INDEVUS PHARMACEUTICALS INC
Form 10-K
December 11, 2008

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

**x** **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended September 30, 2008

or

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

Commission File No. 0-18728

# Indevus Pharmaceuticals, Inc.

**(Exact name of registrant as specified in its charter)**

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

**33 Hayden Avenue**

| Lexington, MA | 02421-7966 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

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

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of each class | Name of each exchange on which registered |
|---|---|
| Common Stock, $0.001 Par Value | Nasdaq Global Market |

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ¨ NO x

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act:

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer x |
| Non-accelerated filer ¨ (Do not check if a smaller reporting company) | Smaller reporting company ¨ |

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

The aggregate market value of the voting and non-voting common equity (excluding preferred stock outstanding as of March 31, 2008 that prior to its conversion in April 2008 was convertible into 622,000 shares of Common Stock and had voting rights on certain matters equivalent to 568,750 shares of Common Stock) held by non-affiliates of the registrant was approximately $308,000,000, based on the last sales price of the Common Stock as of March 31, 2008. Shares of Common Stock held by each executive officer and director and each person who beneficially owns 10% or more of the outstanding Common Stock and individuals or entities related to such persons have been excluded. This determination of affiliate status may not be conclusive for other purposes.

As of December 1, 2008, 78,151,727 shares of Common Stock, $.001 par value per share, of the registrant were issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

See Part III hereof with respect to incorporation by reference from the registrant s definitive proxy statement for the fiscal year ended September 30, 2008 to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 and the Exhibit Index beginning on page number 79 hereto.

**PART I**

***Note Regarding Forward Looking Statements***

Statements in this Form 10-K that are not statements or descriptions of historical facts are forward looking statements under Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA® (trospium chloride tablets), SANCTURA XR (once-daily SANCTURA), NEBIDO®, (injectable testosterone undecanoate), VANTAS® (histrelin implant for prostate cancer) and SUPPRELIN® LA (histrelin implant for central precocious puberty); our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux -related litigation. The words believe, expect, anticipate, intend, plan, estimate or other expressions which predict or indicate future events and tre do not relate to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, this Form 10-K. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR, NEBIDO, VALSTAR , VANTAS and SUPPRELIN LA; need for additional funds and corporate partners, including for the development of our products; risks related to increased leverage; effectiveness of our sales force; competition and its effect on pricing, spending, third-party relationships and revenues; dependence on third parties for supplies, particularly for histrelin, manufacturing, marketing, and clinical trials; risks associated with being a manufacturer of some of our products; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA, SANCTURA XR and SUPPRELIN LA; the manufacture of NEBIDO, VANTAS, SUPPRELIN LA and VALSTAR as well as those relating to the outstanding indebtedness of our subsidiaries; reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity, changes in reimbursement policies and/or rates for SANCTURA, SANCTURA XR, VANTAS, SUPPRELIN LA, DELATESTRYL® and any future products; acceptance by the healthcare community of our approved products and product candidates; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR, NEBIDO, VALSTAR, VANTAS and SUPPRELIN LA; product liability and insurance uncertainties; risks relating to the Redux-related litigation; history of operating losses and expectation of future losses; uncertainties relating to controls over financial reporting; valuation of our Common Stock; risks related to repayment of debts; general worldwide economic conditions and related uncertainties; and other risks. The forward-looking statements represent our judgment and expectations as of the date of this Form 10-K. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward looking statements. See Risk Factors.

Unless the context indicates otherwise, Indevus , the Company , we , our and us refer to Indevus Pharmaceuticals, Inc., and Common Stock to the common stock, $.001 par value per share, of Indevus. In the United States, SANCTURA is a registered trademark of Esprit Pharma, Inc., which became a wholly-owned subsidiary of Allergan, Inc. as of October 16, 2007 (subject to our co-exclusive right to use the mark). The

mark SANCTURA XR is the subject of a pending application for registration by Allergan, Inc. Outside the United States, SANCTURA is a registered trademark of the Company. The marks DELATESTRYL, VANTAS, and SUPPRELIN are also registered trademarks of the Company. The Company also has a pending application for the registration of the mark VALSTAR. NEBIDO is a registered trademark of Bayer Schering Pharma AG, Germany. Other trademarks, trade names and service marks used in this Form 10-K are the property of their respective owners. Symbols for trademarks and registrations are omitted hereinafter for convenience.

