated patients experienced a statistically significant ($p<0.01$) reduction in frequency of urination compared with placebo-treated patients, whereas the reduction in frequency of urination among tolterodine-treated patients failed to reach statistical significance over placebo patients. There was no statistically significant difference in side effects between trospium patients and tolterodine patients.

Current treatments in the United States include Detrol LA and Ditropan XL, which are once-a-day oral formulations. Our current NDA relates to a twice-a-day oral formulation of trospium. In March 2003, we signed an exclusive agreement with Shire under which Shire is developing extended release formulations of trospium. We have begun pharmacokinetic and safety studies with several once-a-day formulations, and we expect to begin advanced clinical trials with one of these formulations in 2004.

Madaus currently manufactures trospium for the European market to current European manufacturing standards. In order to manufacture the product for sale in the United States, Madaus manufacturing must comply with U.S. current Good Manufacturing Practices, (cGMP). We are working with Madaus to prepare for an FDA inspection of their German manufacturing plant.

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We are currently evaluating commercial opportunities and strategic alternatives for the commercialization of trospium, and we have engaged in discussions regarding a variety of alternatives, including co-promotion and licensing arrangements, strategic combinations, and other partnering opportunities.

Pagoclone

General. Pagoclone is under development as a treatment for anxiety disorders, including 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 United States (*Drug and Market Development, October 2001*) and approximately 60 million worldwide with anxiety disorders (*In Vivo, September 2001*).

Anxiety disorders, including panic disorder, 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 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. Earlier trials demonstrated that pagoclone reduced the symptoms of GAD and panic attacks, but in June 2002, Pfizer Inc. (Pfizer), then our licensee, informed us that its most recent clinical trials with pagoclone in GAD and panic disorder did not achieve the level of efficacy seen in previous trials. Pfizer subsequently elected not to pursue further development of the compound and returned to us exclusive, worldwide development and commercialization rights to pagoclone. We believe that the trials conducted to date with pagoclone suggest an efficacy, safety and tolerability profile which could compete favorably with current drugs on the market to treat GAD and panic disorder, but we believe that pagoclone will require additional testing.

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. 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 pursuing new worldwide development and commercialization partnerships for pagoclone, and we are planning to initiate an additional clinical trial with pagoclone in 2004 to build upon the findings from the previous trials.

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,

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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 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 United States. 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.

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Pfizer also conducted a study in panic disorder. Although the patients in the study met the entrance criteria specified by Pfizer, the resulting patent population for this trial had an average number of panic attacks which was substantially lower (3.5 to 4.0 per two week period) than what we believe are usually seen and required to detect efficacy for these agents. 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.

Citicoline

General. Citicoline is under development as a treatment for ischemic stroke. An ischemic stroke occurs when brain tissue dies or is severely damaged as the result of interrupted blood flow caused by a clogged artery which deprives an area of the brain of blood and oxygen, commonly known as an infarct. This loss of blood flow and oxygen causes, among other events, a breakdown of brain cell membranes, and places the surrounding tissue, the penumbra, at risk for death, leading to an extension of the size of infarct.

We believe that citicoline has multiple acute and longer-term mechanisms of action that diminish the effects of stroke. On an acute basis, citicoline appears to limit infarct size by preventing the accumulation of fatty acids, which would otherwise yield toxic oxidation products, by preventing their release. On a longer-term basis, citicoline is believed to promote the formation of additional membrane elements needed by damaged neurons to restore functional activity by raising blood levels of choline, cytidine and other phospholipid precursors, which are substrates believed to be essential for the formation of the nerve cell membrane. Citicoline also appears to increase levels of acetylcholine, a neurotransmitter believed to be associated with learning and memory functions. Citicoline is currently marketed in many countries in Europe and Asia.

Development Program. We have completed three Phase III clinical trials and one Phase II/III clinical trial with citicoline in North America. We believe that these studies may indicate the effectiveness of citicoline in reducing the disability associated with ischemic stroke utilizing various secondary outcome measures. However, only one of these trials has successfully met its primary outcome objective. Therefore, we believe additional clinical testing is required before an NDA for citicoline can be submitted for review by the FDA.

We submitted an NDA for citicoline to the FDA in December 1997. Data in the NDA included the results of one Phase III clinical trial and one Phase II/III clinical trial conducted by us in the United States, a Japanese Phase III clinical trial conducted by Takeda Chemical Industries, Ltd. (Takeda) and supportive clinical and post-marketing data from more than 30 countries where citicoline has already been approved. The NDA was accepted for filing and was assigned priority and fast-track review status. However, based on the results of a subsequent 100-patient Phase III clinical trial which failed to meet its primary endpoint of reducing infarct size (p=.18) among patients taking citicoline versus those taking placebo, we withdrew our NDA in April 1998. Following analysis of the third Phase III clinical trial completed in early 2000, Takeda, then our licensee for citicoline, elected not to pursue further development of citicoline, and returned to us all rights to the compound.

Two meta-analyses of clinical trials, including trials conducted by other companies and researchers abroad and trials conducted in the United States by us, were presented at the 27th International Stroke Conference in February 2002. These meta-analyses and a published analysis of data pooled from various control trials support the results of the individual studies showing that treatment with citicoline may reduce infarct growth after stroke and reduce rates of death or disability over the long-term.

The first of these studies analyzed seven controlled trials enrolling 1,963 patients who received oral or intravenous citicoline at doses ranging from 500 to 2000 milligrams daily and showed that treatment with citicoline was associated with a significant reduction in rates of death or disability over the long-term. On a combined basis across these trials, 54.6 percent of citicoline patients experienced death or disability, compared with 66.4 percent of placebo patients ($p<0.00001$).

The second of these studies analyzed data regarding infarct growth following stroke from two clinical trials in a total of 214 patients. Doses of 500 milligrams/day and 2000 milligrams/day were used in these trials. The

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mean volume increase in infarct size was 84.7 percent for the placebo group, 34.0 percent for the 500 milligram group and 1.8 percent for the 2000 milligram group (p=0.015).

We have defined the design and clinical endpoints of our next stroke trial based on discussions with the FDA, and we continue to have discussions with the FDA regarding the number of additional clinical trials that may be necessary to complete development of citicoline sufficient for filing an NDA. Due to the expense of conducting the additional clinical trials necessary to complete development of citicoline, we plan to seek a corporate partnership or project specific funding for the project.

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 TNF-alpha and IL-beta, and the COX-2 enzyme, which are implicated in pain and inflammation. Unlike most available non-steroidal anti-inflammatory agents (NSAIDS), pre-clinical studies suggest that IP 751 is less likely to produce gastrointestinal ulceration. 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.

Development Program. Pre-clinical development of IP 751 has demonstrated that it is active in multiple pre-clinical models of pain and inflammation. An IND for IP 751 has been filed with the FDA, and 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 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 Phase I and Phase II clinical trials are currently being planned for IP 751.

PRO 2000

General. PRO 2000 is under development as a topical 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 4.7 million new adult HIV infections occurred worldwide in 2000 with the majority of the infections arising from heterosexual intercourse. Other sexually-transmitted diseases (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 United States 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

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HIV, herpes simplex virus, chlamydia and the bacteria that causes gonorrhea. In government-sponsored tests, vaginally applied PRO 2000 was shown to be efficacious in a mouse model for genital herpes infection 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 United States and Europe. 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 United States 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 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 for 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 Africa funded by the European Commission. This trial is assessing the safety of PRO 2000 in approximately 100 sexually active female volunteers. An NIH-sponsored Phase II clinical trial that may extend to a Phase III clinical trial to determine the safety and efficacy of PRO 2000 in blocking male to female HIV transmission is planned to begin in 2004 in Africa and India. The study is expected to involve approximately 10,000 women who have not been infected with HIV but who are at risk for acquiring HIV by virtue of living in countries where the risk of such infection is high.

An international collaboration of research groups in the United Kingdom and Africa was awarded a grant of approximately $22.7 million from the United Kingdom s DFID in February 2002 to test the safety and efficacy of vaginal microbicides, including PRO 2000. The Clinical Trials Unit of the Medical Research Council and Imperial College in London will coordinate the program, which will involve researchers in South Africa, Uganda, Tanzania, Cameroon and Zambia. The DFID grant will support a broad, five-year program that will include a multi-national, randomized, double-blind, placebo-controlled Phase III clinical trial of candidate microbicides.

Aminocandin

General. Aminocandin is a member of a new class of anti-fungal compounds, known as echinocandins, in development for the treatment of a broad spectrum of systemic, invasive fungal infections. Echinocandins 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.

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

The echinocandins function by inhibiting a key component of the cell wall of fungi, and lack cross-resistance with older antifungal agents. Cancidas® (caspofungin, Merck & Co.) is available in the United States 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 filed an NDA for anidulafungin in 2003 based on clinical data in esophageal candidiasis, invasive candidemia/candidiasis and aspergillosis.

Aminocandin has shown in vitro and in vivo activity against a number of candida and aspergillus fungal species. According to reports from Datamonitor, Inc., an industry market research firm, the worldwide market for anti-fungal agents is currently valued in excess of $4 billion, of which approximately $2.5 billion relates to systemic, fungal infections.

Development Program. We expect to initiate Phase I clinical testing of the intravenous formulation of aminocandin in early 2004. We believe that aminocandin also has 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 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

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

In March 2003, we signed an exclusive agreement with Shire under which Shire will develop extended release formulations of trospium enabling trospium 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 trospium. We will be responsible for all development costs and the commercialization of extended release formulations of trospium under this agreement.

