INDEVUS PHARMACEUTICALS INC
Form 10-K
December 24, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended September 30, 2002 or

¨ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from to**

Commission File No. 0-18728

Indevus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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. x

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 $108,000,000, based on the last sales price of the Common Stock as of December 10, 2002. Shares of Common Stock held by each executive officer and director, by each person who beneficially owns 10% or more of the outstanding Common Stock, and individuals or entities related to such persons have been excluded. This determination of affiliate status may not be conclusive for other purposes.

As of December 13, 2002, 46,875,885 shares of Common Stock, $.001 par value, of the registrant were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

See Part III hereof with respect to incorporation by reference from the registrant s definitive proxy statement for the fiscal year ended September 30, 2002 to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 and the Exhibit Index beginning on page number 50 hereto.

PART I

Note Regarding Forward Looking Statements

Statements in this Form 10-K that are not statements or descriptions of historical facts are forward-looking statements under Section 21E of the Securities Exchange Act of 1934, as amended, 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 the Company 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: the Company s ability to successfully develop, obtain regulatory approval for and commercialize any products, including trospium; its ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux™-related litigation. The words believe, expect, anticipate, intend, plan, estimate or other expressions which predict or indicate 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 the Company s products; risks associated with contractual arrangements; dependence on third parties for manufacturing and marketing; competition; need for additional funds and corporate partners; history of operating losses and expectation of future losses; product liability; risks related to certain insurance-related litigation; risks relating to the Redux-related litigation; limited patents and proprietary rights; dependence on market exclusivity; valuation of our common stock; and other risks. The forward-looking statements represent the Company s judgment and expectations as of the date of this Report. The Company assumes no obligation to update any such forward-looking statements. See Risk Factors.

Unless the context indicates otherwise, Indevus and the Company refer to Indevus Pharmaceuticals, Inc., and Common Stock refers 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 product candidates, including multiple compounds in late stage clinical development. The Company is currently developing or has certain rights to five core compounds. The names of these compounds and their intended uses are as follows: trospium for overactive bladder, pagoclone for panic and generalized anxiety disorders (GAD), citicoline for ischemic stroke, IP 751 (initially referred to by the Company as CT-3) for pain and inflammatory disorders, and PRO 2000 for the prevention of infection by the human immunodeficiency virus (HIV) and other sexually transmitted pathogens.

The Company seeks to acquire, develop and commercialize a portfolio of pharmaceutical products for a range of therapeutic indications. The key elements to Indevus business strategy include: 1) identifying products 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 U.S., 3) defining pathways for these compounds through the clinic and to market, 4) adding value to acquired products through clinical testing and regulatory review activities and competencies, and 5) commercializing products independently or through selective corporate partnerships that will help ensure the timely penetration of target markets. The Company s strategy encompasses a range of products and therapeutic areas arising from a variety of partners including biopharmaceutical, regional pharmaceutical, and multi-national pharmaceutical firms, as well as academic and government institutions.

The Company s lead product is trospium, a muscarinic receptor antagonist under development as a treatment for overactive bladder. In September 2002, the Company announced positive results from a 523-patient, Phase III clinical trial demonstrating that patients with overactive bladder treated with trospium had significantly reduced frequencies of micturition (urination) and urinary incontinence episodes compared with patients who received placebo. In addition to meeting these dual primary endpoints, the trial met all of its overactive bladder secondary endpoints, and the drug was well tolerated as evidenced by a favorable safety profile. The Company plans to file a New Drug Application (NDA) for trospium with the U.S. Food and Drug Administration (FDA) in the second quarter of 2003, contingent upon discussions with the FDA. The Company in-licensed rights to develop and commercialize trospium in the United States from Madaus AG (Madaus), a German pharmaceutical company. Trospium is currently marketed in Europe, where it is one of the leading treatments for overactive bladder.

A second product in advanced clinical-stage development is pagoclone, a novel GABA (gamma amino butyric acid) receptor agonist for the treatment of anxiety disorders. In June 2002, Pfizer Inc (Pfizer) returned to the Company exclusive, worldwide development and commercialization rights for pagoclone. To date, there have been three positive Phase II clinical trials of pagoclone, two in panic disorder conducted by Indevus 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 demonstrate statistically significant efficacy. The Company is pursuing a new worldwide development partnership for the commercialization of pagoclone. The Company believes the data from these six clinical trials suggest the potential of pagoclone as a novel anti-anxiety agent that lacks the sedative effects and withdrawal or rebound-anxiety symptoms seen with other agents.

Citicoline has been under development by the Company as a neuroprotective treatment for ischemic stroke. Based on the data from the Company s three Phase III trials with citicoline, the Company believes that additional clinical testing is required before an NDA can be submitted. Two meta-analyses of clinical trials presented at the 27th International Stroke Conference in February 2002 suggest that treatment with citicoline may reduce infarct growth after stroke and reduce rates of death or disability over a long term. As a result of corporate partnering discussions following these findings, Indevus has signed a non-binding memorandum of agreement with a privately held biotechnology company to fund the further development of citicoline. The finalization of this agreement is contingent upon input from the FDA on the design and clinical endpoints of an additional large Phase III trial and the negotiation of a definitive contract.

The Company licensed exclusive, worldwide rights to IP 751, a novel anti-inflammatory and analgesic compound, in June 2002 from Atlantic Technology Ventures, Inc. (ATV). IP 751, a new chemical entity, is a non-psychoactive synthetic derivative of tetrahydrocannabinol (THC). The compound appears to inhibit inflammatory cytokines, particularly interleukin 1-beta and TNF-alpha. Results of a Phase II clinical trial conducted in Germany and announced in December 2002 showed that treatment with IP 751 significantly reduced neuropathic pain among 21 patients and was well tolerated, with no evidence of psychoactive properties. 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, and the Company is currently determining the optimal clinical and regulatory plan for advancing IP 751 as a therapy for pain and inflammatory disorders.

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 studies 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 U.K. Department for International Development (DFID). This program will include a multi-national, randomized, double-blind, placebo-controlled Phase III clinical trial. Additional clinical trials with PRO 2000 are planned to begin in 2003. These include a Phase II trial funded by the European Commission to assess its safety in approximately 100 sexually active female volunteers and a National Institute of Health (NIH)-sponsored Phase II/III pivotal trial to determine its safety and efficacy in blocking male to female HIV transmission intended to begin in 2003.

Under an agreement with Eli Lilly and Company (Lilly), the Company has received royalties on net sales through December 31, 2001 in the U.S. of Sarafem®, a treatment for premenstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome (PMS). In December 2002, the Company entered into a renegotiated licensing agreement with Lilly providing for an initial payment to the Company upon the signing of the agreement and royalty payments from Lilly to the Company based on net sales of Sarafem in the U.S. until the expiration of the Company s patent related to Sarafem. In addition, the agreement includes other potential milestone payments to the Company from Lilly. Upon the completion of the conditional agreement announced by Galen Holdings PLC (Galen) in December 2002, Galen would acquire the U.S. sales and marketing rights to Sarafem from Lilly. If the conditional agreement is consummated between Lilly and Galen, any remaining milestone payments would be accelerated.

On May 30, 2001, the Company entered into the Indemnity and Release Agreement with American Home Products Corporation (subsequently Wyeth, Wyeth) related to product liability cases filed against the Company concerning Redux (the AHP Indemnity and Release Agreement). Redux (dexfenfluramine hydrochloride capsules) C-IV, a prescription weight loss medication, was launched by Wyeth in June 1996 and withdrawn from the market in September 1997, following which the Company has been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 product liability legal actions involving the use of Redux and other weight loss drugs.

The AHP Indemnity and Release Agreement provides for indemnification and funding by Wyeth as follows: (i) complete indemnification for plaintiffs who had as of May 30, 2001 opted out of Wyeth s national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension, (ii) all future legal costs related to the Company s defense of Redux-related product liability cases, and (iii) additional insurance coverage to supplement the Company s existing policies. In exchange, 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. The Company believes that the provisions of this agreement, combined with the Company s existing product liability insurance, are sufficient to address the Company s potential remaining Redux product liability exposure.

The Company was incorporated in Delaware in March 1990. The Company s executive offices are located at One Ledgemont Center, 99 Hayden Avenue, Lexington, Massachusetts 02421-7966.

On April 2, 2002, the Company s shareholders approved the corporate name change from Interneuron Pharmaceuticals, Inc. to Indevus Pharmaceuticals, Inc. to reflect more accurately the Company s mission of product acquisition on an international basis, its core expertise in product development and its evolution from a neurological focus to multiple therapeutic indications. The Company began trading on the Nasdaq Stock Market under its new symbol, IDEV, on April 3, 2002.

(b) Financial Information about Industry Segments

The Company operates in only one business segment.

(c) Narrative Description of Business

PRODUCTS

The following table summarizes, in order of development stage, the core products under development by the Company or to which the Company has certain rights, including product name, indication/use, regulatory status and commercial rights held by the Company with respect to each product. For a more detailed description of each product, see the product descriptions following the chart.

Product Name	Indication/Use	Regulatory Status*	Commercial Rights
Trospium	Overactive bladder	Phase III completed	U.S.
Pagoclone	Panic and Generalized Anxiety Disorders	Phase III in panic disorder; Phase II in generalized anxiety disorder	Worldwide
Citicoline	Ischemic stroke	Phase III	U.S. and Canada
IP 751	Pain/inflammation	Phase I/II	Worldwide
PRO 2000	Prevention of HIV and sexually transmitted diseases	Phase II	Worldwide

*See Government Regulation.