**Where You Can Find More Information**

We are subject to the information and reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, under which we file periodic reports, proxy and information statements and other information with the SEC. Copies of the reports, proxy statements and other information may be examined without charge at the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, or on the Internet at http://www.sec.gov. Copies of all or a portion of such materials can be obtained from the Public Reference Room of the SEC upon payment of prescribed fees. Please call the SEC at 1-800-SEC-0330 for further information about the Public Reference Room.

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

## ITEM 1. *Business*

**Overview**

We are a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Our approved products include SANCTURA® and SANCTURA XR for overactive bladder (OAB), which we co-promote with our partner Allergan, Inc. (Allergan), VANTAS® for advanced prostate cancer, SUPPRELIN® LA for central precocious puberty (CPP), and DELATESTRYL® for the treatment of hypogonadism. We market our products through an approximately 100-person specialty sales force.

Our core urology and endocrinology portfolio contains multiple compounds in development in addition to our approved products. Our most advanced compounds are VALSTAR for bladder cancer, NEBIDO® for hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and the octreotide implant for acromegaly and carcinoid syndrome.

In addition to our core urology and endocrinology portfolio, there are multiple compounds outside of our core focus area which we either currently outlicense for development and commercialization, or intend to outlicense in the future. These compounds include pagoclone for stuttering, which we recently licensed to Teva Pharmaceutical Industries Ltd. (Teva), ALKS 27 for chronic obstructive pulmonary disease (COPD), which we have been jointly developing with Alkermes, Inc. (Alkermes), and aminocandin for systemic fungal infections, the know-how for which we licensed to Novexel S.A. (Novexel).

Indevus Pharmaceuticals, Inc. is a Delaware corporation. Our corporate headquarters is located at 33 Hayden Avenue, Lexington, Massachusetts 02421-7971, and our main telephone number is (781) 861-8444.

**Our Strategy**

Our goal is to become a leading specialty pharmaceutical company focused in urology and endocrinology. The key elements of our strategy, which we employ in our efforts to achieve our goal include:

(1) Identifying and acquiring products, product candidates or companies within our core focus area that are complementary to our current product portfolio.

(2) Adding value to acquired development stage compounds through research, pre-clinical development, clinical testing and regulatory activities.

(3) Commercializing products independently with our specialty sales force or in collaboration with corporate partners in order to help ensure broader penetration of target markets.

**Core Focus Area Urology and Endocrinology**

In the urology and endocrinology markets, we believe we have developed strong capabilities in product development based on our research and development organization and in sales and marketing based upon our approximately 100-person specialty sales force.

Through our business development efforts and our research and development capabilities, we have a late-stage product pipeline. We believe our capabilities will enable us to continue to successfully acquire, develop and commercialize products and product candidates and achieve our strategic goal of becoming a leading specialty pharmaceutical company in our core focus area.

**OUR CORE PRODUCTS AND PRODUCT CANDIDATES**

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

| Product Name | Indication/Use | Status[1] | Commercial Rights[2] |
|---|---|---|---|
| SANCTURA | Overactive bladder | Marketed | U.S. |
| SANCTURA XR | Overactive bladder | Marketed[3] | Worldwide |
| VANTAS | Advanced Prostate Cancer | Marketed[3] | Worldwide |
| SUPPRELIN LA | Central Precocious Puberty | Marketed[3] | Worldwide |
| DELATESTRYL | Hypogonadism | Marketed | U.S. |
| VALSTAR | Bladder Cancer | sNDA[4] Submitted | Worldwide |
| NEBIDO | Hypogonadism | NDA[5] Approvable | U.S. |
| PRO 2000 | HIV and STD prevention | Phase III | Worldwide |
| Octreotide Implant | Acromegaly | Phase III | Worldwide |

1 See Government Regulation.
2 See Agreements.
3 Currently marketed in the U.S.
4 VALSTAR is an approved product awaiting approval of a manufacturing facility and re-introduction to the market.
5 As used in this Form 10-K, the phrase NDA refers to New Drug Application. See discussion of NEBIDO NDA re-submission.

***SANCTURA***

*General.* In August 2004, we launched SANCTURA, a muscarinic receptor antagonist for the treatment of OAB. We co-promote SANCTURA in the U.S. with our marketing partner, Allergan. SANCTURA is indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency and urinary frequency.

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

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

OAB is a medical condition whose symptoms include urinary frequency, urgency, and urge incontinence, the accidental loss of urine that occurs after the strong, sudden urge to urinate. An estimated 33 million Americans suffer from OAB. In 2008, the market for drugs to treat OAB is expected to be approximately $1.8 billion in the United States. OAB represents a significant clinical problem with potential medical, hygienic, and social consequences. When untreated, this condition can lead to disability, dependence, and isolation from the community. It is most prevalent among the elderly and strikes women twice as frequently as men.