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

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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 royalty 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. We are pursuing new development and commercialization partnerships for pagoclone.

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. Our license includes patent and know-how rights in the United States and know-how rights in Canada, and is for a period co-extensive with Ferrer s license from Massachusetts Institute of Technology (MIT). The Ferrer agreement provides that Ferrer may terminate the agreement under certain circumstances, including our insolvency or bankruptcy, in the event more than 50% of our ownership is transferred to a non-affiliated third party or in the event FDA approval of citicoline is not obtained by January 31, 2002. The Ferrer agreement provides for such date to be extended for up to two years if we provide information to Ferrer which tends to establish that we have carried out the steps for obtaining such approval and if such approval has not been obtained for reasons beyond our control. We have been providing such information to Ferrer, and the Ferrer agreement is currently extended to January 31, 2004 and may be extended further, conditional upon approval by Ferrer. The Ferrer agreement requires us to use diligent efforts to obtain regulatory approval.

In June 1998, we licensed to Ferrer worldwide rights, except in the United States and Canada, to our patent relating to the use of citicoline in the protection of brain tissue from cerebral infarction following ischemic stroke. In exchange, we will be entitled to royalties from Ferrer on certain exports to, and sales of, the solid oral form of citicoline in certain countries upon its approval in each country.

In December 1999, we entered into an agreement under which we licensed to Takeda exclusive rights to commercialize citicoline in the United States and Canada. Under the Takeda agreement, we received $13,000,000 in licensing and other payments, and were entitled to receive additional payments contingent upon the achievement of regulatory milestones in the United States and Canada, as well as royalties on net sales. In December 2000, Takeda notified us of its decision not to participate in the further development of citicoline, thereby terminating the Takeda agreement. Consequently, we have reacquired all rights to this compound.

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 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. The effect of these transactions was to enable us to license rights to IP 751 directly from the owner of these rights.

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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.

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.

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 and is marketing the drug 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 United States 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 United States 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 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 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 marketing capabilities, we would require substantial additional funds.

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Trospium. We are responsible for all clinical development, regulatory activities and costs related to trospium in the United States, as well as the commercialization and marketing of trospium in the United States either independently or through marketing partners. We have entered into an agreement with Madaus under which we anticipate that Madaus will manufacture the product for commercial use, provided that it can deliver acceptable product to satisfy the U.S. regulatory and market requirements. Although Madaus manufactures the product for sale in Europe, it has not yet been inspected for compliance with cGMP requirements. We are working with Madaus to prepare for an FDA inspection of their German manufacturing plant in which the FDA will assess whether Madaus manufacturing facility complies with cGMP, as it must if it is to manufacture the product for sale in the United States. Failure to meet cGMP requirements in a timely manner could cause a material delay in FDA approval, if any, and commercialization of trospium. While we may seek a second source of supply for trospium if Madaus is unable to meet all regulatory requirements or provide the necessary quantities of trospium in a timely manner, this could also cause a material delay in FDA approval, if any, and commercialization of trospium.

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

Citicoline. We will be dependent upon third party suppliers of citicoline bulk compound, finished product and packaging for manufacturing and would be dependent on third parties for the marketing and distribution of citicoline. Supplies of citicoline finished product used for clinical purposes have been produced on a contract basis by third party manufacturers. Our agreement with Ferrer requires the purchase from Ferrer of citicoline bulk compound for commercial purposes. If such conditions permit the purchase of bulk compound from a third party, we entered into an agreement with a manufacturer to supply citicoline bulk compound for commercial purposes.

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.

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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.

Trospium. Current therapy for overactive bladder includes anticholinergics, such as Detrol and Detrol LA (tolterodine) by Pfizer, Ditropan and Ditropan XL (oxybutynin) by Johnson & Johnson, Inc. and Oxytrol (oxybutynin transdermal patch) by Watson Pharmaceuticals. We are aware of other companies evaluating specific antimuscaranics and antispasmodics in pre-clinical and clinical development for overactive bladder, including Vesicare® (solifenacin) by Yamanouchi Pharma America and Enablex® (darifenacin) by Novartis AG. Certain products currently on the market for the treatment of overactive bladder are available in once-a-day formulations unlike the twice-a-day formulation of trospium which is the subject of our pending NDA.

Pagoclone. 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, and selective serotonin reuptake inhibitors such as Paxil® (paroxetine, Glaxo SmithKline), Zoloft® (sertraline, Pfizer), Prozac® (fluoxetine, Eli Lilly), and Effexor® (venlafaxine, Wyeth). 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 effectsand 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.

Citicoline. Activase® (alteplase), marketed by Genentech, Inc., is the first and only therapy to be approved for the management of stroke. A genetically engineered version of naturally occurring tissue plasminogen activator (t-PA), Activase is indicated for the treatment of acute ischemic stroke within three hours of symptom onset. Although t-PA improves clinical outcome, intracranial hemorrhage, a serious side effect, occurs in six percent of the t-PA-treated patients. Several other companies have later stage programs in stroke treatment including Ancrod (*Arvin*, BASF/Abbott/Knoll), NXY-059 (*Cerovive*, AstraZeneca), Abciximab (*ReoPro*, Johnson & Johnson), Pro-urokinase (*PROACT*, Abbott), and BAY-x-3702 (*Repinotan*, Bayer). However, to date, none of these has shown unequivocal safety and efficacy in clinical trials. Further, each of these competing compounds under development exhibits a relatively short therapeutic window and potentially dose-limiting toxicity. A number of additional compounds have produced unsatisfactory results in clinical trials, and have been terminated or are likely to have their development discontinued. Based on existing clinical data on citicoline, we believe that citicoline may be an attractive post-stroke therapy, particularly in patients with moderate to severe strokes, due to its potentially broader, 24-hour post-stroke therapeutic window and that it may be used as combination therapy with other compounds in development or on the market.

IP 751. A variety of treatments are currently prescribed for pain and inflammatory disorders, including opioids, NSAIDs (non-steroidal anti-inflammatories) / COX-II 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, Vioxx® (rofecoxib), marketed by Merck, 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. Unlike most available NSAIDS, pre-clinical studies suggest that IP 751 is less likely to produce gastrointestinal ulceration.

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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. These drugs or formulations include, Merck s Cancidas (caspofungin), Fujisawa s micafungin, and Vicuron Pharmaceuticals anidulafungin.

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 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.

Trospium. There are no existing U.S. composition of matter patents covering the use of orally-administered trospium to treat overactive bladder. We intend to rely on the provisions of the Waxman-Hatch Act to obtain a period of market exclusivity in the United States if the FDA approves trospium in the United States for the intended indication, although there is no assurance that market exclusivity will be granted. The Waxman-Hatch Act establishes a period of time from the date of FDA approval of certain new drug applications during which we would have market exclusivity. The applicable period is five years in the case of drugs containing an active ingredient not previously approved. We intend to seek more extensive market exclusivity protection for trospium through the development of a once-a-day formulation of the drug. If successful in achieving the intended performance specifications for the once-a-day formulations, we will seek patent protection with respect to such formulations, which if granted, is likely to include a term of up to twenty years, although 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.

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Pagoclone. We licensed from Aventis rights under United States 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.

Citicoline. The compound citicoline is not covered by a composition of matter patent. Pursuant to the Ferrer agreement, we licensed from Ferrer a U.S. patent covering the administration of citicoline to treat patients afflicted with conditions associated with the inadequate release of brain acetylcholine, which has expired. As described in the licensed patent, the inadequate release of acetylcholine may be associated with several disorders, including the behavioral and neurological syndromes seen after brain traumas and peripheral neuromuscular disorders and post-stroke rehabilitation. Although the claim of the licensed patent is broadly directed to the treatment of inadequate release of brain acetylcholine, there can be no assurance this patent will afford protection against competitors of citicoline to treat ischemic stroke.

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, except in the United States 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. We are also pursuing foreign counterparts of this patent in many countries. In addition to any proprietary rights provided by these patents, we intend to rely on the provisions of the Waxman-Hatch Act to obtain a period of marketing exclusivity in the United States if the FDA approves citicoline for marketing in the United States, although there is no assurance market exclusivity will be granted.

IP 751. In June 2002, we licensed exclusive, worldwide rights to IP 751 from Manhattan, in exchange for an up-front licensing payment, development milestones and royalty payments. 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 exchange for up-front, milestone and royalty payments. 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 and whereby our financial obligations to Manhattan related to the future development of IP 751 were terminated, in exchange for a combination of cash and equity payments from us to Manhattan. The Manhattan patent portfolio includes patents and patent applications covering the composition of matter, formulations and uses of IP 751. The Manhattan patent portfolio also includes patent coverage for certain cannabinoid analogs and their uses. Foreign counterpart patent applications to cannabinoid drugs and their analogs were filed recently on behalf of Manhattan. We are responsible for the clinical development, regulatory review activities and commercialization of this compound.

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 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 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.

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GOVERNMENT REGULATION

Therapeutic. Prior to commercialization, our products will require, prior to commercialization, 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 United States, 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 United States 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

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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.

We believe that citicoline and pagoclone may be entitled to patent extension and that trospium and citicoline may be entitled to five years of market exclusivity 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 United States, 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, 2003, we had 27 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 $448,000. We believe such space is adequate for our current needs.