TROSPIUM

General: Trospium is under development as a drug to treat overactive bladder, defined as urinary frequency and urgency that may be associated 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 are women. According to the *SCRIP* Report dated September 2000, only 20 percent of overactive bladder patients are currently treated with pharmacotherapy. Economic costs related to diagnosis and treatment of overactive bladder are estimated to exceed $26 billion, as stated in the *Journal of the American Medical Association* report on December 16, 1998.

Trospium belongs to the anticholinergic class of compounds and binds specifically to the muscarinic receptors. These compounds relax smooth muscle, or detrusor, tissue in the bladder, thus decreasing bladder contractions. Overactive or unstable detrusor muscle function is believed to be the cause of overactive bladder. Trospium is currently marketed in most European countries.

Current treatments for overactive bladder include compounds in the same class as trospium, such as Detrol LA (tolterodine) and Ditropan XL (oxybutynin). In contrast to trospium, these drugs are lipophilic and have been shown to cross the blood-brain barrier. Based on the hydrophilic nature of trospium and pre-clinical and clinical findings to date, the Company believes that trospium does not cross the blood-brain barrier, thereby possibly avoiding central nervous system side effects. In addition, at therapeutic concentrations trospium is not an inhibitor of specific enzymes in the Cytochrome P450 system, a metabolic pathway commonly associated with drug-drug interactions. Furthermore, trospium is excreted largely unchanged in the urine. Finally, clinical data have shown that patients treated with trospium have a relatively low rate of dry mouth, and the degree of dry mouth they do experience is well tolerated.

Development Program: In September 2002, the Company announced that a 523-patient, double-blind, placebo-controlled Phase III clinical trial with trospium met both of its primary endpoints, achieving significantly reduced frequencies of micturition ($p \leq 0.01$) and urinary incontinence episodes ($p \leq 0.01$) among patients treated with trospium 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 evidenced by a favorable safety profile. The incidence of dry mouth and other adverse events observed in this trial suggests a product profile for trospium that will make it competitive in the marketplace. Over 400 patients from this trial entered an ongoing nine-month open label extension of the study. The Company plans to submit complete, detailed results from this trial to a peer-reviewed journal with the key objective of publication in 2003. Prior to its Phase III trial, the Company successfully completed an electrocardiographic study recommended by the FDA for drugs in the pharmacological class of trospium.

Based on the results of its Phase III trial, Indevus plans to file an NDA for trospium with the FDA that will include the European clinical trial database during the second quarter of 2003, contingent upon discussions with the FDA regarding stability testing and manufacturing issues. The Company is working with Madaus to achieve compliance with U.S. current Good Manufacturing Practices (cGMP) standards in anticipation of a future FDA inspection of their German manufacturing plant. Madaus currently manufactures trospium for the European market to current European manufacturing standards. See Risk Factors We will depend on the success of trospium and We will rely on third parties to commercialize and manufacture our products.

The clinical database for trospium trials encompasses over 2,300 patients in 32 clinical trials, of which twelve are double-blind, controlled studies, including nine double-blind, placebo-controlled studies, and three are active-controlled trials. Based upon previous discussions with the FDA, the Company believes that, in combination with existing efficacy and safety data on trospium, its recently concluded, successful Phase III trial is sufficient for submission of the NDA. See Risk Factors We will rely on the favorable outcome of clinical trials of our products.

The Company has exclusive U.S. commercialization rights to trospium in the U.S. and is currently evaluating commercialization opportunities for the drug. See Risk Factors We will rely on third parties to commercialize and manufacture our products.

Licensing and Proprietary Rights: In November 1999, the Company licensed exclusive U.S. rights from Madaus to market trospium (the Madaus Agreement). In exchange, the Company agreed to pay Madaus regulatory milestone, royalty and sales milestone payments. Indevus is responsible for all clinical development and regulatory activities and costs related to the compound and for manufacturing and marketing the compound in the U.S. There are no existing U.S. patents covering the use of orally-administered trospium to treat overactive bladder. The Company expects to rely on the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman-Hatch Act) to obtain a period of market exclusivity in the U.S., if the FDA approves trospium in the U.S. for the intended indication. The Company intends to seek additional patent protection for trospium through the development of a once-a-day formulation of the drug. The Madaus Agreement includes a license of the know-how relating to the European clinical trials of trospium. See Agreements, Patents and Proprietary Rights, and Government Regulation.

Madaus Development: The current clinical database for trospium includes over 2,300 subjects and patients (over 1,700 treated with active drug). The database comprises two double-blind, placebo-controlled dose-ranging studies, seven double-blind, placebo-controlled studies, one of which included an active-controlled treatment arm, and several comparative trials, one of which was a long-term comparative 52-week study on safety, tolerability, and efficacy. 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 micturition frequency diary data. In addition to this clinical database, over 10,000 patients have been followed in post-marketing trials. To supplement the clinical database, Indevus will also utilize Madaus extensive pharmacology, toxicology and pharmacokinetic studies, including acute, sub-acute, chronic, carcinogenicity, genotoxicity, and reproduction studies, as well as numerous pre-clinical and clinical biopharmaceutical studies.

Madaus 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. Hofner et al. (*Neurourol Urodyn 19, 2000, 487-88*) reported that there was no significant difference between trospium and oxybutynin in the reduction in micturitions 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 with 187 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 micturitions compared with placebo-treated patients, whereas the reduction in micturitions 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.

PAGOCLONE

General: Pagoclone is a compound under development to treat panic and generalized anxiety disorders. Panic disorder is a severe anxiety condition characterized by panic attacks, acute episodes of anxiety comprised of distressing symptoms, such as breathing difficulty, sweating, heart palpitations, dizziness or fainting, and fear of losing control. Generalized anxiety disorder 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 generalized anxiety disorder experience persistent diffuse anxiety without the specific symptoms that characterize phobic disorders, panic disorders or obsessive-compulsive disorders. There are approximately 20 million people in the U.S. (*Drug and Market Development, October 2001*) and 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. The Company believes 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 generally include benzodiazepines, serotonin agonists and selective serotonin reuptake inhibitors. 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 and sexual dysfunction related to serotonin reuptake inhibitors. Pre-clinical and early clinical data suggest that treatment with pagoclone may have advantages over these treatments by limiting these common side effects.

Pfizer Agreement: In December 1999, the Company entered into an agreement with Pfizer, subsequently amended, under which the Company licensed to Pfizer exclusive, worldwide rights to develop and commercialize pagoclone (the Pfizer Agreement). Under the Pfizer Agreement, the Company received $16,750,000, including an up-front payment of $13,750,000, and was entitled to receive up to an additional $62,000,000 in 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 clinical development, regulatory review, manufacturing and marketing of pagoclone on a worldwide basis. See Agreements.

In June 2002, Pfizer informed the Company of the results of its most recent clinical trials with pagoclone in GAD and panic disorder, which did not achieve the level of efficacy established in previous trials. Accordingly, Pfizer elected not to pursue further development of the compound and returned to the Company exclusive, worldwide development and commercialization rights to pagoclone. The Company is therefore seeking a corporate partnership to conduct the further clinical development, regulatory review and commercialization of pagoclone.

Development Program: To date, a total of six clinical trials have been conducted with pagoclone in generalized anxiety disorder and panic disorder, including three positive Phase II clinical trials, two in panic disorder conducted by Indevus and one in generalized anxiety disorder conducted by Pfizer. Pfizer s most recent data in two Phase II generalized anxiety disorder trials and one Phase III panic disorder trial did not show statistically significant efficacy. As demonstrated in previous clinical trials, pagoclone was well tolerated in these latest trials, with no significant differences from placebo with respect to adverse events, including sedation and

withdrawal effects. The Company believes that the complete data package from these six 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.

Phase II Clinical Trial: 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.

The six-week 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. With respect to side effects, there were no statistically significant differences between pagoclone-treated and placebo-treated patients in sleepiness, as measured by the Stanford Sleepiness Scale, and in withdrawal symptoms, as measured by the Rickel s Withdrawal Symptom Checklist. In addition, there were no serious clinical or laboratory adverse events among patients treated with pagoclone.

Phase II/III Clinical Trial: In August 1998, the Company announced results of its Phase II/III 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, which included a tapering-off period.

The double-blind, placebo-controlled, parallel group study 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, conducted on a Last Observation Carried Forward (LOCF) basis, 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 a low incidence of side effects in all dosage groups and 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. Of note, 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 sedation, lack of mental acuity, withdrawal and rebound anxiety related to the benzodiazepine class of drugs, and agitation, insomnia and sexual dysfunction related to selective serotonin reuptake inhibitors.

Pilot Study: In November 1997, the Company announced that data from a pilot study among 16 patients suffering from panic attacks showed that those who were treated with three doses per day, orally, of pagoclone experienced a marked reduction in the number of their panic attacks compared to those who received placebo. This double-blind, placebo controlled crossover study was conducted by a team of researchers in the U.K. 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.

Licensing and Proprietary Rights: In February 1994, the Company licensed from Rhône-Poulenc Rorer, S.A., now Aventis, S.A. (Aventis) exclusive, worldwide rights to pagoclone, subject to Aventis option to obtain a sublicense in France, in exchange for license fees, milestone payments and royalties based on net sales. In August 2002, Aventis declined to exercise a contractual option to continue the development of pagoclone. A composition of matter patent and several process patents for pagoclone have issued in the U.S. and Europe. See Agreements and Patents and Proprietary Rights.

CITICOLINE

General: Citicoline has been 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.

Mechanism of Action: Citicoline is believed to have multiple acute and longer-term mechanisms of action in diminishing 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 is thereby believed to help stabilize the cell membrane and, as a result, decrease edema, or brain swelling, caused when blood flow to brain cells is stopped, and help to re-establish normal neurochemical function in the brain. Citicoline also appears to increase levels of acetylcholine, a neurotransmitter believed to be associated with learning and memory functions.