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

*Commercialization.* We currently co-promote SANCTURA in the U.S. with Allergan. To support the commercialization of SANCTURA and as a platform for future growth, we have a sales and marketing infrastructure which includes a specialty sales force who call on urologists and other prescribers specializing in treating patients with OAB. Effective October 16, 2007, Allergan acquired our previous partner, Esprit Pharma Inc. ( Esprit ), and we entered into a revised agreement whereby we granted Allergan certain rights to SANCTURA. Esprit had previously acquired the rights to market SANCTURA in the U.S. from Odyssey Pharmaceuticals, Inc. ( Odyssey ), a specialty-branded subsidiary of PLIVA d.d. ( PLIVA ). See Agreements.

***SANCTURA XR***

*General.* SANCTURA XR is a once-daily formulation of SANCTURA, our currently marketed product for the treatment of OAB. SANCTURA XR belongs to a class of anticholinergic compounds known as muscarinic receptor antagonists. Current treatments in the U.S. for OAB include compounds in the same therapeutic class as SANCTURA XR.

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

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

*Development.* On August 3, 2007, the FDA approved the NDA for SANCTURA XR. Our development program for SANCTURA XR included two randomized, double-blind, placebo-controlled Phase III trials conducted in the U.S. that were submitted in the NDA. We announced positive data from the first Phase III trial in June 2006 and positive data from the second Phase III trial in July 2006. The first trial included 601 patients who were studied at 55 sites. The second trial included 564 patients who were studied at 62 sites. Both trials were 12-week trials and measured the effects of 60 mg of SANCTURA XR versus placebo, once-daily, on symptoms

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

In June 2005, we announced positive results from a pilot Phase II trial of SANCTURA XR. The trial was a two-week, multi-center, placebo-controlled, double-blind study designed to evaluate the efficacy and safety of 60 mg SANCTURA XR versus placebo, once-daily, in 148 patients with OAB.

*Commercialization.* SANCTURA XR was launched in the U.S. in January 2008. We market the product with our partner, Allergan, in the U.S. through our specialty sales force. We have extended our co-promotion rights through March 2009. We entered into (i) a License and Supply Agreement and (ii) an amendment to the original license agreement with Madaus (collectively, the Madaus Agreements ). Under the Madaus Agreements, we agreed to (a) purchase from Madaus all required trospium active pharmaceutical ingredient through November 2007 (b) license Madaus the rights to sell SANCTURA XR in all countries outside of the U.S. (the Madaus Territory ) except Canada, Japan, Korea and China (the Joint Territory ), (c) pay to Madaus a fee based on the number of capsules of SANCTURA XR sold by us in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share, (d) supply SANCTURA XR to Madaus for a specified period of time (e) provide development committee support for a defined period and (f) provide future know-how to Madaus.

In May 2008, we signed a License Agreement with Allergan Inc., a Canadian affiliate of Allergan, Inc., granting Allergan the right to market SANCTURA XR throughout Canada. See Agreements. Our partner, Madaus, has received marketing approval in October 2008 from their Reference Member State which they designated as Germany. Nine additional European countries are expected to grant marketing approvals by December 2008.

***VANTAS***

*General.* VANTAS was launched in the U.S. in November 2004. We obtained VANTAS through our acquisition of Valera Pharmaceuticals, Inc. ( Valera ) in April 2007. VANTAS is a soft, flexible 12-month hydrogel implant based on our patented HYDRON® Polymer Technology ( HYDRON Polymer Technology ) that delivers histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH agonist and is indicated for the palliative treatment of advanced prostate cancer. See HYDRON Polymer Technology below for additional information.

The current standard of care for the palliative treatment of prostate cancer is LHRH agonist therapy. An agonist is a chemical substance capable of activating a receptor to induce a full or partial pharmacological response. LHRH agonist therapies for advanced prostate cancer are designed to suppress the production of testosterone because testosterone promotes and accelerates the growth of tumors associated with prostate cancer. Histrelin, a powerful inhibitor of testosterone production, is the most potent LHRH agonist available.