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

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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.

Insurance Litigation. In August 2001, Columbia Casualty Company (CNA), filed an action in the U.S. District Court for the District of Columbia against us. The lawsuit was based upon a claim for breach of contract and declaratory judgment, seeking damages against us in excess of $20,000,000, the amount that CNA had paid to us under its insurance policy. In February 2003, CNA agreed to dismiss, with prejudice, its lawsuit against us and we in turn agreed to dismiss, with prejudice, our claims against CNA, without costs or fees to either side.

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

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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	50	President, Chief Executive Officer and Chairman
Mark S. Butler	57	Executive Vice President, Chief Administrative Officer and General Counsel
Michael W. Rogers	43	Executive Vice President, Chief Financial Officer and Treasurer
Bobby W. Sandage, Jr., Ph.D	50	Executive Vice President, Research and Development and Chief Scientific 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.

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.

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.

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

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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.

RISK FACTORS

The following factors should be reviewed carefully, in conjunction with the other information 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 Company 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 trospium.

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

Regulatory risks

On April 28, 2003, we submitted an NDA for trospium with the FDA and on June 27, 2003 the FDA accepted the NDA for filing. We would be materially adversely affected if we are unable to obtain FDA approval for trospium or if the FDA should require additional testing prior to FDA approval. In addition, the FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of trospium. In addition, although trospium 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.

Risks related to the commercialization of trospium

Even if we receive FDA approval for trospium, we do not have the necessary sales and marketing capability or financial resources to market trospium. Although we have been in discussions regarding a variety of strategic transactions and collaborative arrangements, we would be materially adversely affected if we were unable to find a corporate partner on acceptable terms or at all. We will be highly dependent on any strategic or collaborative partner for the commercialization of trospium and we, in combination or collaboration with any partner, may not be successful in commercializing trospium. We would be materially adversely affected if trospium did not achieve or maintain market acceptance. We will also be dependent on Madaus, the licensor of trospium to us and the current manufacturer of trospium, to manufacture trospium for us. We are working with Madaus to achieve compliance with FDA requirements for manufacturers of drugs sold in the United States. If Madaus were unable to achieve or maintain compliance, we would need to seek alternative sources of supply, which could delay the commercialization or create disruptions in the supply of trospium. Our pending NDA relates to an immediate release, twice-a-day formulation of trospium. We have entered into an agreement with Shire to develop extended release, once-a-day formulations of trospium. 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.

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Risks related to competition in the overactive bladder market

Competition in the overactive bladder market is intense and expected to increase. Trospium may not compete successfully with current drug therapies for overactive bladder or with new drugs which may reach the market in the future. Trospium will compete with drugs from large, multinational companies who have substantially greater marketing and financial resources and experience than us. Trospium 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. No assurance can be given that trospium, if approved by the FDA, will be able to compete successfully against existing or new products. In addition, our ability to compete with existing or new products will also be affected by labeling that may be approved by the FDA.

Lack of Patent Protection

Our license for trospium does not include any patents that we expect to use in commercializing the product for overactive bladder. Assuming FDA approval for trospium is obtained, our ability to successfully commercialize trospium in the United States will depend on the availability of market exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, which is 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. If we receive favorable treatment under the Waxman-Hatch Act for trospium, we may obtain market exclusivity for a period of five years from the date of FDA approval. The marketing of trospium could be materially adversely affected if market exclusivity is not available to us or if the period of market exclusivity is shortened. We expect to seek patent protection for an extended release, once-a-day formulation of trospium. If we were unable to obtain a patent on such formulation we would have to rely solely on market exclusivity for the twice-a-day formulation.

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

In addition to trospium, we currently have five 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

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earlier trials. For example, while there have been three Phase II clinical trials of pagoclone that demonstrated statistically significant efficacy, two in panic disorder and one in GAD, other trials have failed to demonstrate statistically significant efficacy, prompting Pfizer to elect not to pursue further development of the compound and to return to us exclusive, worldwide development and commercialization rights to pagoclone.

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

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

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

We currently contract with third parties for all of our manufacturing needs and do not manufacture any of our own products or product candidates. 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 cGMP. 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 will need additional funds in the future.

Our existing cash resources will be insufficient to commercialize trospium or any of our other product candidates on our own. In addition, we continue to expend substantial funds for product development activities, research and development, pre-clinical and clinical testing, operating expenses, regulatory approval, licensing and other strategic relationships, manufacturing and marketing. These amounts have increased since our filing of the NDA for trospium in April 2003. In fiscal 2003, net cash used in operating activities was $26,495,000, including approximately $9,416,000 used in the fourth quarter of fiscal 2003. We expect to continue to use substantial cash for operating activities in fiscal 2004 as we continue to fund our development activities, as well as premarketing

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

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

- our ability to receive FDA approval for trospium and successfully commercialize trospium and the nature of any strategic combination, collaboration or funding source regarding the commercialization of trospium;
- the progress of research and development programs;
- costs and results of pre-clinical and clinical testing;
- 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.

Other than in fiscal 2000, we have incurred substantial net losses over the past five fiscal years including net losses of approximately $37,800,000, $1,500,000, $17,600,000 and $31,800,000 for fiscal years 1999, 2001, 2002 and 2003 respectively. Through September 30, 2003, we had accumulated net losses since inception of approximately $301,000,000.

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

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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, uninsured or insufficiently insured Redux-related claims or Redux-related claims which are not covered by the AHP indemnity and release agreement may arise. Any 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 trospium, a compound under development for treatment of overactive bladder, does not include any patents that we expect to use in commercializing the product for overactive bladder.

Our licensed U.S. patent covering the administration of citicoline to treat patients afflicted with conditions associated with the inadequate release of brain acetylcholine has expired. This patent, along with the additional patents issued to us relating to citicoline, may not afford protection against competitors of citicoline to treat ischemic stroke.

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.

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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.

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 agreement with Madaus, under which we license trospium, or our agreement with Aventis, under which we license pagoclone, could substantially reduce the likelihood of successful commercialization of our product candidates which would materially harm us. The agreements with Madaus or Aventis may be terminated by either of them if we are in material breach of our agreements with them or if we become insolvent or file for bankruptcy protection.

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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, Mark S. Butler, our chief administrative officer and general counsel, Michael W. Rogers, our chief financial officer and Bobby W. Sandage, Jr., our chief scientific officer. Our business could be adversely affected by the loss of any of these individuals. In addition, we rely on the assistance of independent consultants to design and supervise clinical trials and prepare FDA submissions.

Competition for qualified employees 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. 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 $20,000,000. This insurance covers our clinical trials and our currently marketed product, Sarafem. We will need to obtain additional coverage for products that may be marketed in the future, including trospium. 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 and licensees and may be required to indemnify additional licensors or licensees 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.

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

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

The price for our securities is volatile.

The market 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:

- 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: $6.25 and $1.12 for fiscal 1999, $8.75 and $1.34 for fiscal 2000, $10.00 and $1.16 for fiscal 2001, $12.83 and $0.85 for fiscal 2002, and $6.90 and $1.32 for fiscal 2003 through September 30, 2003. 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, 2003, we had 47,175,661 shares of common stock 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

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Plan, 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan and 2000 Stock Option 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, 2003, we had reserved the following shares of our common stock for issuance:

- 10,817,309 shares issuable upon conversion of the $72,000,000 Convertible Senior Notes issued in July 2003, which are due in July 2008;
- 10,655,270 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;
- 622,2222 shares upon conversion of preferred stock owned by Wyeth, subject to anti-dilution provisions; and
- 512,490 shares reserved for grant and issuance under our stock option plans, stock purchase plan and equity incentive plan.

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 the convertible debt offering may harm our financial condition and results of operations.

At September 30, 2003, we had $72,000,000 of outstanding debt reflected in our balance sheet. We may incur additional indebtedness in the future and the convertible notes we have issued 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 we have issued;
- to sell selected assets; or
- to reduce or delay planned expenditures on clinical trials, and development and commercialization activities.

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

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PART II

ITEM 5. ***Market for Registrant s Common Equity and Related Stockholder Matters***

Price Range of Securities

Our Common Stock trades on the Nasdaq National Market under the symbol IDEV. On April 2, 2002, our shareholders approved the corporate name change from Interneuron Pharmaceuticals, Inc. to Indevus Pharmaceuticals, Inc. The Company began trading on the Nasdaq Stock Market under its new symbol, IDEV, on April 3, 2002. 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, 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
Fiscal Year Ended September 30, 2002		
July 1 through September 30, 2002	$ 1.95	$ 0.95
April 1 through June 30, 2002	8.99	0.85
January 1 through March 31, 2002	12.83	7.57
October 1 through December 31, 2001	12.32	4.55

Approximate Number of Equity Security Holders

The number of holders of record of our Common Stock as of September 30, 2003 was approximately 559.

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, 2003:

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	10,500,270	$ 4.17	499,408
Equity compensation plans or arrangements not approved by security holders	155,000(1)	$ 5.51	13,082(2)
Total	10,655,270	$ 4.19	512,490

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(1) Includes (i) an option to purchase 50,000 shares of Common Stock granted to a director and (ii) warrants to purchase 105,000 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).