Development Strategy: The Company has completed three Phase III clinical trials and one Phase II/III trial with citicoline in North America. Based on the results of these trials, the Company believes additional clinical testing is required before an NDA for citicoline can be submitted for review by the FDA.

Two meta-analyses of clinical trials, including trials conducted by other companies and researchers abroad and trials conducted in the U.S. by Indevus, were presented at the 27th International Stroke Conference in February 2002. These meta-analyses suggest that treatment with citicoline may reduce infarct growth after stroke and reduce rates of death or disability over a 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 at long-term follow-up. 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 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, $p=0.015$.

Following these meta-analyses, the Company has signed a non-binding memorandum of agreement with a privately held biotechnology company to fund the further development of citicoline. The finalization of this agreement is contingent upon input from the FDA on the design and clinical endpoints of an additional large Phase III trial and the negotiation of a definitive contract.

Regulatory Review: The Company had submitted an NDA for citicoline to the FDA in December 1997. Data in the NDA included the results of two Phase III clinical trials conducted by the Company in the U.S., 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 trial which failed to meet its primary endpoint of reducing infarct size among patients taking citicoline versus those taking placebo, the Company withdrew its NDA in April 1998.

Takeda Agreement: In December 1999, the Company entered into an agreement, subsequently amended, with Takeda (the Takeda Agreement) under which the Company licensed to Takeda exclusive rights to commercialize citicoline in the U.S. and Canada. Under the Takeda Agreement, the Company received $13,000,000 in licensing and other payments and was entitled to receive up to $60,000,000 in payments contingent upon the achievement of regulatory milestones, as well as royalties on net sales. Following analysis of a Phase III trial completed in early 2000, Takeda notified the Company of its decision not to participate in the further development of citicoline, thereby terminating the Takeda Agreement. The Company reacquired all rights to the compound.

Licensing and Proprietary Rights: In January 1993, the Company licensed from Ferrer Internacional, S.A. (Ferrer) exclusive marketing and manufacturing rights based on certain patent rights relating to the use of citicoline, including certain patent and know-how rights in the U.S. and know-how rights in Canada, in exchange for royalties based on sales (the Ferrer Agreement). In June 1998, the Ferrer Agreement was amended to extend to January 31, 2002 the date upon which Ferrer may terminate the Ferrer 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 that 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, 2003 and is expected to be extended beyond such date.

The Company has licensed both know-how and a use patent from Ferrer related to citicoline. In addition, a U.S. composition of matter patent for a hyperhydrated form of citicoline and three U.S. use patents have been issued to the Company. In addition to these proprietary rights, the Company anticipates that citicoline would be entitled to market exclusivity under Waxman-Hatch Act.

IP 751

General: IP 751, initially referred to by the Company as CT-3, is a non-psychoactive synthetic derivative of tetrahydrocannabinol (THC) in early clinical development to treat pain and inflammatory disorders. An analgesic and anti-inflammatory compound, 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), in pre-clinical studies IP 751 does not appear to produce gastrointestinal ulceration. The Company believes IP 751 has a broad potential to treat painful inflammatory conditions such as arthritis, post-operative pain, musculoskeletal injuries, headache and neuropathic pain.

Development Program: In December 2002, the Company 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 evidence of psychoactive properties.

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, as shown by visual analog scores (VAS) decreased significantly during treatment periods ($p<0.05$). Based on these results, Indevus is currently determining the optimal clinical and regulatory plan for advancing IP 751 as a therapy for pain and inflammatory disorders.

Pre-clinical development of IP 751 has demonstrated that it is active in multiple pre-clinical models of pain and inflammation, including multiple sclerosis and the cutaneous inflammation associated with exposure to the chemical warfare blister agent sulfur mustard. 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 psychotropic activity. See Risk Factors Our products are early stage and may not be successful or achieve market acceptance.

Licensing and Proprietary Rights: The Company licensed exclusive, worldwide rights to IP 751 from ATV in June 2002, in exchange for an up-front licensing payment, development milestones and royalty payments (the ATV Agreement). The Company is responsible for the clinical development, regulatory activities and commercialization of this compound. The Company holds an exclusive license to all intellectual property relating to IP 751, including patents and patent applications covering the composition of matter, formulations and uses.

PRO 2000

General: PRO 2000 is under development as a topical microbicide to prevent the sexual transmission of HIV and certain other 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 were acquired worldwide in 2000, the majority through heterosexual intercourse. Heterosexual contact has also become the most common route of HIV infection in U.S. women. Other STDs such as genital herpes, chlamydia and gonorrhea can lead to serious complications, especially in women, and can increase the risk of HIV infection. Based on estimates by the Kaiser Family Foundation and the World Health Organization, there are 15 million new STD cases each year in the U.S. and more than 340 million worldwide. Topical microbicides represent a new class of protective substances that are designed to be applied vaginally before sexual contact. Topical microbicides have the potential to offer an appealing, female-controlled alternative to condoms, the only products currently known to prevent HIV transmission.

The Company believes that PRO 2000 s use as a topical microbicide is based upon its ability to block infection by HIV and other sexually transmitted disease pathogens by preventing their attachment and entry into cells. Laboratory studies have shown that the drug is active against HIV, herpes simplex virus, chlamydia and the bacteria that cause gonorrhea. Moreover, 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. The product is also highly stable, odorless and virtually colorless. PRO 2000 differs significantly from nonoxynol-9-containing spermicides, which have failed to provide protection against HIV infection in previous human clinical trials.

Development Program: A number of pre-clinical and early clinical studies with PRO 2000 have been completed under the sponsorship of government agencies and research organizations in the U.S. and Europe. Following the completion of these studies, a number of additional clinical trials are ongoing or planned. These include a Phase II clinical trial in Africa funded by the European Commission and scheduled to begin in early 2003. This trial will assess the safety of PRO 2000 in approximately 100 sexually active female volunteers. In addition, an NIH-sponsored Phase II/III pivotal trial to determine the safety and efficacy of PRO 2000 in blocking male to female HIV transmission is planned to begin in 2003 in Africa and India. The study is expected to involve approximately 10,000 HIV-uninfected women at risk for acquiring HIV by virtue of living in countries where the risk of such infection is high. See Risk Factors We rely on the favorable outcome of clinical trials of our products.

An international collaboration of research groups in the United Kingdom and Africa was awarded a grant of approximately $22.7 million from the U.K. 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 (MRC) 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.

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

In September 2001, the Company was awarded a grant by the Contraceptive Research and Development (CONRAD) Program under its Global Microbicide Project to support two toxicity studies performed by the Company with PRO 2000.

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*).

Licensing and Proprietary Rights: In June 2000, the Company licensed exclusive, worldwide rights to develop and market PRO 2000 from HeavenlyDoor.com, Inc., formerly Procept, Inc. (HDCI), in exchange for an up-front payment, as well as potential future milestone payments and royalties on net sales. The Company is responsible for all remaining development and commercialization activities for PRO 2000. The Company holds an exclusive license to all intellectual property relating to PRO 2000, including four issued U.S. patents: one covering the composition of matter, two covering the use of PRO 2000 to prevent or treat HIV infection, and one covering the use of PRO 2000 to prevent pregnancy. 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. See Agreements and Patents and Proprietary Rights.

OTHER PRODUCTS

Dersalazine

General: Dersalazine is a compound for the treatment of inflammatory bowel disease (IBD), which includes ulcerative colitis and Crohn s disease. IBD results from an abnormal immune system response to stimuli in the digestive tract. Several types of cells, cytokines and other mediators are involved in the inflammatory cascade initiated by the exacerbated immune response. Interfering with or halting multiple stages of the inflammatory cascade may provide an effective therapeutic approach to IBD. Ulcerative colitis is a chronic disease that primarily affects the colon and causes inflammation in the upper layers of the large intestine, while Crohn s disease usually occurs in the small intestine and causes inflammation deeper within the wall of the intestine. Up to one million people in the U.S. (*Journal of the American Medical Association, February 7, 2001*) and two million worldwide (*Pharmaprojects 2001*) suffer from these diseases. Fifty percent of these are affected by ulcerative colitis and 50 percent by Crohn s disease (*MEDACorp Survey, 2001*).

Dersalazine is a new chemical entity combining a novel potent anti-inflammatory agent that inhibits key interleukin cytokines and acts as a PAF (platelet activating factor) antagonist with a well-known anti-inflammatory agent, 5-ASA (5-aminosalicylic acid). The chemical cleavage of dersalazine by bacteria in the colon releases these two active components.

The cytokines inhibited by dersalazine include TNF-alpha, IL-1 beta and IL-8, all of which are believed to contribute significantly to the inflammatory cascade leading to IBD. Dersalazine also appears to block the effects of platelet activating factor, a naturally occurring mediator with pro-inflammatory effects implicated in the pathogenesis of IBD. The 5-ASA molecule contained within dersalazine has known anti-inflammatory and antioxidant properties which may also ameliorate the deleterious inflammatory effects ascribed to the overproduction of free radicals.

Development Program: The Company recently completed a multi-dose Phase I trial in Europe. The Company does not believe that the trial met all of its objectives and is currently in discussions with its partner, J. Uriach & Cia., S.A. (Uriach), on whether or not the Company will participate in future clinical trials.

Licensing and Proprietary Rights: In September 2001, the Company acquired worldwide marketing rights to dersalazine from Uriach in exchange for an up-front licensing payment, development milestones and royalty payments. Indevus is responsible for the clinical development, regulatory activities and commercialization of dersalazine. The patents licensed by the Company from Uriach cover compositions and processes for manufacturing dersalazine and the cytokine inhibiting portion of the molecule following bacterial cleavage. See Agreements and Patents and Proprietary Rights.