Prostate cancer is the most common cancer for men other than skin cancers and the second leading cause of cancer death in men. According to the American Cancer Society, every year approximately 190,000 men will be diagnosed with prostate cancer and approximately 29,000 will die from this disease in 2008. The National Cancer Institute s SEER Program and the National Oncology Database each project that this patient group will grow at an annual rate of 2% to 3% per year. In 2007, the LHRH market, according to IMS Health, was approximately $820 million in the United States.

*Development and Commercialization*. On October 12, 2004 the FDA approved the NDA for VANTAS. In November 2005, VANTAS was approved for marketing in Denmark. In March 2006, Paladin Labs, Valera s marketing partner in Canada, received approval from Health Canada to market VANTAS in Canada although we believe marketing of the product will require the establishment of a reimbursement price for VANTAS, which has not been achieved to date by Paladin.

Mutual Recognition Procedure (MRP) in Germany, Ireland, Italy, Spain and the United Kingdom for marketing authorization began in July 2006. Approval was granted in May 2007. In April 2008, we entered into a License, Supply and Distribution Agreement with Orion Corporation ( Orion ) granting them the rights to market VANTAS throughout Europe as well as certain other countries.

As of August 2007, in conjunction with BioPro Pharmaceutical Inc., our marketing partner for most countries in Asia, VANTAS was approved in Thailand, Singapore and Malaysia and approval is pending in Taiwan, Korea, Hong Kong and China. In addition, our partner Teva-Tuteur has received approval and begun marketing VANTAS in Argentina. See Agreements.

***SUPPRELIN LA***

*General.* We launched SUPPRELIN LA in the U.S. in June 2007. We obtained SUPPRELIN LA through our acquisition of Valera. SUPPRELIN LA is a soft, flexible 12-month hydrogel implant based on our patented HYDRON Polymer Technology that delivers histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH agonist and is indicated for the treatment of CPP.

CPP is the early onset of puberty in young children resulting in the development of secondary sex characteristics and short stature, if left untreated. The development of these secondary sex characteristics is due to an increase in the secretion of sex hormones, the cause of which is unknown. The incidence of CPP has been reported from national registries in the EU. A recent study has shown that CPP, subdivided by gender and age at diagnosis was <1 per 10,000 in girls who were younger than 4 years, thereafter gradually rising to 8 per 10,000 for girls aged 5 to 9 years. The incidence in boys younger than 8 years was <1 per 10,000. CPP is treated by pediatric endocrinologists in the U.S. The current standard of care for the treatment of CPP is LHRH agonist therapy. An agonist is a chemical substance capable of activating a receptor to induce a full or partial pharmacological response. LHRH agonist therapies for CPP are designed to suppress the secretion of sex hormones in order to delay the onset of puberty. Histrelin, a powerful inhibitor of hormone secretion, is the most potent LHRH agonist available.

*Development and Commercialization.* On May 3, 2007, the FDA approved the NDA for SUPPRELIN LA. Meetings have been held with various European regulatory authorities to seek scientific advice regarding the strategies for filing marketing applications for SUPPRELIN LA in Europe. Various strategies being evaluated include seeking marketing partners in territories outside of the United States.

We market SUPPRELIN LA in the U.S. through our specialty sales force primarily to pediatric endocrinologists. There are approximately 900 pediatric endocrinologists that are members of the Lawson Wilkins Pediatric Endocrine Society, however, about half of them see patients and most are located within major teaching hospitals in major metropolitan areas in the U.S. In 2008, the market for drugs to treat CPP, reported by IMS Health, is estimated to be approximately $100 million in the United States. If SUPPRELIN LA is approved in territories outside of the U.S., we intend to seek partners for commercialization and marketing.

***NEBIDO***

*General.* In July 2005, we licensed the exclusive U.S. rights for NEBIDO from Bayer Schering Pharma AG, Germany ( BayerSchering ). Currently under development as a testosterone therapy for male patients with hypogonadism, NEBIDO is an intramuscular depot injection which was designed to provide testosterone treatment in hypogonadal men for up to three months before requiring the next injection. NEBIDO has been approved in over 80 countries and is being marketed by BayerSchering and its partners in Europe and a number of other countries outside of the U.S. as the first injectable product for treating hypogonadism requiring dosing only once every 10 to 14 weeks.

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

We believe NEBIDO is highly differentiated when compared to the current testosterone therapies available today. Based on the benefits of its dosing regimen, NEBIDO has the potential to offer an attractive treatment option to current therapies that require either more frequent injection or daily application of topical gels and patches.

*Development.* The NDA for NEBIDO was submitted to the FDA by us on August 28, 2007. The NDA was accepted for review and the FDA Prescription Drug User Fee Act ( PDUFA ) target action date was June 27, 2008.