Recent Sales of Unregistered Securities

During the quarter ended September 30, 2003, we issued the following securities without registration under the Securities Act of 1933, as amended (the Securities Act):

On July 16, 2003, we issued $72,000,000 principal amount of 6.25% Convertible Senior Notes due 2008 (Notes) in a private placement to Lehman Brothers Inc. and Wachovia Capital Markets, LLC (collectively, the Initial Purchasers), which included the exercise by the Initial Purchasers of an option to purchase an additional $12,000,000 aggregate principal amount of the Notes. The Initial Purchasers resold the Notes to certain qualified institutional buyers pursuant to Rule 144A under the Securities Act. We received proceeds of approximately $68,700,000 from the sale of the Notes, net of the discounts and commissions paid to the Initial Purchasers and estimated offering expenses payable by us. The Notes mature on July 15, 2008 and are redeemable at our option on or after July 20, 2006 if the price of our common stock exceeds specified levels. In addition, the holders of the Notes may require us to repurchase the Notes if we undergo a change in control.

The offer and sale of the Notes to the Initial Purchasers was exempt from registration with the Securities and Exchange Commission pursuant to Section 4(2) of the Securities Act because of the nature of the purchasers and the circumstances of the offering. The Notes were resold by the Initial Purchasers upon reliance on Rule 144A. Each Initial Purchaser made representations to us that it was an accredited investor, as defined in Rule 501 under the Securities Act, and as to its compliance with Rule 144A. In addition, appropriate legends were affixed to the Notes issued in the transaction described above.

The Notes are convertible at any time through maturity into shares of our Common Stock at the rate of 150.2404 shares per $1,000 principal amount of the Notes, subject to adjustment, for an aggregate of 10,817,309 shares (the Shares). The Notes and the Shares are subject to transfer restrictions. We have registered with the Securities and Exchange Commission the Notes and Shares for resale. We will not receive any proceeds from the resale by the holders of the Notes and Shares pursuant to this Registration Statement.

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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,				
	2003	2002	2001	2000	1999
	(Amounts in thousands except per share)				
Statement of Operations Data:					
Revenues:					
Royalties	$ 4,316	$ 3,439	$ 1,952	$	$
Contract and license fees	929	968	13,281	27,754	1,599
Total revenues	5,245	4,407	15,233	27,754	1,599
Cost of revenues	1,225	1,038	698	3,024	200
Research and development	24,314	13,309	5,301	3,158	35,510
Marketing, general and administrative	11,105	8,090	7,238	6,823	11,030
Product withdrawal (1)			(5,582)	(1,757)	
Purchase of in-process research and development					2,421
Income (loss) from operations	(31,399)	(18,030)	7,655	16,506	(47,562)
Investment income	664	987	1,811	1,868	2,407
Interest expense	1,077				218
Income (loss) from continuing operations	(31,812)	(17,586)	8,509	19,956	(38,578)
Cumulative effect of change in accounting principle (2)			(10,000)		
Net income (loss)	(31,812)	$ (17,586)	$ (1,491)	$ 19,956	$ (37,762)
Income (loss) per common share from continuing operations-diluted	$ (0.68)	$ (0.38)	$ 0.19	$ 0.46	$ (0.92)
Loss per common share from cumulative effect of change in accounting principle-diluted			$ (0.22)		
Net income (loss) per common share-diluted	$ (0.68)	$ (0.38)	$ (0.03)	$ 0.46	$ (0.90)
Weighted average common shares-diluted	46,930	45,896	45,628	43,838	41,898
Proforma amounts assuming the 2001 accounting change relating to revenue recognition is applied retroactively (2):			$ 8,509	$ 9,956	
Net income per common share:					
Basic			$ 0.20	$ 0.23	
Diluted			$ 0.19	$ 0.23	

	September 30,				
	2003	2002	2001	2000	1999
	(Amounts in thousands)				
Balance Sheet Data:					
Working capital	$ 73,866	$ 34,876	$ 23,970	$ 26,325	$ 4,083
Total assets	90,071	43,931	34,917	46,826	26,638
Convertible notes, long-term	72,000				

Total liabilities	83,817	6,700	6,160	18,728	20,327
Accumulated deficit	(300,691)	(268,879)	(251,293)	(249,802)	(269,758)
Total stockholders equity	6,241	37,218	28,660	27,766	6,122

(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. See Note C of Notes to the Consolidated Financial Statements.

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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 report and audited consolidated financial statements and notes thereto included in our Annual Report on this Form 10-K.

Description of the Company

Indevus is 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 have six compounds in development: trospium for overactive bladder, pagoclone for panic and generalized anxiety disorders, citicoline for ischemic stroke, 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.

Significant Product Developments in Fiscal 2003

In December 2002, we announced the results of a Phase II clinical trial in Germany, subsequently published in the Journal of the American Medical Association in September 2003, showing that treatment with IP 751 significantly reduced neuropathic pain, with no evidence of significant adverse events or psychoactive properties. We plan to initiate additional clinical trials with IP 751 in 2004. In August 2003, we restructured our licensing agreement arrangement for IP 751 by renegotiating our licensing agreement with Manhattan whereby all remaining rights to IP 751 owned by Manhattan were assigned to us and whereby our financial obligations to Manhattan related to the future development of IP 751 were terminated, in exchange for a combination of cash and equity payments from us to Manhattan. At that time, 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. We took a charge to operations of approximately $1,060,000 for these transactions.

In December 2002, we entered into an amended licensing agreement with Lilly related to Sarafem, a currently marketed treatment for premenstrual dysphoric disorder, providing for a $777,000 initial payment to us upon the signing of the agreement and royalty payments from Lilly to us based on net sales of Sarafem in the U.S. from October 1, 2002 until the expiration of our patent on Sarafem. In January 2003, Galen Holdings PLC announced the completion of its acquisition of the U.S. sales and marketing rights to Sarafem from Lilly. Pursuant to our agreement with Lilly, the remaining milestone payments of $2,184,000 were accelerated and received by us from Lilly in February 2003 and reflected as royalty revenue. MIT, our licensor of patent rights to Sarafem, is entitled to a portion of payments made to us by Lilly. We initially licensed to Lilly exclusive, worldwide rights to a patent covering the use of fluoxetine to treat conditions and symptoms associated with premenstrual syndrome in June 1997.

In April 2003, we submitted an NDA to the FDA for trospium. During fiscal 2003, we initiated a broad range of pre-commercialization activities for trospium. We are conducting additional clinical studies with trospium, and we signed an exclusive agreement with Shire Laboratories, Inc. in March 2003 to develop extended release formulations of trospium. We have begun pharmacokinetic and safety studies with several once-a-day formulations, and we expect to begin advanced clinical trials with one of these formulations in 2004.

In April 2003, we licensed exclusive, worldwide rights from Aventis to aminocandin, a member of a new class of drugs known as echinocandins for the treatment of systemic fungal infections. In exchange for these rights and for Aventis inventory of aminocandin, we made an up-front, licensing payment to Aventis of $1,500,000 and are responsible for milestone payments and royalties on future sales to Aventis. We are also responsible for all development and commercialization activities for aminocandin, and we plan to initiate clinical testing with the current intravenous formulation of aminocandin in 2004. In addition, we plan to pursue the development of an oral formulation of this drug.

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Critical Accounting Policies and 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 constantly 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.

Critical Accounting Policies

We believe a critical accounting policy is a policy that is both important to the portrayal of our financial conditions and results, and requires management s most difficult, subjective or complex judgments and estimates. While our significant accounting policies are more fully described in the notes to our audited consolidated financial statements included in this Form 10-K for the fiscal year ended September 30, 2003, we consider our revenue recognition policy critical and therefore we state it below.

Revenue Recognition

Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize our licensed technologies and is recognized when the amount of and basis for such royalty payments are reported to us in accurate and appropriate form and in accordance with the related license agreement.

Contract and license fee revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of our 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 contract and license fee revenue when we have a contractual right to receive such payment provided a contractual arrangement exists, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement.

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

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

Significant Judgments and Estimates

Insurance Claim Receivable

As of September 30, 2003, 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

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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 have 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, 2003 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.

Results of Operations

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 trospium, 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. Royalty revenue, which comprises 82% of total revenue, relates to royalties received from Lilly for sales of Sarafem and increased $877,000, or 26%, to $4,316,000 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 $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, 2001which resulted from sales of Sarafem in a higher royalty payment bracket. Contract and license fee revenue of $929,000 in fiscal 2003 consisted primarily of $777,000 from an initial payment received from Lilly related to the renegotiated agreement for Sarafem. The balance of contract and license fee revenue relates to 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 $1,225,000 and $1,038,000 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. Additionally, cost of revenues includes the development costs related to the PRO 2000 development agreements.

Research and development expenses increased $11,005,000, or 83%, to $24,314,000 in fiscal 2003 from $13,309,000 in fiscal 2002. This increase is primarily related to trospium and includes increased clinical costs, including costs for the ongoing clinical trial, continuing development of extended release formulations of

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trospium, 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: trospium $17,977,000, pagoclone $1,523,000, citicoline $128,000, IP 751 $1,400,000, aminocandin $1,545,000, and PRO 2000 $1,208,000. We also incurred research and development expenses for fiscal 2003 of $533,000 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 trospium, 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 trospium, we have increased our rate of expenditure for trospium 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. As a result of our July 2003 issuance of $72,000,000 of Notes and depending upon the level of spending in fiscal 2004, we expect to achieve increased investment income in fiscal 2004.

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.

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.