SUBSIDIARIES

In July 1999, the Company reduced its ownership of Incara Pharmaceuticals, Inc. (Incara) and increased its ownership interest in CPEC LLC, previously a majority-owned subsidiary of Incara. InterNutria, Inc., a majority-owned subsidiary of the Company, discontinued operations in September 1998. (See Note N of Notes to Consolidated Financial Statements.)

MANUFACTURING AND MARKETING

General: The Company s ability to conduct clinical trials on a timely basis, to obtain regulatory approvals and to commercialize its products will depend in part upon its ability to manufacture its products, either directly or through third parties, at a competitive cost and in accordance with applicable FDA and other regulatory requirements, including cGMP regulations. The Company has no manufacturing facilities and limited marketing capabilities. In general, the Company intends to seek to contract with third parties to manufacture and market products.

Development Strategy: The Company believes it does not have sufficient funds to complete regulatory testing of any products under development, other than trospium, or to commercialize any of its products. In general, the Company intends to seek corporate collaborations in which a third party assumes responsibility and funding for drug development, manufacturing and marketing or to obtain additional financing to fund such development.

To the extent the Company enters 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 the Company 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, the Company will be dependent on such third parties for the manufacturing and marketing of products subject to the

collaboration. There can be no assurance the Company 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 the Company marketed a product itself. In the event the Company determines to establish its own manufacturing or marketing capabilities, it would require substantial additional funds. See Risk Factors We will rely on third parties to commercialize and manufacture our products, Our failure to acquire and develop additional product candidates will impair our ability to grow, and We need additional funds in the future.

Trospium: Under the Madaus Agreement, the Company is responsible for all clinical development, regulatory activities and costs related to trospium in the U.S., as well as the commercialization and marketing of trospium in the U.S. either independently or through marketing partners. The Company anticipates 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. The Company believes that Madaus manufacturing facility does not currently meet cGMP requirements. Although Madaus is endeavoring to bring its manufacturing facility into compliance with cGMP, failure to do so in a timely manner could cause a material delay in the NDA submission, FDA approval, if any, and commercialization of trospium. While the Company may seek a second manufacturing source for trospium if Madaus is unable to meet all regulatory requirements or to provide the necessary quantities of trospium in a timely manner, this could also cause a material delay in the NDA submission, FDA approval, if any, and commercialization of trospium.

Pagoclone: Following the termination of the Pfizer Agreement (See Agreements Pagoclone), the Company is responsible for the manufacturing and marketing of pagoclone, either independently or through a corporate partner.

Citicoline: The Company 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. The Ferrer Agreement 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, the Company entered into an agreement with a manufacturer to supply citicoline bulk compound for commercial purposes.

IP 751: Under the ATV Agreement, the Company is responsible for the clinical development, regulatory review activities, manufacturing and marketing of this compound, either independently or through a corporate partner.

PRO 2000: The Company is responsible for providing adequate amounts of PRO 2000 for use in government-sponsored clinical trials. The Company will be dependent upon third-party contractors for the manufacture and delivery of these supplies. The Company intends to seek a partner for commercial manufacture, marketing and distribution of the product.

Dersalazine: Under its agreement with Uriach, the Company anticipates that Uriach will manufacture dersalazine through the completion of Phase II clinical testing. Prior to the end of Phase II clinical trials, the Company and Uriach shall jointly decide whether Uriach will manufacture dersalazine for additional clinical trials and for commercial use. The Company is currently in discussions with Uriach on whether or not it will participate in future clinical trials.

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 the Company. Many of the Company s 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 the Company. In the event the Company or its licensees market any products, 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 the Company s 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 the Company, render the Company s products or potential products obsolete or uneconomical, or result in treatments or cures superior to any therapy developed by the Company, or that any therapy developed by the Company will be preferred to any existing or newly developed products or technologies. Other companies may succeed in developing and commercializing competing products earlier than the Company or products which are safer and more effective than those under development by the Company. 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 the Company could also adversely affect the Company s ability to attract and maintain patients in clinical trials for the same indication or otherwise to complete its clinical trials successfully or on a timely basis. Further, certain of Indevus agreements eliminate or provide for reduced royalties in the event of generic competition.

Colleges, universities, governmental agencies and other public and private research organizations continue to conduct research and are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed, some of which may be directly competitive with that of the Company. In addition, these institutions may compete with the Company in recruiting qualified scientific personnel. The Company expects technological developments in its fields of product development to occur at a rapid rate and expects competition to intensify as advances in these fields are made. See Risk Factors Our products may be unable to compete successfully with other products.

Trospium: Current therapy for overactive bladder includes anticholinergics, such as Detrol and Detrol LA by Pharmacia Corporation and Ditropan XL by Johnson & Johnson, Inc. Watson Pharmaceuticals has re-submitted their NDA for the oxybutynin patch, Oxytrol® Patch. The Company is aware of other companies evaluating specific antimuscaranics and antispasmodics in pre-clinical and clinical development for overactive bladder, including solifenacin by Yamanouchi Pharma America, for which an NDA is expected to be filed in the first quarter of 2003, and darifenacin by Pfizer, also expected to file in the first half of 2003.

Pagoclone: Current pharmacological treatments for anxiety and panic disorders generally include benzodiazepines, such as Valium and Xanax, serotonin agonists such as BuSpar, and selective serotonin reuptake inhibitors such as Paxil, Zoloft, Prozac, and Effexor. 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 and sexual dysfunction related to serotonin reuptake inhibitors. The Company is 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, the Company is aware that other companies are developing compounds for anxiety that are in pre-clinical or clinical development.

Citicoline: Activase, 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), Pro-urokinase (*PROACT*, Abbott), and BAY-x-3702 (*Repinotan*, Bayer).

However, to date, none of these has shown unequivocal safety and efficacy in pivotal 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 pivotal studies, and have been terminated or are likely to have their development discontinued. Based on existing clinical data on citicoline, the Company believes 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, co-promoted by Pfizer and Pharmacia, Vioxx, marketed by Merck, and Bextra, co-promoted by Pfizer and Pharmacia. 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, in pre-clinical studies IP 751 does not appear to produce gastrointestinal ulceration.

PRO 2000: No comparable product to prevent sexually transmitted infections has been approved for use in the U.S., Europe or Japan. Marketed vaginal spermicides containing the detergent nonoxynol-9 have been found to be ineffective at reducing HIV transmission, and may actually increase the risk of infection. Approximately 60 new substances are being evaluated for this indication, but the Company believes 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.

Dersalazine: Various formulations of 5-ASA, which has long been used to treat IBD, are available as oral preparations, suppositories and enemas. Often used as first-line therapy for IBD, they include Asacol® (mesalamine) tablets, Dipentum (olsalazine) capsules, Pentasa® (mesalamine) capsules and Colazal® (balsalazide) capsules. Corticosteroid therapy, such as prednisone or hydrocortisone, is given when the 5-ASA products cannot control inflammation and usually reserved for short-term use in moderate or severe cases. If the patient does not respond to these treatments, anti-immune therapy is an option. This therapy utilizes drugs that suppress the body s ability to make antibodies against the disease and includes azathioprine and 6-mercaptopurine. Investigational therapies include metronidazole, other antibiotics and immunosuppressive agents, and monoclonal antibodies. A significant percentage of those with ulcerative colitis and Crohn s disease will eventually require surgery. New treatment options that induce and maintain remissions, minimize side effects and improve quality of life are needed.

AGREEMENTS

Trospium: In November 1999, the Company entered into the Madaus Agreement under which it licensed from Madaus exclusive U.S. rights to develop and market trospium, an orally-administered prescription drug product currently marketed as a treatment for overactive bladder in Europe. In exchange, the Company has agreed to pay Madaus potential regulatory milestone, royalty and sales milestone payments. Indevus is responsible for all clinical development and regulatory activities and costs related to the compound in the United States. Pursuant to the Madaus Agreement, Madaus is required to manufacture the product, provided certain conditions are met.

Pagoclone: In December 1999, the Company entered into the Pfizer Agreement, under which the Company licensed to Pfizer exclusive, worldwide rights to develop and commercialize pagoclone.Under the Pfizer Agreement the Company received $16,750,000, including an up-front payment of $13,750,000, and was entitled to receive up to an additional $62,000,000 in payments contingent upon the achievement of clinical and regulatory milestones, as well as royalties on net sales. 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 informed the Company of the results of its most recent clinical trials with pagoclone in generalized anxiety disorder and panic disorder, which did not achieve the level of efficacy established in previous trials. Accordingly, Pfizer elected not to pursue further development of the compound and returned to the Company exclusive, worldwide development and commercialization rights to pagoclone. In August 2002, Aventis, licensor of pagoclone to the Company, declined to exercise its contractual option to develop pagoclone. As a result, the Company is seeking a new worldwide development partnership for the commercialization of pagoclone.

In February 1994, the Company licensed from Aventis exclusive, worldwide rights for the manufacture, use and sale of pagoclone under patent rights and know-how related to the drug, except that Indevus granted Aventis an option to sublicense from Indevus, under certain conditions, rights to market pagoclone in France. In exchange, the Company paid Aventis a license fee and agreed to make milestone payments based on clinical and regulatory developments, and to pay royalties based on net sales or, if sublicensed by the Company, the Company would pay to Aventis a portion of receipts from the sublicensee in lieu of milestone and royalty payments. The Company is responsible for all costs of developing, manufacturing, and marketing pagoclone.