In January 2008, we announced the final results of an additional Phase III pharmacokinetic trial for NEBIDO. The data from the trial showed that NEBIDO met its primary endpoints, including a responder analysis based on an average testosterone concentration during the steady state dosing interval and an outlier analysis based on the maximum testosterone concentration during the steady state closing interval. In addition, the drug was well-tolerated.

As part of our development program we conducted a pharmacokinetic trial which enrolled 237 hypogonadal men to supplement the existing BayerSchering clinical database. The trial was a randomized open-label (unblinded) study that included the evaluation of the pharmacokinetics of NEBIDO dosed as either 1000 mg every 12 weeks or as 750 mg every 12 weeks, both via intramuscular injection. We announced positive data from the trial in June 2007. Of the 97 patients in the 1000 mg arm receiving their fourth injection, 94% had a Cavg over the course of the 12-week injection period that was within the normal range, demonstrating that treatment with NEBIDO was sufficient to maintain clinically therapeutic testosterone levels in hypogonadal men with injections given only once every 12 weeks. Further, no patients in the 1000 mg arm exceeded a testosterone concentration of 2500 ng/dL; four of 97 (4.1%) patients had a peak level over 1800 ng/dL; and 11 of 97 (11.3%) patients had a peak level exceeding 1500 ng/dL. Of the 102 patients in the 750 mg arm receiving their fourth injection, 86% had a Cavg within the normal range. No patients in the 750 mg arm exceeded a testosterone level of either 2500 ng/dL or 1800 ng/dL, and only four of 102 (3.9%) patients had a peak level exceeding 1500 ng/dL. Both treatment arms demonstrated improvements from baseline in the key secondary clinical outcome variables. Both doses of the drug were well-tolerated as indicated by the analysis of the safety measurements collected and the persistence with study treatment. Furthermore, the spectrum of adverse events reported were comparable to other injectable hypogonadism treatments reported in the literature. There were no significant adverse changes in laboratory parameters with NEBIDO treatment.

The existing combined database from BayerSchering and Indevus clinical development program contains over 2,500 patients, which includes over 500 patients from Indevus US studies and over 2,000 patients from BayerShering s European studies. Some of these patients have been treated for up to eight years in five clinical trials. These studies assessed the pharmacokinetic parameters of various dosing regimens of NEBIDO. Approved in over 80 countries and marketed in over 60 countries, commercial use has totaled more than 700,000 doses as of March 2008.

On June 4, 2008, we announced that after a discussion with the FDA that we expected the FDA to request that we provide additional safety data prior to its approval of NEBIDO. We believed at the time that this request would result in approximately a 24-month delay in approval. We also believed the FDA s concern related to a reaction immediately following the injection and is a known, rare complication of oil-based depot injections. The reaction is characterized by short-term coughing episodes, urge to cough or a shortness of breath. In rare cases, the reaction has been classified as serious or the patient experiences other symptoms such as dizziness, flushing or fainting. In addition, we believed the FDA s safety concerns were related to spontaneous post-marketing adverse event reports from the European experience using NEBIDO 1000 mg dose. In our U.S. clinical trials, using the 750 mg dose, which include approximately 500 patients, there was a single, non-serious, instance of this reaction. The patient did not require medical intervention and the event resolved without issue within 10 minutes.

On June 30, 2008, we announced that we had received an approvable letter for NEBIDO from the FDA. The letter confirmed our previously-announced indications from the FDA. The FDA expressed a concern about the relatively small number of patients who experienced respiratory symptoms immediately following the intramuscular injection of NEBIDO 1000 mg. The FDA also indicated that four of the cases in the European post-marketing database may have had an allergic, anaphylactoid reaction. We believe that each of the four cases were improperly classified and represent the same oil-based reaction. The FDA requested that we address these clinical deficiencies by providing additional safety information to determine the precise incidence of serious post-injection oil-based reactions and allergic reactions. Specifically, the FDA has requested follow-up data from the on-going U.S. and European studies in which patients are being treated with NEBIDO on an extended basis. A majority of these trials are scheduled to be completed within twelve months. The FDA stated that depending on the findings, the number of subjects and the number of injections of testosterone undecanoate, the safety database may need to include data from additional clinical studies. Additionally, the FDA has requested that we provide a plan to minimize the risks associated with the clinical use of testosterone undecanoate intramuscular injection to reduce the incidence and/or severity of the serious oil-based reactions. Additionally, they requested certain data to exclude an allergic component to the truc or some of its excipients.