Fiscal Year Ended September 30, 2002 Compared to Fiscal Year Ended September 30, 2001

Our net loss increased $16,095,000 to $(17,586,000), or $(0.38) per share, basic, in fiscal 2002 from $(1,491,000), or $(0.03) per share, basic, in fiscal 2001. This increased net loss is primarily the result of a decrease in total revenues of $10,826,000, reflecting primarily the absence of the Takeda license revenue, increased research and development expense related to trospium, primarily for a Phase III trial which ended in September 2003, the $5,582,000 credit in fiscal 2001 in product withdrawal resulting from the AHP Indemnity and Release Agreement, noncash compensation expense related to a stock option grant and modifications of stock option grants to a director and executive officers of the Company, offset by the $10,000,000 charge recognized in fiscal 2001 for the cumulative effect of a change in accounting principle resulting from our adoption of SAB 101 (See Notes C and M of Notes to Consolidated Financial Statements).

Royalty revenue of $3,439,000 and $1,952,000 in fiscal 2002 and fiscal 2001, respectively, pertained primarily to royalties from Lilly for sales of Sarafem. Contract and license fee revenue of $968,000 in fiscal 2002 consisted of a milestone payment from Amgen Inc. (Amgen) related to Amgen s continuation of development of leptin receptor technology, funding of PRO 2000 development from CONRAD and FHI and other revenue. Contract and license fee revenue of $13,281,000 in fiscal 2001 consisted primarily of $13,000,000 related to the Takeda Agreement, which was recognized when Takeda s rights under an option expired on September 30, 2001. Of the amount received from Takeda, $10,000,000

was recognized as revenue in fiscal 2000, deferred upon our

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adoption of SAB 101 and reflected as a $10,000,000 cumulative effect of a change in accounting principle in our fiscal 2001 results. This $10,000,000 was recognized as revenue in fiscal 2001 upon expiration of Takeda s rights under the agreement.

Cost of revenues of $1,038,000 and $698,000 in fiscal 2002 and 2001, respectively, consisted primarily of amounts due or paid to MIT for its portion of the Sarafem royalty revenue and costs pertaining to the PRO 2000 development agreements.

Research and development expense increased $8,008,000, or 151%, to $13,309,000 in fiscal 2002 from $5,301,000 in fiscal 2001. This increase is primarily due to increased costs in fiscal 2002 from our development of trospium, including our 523-person Phase III clinical trial for trospium. Total research and development expenses for fiscal 2002 substantially relate to our major compounds being developed as follows: trospium $10,625,000, pagoclone $323,000, citicoline $229,000, IP 751 $535,000 and PRO 2000 $884,000. We also incurred research and development expenses for fiscal 2002 of $1,477,000 related to dersalazine and other compounds and initiatives.

General and administrative expense increased $852,000, or 12%, to $8,090,000 in fiscal 2002 from $7,238,000 in fiscal 2001. This increase was primarily due to noncash compensation charges from modifications in fiscal 2002 of stock option grants to a director and executive officers of the Company, increased legal costs and pre-marketing costs related trospium partially offset by the absence in fiscal 2002 of costs related to our lawsuit against Wyeth and other decreased compensation-related costs.

The product withdrawal net credit of $5,582,000 for the year ended September 30, 2001 consisted of credits of approximately $7,900,000 for Redux-related accruals reversed in fiscal 2001, as well as for insurance reimbursements of other Redux-related expenses, partially offset by a reserve for the insurance claim on Reliance and a noncash charge for the fair value of stock options granted to attorneys involved in the Wyeth Litigation. (See Note I of Notes to Consolidated Financial Statements and Item 3. Legal Proceedings.)

Investment income decreased $824,000, or 45%, to $987,000 in fiscal 2002 from $1,811,000 in fiscal 2001 resulting from substantially reduced market interest rates despite higher average invested cash balances.

Impairment of equity securities of $487,000 and $810,000 in fiscal 2002 and 2001, respectively, reflects write downs of our investment in 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, 2003, we had consolidated cash, cash equivalents and marketable securities of $84,087,000 compared to $41,543,000 at September 30, 2002. This increase of $42,544,000 resulted primarily from approximately $68,700,000 of net proceeds from the issuance of the Notes offset by $26,495,000 of cash used by operating activities.

In July 2003, we received net proceeds of approximately $68,700,000 from the issuance of $72,000,000 of Notes to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The Notes are convertible at anytime prior to the July 15, 2008 maturity date into our Common Stock at an initial conversion price of $6.656 per share, subject to adjustment for certain events; we have reserved approximately 10,800,000 shares of Common Stock for issuance pursuant to such a conversion and have registered the Notes and Common Stock with the SEC for resale. Additionally, all or a portion of the Notes are redeemable by us for cash at any time after July 20, 2006 provided our 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 us at the option of the Note holders if a change

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in control occurs. If the Notes are not previously converted into Common Stock, interest of $2,250,000 is payable semiannually in arrears on January 15 and July 15 each year through the maturity date, at which time the principle becomes due and payable.

We are continuing to invest substantial amounts in the ongoing development and pre-commercialization activities related to trospium. We do not currently have sufficient funds to commercialize trospium and are currently in discussions with prospective partners for the commercialization of trospium. We believe we have sufficient cash for currently planned expenditures for at least the next twelve months.

We will require additional funds or corporate collaborations for the development and commercialization of our other 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 be no assurance that we will be able to obtain additional financing to satisfy future cash requirements on acceptable terms, or at all. If additional funds are not obtained, we will 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 trospium, including clinical trials to explore further certain attributes of trospium and the development of extended release formulations. 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 under which we anticipate Madaus will manufacture trospium for commercial use provided that it can deliver acceptable product to satisfy U.S. regulatory and market requirements. Although Madaus manufactures the product for sale in Europe, it has not yet been inspected for compliance with cGMP requirements. We are working with Madaus to prepare for an FDA inspection of their German manufacturing plant. In order to manufacture the product for sale in the United States, Madaus manufacturing facility must comply with cGMP. Failure to meet cGMP requirements in a timely manner could cause a material delay in FDA approval, if any, and commercialization of trospium. While we may seek a second source for trospium if Madaus is unable to meet all regulatory requirements or provide the necessary quantities of trospium in a timely manner, this could also cause a material delay in FDA approval, if any, and commercialization of trospium.

Total research and development expenses incurred by us through September 30, 2003 on the major compounds currently being developed, including allocation of corporate general and administrative expenses, are approximately as follows: $48,600,000 for trospium, $17,800,000 for pagoclone, $82,400,000 for citicoline, $9,100,000 for PRO 2000, $1,700,000 for aminocandin and $2,000,000 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

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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, 2003 through the preparation of an NDA for our major compounds currently being developed as follows: approximately $15,000,000 for PRO 2000, approximately $45,000,000 for IP 751, approximately $30,000,000 for aminocandin, and approximately $40,000,000 for pagoclone. In addition, we are continuing to expend substantial funds for trospium. We do not plan to develop citicoline further without a corporate partner or project-specific funding. 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 we do not intend to complete development of citicoline unless a partnership for such development is established. 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 used in operating activities during fiscal 2003 of $26,495,000 consisted primarily of the net loss of $31,812,000 offset by an increase in accrued expenses and other liabilities of $3,532,000 and accounts payable of $1,608,000. Accrued expenses and other liabilities increased $3,532,000 in fiscal 2003 primarily due to increased trospium development and pre-marketing activities.

Cash used by investing activities during fiscal 2003 of $4,878,000 consisted primarily of $4,845,000 of net outflows from purchases of marketable securities.

Cash provided by financing activities of $69,113,000 consisted of approximately $68,700,000 of net proceeds from the issuance of the Notes and $414,000 from the issuance of Common Stock pursuant to our stock option and purchase plans.

Contractual Obligations and Off-Balance Sheet Arrangements

The following chart summarizes our contractual payment obligations as of September 30, 2003. The Notes and license fees are reflected as liabilities on our Balance Sheet as of September 30, 2003. Operating leases are accrued and paid on a monthly basis. Purchase obligations relate to research and development agreements and arrangements and trospium premarketing agreements and arrangements; portions of these amounts are reflected as accrued expenses on our Balance Sheet as of September 30, 2003.

	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)	565,000	1,129,000	312,000		2,006,000
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)	11,602,000	252,000			11,854,000
Total	$ 16,767,000	$ 10,581,000	$ 81,312,000	$	$ 108,660,000

(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 trospium.

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Pursuant to certain of our in-licensing arrangements, we will owe payments to its 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 $5,000,000 in fiscal 2004.

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

Other

Recent Accounting Pronouncement

In January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an interpretation of ARB No. 51 (FIN 46). This interpretation addresses the consolidation of certain variable interest entities (VIE s) for which a controlling financial interest exists, and may be applied prospectively with a cumulative effect adjustment of by restating previously issued financial statements with a cumulative effect adjustment as of the beginning of the first year restated. In October 2003, the FASB issued FASB Staff Position No. FIN 46-6, effective date of FASB Interpretation No. 46, Consolidation of Variable Interest Entities which deferred the effective date of FIN 46 for interest held in VIE s created before February 1, 2003 until the end of the first interim or annual period ending after December 15, 2003. The adoption of FIN 46 is not expected to have a material effect on the Company s financial position or results of operations.

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 $63. 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 $20. 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.

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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, 2003. 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.

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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 and Related Stockholder Matters.