Citicoline: In December 1999, the Company entered into the Takeda Agreement under which the Company licensed to Takeda exclusive rights to commercialize citicoline in the U.S. and Canada. Under the Takeda Agreement, the Company received $13,000,000 in licensing and other payments, and was entitled to receive up to $60,000,000 in payments contingent upon the achievement of regulatory milestones in the U.S. and Canada, as well as royalties on net sales. 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 has reacquired all rights to this compound. Indevus has signed a non-binding memorandum of agreement with a privately held biotechnology company to fund further development of citicoline. The finalization of this agreement is contingent upon input from the FDA on the design and clinical endpoints of an additional large Phase III trial and the negotiation of a definitive contract.

In January 1993, the Company entered into the Ferrer Agreement, subsequently amended, granting the Company 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. The Company s license includes patent and know-how rights in the U.S. and know-how rights in Canada, and is for a period co-extensive with Ferrer s license from the Massachusetts Institute of Technology (MIT). The Ferrer Agreement provides that Ferrer may terminate the agreement under certain circumstances, including the insolvency or bankruptcy of Indevus, in the event more than 50% of the ownership of Indevus 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 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, 2003 and is expected to be extended beyond such date. The Ferrer Agreement requires Indevus to use diligent efforts to obtain regulatory approval.

In June 1998, the Company licensed to Ferrer worldwide rights, except in the U.S. and Canada, to the Company s patent relating to the use of citicoline in the protection of brain tissue from cerebral infarction following ischemic stroke. In exchange, the Company 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. See Patents and Proprietary Rights Citicoline.

IP 751: The Company licensed exclusive, worldwide rights to IP 751 from ATV in July 2002, in exchange for an up-front licensing payment, development milestones and royalty payments. The Company is responsible for the clinical development, regulatory review activities and commercialization of this compound. A director of

the Company is a shareholder of ATV, and the transaction was approved by all of the disinterested directors of Indevus.

PRO 2000: In June 2000, the Company licensed exclusive, worldwide rights from HDCI 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, future milestone payments, and royalties on net sales. The Company is responsible for all remaining development and commercialization activities for PRO 2000.

Dersalazine: In September 2001, the Company acquired worldwide rights to dersalazine from Uriach, in exchange for an up-front licensing payment, and potential development milestone and royalty payments. The Company is responsible for the clinical development, regulatory activities and commercialization of dersalazine. Under this agreement, the Company anticipates that Uriach will manufacture dersalazine through the completion of Phase II clinical testing. Uriach retains an option to co-market the product in Spain.

Sarafem: In June 1997, the Company entered into the Lilly Agreement, under which it sublicensed to Lilly exclusive, worldwide rights under an MIT patent that was licensed exclusively by MIT to the Company and which is directed to the use of fluoxetine to treat certain conditions and symptoms associated with PMS (the Lilly Agreement). In July 2000, Lilly received approval for fluoxetine to treat PMDD 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 U.S. up to an annual maximum limit. In December 2002, the Company entered into a renegotiated licensing agreement with Lilly providing for an initial payment to the Company upon the signing of the agreement and royalty payments from Lilly to the Company based on net sales of Sarafem in the U.S. from October 1, 2002 until the expiration of the Company s patent related to Sarafem. In addition, the agreement includes other potential milestone payments to the Company from Lilly. Upon the completion of the conditional agreement announced by Galen in December 2002, Galen would acquire the U.S. sales and marketing rights to Sarafem from Lilly. If the conditional agreement is consummated between Lilly and Galen, any remaining milestone payments to Indevus from Lilly would be accelerated. MIT is entitled to a portion of all payments, including royalties, made to Indevus by Lilly.

Redux Agreements (See Redux Withdrawal and Item 3. Legal Proceedings)

AHP Indemnity and Release Agreement: In May 2001, the Company entered into an agreement with Wyeth 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 existing plaintiffs who have already 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. The agreement also provides for Wyeth to fund 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.

Servier Agreements: In February 1990, the Company and Les Laboratoires Servier (Servier) entered into agreements, subsequently amended (the Servier Agreements), granting the Company an exclusive right to market dexfenfluramine in the U.S. to treat obesity associated with abnormal carbohydrate craving. The Servier Agreements provide for royalties on net sales, with certain required minimum royalties. Servier has the right to terminate the license agreement upon the occurrence of certain events. 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.

Wyeth Agreements: In November 1992, the Company entered into a series of agreements (the Wyeth Agreements) which granted American Cyanamid Company the exclusive right to manufacture and market dexfenfluramine in the U.S. for use in treating obesity associated with abnormal carbohydrate craving, with the Company retaining co-promotion rights. In 1994, Wyeth acquired American Cyanamid Company. The Wyeth Agreements are for a term of 15 years commencing on the date dexfenfluramine is first commercially introduced by Wyeth, subject to earlier termination. Wyeth has the right to terminate the Wyeth Agreements upon 12 months notice to the Company.

Effective June 1996, the Company entered into a three-year copromotion agreement with Wyeth-Ayerst Laboratories (Wyeth-Ayerst), a Wyeth company (the Copromotion Agreement). The Copromotion Agreement provided for Indevus to promote Redux to certain diabetologists, endocrinologists, bariatricians and weight management specialists, subject to certain restrictions, and receive payments from Wyeth for a portion of the Company s actual costs. Indevus was also entitled to varying percentages of profit derived from sales generated by its sales force, after deducting certain costs.

Under the Wyeth Agreements, under certain circumstances, the Company was required to indemnify Wyeth, and the Company was entitled to indemnification by Wyeth against certain claims, damages or liabilities incurred in connection with Redux. The cross indemnification between the Company and Wyeth generally related to the activities and responsibilities of each company. The Company and Wyeth mutually released each other from any rights to indemnification pursuant to the Wyeth Agreements as part of the AHP Indemnity and Release Agreement described above.

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 cGMP regulations. Boehringer has made certain claims on the Company related to the Company s cancellation of the manufacturing agreement with Boehringer. (See Note M of Notes to Consolidated Financial Statements.)

PATENTS AND PROPRIETARY RIGHTS

Trospium: The compound trospium is not covered by a composition of matter patent. Along with know-how, the Company licensed from Madaus two U.S. patents, one of which relates to a process for manufacturing trospium and the other relates to the use of trospium to treat certain asthmatic conditions. These patents were issued in August 1989 and October 1988, respectively. The commercialization of trospium by the Company will not utilize these patents, and the Company intends to rely on the provisions of the Waxman-Hatch Act to obtain a period of market exclusivity in the U.S. if the FDA approves trospium in the U.S. 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 the Company would have market exclusivity. The applicable period is five years in the case of drugs containing an active ingredient

not previously approved. The Company intends 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 formulation, the Company will seek patent protection with respect to such formulation, which if granted, is likely to include a term of up to twenty years, although the Company cannot provide any assurance that any patent on such a once-a-day formulation, if granted, can or will preclude eventual market erosion from new technologies or competing products.

Pagoclone: The Company licensed from Aventis rights under U.S. and foreign patents and patent applications covering compositions of matter, processes, and metabolites of pagoclone. A U.S. composition of matter patent was issued in October 1990 and four related U.S. patents were issued in February and March 1996 and February and October 1997. The Company sublicensed to Pfizer worldwide rights to these patents. In June 2002, Pfizer returned these rights to the Company.

Citicoline: The compound citicoline is not covered by a composition of matter patent. Pursuant to the Ferrer Agreement, the Company 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 expires in 2003. 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 the Company 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. The Company licensed worldwide rights to these patents to Ferrer, except in the U.S. and Canada, in exchange for which the Company 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 the Company.

In May 2000, the Company was 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. The normal term of this patent does not expire until 2018. The Company is also pursuing foreign counterparts of this patent in Canada, China, all European countries subscribing to the European Patent Convention, Hungary, Japan, Mexico and Norway.

In addition to any proprietary rights provided by these patents, the Company intends to rely on the provisions of the Waxman-Hatch Act to obtain a period of marketing exclusivity in the U.S. if the FDA approves citicoline for marketing in the U.S., although there is no assurance market exclusivity will be granted. See Risk Factors We may depend on market exclusivity for trospium and other products.

IP 751: The Company holds an exclusive, worldwide license from ATV to all intellectual property ATV owns or controls relating to IP 751, including patents and patent applications covering the composition of matter, formulations and uses of IP 751. Method claims include methods for the treatment of pain and inflammation, and the treatment of cancer. The ATV 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 ATV.

PRO 2000: The Company holds 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.

Dersalazine: The Company licensed from Uriach exclusive, worldwide rights under patents and patent applications covering composition of matter, uses and manufacturing processes for dersalazine. Dersalazine is metabolized into 5-aminosalicylic acid and an antagonist of cytokine activity following bacterial cleavage. U.S. patents issued in January 1998 and May 1998.

General: There can be no assurance that patent applications filed by the Company or others, in which the Company has 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 the Company is developing are not covered by any patents and, accordingly, the Company will be dependent on obtaining market exclusively under the Waxman-Hatch Act for such products. If the Company is unable to obtain strong proprietary rights protection of its products after obtaining regulatory clearance, competitors may be able to market competing generic products by obtaining regulatory clearance, by demonstrating equivalency to the Company s product, without being required to conduct the lengthy clinical tests required of the Company. Certain of the Company s agreements provide for reduced royalties, or forgo royalties altogether, in the event of generic competition. See Risk Factors We may depend on market exclusivity for trospium and other products.

The products being developed by the Company may conflict with patents which have been or may be granted to competitors, universities or others. Third parties could bring legal actions against the Company or its 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, the Company could be required to obtain a license, which may not be available, in order to continue to manufacture or market the affected product or use the affected process. The Company also relies upon unpatented proprietary technology and may determine in some cases that its 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 the Company can meaningfully protect its rights in such unpatented proprietary technology. The Company 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 the Company to obtain a license to such patents or other rights. See Risk Factors We have limited patent protection on our products.