On September 26, 2008, we announced that we had reached an agreement with the FDA regarding additional data and risk management strategy that will lead to a re-submission of the NDA for NEBIDO in the first quarter of calendar 2009. The re-submission will include over 14,000 injections in more than 2,600 patients, all of which come from existing clinical trials conducted in the U.S. and in Europe.

The FDA also agreed on an education plan to minimize the risks associated with the clinical use of NEBIDO. This plan is intended to reduce the incidence and/or severity of the serious oil-based reactions. Additionally, we have agreed to gather skin-testing data to characterize an allergic component to the drug or any of its excipients in certain patients. We have also agreed to conduct a large, simple post-marketing study of the safety of NEBIDO in approximately 10,000 patients.

*Commercialization*. We are conducting additional trials for marketing and if applicable, regulatory purposes. If approved, we intend to commercialize NEBIDO in the U.S. utilizing our specialty sales force. We may expand our existing 100-person sales force for the launch of NEBIDO, if approved.

***VALSTAR***

*General.* We obtained VALSTAR through our acquisition of Valera. VALSTAR was acquired by Valera in March 2006 from Anthra Pharmaceuticals. VALSTAR is a sterile solution of valrubicin for intravesical instillation and is the only product approved by the FDA for therapy of bacillus Calmette-Guerin ( BCG )-refractory carcinoma *in situ* ( CIS ) of the urinary bladder.

Bladder cancer incidence is nearly four times higher in men than in women and almost two times higher in Caucasians than in African Americans. According to the American Cancer Society, approximately 69,000

individuals will be diagnosed with bladder cancer and approximately 14,000 will die from the disease in 2008. In 2008, according to Decision Resources, the value of the non-muscle invasive bladder cancer market in the U.S. is estimated to be approximately $115 million.

*Development and Commercialization.* VALSTAR was originally approved by the FDA in 1998 and was marketed in the U.S. until its withdrawal in 2002. In 2002, VALSTAR was withdrawn from the market due to a manufacturing problem involving impurity issues in the original formulation and was placed on the FDA Drug Shortages List. In April 2007, we submitted a supplemental New Drug Application ( sNDA ) to the FDA seeking approval to reintroduce VALSTAR and in May 2007, we submitted a chemistry, manufacturing and controls ( CMC ) NDA supplement to the FDA.

In August 2007, we received an approvable letter from the FDA asking for clarification regarding manufacturing validation protocols and for additional data on the manufacturing process. We submitted a response to the approvable letter in October 2007. In December 2007, we received a non-approvable letter from the FDA for VALSTAR limited only to issues at the manufacturing facility.

We believe the VALSTAR-specific issues that caused the 2002 withdrawal of the product from the market have been satisfactorily resolved. However, based on the 2007 non-approvable letter, deficiencies were identified with respect to our third-party manufacturing facility for VALSTAR that require resolution prior to approval. We believe that successfully addressing the deficiencies at the manufacturing plant is the only remaining item for product approval. Upon resolution, which we expect to occur within the first half of calendar 2009, we will respond to the FDA and request re-inspection of the facility.

We anticipate resolving these manufacturing issues during the first half of calendar 2009. If marketing clearance is received, we intend to commercialize VALSTAR in the U.S. utilizing our specialty sales force, and we are seeking commercialization partners in territories outside of North America. Additionally, we are evaluating opportunities for the use of VALSTAR in other indications and potential clinical development requirements of such opportunities.

***DELATESTRYL***

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

*Commercialization.* We market DELATESTRYL in the U.S. through our specialty sales force primarily to urologists and endocrinologists.

***PRO 2000***

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

We believe that PRO 2000 (aldehyde and sulfonic acid condensation polymer) may block HIV infection and other sexually transmitted infections by preventing their attachment and entry into susceptible cells. Laboratory studies have shown that the drug is active against HIV, herpes simplex virus, chlamydia and the bacterium that

causes gonorrhea. In government-sponsored tests, vaginally applied PRO 2000 was shown to be efficacious in mouse models for genital herpes infection and gonorrhea, and in a simian model for vaginal HIV infection.

HIV infection usually leads to AIDS, a life-threatening impairment of the immune system. According to an August 2008 UNAIDS report, an estimated 2.7 million new HIV infections were acquired in 2007. Other STDs, such as genital herpes, chlamydia and gonorrhea, can lead to serious complications, especially in women, and can increase the risk of HIV infection. The Kaiser Family Foundation and the World Health Organization have estimated that there are approximately 15 million new STD cases each year in the U.S. and more than 340 million worldwide.