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PART IV

ITEM 15. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(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) Reports on Form 8-K

The following reports on Form 8-K were filed during the three month period ended September 30, 2003.

1. On July 3, 2003, we filed a current report on Form 8-K reporting that on June 30, 2003, we announced that the U.S. Food and Drug Administration has accepted for review our New Drug Application for trospium for the treatment of overactive bladder.

2. On July 8, 2003, we filed a current report on Form 8-K reporting that on July 7, 2003, we issued a press release announcing that we intend to offer, subject to market and other conditions, approximately $50 million of convertible senior notes due 2008 through an offering to qualified institutional buyers.

3. On July 14, 2003, we filed a current report on Form 8-K reporting that on July 11, 2003, we issued a press release announcing the pricing of our offering of $60 million of convertible senior notes due 2008 to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

4. On July 25, 2003, we filed a current report on Form 8-K reporting that on July 16, 2003, we closed on our offering of convertible senior notes due 2008 to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

5. On August 12, 2003, we filed a current report on Form 8-K reporting that on August 12, 2003, we furnished to the SEC a press release announcing our third quarter fiscal 2003 results.

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(c) 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)

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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)

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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)

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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)
21	-	List of Subsidiaries (52)
23	-	Consent of PricewaterhouseCoopers LLP (52)
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 (52)
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 (52)
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 (52)
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 (52)

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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.

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(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) Filed with this report.

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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 22, 2003

INDEVUS PHARMACEUTICALS, INC.

By: /s/ GLENN L. COOPER

Glenn L. Cooper, M.D.

President, Chief Executive Officer and Chairman

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

Name	Title	Date
/s/ GLENN L. COOPER **Glenn L. Cooper, M.D.**	President, Chief Executive Officer and Chairman (Principal Executive Officer)	December 22, 2003
/s/ HARRY GRAY **Harry Gray**	Director	December 22, 2003
/s/ STEPHEN C. MCCLUSKI **Stephen C. McCluski**	Director	December 22, 2003
/s/ MALCOLM MORVILLE **Malcolm Morville**	Director	December 22, 2003
/s/ CHERYL P. MORLEY **Cheryl P. Morley**	Director	December 22, 2003
/s/ LEE J. SCHROEDER **Lee J. Schroeder**	Director	December 22, 2003
	Director	December , 2003

David B. Sharrock /s/ MICHAEL W. ROGERS **Michael W. Rogers**	Executive Vice President, Chief Financial Officer, and Treasurer (Principal Financial Officer)	December 22, 2003
Dale Ritter /s/ DALE RITTER	Senior Vice President, Finance, (Principal Accounting Officer)	December 22, 2003

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT AUDITORS

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 and of cash flows present fairly, in all material respects, the financial position of Indevus Pharmaceuticals, Inc. and its subsidiaries at September 30, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2003 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 auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of 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

November 18, 2003

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INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands except share data)

	September 30, 2003	September 30, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,717	$ 19,977
Marketable securities	26,370	20,516
Accounts receivable	155	550
Prepaids and other current assets	1,241	533
Total current assets	85,483	41,576
Marketable securities		1,050
Equity securities	134	31
Property and equipment, net	33	16
Insurance claim receivable	1,258	1,258
Prepaid debt issuance costs	3,163	
Total assets	$ 90,071	$ 43,931
LIABILITIES		
Current liabilities:		
Accounts payable	$ 1,958	$ 350
Accrued expenses	8,721	6,326
Accrued interest	938	
Deferred revenue		24
Total current liabilities	11,617	6,700
Convertible Notes	72,000	
License fees payable	200	
Minority interest	13	13
Commitments and contingencies (Notes G and I)		
STOCKHOLDERS EQUITY		
Convertible preferred stock, $.001 par value, 5,000,000 shares authorized:		
Series B, 239,425 shares issued and outstanding (liquidation preference at September 30, 2003 $3,026)	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference at September 30, 2003 $502)	500	500
Common stock, $.001 par value, 80,000,000 shares authorized; 47,175,661 and 46,875,885 shares issued and outstanding at September 30, 2003 and 2002, respectively	47	47
Additional paid-in capital	303,452	302,678
Accumulated deficit	(300,691)	(268,879)
Accumulated other comprehensive loss	(67)	(128)

Total stockholders equity	6,241	37,218
Total liabilities and stockholders equity	$ 90,071	$ 43,931

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

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INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands except per share data)

	For the years ended September 30,		
	2003	2002	2001
Revenues:			
Royalties	$ 4,316	$ 3,439	$ 1,952
Contract and license fees	929	968	13,281
Total revenues	5,245	4,407	15,233
Costs and expenses:			
Cost of revenues	1,225	1,038	698
Research and development	24,314	13,309	5,301
Marketing, general and administrative	11,105	8,090	7,238
Product withdrawal, net			(5,582)
Total costs and expenses	36,644	22,437	7,655
Income (loss) from operations	(31,399)	(18,030)	7,578
Investment income	664	987	1,811
Interest expense	(1,077)		
Impairment of equity securities		(487)	(810)
Loss on disposition of equity securities			(43)
Minority interest		(56)	(27)
Income (loss) before cumulative effect of change in accounting principle	(31,812)	(17,586)	8,509
Cumulative effect of change in accounting principle			(10,000)
Net loss	$ (31,812)	$ (17,586)	$ (1,491)
Income (loss) per common share:			
Basic:			
Income (loss) before cumulative effect of change in accounting principle	$ (0.68)	$ (0.38)	$ 0.20
Cumulative effect of change in accounting principle	$	$	(0.23)
Net loss	$ (0.68)	$ (0.38)	$ (0.03)
Diluted:			
Income (loss) before cumulative effect of change in accounting principle	$ (0.68)	$ (0.38)	$ 0.19
Cumulative effect of change in accounting principle	$	$	$ (0.22)
Net loss	$ (0.68)	$ (0.38)	$ (0.03)
Weighted average common shares outstanding:			
Basic	46,930	45,896	42,948
Diluted	46,930	45,896	45,628

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

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INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(Dollar amounts in thousands)

	Common Stock		Preferred Stock		Additional
	Number of Shares	Par Value Amount	Number of Shares	Amount	Paid-In Capital
Balance at September 30, 2000	42,780,492	$ 43	244,425	$ 3,500	$ 274,011
Purchase of treasury stock					
Proceeds from exercise of stock options	232,000				644
Proceeds from offering of Employee Stock Purchase Plan	33,713				47
Dividends on preferred stock					(35)
Stock-based compensation and other	236,811				1,732
Comprehensive loss:					
Net loss					
Unrealized net loss on marketable and equity securities					
Total comprehensive loss					
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 gain on marketable and equity securities					
Total comprehensive loss					
Balance at September 30, 2003	47,175,661	$ 47	244,425	$ 3,500	$ 303,452

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

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INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

(Dollar amounts in thousands)

	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Equity	Comprehensive Loss
			Number of Shares	Amount		
Balance at September 30, 2000	$ (249,802)	$ 14			$ 27,766	
Purchase of treasury stock			(14,500)	$ (75)	(75)	
Proceeds from exercise of stock options					644	
Proceeds from offering of Employee Stock Purchase Plan			14,500	75	122	
Dividends on preferred stock					(35)	
Stock-based compensation and other					1,732	
Comprehensive loss:						
Net loss	(1,491)				(1,491)	$ (1,491)
Unrealized net loss on marketable and equity securities		(3)			(3)	(3)
Total comprehensive loss						$ (1,494)
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 income:						
Net loss	(31,812)				(31,812)	$ (31,812)

Unrealized net gain on marketable and equity securities		61			61	61
Total comprehensive loss						$ (31,751)
Balance at September 30, 2003	$ (300,691)	$ (67)		$	$ 6,241	

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INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands)

	For the years ended September 30,		
	2003	**2002**	**2001**
Cash flows from operating activities:			
Net loss	$ (31,812)	$ (17,586)	$ (1,491)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	16	59	105
Amortization of convertible note issuance costs	138		
Minority interest in net income of unconsolidated subsidiary		56	27
Loss on disposal of property and equipment		2	
Loss on disposition of investment securities			43
Noncash compensation		2,188	1,697
Noncash license fee	360		
Impairment of equity securities		487	810
Changes in assets and liabilities:			
Accounts receivable	395	(219)	102
Insurance claim receivable			7,177
Settlement deposit receivable			1,757
Prepaid and other assets	(708)	(136)	280
Accounts payable	1,608	297	(69)
Deferred revenue	(24)	24	(3,000)
Accrued expenses and other liabilities	3,532	219	(9,419)
Net cash used in operating activities	(26,495)	(14,609)	(1,981)
Cash flows from investing activities:			
Capital expenditures	(33)	(11)	(26)
Proceeds from sale of property and equipment		1	
Purchase of marketable securities	(26,836)	(26,297)	(9,718)
Proceeds from maturities and sales of marketable securities	21,991	12,015	11,350
Net cash (used in) provided by investing activities	(4,878)	(14,292)	1,606
Cash flows from financing activities:			
Net proceeds from issuance of common and treasury stock	414	24,095	766
Proceeds from issuance of convertible notes	72,000		
Costs related to issuance of convertible notes	(3,301)		
Distribution to minority interest stockholder		(140)	(262)
Purchase of treasury stock			(75)
Principal payments of capital lease obligations			(2)
Net cash provided by financing activities	69,113	23,955	427
Net change in cash and cash equivalents	37,740	(4,946)	52

Cash and cash equivalents at beginning of period	19,977	24,923	24,871
Cash and cash equivalents at end of period	$ 57,717	$ 19,977	$ 24,923

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

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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 development and commercialization of a diversified portfolio of product candidates, including multiple compounds in late stage clinical development. The Company currently has six compounds in development: trospium for overactive bladder, pagoclone for panic and generalized anxiety disorders (GAD), citicoline for ischemic stroke, 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 treatment of systemic fungal infections.