GOVERNMENT REGULATION

Therapeutics: The Company s 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 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. The Waxman-Hatch Act also establishes periods of market exclusivity, which 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.

The Company believes that citicoline 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 the Company will be able to take advantage of either the patent term extension or marketing exclusivity provisions or that other parties will not challenge the Company s rights to such patent extension or market exclusivity.

Other: The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow the Company to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the Federal Food, Drug, and Cosmetic Act involving medical devices. 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.

REDUX WITHDRAWAL (See Item 3. Legal Proceedings)

On September 15, 1997, the Company announced a market withdrawal of its first prescription product, the weight loss medication Redux (dexfenfluramine hydrochloride capsules) C-IV, which had been launched by Wyeth, the Company s licensee, in June 1996. Since the withdrawal of Redux, the Company has been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 product liability legal actions, some of which purport to be class actions, in federal and state courts involving the use of Redux and other weight loss drugs. To date, there have been no judgments against the Company, nor has the Company paid any amounts in settlement of any of these claims.

Background, Regulatory Approval, Labeling and Safety Issues: Redux (dexfenfluramine) is chemically related to Pondimin (fenfluramine). Fenfluramine is a drug made up of two mirror-image halves a right-handed half (d-isomer) and left-handed half (l-isomer) and dexfenfluramine is the right-handed isomer of fenfluramine (the left-handed half is levofenfluramine). Dexfenfluramine alone is a separate drug from the combined dexfenfluramine/levofenfluramine molecule that is fenfluramine.

Redux received clearance on April 29, 1996 by the FDA for marketing as a twice-daily prescription therapy to treat obesity and was launched in June 1996. Until its withdrawal, under the Wyeth Agreements, Redux was marketed in the U.S. by Wyeth-Ayerst and copromoted by the Company.

Included in the FDA-approved labeling for Redux were references to certain risks that may be associated with dexfenfluramine and which were highlighted during the FDA s review of the drug. One issue related to whether there is an association between appetite suppressants, including dexfenfluramine, and the development of primary pulmonary hypertension (PPH), a rare but serious lung disorder estimated to occur in the general population at one to two cases per million adults per year. An epidemiologic study conducted in Europe known as IPPHS (International Primary Pulmonary Hypertension Study) examined risk factors for PPH and showed that among other factors, weight reduction drugs, including dexfenfluramine, and obesity itself were associated with a higher risk of PPH. In the final report of IPPHS, published in *The New England Journal of Medicine* (August 29, 1996), the authors re-classified and included certain previously excluded cases of PPH, resulting in an increase in the estimated yearly occurrence of PPH for patients taking appetite suppressants for greater than three months duration to be between 23 and 46 cases per million patients per year. The revised labeling for Redux disclosed this revised estimate.

The FDA-approved labeling for Redux also included discussion as to whether dexfenfluramine is associated with certain neurochemical changes in the brain. Certain studies conducted by third parties related to this issue purport to show that very high doses of dexfenfluramine cause prolonged serotonin depletion in certain animals, which some researchers believe is an indication of neurotoxicity. In connection with the approval of Redux, the Company and Wyeth-Ayerst had agreed with the FDA to conduct a Phase IV, or post-marketing, study with patients taking Redux. Following the withdrawal of Redux, this study was terminated.

In July 1997, the Mayo Clinic reported observations of heart valve abnormalities in 24 patients taking the combination of fenfluramine and phentermine (commonly referred to as the fen-phen combination). The Mayo Clinic cases were subsequently reported in an article appearing in the August 28, 1997 issue of *The New England Journal of Medicine*. This article was accompanied by a letter to the editor from the FDA reporting additional cases of heart valve disease in 28 patients taking the combination of phentermine and fenfluramine, two patients taking fenfluramine alone, four patients taking Redux alone and two patients taking Redux and phentermine.

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 the Company in September 1997, indicated an incidence of approximately 30%. 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, the Company believed it was prudent, in light of this information, to have withdrawn Redux from the market.

Additional adverse event reports of abnormal heart valve findings in patients using Redux or fenfluramine alone or in combination with other weight loss agents continue to be received by the Company, Wyeth-Ayerst, and the FDA. These reports have included symptoms such as shortness of breath, chest pain, fainting, swelling of the ankles or a new heart murmur.

Subsequent Clinical Studies: Subsequent to the withdrawal of Redux, a number of studies have been conducted by third parties, including Wyeth-Ayerst, and one study was conducted by the Company, to assess the differences in cardiovascular clinical outcomes between patients who had taken Redux or the fen-phen combination, compared to an untreated group. In general, these studies were conducted and analyzed by independent panels of cardiologists to compare the incidence of significant heart valve abnormalities in treated compared to non-treated groups. Patients were selected and assigned to these groups randomly. Readings of patient echocardiograms have generally been made on a blinded basis by cardiologists who do not know from which group individual echocardiograms were taken. Findings of these studies have been presented or reported by their respective third party sponsors or researchers. Based on the results of studies announced to date, the incidence of cardiac valve abnormalities has been shown to be less than that suggested by the original FDA preliminary analysis. In general, these studies have shown either no or relatively small differences, although in some cases statistically significant, between the incidence of cardiac valve abnormalities, as defined by the FDA, among patients who took Redux and placebo-treated patients and that the incidence of such abnormalities among Redux patients was less than previously reported estimates. Findings from these studies differ with regard to the strength and clinical significance of the association. Differences in trial design preclude precise comparison. A summary of the results of the study sponsored by the Company follows.

Indevus Sponsored Clinical Study: Preliminary results of a blinded, matched control group, multi-center clinical study sponsored by the Company and presented on November 10, 1998 at the Scientific Sessions of the American Heart Association showed a low overall incidence of FDA-defined cardiac valve abnormalities among 223 patients who took Redux for three months or longer when compared to 189 individuals who had not taken Redux. Final results were published in the November 23, 1999 issue of *Circulation*. No severe and very few moderate cases of valvular regurgitation were found in either Redux patients or non-Redux subjects. The incidence of cardiac valve abnormalities among Redux patients reported in this study, although statistically significant, was far less than some previously reported estimates.

The average duration of Redux use among all Redux patients in this study was approximately seven months. The study was designed to evaluate the impact of long-term use of Redux alone upon the incidence of cardiac valve disease as defined by the FDA. Market research data indicates that more than 80% of patients who were prescribed Redux in the U.S. received drug therapy for 90 days or less and only approximately 6.5% of patients took Redux for six months or more.

Analyses were conducted based on echocardiographic data from the total patient population entered into the study and also from the core group, which included only the matched pairs. The FDA has defined significant cardiac valve regurgitation as mild or greater aortic valve regurgitation and/or moderate or greater mitral valve regurgitation. Previous reports had estimated rates of cardiac valve regurgitation among anorexigen-treated patients of up to 30%.

Final analyses showed that among all study participants, 1.3% of Redux patients and 0.5% of non-treated patients (p=not significant) met the FDA s definition of mitral valve regurgitation. With respect to aortic valve regurgitation, in all patients, 6.3% of Redux patients and 1.6% of non-treated patients met the FDA s definition (p=0.01). Among the core group of matched pairs, 6.4% of Redux patients and 1.7% of non-treated controls (p=0.03) met this definition. Among the core group of matched pairs, there was no statistically significant difference in mitral valve regurgitation. For all patients with either aortic or mitral valve regurgitation meeting FDA criteria, the incidence was 2.1% for controls and 7.6% for the Redux patients (p=0.02). In summary, the prevalence of aortic valve regurgitation was statistically significantly greater in the Redux-treated group than in the control group.

When the time from discontinuation of Redux treatment to echocardiogram was analyzed, there was a statistically significant difference in regurgitation rates in Redux patients versus controls for the less than 8.3 month group but not the greater than 8.3 month group, possibly indicating decreased prevalence over time after discontinuation. There was a significant interaction between Redux treatment and blood pressure at the time of echocardiogram, resulting in an increased prevalence of aortic regurgitation with higher blood pressure. This interaction did not exist for the control group. The Redux patients and controls had similar blood pressures at baseline, but the Redux patients had significantly higher post-echocardiogram blood pressures than did the controls. Finally, concomitant use of a drug with MAO (monoamine oxidase) inhibitory properties may be a factor contributing to the occurrence of regurgitation. Such drugs were contraindicated with the use of Redux.

Marketing and Manufacturing: With respect to the marketing and manufacture of Redux, the Company sublicensed U.S. marketing rights to Wyeth, while retaining copromotion rights. Redux was launched in June 1996 and withdrawn in September 1997. The Company relied on Wyeth to target the obesity market and for distribution and advertising and promotional activities. The Company copromoted Redux through an approximately 30-person sales force to selected diabetologists, endocrinologists, bariatricians, nutritionists and weight management specialists, subject to certain restrictions. Under a contract manufacturing agreement, Boehringer produced on behalf of the Company commercial scale quantities of the finished dosage formulation of Redux in capsule form.

Patents and Proprietary Rights: The Servier Agreements granted the Company an exclusive license to sell dexfenfluramine in the U.S. under a patent covering the use of dexfenfluramine to treat abnormal carbohydrate craving, which was sublicensed by the Company to Wyeth. Use of dexfenfluramine for the treatment of abnormal carbohydrate craving was patented by Drs. Richard Wurtman and Judith Wurtman. Dr. Richard Wurtman was a consultant to and a director of the Company. This use patent was assigned to MIT and licensed by MIT to Servier, and pursuant to the Servier Agreements, was licensed to the Company.

EMPLOYEES

As of September 30, 2002, the Company had 24 full-time employees. None of the Company s employees is represented by a labor union and the Company believes its employee relations are satisfactory. The Company is highly dependent upon certain key personnel and believes its future success will depend in large part on its ability to retain such individuals and attract other highly skilled management, marketing and scientific personnel.