*Development and Commercialization.* PRO 2000 is being studied, as the only agent, in a large, multi-national Phase III trial sponsored by the Microbicides Development Programme ( MDP ), an international partnership to develop and test vaginal microbicides. The MDP was established in February 2002 with funding of approximately $22,700,000 from the United Kingdom s Department for International Development. The program is administered by the Clinical Trials Unit of the Medical Research Council ( MRC ) and Imperial College in London, and involves researchers in the U.K., Cameroon, South Africa, Tanzania, Uganda and Zambia. This trial commenced in October 2005, and is designed to examine the safety and efficacy of PRO 2000 in preventing HIV infection and transmission of other STDs in women. Enrollment into the trial was completed in August 2008, with a total of 9,395 women enrolled. Results from the MRC trial should be available in late 2009. PRO 2000 is also being studied, as one of two investigational topical microbicides, in a large, multi-national Phase II/III clinical trial sponsored by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health ( NIH ). The trial, which commenced in February 2005, is designed to examine the safety and effectiveness of two candidate topical microbicides, including PRO 2000, in preventing HIV infection and transmission of other STDs in women. Approximately 3,100 women were enrolled in the study at multiple sites in Africa and the United States. Enrollment was completed in July 2007. We expect results from the NIH-sponsored trial to be available in early 2009.

In February 2008, we were advised by the MRC that after review of data from the Phase III clinical trial of PRO 2000, our candidate vaginal microbicide for HIV prevention, the Independent Data Monitoring Committee ( IDMC ) has recommended that the low-dose arm (0.5%) continue to be tested for safety and effectiveness in the trial. The IDMC, a group of independent experts providing oversight to the MDP 301 trial, also recommended the high-dose arm (2.0%) be closed as there is no more than a small chance of the high dose showing protection against HIV infection compared to placebo gel.

Prior to the initiation of the Phase III trials in 2005, a number of pre-clinical and early clinical studies with PRO 2000 had been completed under the sponsorship of government agencies and research organizations in the U.S., Europe, Africa and India.

We are currently considering strategic partners for future development and commercialization of PRO 2000.

***OCTREOTIDE IMPLANT***

*General.* We obtained the octreotide implant through our acquisition of Valera. Our octreotide implant is a soft, flexible 6-month hydrogel implant based on our patented HYDRON Polymer Technology that delivers octreotide, a somatostatin analogue, to reduce growth hormone ( GH ) and insulin-like growth factor ( IGF-1 ) levels in patients with acromegaly.

Acromegaly is a chronic hormonal disorder that occurs when a pituitary tumor produces excess growth hormone. It most commonly affects middle-aged adults, and if untreated, causes enlargement of certain bones, cartilage, muscles, organs and other tissue, leading to serious illness and potential premature death.

Octreotide is also approved to treat the symptoms associated with metastatic carcinoid tumors and vasoactive intestinal peptide secreting adenomas, which are gastrointestinal tumors.

*Development and Commercialization.* In 2004, Valera initiated and completed a Phase I/II pharmacokinetic clinical trial with eleven patients with acromegaly. The trial was designed to evaluate the release characteristics of the octreotide implant and to examine safety and efficacy parameters. The endpoints achieved in the trial were the reductions in GH and IGF-1 levels in the blood in these patients. During the trial, side effects included diarrhea, low blood sugar and implant site reactions.