The Company has also engaged in the development of products and technologies through consolidated subsidiaries.

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.

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, and 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, 2003 and 2002, 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.

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 equipment	2 to 5 years
Laboratory equipment	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

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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: Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize the Company s licensed technologies and is recognized 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.

Contract and license fee revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of the Company s 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 contract and license fee revenue when the Company has a contractual right to receive such payment, provided a contractual arrangement exists, 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.

Revenues from milestone payments related to arrangements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone. 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.

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: 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.

Pro forma information regarding net loss shown below was determined as if the Company and its consolidated subsidiaries had accounted for employee stock options and shares purchased under stock purchase

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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:

	2003	2002	2001
Dividend yield	0%	0%	0%
Expected volatility	90%	90%	90%
Risk-free interest rate	1.7%-3.5%	1.8%-4.6%	3.2%-5.8%
Expected option life	4 years	3 years	3 years
Weighted average grant date fair value:			
Options granted at fair market value	$ 3.64	$ 3.10	$ 2.36
Options granted at greater than fair market value			$ 0.05
Options granted at less than fair market value		$ 3.48	$ 1.96

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.

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,		
	2003	2002	2001
As reported net loss	$ (31,812,000)	$ (17,586,000)	$ (1,491,000)
Adjustment to compensation expense for stock-based awards	$ (1,231,000)	$ (2,306,000)	$ (6,439,000)
Pro forma net loss	$ (33,043,000)	$ (19,892,000)	$ (7,930,000)
As reported net loss per common share:			
Basic	$ (0.68)	$ (0.38)	$ (0.03)
Diluted	$ (0.68)	$ (0.38)	$ (0.03)
Pro forma net loss per common share:			
Basic	$ (0.70)	$ (0.43)	$ (0.18)
Diluted	$ (0.70)	$ (0.43)	$ (0.17)

Comprehensive Income or Loss: Components of comprehensive income or loss are 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.

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.

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Recent Accounting Pronouncement:

In January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an interpretation of ARB No. 51 (FIN 46). This interpretation addresses the consolidation of certain variable interest entities (VIE s) for which a controlling financial interest exists, and may be applied prospectively with a cumulative effect adjustment of by restating previously issued financial statements with a cumulative effect adjustment as of the beginning of the first year restated. In October 2003, the FASB issued FASB Staff Position No. FIN 46-6, effective date of FASB Interpretation No. 46, Consolidation of Variable Interest Entities which deferred the effective date of FIN 46 for interest held in VIE s created before February 1, 2003 until the end of the first interim or annual period ending after December 15, 2003. The adoption of FIN 46 is not expected to have a material effect on the Company s financial position or results of operations.

C. Change in Accounting Principle

In the fourth quarter of fiscal 2001, the Company adopted the Securities and Exchange Commission s (SEC) Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements (SAB 101), retroactive to October 1, 2000, the beginning of fiscal 2001. SAB 101 was issued to provide guidance related to revenue recognition policies based upon interpretations and practices followed by the SEC. Prior to the Company s adoption of SAB 101, the Company recognized revenue from license agreements when earned under the terms of the agreements. License payments were recognized as revenue when the Company had a contractual right to receive such payments and contractual milestone payments were recognized when the Company received appropriate notification that such milestones were achieved. In adopting SAB 101, where the Company has no continuing involvement, non-refundable license payments are recorded as revenue when the Company has a contractual right to such payments and milestones are recorded when the Company receives appropriate notification from the licensee of achievement of the milestone. However, when non-refundable license fees are received pursuant to an arrangement in which the Company has no continuing involvement but which also provides the licensee with an option to license additional compounds from the Company, SAB 101 requires deferral of such license fees until the licensee s option has lapsed. 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.

D. Marketable Securities

Investments in marketable securities consisted of the following at September 30, 2003 and 2002:

	2003	2002

	Cost	Market Value	Cost	Market Value
U.S. government obligations	$ 14,944,000	$ 14,944,000	$ 5,050,000	$ 5,063,000
U.S. corporate notes	9,666,000	9,669,000	15,479,000	15,505,000
Foreign corporate obligations	1,055,000	1,056,000	997,000	998,000
State government obligations	700,000	701,000		
	$ 26,365,000	$ 26,370,000	$ 21,526,000	$ 21,566,000

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

At September 30, 2003, gross unrealized gains and losses on marketable securities were $6,000 and $1,000, respectively. At September 30, 2002, gross unrealized gains and losses were $49,000 and $9,000 respectively. At September 30, 2003, all marketable securities mature within one year from the balance sheet date. At September 30, 2002, $20,516,000 of marketable securities mature within one year and $1,050,000 mature beyond one year but within two years from the balance sheet date.

E. Property and Equipment

At September 30, 2003 and 2002, property and equipment consisted of the following:

	2003	2002
Office equipment	$ 788,000	$ 762,000
Leasehold improvements	362,000	362,000
	1,150,000	1,124,000
Less: accumulated depreciation and amortization	(1,117,000)	(1,108,000)
	$ 33,000	$ 16,000

There were no assets under capital leases at September 30, 2003 and 2002, respectively. Depreciation expense related to assets under capital leases was $4,000 for the year ended September 30, 2001. Assets financed through capital leases consisted primarily of office equipment.

Depreciation and amortization expenses for the years ended September 30, 2003, 2002, and 2001 were $16,000, $59,000, and $105,000, respectively.

F. Accrued Expenses

At September 30, 2003 and 2002, accrued expenses consisted of the following:

	2003	2002

Clinical and sponsored research	$ 4,799,000	$ 2,405,000
Redux related	717,000	1,321,000
Compensation related	1,228,000	1,425,000
Professional fees	1,121,000	629,000
Other	856,000	546,000
	$ 8,721,000	$ 6,326,000

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 $557,000, $484,000, and $404,000, for the years ended September 30, 2003, 2002, and 2001, respectively.

At September 30, 2003, the Company s future minimum payments under non-cancelable lease arrangements are as follows:

Fiscal Year	Operating Leases
2004	$ 565,000
2005	560,000
2006	569,000
2007	312,000
Thereafter	
Total lease payments	$ 2,006,000

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

In November 2002, the FASB issued FASB Interpretation No. 45, "Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34" (" FIN No. 45"). FIN No. 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of certain guarantees. The initial recognition and initial measurement provisions of FIN No. 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. Since January 1, 2003, we have not issued or modified any guarantees as defined by FIN No. 45.

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, 2003, the market value of a $1000 Note was approximately $1,095.

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

As a result of the AHP Indemnity and Release Agreement, the Company believed that it was no longer probable that it would have to pay approximately $7,900,000 for estimated liabilities that had been established at the time Redux was withdrawn. Accordingly, the Company reversed these accruals in the year ended September 30, 2001 and reflected the reversal as a credit in product withdrawal in the Company s Statement of Operations.

In January 2001, the Company was reimbursed $8,419,000 from one of its insurers for litigation expenses previously paid by the Company and for other Redux-related costs. Of this amount, $618,000 of other Redux-related expenses are included as a credit in the Company s Statement of Operations for the year ended September 30, 2001 under product withdrawal. 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.

As of September 30, 2003, 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

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2003. 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.

In October 2000, the District Court returned $1,757,000 to the Company from an initial payment the Company made to the District Court pursuant to a proposed settlement which was rejected by the District Court.

The product withdrawal net credit of $5,582,000 for the year ended September 30, 2001 consisted of credits of approximately $7,900,000 for Redux-related accruals reversed in fiscal 2001, as well as for insurance reimbursements of other Redux-related expenses, partially offset by a reserve for the insurance claim on Reliance and a noncash charge for the fair value of stock options granted to attorneys involved in the Company s lawsuit against Wyeth.

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).

Common Stock: In December 2001, the Company completed a private placement of 3,125,000 shares of its Common Stock which resulted in net proceeds to the Company of $23,313,000.

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 shares may be granted. Under the 1994 Plan, the 1998 Plan, and the 2000 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, and 2000 Plans cannot exceed ten years and the term of each grant under the 1998 Plan cannot exceed seven years.

The Company has also granted outside of the Option Plans options to purchase shares of the Company s Common Stock (Non-Plan Options). At September 30, 2003, 50,000 Non-Plan Options were outstanding.

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2000	9,694,917	$4.12	750,000	$5.00-$10.00
Granted	367,500	$4.82		
Exercised	(232,000)	$2.78		
Cancelled	(239,459)	$5.49	(45,000)	$6.16
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

At September 30, 2003, stock options were outstanding and exercisable as follows:

	Outstanding			Exercisable	
Range of Exercise Price	Number	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
$1.22-$ 2.06	729,417	6.8 years	$ 1.70	541,452	$ 1.84
$2.15-$ 3.75	4,088,834	7.1 years	$ 2.68	3,104,670	$ 2.42
$3.80-$ 4.35	1,824,750	2.6 years	$ 4.11	1,809,750	$ 4.12
$4.38-$ 6.50	3,106,417	2.3 years	$ 6.01	2,968,336	$ 6.04
$6.68-$20.13	513,752	6.9 years	$ 8.55	348,755	$ 8.86

$1.22-$20.13	10,263,170	4.8 years	$	4.17	8,772,963	$ 4.21

All outstanding options vest at various rates over periods up to four years and expire at various dates from December 6, 2003 to June 3, 2013. At September 30, 2002, 9,301,144 options were exercisable at a weighted average exercise price of $4.20. At September 30, 2001, 9,590,958 options were exercisable at a weighted average exercise price of $4.15.