ITEM 2. ***Properties***

The Company leases 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. The Company has guaranteed certain of Incara s lease obligations. See Note G of Notes to Consolidated Financial Statements. The Company believes such space is adequate for its current needs.

ITEM 3. ***Legal Proceedings (See Item 1 Narrative Description of Business)***

Product Liability Litigation: Subsequent to the market withdrawal of Redux in September 1997, the Company has been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 legal actions, many of which purport to be class actions, in federal and state courts relating to the use of Redux. The actions generally have been brought by individuals in their own right or on behalf of putative classes of persons who claim to have suffered injury or who claim that they may suffer injury in the future due to use of one or more weight loss drugs including Pondimin (fenfluramine), phentermine and Redux. Plaintiffs allegations of liability are based on various theories of recovery, including, but not limited to, product liability, strict liability, negligence, various breaches of warranty, conspiracy, fraud, misrepresentation and deceit. These lawsuits typically allege that the short or long-term use of Pondimin and/or Redux, independently or in combination

(including the combination of Pondimin and phentermine popularly known as fen-phen), causes, among other things, PPH, 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. To date, there have been no judgments against the Company, nor has the Company paid any amounts in settlement of any of these claims.

The Company entered into the AHP Indemnity and Release Agreement on May 30, 2001 pursuant to which Wyeth agreed to indemnify the Company against certain classes of product liability cases filed against Indevus related to Redux. The Company s indemnification covers existing plaintiffs who have already 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. The agreement also provides for Wyeth to fund 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.

Complaint Against Wyeth: On January 24, 2000, the Company announced it had filed a complaint against Wyeth in the Superior Court of the Commonwealth of Massachusetts (the Wyeth Litigation). The complaint sought unspecified but substantial damages and attorneys fees pursuant to common and statutory law for Wyeth s knowing and willful deceptive acts and practices, fraud and misrepresentations and breach of contract. Wyeth filed an answer denying the allegations of such complaint. Pursuant to the AHP Indemnity and Release Agreement, described above, such complaint was dismissed on June 28, 2001.

Insurance Litigation: On August 7, 2001, Columbia Casualty Company (CNA), one of the Company s insurers for the period May 1997 through May 1998, filed an action in the United States District Court for the District of Columbia against the Company. The lawsuit is based upon a claim for breach of contract and declaratory judgment, seeking damages against the Company in excess of $20,000,000, the amount that the plaintiff has paid to the Company under its insurance policy. The plaintiff alleges that under the policy it was subrogated to any claim for indemnification that Indevus may have had against Wyeth related to Redux and that such claim was compromised without its consent when the Company entered into the AHP Indemnity and Release Agreement. On March 8, 2002, the Company filed an Answer, Affirmative Defenses and Counterclaims to the action, including counterclaims for breach of contract, breach of the implied covenant of good faith and fair dealing, declaratory judgment pursuant to 28 U.S.C. Sections 2201 and 2202, and unfair or deceptive acts and/or unfair claims settlement practices. The Company is vigorously defending this litigation. On April 30, 2002, CNA moved to dismiss our counterclaims, and that motion was denied on November 8, 2002 with respect to all but one of our counterclaims. On July 12, 2002, we moved for judgment on the pleadings to dismiss CNA s complaint.

Although the Magistrate Judge recommended that the motion be denied, it is now on review before the District Court. In the meantime, we and CNA are actively participating in discovery. No trial date has been set. The Company believes it has meritorious defenses to this suit, however it is unable to predict the outcome of this litigation or the range of potential damages payable to either party if their respective claims or counterclaims are successful. An unfavorable outcome of this litigation could have a material adverse effect on our financial position and results of operations.

General: Pursuant to agreements between the parties, under certain circumstances, the Company may be required to indemnify Servier, Boehringer and other parties.

Although the Company maintains certain product liability and director and officer liability insurance and intends to defend these and similar actions vigorously, the Company has 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 the Company and its officers and directors, the Company s 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 the Company s Common Stock and on the Company s ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, or to obtain product liability insurance for other products at costs acceptable to the Company, or at all, any or all of which may materially adversely affect the Company s business, financial condition and results of operations. See Management s Discussion and Analysis of Financial Condition and Results of Operations, Risk Factors The outcome of the Redux litigation could materially harm us, and Note H of Notes to Consolidated Financial Statements.

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.	49	President, Chief Executive Officer and Chairman
Mark S. Butler	56	Executive Vice President, Chief Administrative Officer and General Counsel
Michael W. Rogers	42	Executive Vice President, Chief Financial Officer and Treasurer
Bobby W. Sandage, Jr., Ph.D.	49	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 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 the Company s 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 Report and presented elsewhere by Company management from time to time. See Part I Note Regarding Forward Looking Statements.

We will depend on the success of trospium.

Our future success may depend in large part on the success of trospium. There are many risks associated with the successful approval, manufacturing and commercialization of trospium. We intend to file a New Drug Application for trospium with the United States Food and Drug Administration in the second quarter of 2003, contingent upon our discussion with the FDA regarding stability testing and manufacturing issues. We would be materially adversely affected if we do not file the NDA for trospium in a timely manner or at all, if our NDA for trospium is not accepted for filing by the FDA, if we are unable to obtain FDA approval for trospium, or if approved, we do not receive favorable labeling for trospium from the FDA. In addition, the FDA may impose post-marketing or other regulatory procedures after approval, which could prolong the process for commercialization of trospium. In addition, although trospium has thus far demonstrated a favorable safety profile in clinical trials, there can be no assurance that the safety profile of the drug would not change when taken by a larger population of users.

Even if we receive FDA approval for trospium, we do not have the necessary sales and marketing capability or financial resources to market trospium. We are currently evaluating commercialization alternatives for trospium, including seeking a corporate partner or partners to assist in the commercialization of trospium. We would be materially adversely affected if we were unable to find a corporate partner for trospium on acceptable terms or at all. We would likely be dependent on such collaborative partner for the commercialization of trospium and our partner may not be successful in commercializing trospium. The market for overactive bladder therapy is highly competitive and trospium may not compete successfully with current drug therapies for overactive bladder or with new drugs which are in development and may reach the market in the future. We would be materially adversely affected if trospium did not achieve or maintain market acceptance. We will also be dependent on Madaus to manufacture trospium. We are working with Madaus to achieve compliance with FDA requirements for manufacturers of drugs. If Madaus were unable to achieve compliance, we would need to seek alternative sources of supply, which could delay the commercialization of trospium.

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

We currently have rights to five core compounds which are in various stages of testing and have not been approved by the United States Food and Drug Administration. The five core compounds which are the focus of our development program are trospium, for which we have completed a Phase III clinical trial and intend to file a New Drug Application during the second quarter of 2003, pagoclone, which is in Phase III development for panic disorder and Phase II development for generalized anxiety disorder, citicoline, which is in Phase III development, PRO 2000, which is in Phase II development, and IP 751 which is in Phase I/II development. The products we are developing 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 our products 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 or procedures are long and uncertain. Even if our products receive regulatory clearance, our products may not achieve or maintain market acceptance.

We rely on the favorable outcome of clinical trials of our products.

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 United States Food and Drug Administration and other regulatory approval is lengthy and expensive. If clinical trials do not demonstrate the safety and efficacy of certain products under development, we will be materially adversely affected. The results of pre-clinical studies and early clinical trials may not predict results that will be obtained in large-scale testing or use. Clinical trials of products we are developing may not demonstrate the safety and efficacy of such products. Regardless of clinical trial results, the FDA may not approve marketing of the product. The costs to obtain regulatory approvals could be considerable and the failure to obtain, or delays in obtaining regulatory approval could have a significant negative effect on our business performance and financial results. Even if pre-market approval of a product is obtained, the FDA is authorized to impose post-marketing requirements. A number of companies in the pharmaceutical industry, including our company, have suffered significant setbacks in advanced clinical trials or have not received FDA approval, even after promising results in earlier trials. In 1998, we withdrew our New Drug Application for citicoline, a compound designed to treat ischemic stroke, after the failure to meet our primary objective in a small Phase III clinical study.

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

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

We require substantial additional funds to complete development of our products and anticipate forming partnerships to manufacture and market our products. We seek corporate partners to fund development and commercialization of our products. We may not be successful in finding corporate partners or obtaining other financing and, if obtained, the terms of any such arrangements may not be favorable to us. If we are not able to obtain any such corporate partners or financing, development of our products 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. Typically purchase orders for supplies or clinical compounds are filled 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 any of our products or product candidates on reasonable terms or at all. Any manufacturing facilities for any of our compounds are subject to United States Food and Drug Administration inspection both before and after New Drug Application approval to determine compliance with current Good Manufacturing Practices requirements. Facilities used to produce our compounds may not have complied, or may not be able to maintain compliance, with current Good Manufacturing Practices. The current Good Manufacturing Practices regulations are complex and failure to be in compliance could lead to non-approval or delayed approval of the New Drug Application. 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.

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

We need additional funds in the future.

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. In fiscal 2002, net cash used in operating activities was $14,609,000. We expect that net cash used in operating activities will increase in fiscal 2003 as we continue to fund our development activities. Accordingly, we may seek such additional funds during or after fiscal 2003 through corporate collaborations or public or private equity or debt financings. 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, however, 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 file, and receive U. S. Food and Drug Administration approval of, a New Drug Application for trospium and successfully commercialize trospium and the nature of any collaboration 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;
- whether we are successful in either in-licensing or out-licensing products;
- whether we are successful in defending against our Redux product liability litigation; and
- the timing and extent of reimbursement from insurers.

As a result of the uncertainties and costs associated with business development activities, market conditions, the Redux-related litigation 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 $70,000,000, $38,000,000 $1,500,000 and $18,000,000 for fiscal years 1998, 1999, 2001, and 2002, respectively.

Through September 30, 2002, we had accumulated net losses since inception of approximately $269,000,000. We expect to have losses and use cash in operating activities for the foreseeable future. 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. In addition, payments made by us in connection with product liability litigation would result in significant charges to operations and would materially adversely affect our results of operations and financial condition.

We may not be profitable in the future.

We may never achieve or sustain profitability in the future. Our cumulative revenues received through September 30, 2002 were approximately $150,000,000 of which approximately $73,000,000 was derived from Redux, which was withdrawn from the market in September 1997. We expect to continue to experience fluctuations in revenue as a result of the timing of regulatory filings or approvals, product launches, license fees, royalties, product shipments, and milestone payments.

We 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 insurance in the amount of $20,000,000. 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. One of our insurers is in liquidation proceedings and may not be able to reimburse us under our policy. Another insurer has claimed it is entitled to recover twenty million dollars that it has paid to us under our policy. We cannot predict the extent to which the Redux-related litigation may affect our ability to obtain sufficient product liability insurance for other products at costs acceptable to us. 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.

An unfavorable outcome of certain insurance-related litigation may materially harm us.

On August 7, 2001, Columbia Casualty Company, known as CNA, one of our insurers for the period May 1997 through May 1998, filed an action in the United States District Court for the District of Columbia against us. The lawsuit is based upon, among other things, a claim for breach of contract and seeks damages against us in excess of $20,000,000, the amount that CNA has paid to us under our insurance policy related to the Redux litigation. In the lawsuit, CNA alleges that under the insurance policy, CNA had the right to use our rights to indemnification against Wyeth which CNA alleges was compromised without its consent when we entered into the AHP Indemnity and Release Agreement. We are unable to predict the outcome of this litigation or the range of potential damages payable to CNA if CNA is successful. An unfavorable outcome of this litigation could have a material adverse effect on our financial position and results of operations.

The outcome of the Redux litigation could materially harm us.

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. Following the withdrawal, we have been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 product liability legal actions, many of which purport to be class actions, in federal and state courts involving the use of Redux and other weight loss drugs. In related litigation, we have been sued by one of our insurers, alleging that we compromised its subrogation rights by entering into an agreement with American Home Products Corporation, now called Wyeth, providing us with certain indemnification and release of claims related to Redux.

The existence of such litigation may continue to materially adversely affect our business, including our ability to obtain sufficient financing to fund operations. 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 costs and 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. The AHP Indemnity and Release Agreement provides for indemnification of Redux-related claims brought by plaintiffs who have elected not to stay in American Home Products 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. 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 have limited patent protection on our products.

Our compounds are currently covered by approximately 200 registered patents and patent applications. The issued patents expire between the years 2003 and 2017.

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 to trospium, a compound under development for treatment of overactive bladder, does not include any patents expected to be used in commercializing the product.

Our licensed United States patent covering the administration of citicoline to treat patients afflicted with conditions associated with the inadequate release of brain acetylcholine expires in 2003. 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.

The outcome of any litigation is highly 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 trospium and other products.

Assuming regulatory approvals are obtained, our ability to commercialize successfully certain drugs, including trospium, may depend on the availability of market exclusivity or patent extension 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 United States Food and Drug Administration determines such compound to be a new chemical entity. If we receive favorable treatment under the Waxman-Hatch Act for trospium, we can obtain market exclusivity for a period of five years from the date of United States Food and Drug Administration approval. The marketing of trospium could be materially adversely affected if marketing exclusivity is not available to us.

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.

Trospium would compete with other therapies for overactive bladder, including anticholinergics, such as Detrol and Detrol LA and Ditropan and Ditropan XL. In addition, we are aware of other companies evaluating specific antimuscaranic and antispasmodics for overactive bladder in pre-clinical and clinical development, including darifenacin by Pfizer and solifenacin by Yamanouchi.

Pagoclone would compete with a number of drugs available and under development to treat anxiety or panic disorders, including serotonergic drugs such as BuSpar, Paxil, Zoloft, Prozac and Effexor and benzodiazepines such as Valium and Xanax.

With respect to citicoline, Genentech, Inc. markets Activase, a thrombolytic agent, as a treatment for stroke. We are aware that other companies are conducting clinical trials on a number of other products for stroke which could also compete with citicoline.

In addition to PRO 2000, many new substances are being evaluated for the prevention of HIV transmission. Among the most advanced are BufferGel, Savvy, Emmelle, Carraguard and cellulose sulfate gel.

IP 751 would compete with currently prescribed treatments for pain and inflammatory disorders, including opioids and NSAIDs (non-steroidal anti-inflammatories) / COX-II inhibitors. The principal marketed opioids include oxycontin and morphine, and NSAIDs include Celebrex, co-promoted by Pfizer and Pharmacia, Vioxx, marketed by Merck, and Bextra, co-promoted by Pfizer and Pharmacia.

Dersalazine initially would compete with various formulations of 5-aminosalicylic acid often used as first line therapy for inflammatory bowel disease and including Asacol, Dipentum, Pentasa and Colazal.

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 may compete with other companies in acquiring rights to products or technologies.

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

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

We have never paid any dividends on our Common Stock.

We have not paid any cash dividends on our Common Stock since inception and do not expect to do so in the foreseeable future. Any dividends will be subject to the preferential cumulative 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.

Our stock price is volatile.

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

results of clinical studies and regulatory reviews;

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

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

market conditions in the pharmaceutical and biotechnology industries;

competitive products;

financings or corporate collaborations;

sales or the possibility of sales of our Common Stock;

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 National Market were: $6.25 and $1.13 for fiscal 1999, $8.75 and $1.34 for fiscal 2000, $10.00 and $1.16 for fiscal 2001 and $12.83 and $0.85 for fiscal 2002. 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 NASDAQ s continued listing requirements, our Common Stock could

be delisted from NASDAQ, 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 uncertainties associated with the Redux-related litigation have adversely affected and may continue to adversely affect the market price of our Common Stock. Furthermore, the stock market has experienced 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.

Our stock price could be negatively affected if our shares are sold, if we issue additional shares or if third parties exercise registration rights.

As of December 13, 2002, we had 46,875,885 shares of Common Stock outstanding. Substantially all of these shares are eligible for sale without restriction. We issued 3,125,000 shares of our Common Stock in private placement in December 2001. The re-sale of those shares into the public market is covered under a prospectus filed with the Securities and Exchange Commission. These shares may be sold to the public by the owners with limited restrictions. Some of our other stockholders own restricted securities, and they may have to rely on Rule 144 of the Securities Act of 1933 which regulates the sale of restricted securities. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including persons who may be deemed to be affiliates of our company as that term is defined under the Securities Act of 1933, is entitled to sell within any three-month period a number of restricted shares beneficially owned for at least one year that does not exceed the greater of:

(i) one percent of the then outstanding shares of Common Stock, or

(ii) the average weekly trading volume in the Common Stock during the four calendar weeks preceding such sale.

Sales of restricted securities under Rule 144 are also subject to certain requirements as to the manner of sale, notice and the availability of current public information about us. However, a person who is not an affiliate and has beneficially owned such shares for at least two years is entitled to sell such shares without regard to the volume or other requirements.

Wyeth has the right, under certain circumstances, to require the Company to register for public sale 622,222 shares of Common Stock issuable to it upon conversion of the Series B and C Preferred Stock it owns. We have outstanding registration statements on Form S-3 relating to the resale of our shares of Common Stock and on Form S-8 relating to shares issuable under our 1989 Stock Option Plan, 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan and 2000 Stock Option Plan.

Sales of the shares of Common Stock subject to restricted stock awards, and 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, stock awards or other arrangements.

As of October 31, 2002, we had reserved the following shares of Common Stock for issuance:

10,224,000 shares issuable upon exercise of outstanding options and warrants, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option and warrant holders if we issue additional securities below certain prices;

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

1,446,000 shares reserved for grant and issuance under the Company s stock option plans, stock purchase plan and equity incentive plan.

We may grant additional options, warrants or stock awards. In addition, we may be required to issue additional shares of Common Stock in connection with technology acquisitions. To the extent such shares are issued, the interest of holders of Common Stock will be diluted.

PART II

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

Price Range of Securities

The Company s Common Stock trades on the Nasdaq National Market under the symbol IDEV. On April 2, 2002, the Company s 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 the Company s 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, 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
Fiscal Year Ended September 30, 2001:		
July 1 through September 30, 2001	$ 8.90	$ 3.65
April 1 through June 30, 2001	10.00	2.53
January 1 through March 31, 2001	4.12	1.31
October 1 through December 31, 2000	2.44	1.16

Approximate Number of Equity Security Holders

The number of holders of record of the Company s Common Stock as of September 30, 2002 was approximately 562.

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 the Company s equity compensation plans and arrangements as of September 30, 2002:

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	10,069,377	$ 4.21	1,395,184
Equity compensation plans or arrangements not approved by security holders	155,000 (1)	$ 5.51	13,082 (2)
Total	10,224,377	$ 4.23	1,408,266

(1) Includes (i) an option to purchase 50,000 shares of Commons 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 I 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 the Company s 1997 Equity Incentive Plan which are available for future issuance other than upon the exercise of an option, warrant or right (see Note I of the Notes to Consolidated Financial Statements).

ITEM 6. Selected Financial Data

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

	Fiscal Years Ended September 30,				
	1998	1999	2000	2001	2002
	(Amounts in thousands except per share data)				
Statement of Operations Data:					
Revenues:					