All outstanding warrants expire at various dates from December 31, 2003 to July 17, 2006 and have a weighted average exercise price of $6.15 per share.

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

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

noncash charge of approximately $1,475,000. The Company has granted stock options to consultants to the Company and has incurred noncash charges to operations of approximately $317,000 and $955,000 in fiscal 2002 and 2001, respectively.

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, 2003, restricted stock awards to acquire an aggregate of 1,736,918 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, 2003, 1,736,918 shares have vested and been issued and there were 13,082 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 $134,000 and $534,000 in fiscal 2002 and 2001, 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 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, 2003, 212,308 shares remain to be purchased under the 1995 Plan.

Treasury Stock: In September 2001, the Company s Board of Directors approved the repurchase from time to time by the Company of up to 1,000,000 shares of Indevus Common Stock in the open market and through September 30, 2001, the Company repurchased an aggregate of 14,500 shares for $75,000 and reissued such shares for purchases of Common Stock pursuant to the 1995 Plan. The Company has made no additional purchase of treasury stock.

Other: In addition to the 47,176,000 shares of Common Stock outstanding at September 30, 2003, there were approximately 27,075,000 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) 10,500,000 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) 225,000 shares reserved for issuance under the 1995 and 1997 Plans; and (vi) approximately 155,000 shares reserved for issuance from exercise of outstanding warrants and Non-Plan Options.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

K. Weighted Average Common Shares

The following table sets forth the reconciliation of the denominator for basic and diluted earnings per share for the years ended September 30, 2003, 2002, and 2001:

	2003	2002	2001
Denominator for basic:			
Weighted average shares outstanding	46,930,000	45,896,000	42,948,000
Denominator for diluted:			
Weighted average shares outstanding	46,930,000	45,896,000	42,948,000
Stock options and stock issuable under employee compensation plans			2,058,000
Common Stock issuable under outstanding convertible preferred stock			622,000
	46,930,000	45,896,000	45,628,000

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.

During the year ended September 30, 2001, 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 5,836,042 share of Common Stock at prices ranging from $4.06 to $20.13 with expiration dates ranging up to March 9, 2011, and (ii) warrants to purchase 705,000 shares of Common Stock with exercise prices ranging from $5.00 to $12.77 and with expiration dates ranging up to July 17, 2006.

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

L. Income Taxes

At September 30, 2003 and 2002, the significant components of the Company s deferred tax asset consisted of the following:

	2003	2002
Federal and state net operating loss carryforwards	$ 75,105,000	$ 64,397,000
Federal and state tax credit carryforwards	5,788,000	5,231,000
Capital loss carryforwards	3,257,000	3,297,000
Accrued expenses	6,922,000	6,112,000
Investment in CPEC LLC	7,558,000	8,230,000
Investment in unconsolidated subsidiaries	13,755,000	13,797,000
Total deferred tax asset before valuation allowance	112,385,000	101,064,000
Valuation allowance against total deferred tax asset	(112,385,000)	(101,064,000)
Net deferred tax asset	$	$

At September 30, 2003, the Company had net operating loss carryforwards available for federal income tax purposes of approximately $198,000,000 which expire at various dates from 2004 to 2023. In addition, the Company had approximately $4,000,000 of tax credit carryforwards for federal income tax purposes expiring at various dates through 2023 and capital loss carryforwards of approximately $8,100,000 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 $15,200,000 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.

Due to the uncertainty surrounding the realization of favorable tax attributes in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance.

M. Related Party Transactions

The Company has or had agreements with certain directors, former 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 $324,000, $198,000 and $215,000 in fiscal 2003, 2002, and 2001, 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

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.

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Shire: In March 2003, the Company signed an exclusive development agreement with Shire Laboratories Inc. (Shire) under which Shire is developing extended release formulations of trospium. 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 trospium. Indevus will be responsible for all development costs and the commercialization of extended release formulations of trospium under this agreement.

Pfizer: In December 1999, the Company entered into an agreement, subsequently amended, with the Warner-Lambert Company, now Pfizer Inc. (Pfizer), under which it licensed to Pfizer exclusive, worldwide rights to develop and commercialize pagoclone (the Pfizer Agreement). Under the Pfizer Agreement, Pfizer was responsible for conducting and funding all clinical development, regulatory review, manufacturing and marketing of pagoclone on a worldwide basis. On June 7, 2002, the Company announced that Pfizer had decided to return to the Company its rights to pagoclone, thereby terminating the Pfizer Agreement.

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. Aventis had a contractual right for a period of 90 days from the termination of the Pfizer Agreement to elect to develop pagoclone under the terms of the Pfizer Agreement and declined to exercise that right.

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.

Takeda: In December 1999, the Company entered into an agreement with Takeda Chemical Industries, Ltd. (Takeda), subsequently amended, under which the Company licensed to Takeda exclusive U.S. and Canadian commercialization rights to citicoline (the Takeda Agreement). Under the Takeda Agreement, the Company received $13,000,000 in licensing and other payments, and was entitled to receive additional payments contingent upon the achievement of regulatory milestones, as well as royalties on potential net sales. The Takeda Agreement also provided an exclusive option to Takeda to negotiate a license for any one alternative Indevus compound, excluding pagoclone and trospium, in the event Takeda decided to terminate the citicoline license following a review of the 899-person Phase III clinical trial. In December 2000, Takeda notified the Company of its decision not to participate in the further development of citicoline, thereby terminating the Takeda Agreement. Therefore, the Company reacquired all rights to citicoline. In April 2001, Takeda exercised its option under the Takeda Agreement to negotiate a license of another one of the Company s compounds and selected IP 501 as such compound. Under this option, Takeda had a six-month period during which the Company could not offer IP 501 for sublicensing without first re-offering it to Takeda under the new terms.

The six-month period expired on September 30, 2001 and all of Takeda s rights to IP 501 expired. In fiscal 2000, the Company recognized $10,000,000 of the Takeda payments as license fee revenue and $3,000,000 related to the product option as

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

deferred revenue. In fiscal 2001, the Company recognized the previously deferred $3,000,000 related to the product option as contractual license fee revenue. In the fourth quarter of fiscal 2001 the Company adopted SAB 101 and, in doing so, reversed the $10,000,000 license fee revenue previously recognized in fiscal 2000 as the cumulative effect of a change in accounting principle and then recognized the $10,000,000 as revenue in September 2001 upon expiration of Takeda s rights under the contract. (See Note C.)

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 (the Ferrer Agreement). In June 1998, the Company amended the Ferrer Agreement to extend to January 31, 2002 the date upon which Ferrer may terminate the citicoline license agreement if FDA approval of citicoline is not obtained. The Ferrer Agreement provides for such date to be extended for up to two years if the Company provides information to Ferrer which tends to establish that the Company has carried out the steps for obtaining such approval and if such approval has not been obtained for reasons beyond the Company s control. The Company has been providing such information to Ferrer and the Ferrer Agreement is currently extended to January 31, 2004, and is expected to be extended beyond such date. A license fee and future royalties on potential net sales of citicoline were consideration provided to Ferrer.

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. The Company is responsible for all remaining development and commercialization activities for 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 and 2001, the Company recorded approximately $254,000 and $281,000, respectively, of revenue and cost of revenue pursuant to this grant.

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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, and is marketing the drug under the trade name Sarafem. 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 $4,319,000 (including $2,184,000 of accelerated milestone payments), $3,437,000 and $1,952,000 in fiscal 2003, 2002 and 2001, respectively, on Lilly s sales of Sarafem.

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, 2002 and 2001. 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. Additionally, these agreements required the Company to purchase the bulk compound from an affiliate of Servier. Indevus agreed to indemnify Servier under certain circumstances and Indevus was required to name Servier as an additional insured on its product liability insurance policies, which are subject to ongoing claims by Servier. (See Note I.)

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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 minimum purchase, 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 Incara

Subsidiary

CPEC LLC is owned 65% by the Company and 35% by Incara 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 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 Incara

At September 30, 2003 and 2002, the Company s investment in Incara Pharmaceuticals, Inc. (Incara) was comprised of 447,186 shares, or approximately 3%, of Incara common stock valued at $134,000 and $31,000, respectively. In fiscal 2002 and 2001, the Company recorded charges to operations of $487,000 and $810,000, respectively, to write down its investment in Incara to fair value as the decline in the value of Incara common stock was deemed other than temporary. The Company classifies its investment in Incara 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	Third Quarter	Fourth Quarter
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)
Fiscal 2002				
Total revenues	$ 3,541,000	$ 86,000	$ 228,000	$ 552,000
Net loss	(1,946,000)	(4,808,000)	(6,015,000)	(4,817,000)
Net loss per common share, basic and diluted	$ (0.04)	$ (0.10)	$ (0.13)	$ (0.10)