In November 2007, we announced positive results from a Phase II clinical trial of the octreotide implant. The trial was an open-label study designed to evaluate the pharmacokinetic and pharmacodynamic response of octreotide implants in patients with acromegaly. The trial evaluated the release effectiveness of both pre-hydrated and non-hydrated octreotide implants and evaluated the suppression of growth hormones ( GH ) and insulin-like growth factor 1 ( IGF-1 ). The trial enrolled and evaluated a total of 34 patients who had previously demonstrated a full or partial GH and IGF-1 response to octreotide. Approximately half of the patients had a baseline growth hormone of <5 ng/mL on entry into the study indicating that the prior octreotide injections were providing adequate control. In these patients, the octreotide implant successfully maintained GH in 94% of patients. Approximately 60% of these implant trial patients achieved a normal age-adjusted IGF-1 concentration. The remaining patients had entered the trial with baseline GH levels >5 ng/mL, and 59% achieved GH suppression to <5 ng/mL and 35% achieved suppression to <2.5 ng/mL. The trial also confirmed by pharmacokinetic analysis that there was no difference in the predictable, steady release of octreotide from either the pre-hydrated or non-hydrated octreotide implant. All patients enrolled completed the six month trial and there were no serious or severe adverse events reported. We announced the initiation of a Phase III trial on September 30, 2008. Approximately 34 clinical sites in six countries are participating in this trial. Participants in the open-label trial will be randomized in a 3:1 ratio to either the octreotide implant or month injections of Sandosatatin® LAR® ( S-LAR ). The trial is expected to recruit approximately 140 patients in the U.S. and Europe. Patients must be known responders, having well-maintained GH and IGF-1 levels, to somatostatin analogues. The primary efficacy endpoint of this trial is the suppression of GH and IGF-1. If approved, we intend to commercialize the octreotide implant in the U.S. utilizing our specialty sales force primarily to endocrinologists and medical oncologists. We are seeking partners for commercialization in territories outside the United States.

***URETERAL STENT***

*General.* We obtained our biodegradable ureteral stent technology through our acquisition of Valera. Ureteral stents are plastic tubes inserted into the ureter to allow urine to drain from the kidney to the bladder when the flow of urine may be obstructed due to a number of conditions, including kidney stones and inflammation. Current available ureteral stents require physician intervention for removal from the body. A biodegradable ureteral stent could be naturally voided by the body, a potentially important advantage over existing stents.

*Development.* In November 2006, Valera announced that it completed proof-of-concept studies on a flexible, biodegradable polymer-based ureteral stent. Beginning in February 2007, we conducted studies in several animal models to establish safety and effectiveness in order to support the submission of a 510K device application for this product candidate. Upon consideration of the results of these studies, as well as several other factors, including clinical benefit, market size, and cost-benefit analysis, we have concluded that further development of this stent is not warranted at this time.

**OUR NON-CORE PRODUCTS AND PRODUCT CANDIDATES**

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

The following table summarizes the status of our other products:

| Product Name | Indication/Use | Status[1] | Commercial Rights[2] / Licensee |
|---|---|---|---|
| Pagoclone | Stuttering | Phase IIb | Worldwide / Teva |
| HYDRON Polymer Technology | Multiple indications | Pre-clinical | Worldwide |
| Bucindolol | Congestive heart failure | NDA filed | Worldwide |
| ALKS 27 | Chronic Obstructive Pulmonary Disease | Phase II | Worldwide[3] |
| Aminocandin | Systemic fungal infections | Phase I | Worldwide / Novexel |

1 See Government Regulation.
2 See Agreements.
3 Jointly being developed with Alkermes, Inc.

***Pagoclone***

*General.* Pagoclone is a novel, non-benzodiazepine, GABA-A receptor modulator and is under development as a treatment for stuttering. In early 2005, we were granted a new method of use patent in the U.S. that covers the use of pagoclone as a therapeutic agent for stuttering. Stuttering is a disease of uncertain etiology that affects approximately three million adults and children in the United States. The treatment for stuttering consists mainly of behavioral modification and speech therapy. There are currently no drugs approved in the U.S. for the treatment of stuttering.

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

*Stuttering Development and Commercialization*. In May 2006, we announced results of our Phase II trial for pagoclone in stuttering. The trial, known as the EXPRESS study, was an eight-week, randomized, double-blind, placebo-controlled trial, with an open-label extension. There were a total of 132 patients randomized in the study at 16 sites in the United States. Results from the trial showed that pagoclone produces a statistically significant benefit in multiple primary and secondary endpoints compared to placebo. Additionally, pagoclone produced either numerically superior improvements or trends for significant improvement on virtually all other primary and secondary endpoints when compared to placebo. Pagoclone was also shown to be well-tolerated and not associated with any serious adverse events.

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

On September 26, 2008, we announced that we had signed a development, license and commercialization agreement with Teva Pharmaceutical Industries Ltd. ( Teva ) for the exclusive, worldwide rights to pagoclone. We will conduct and Teva will reimburse us for expenses we incur for the Phase IIb study. Teva will conduct all development after the Phase IIb study and be responsible for commercialization if development is successful. We

plan to initiate the Phase IIb study in the first calendar quarter of 2009. The trial will be a six-month, randomized, double-blind, placebo-controlled trial, with an open-label extension. There will be approximately 300 patients randomized in the study at 40 sites in the United States. See Agreements.

*Pre-Stuttering Development*. Prior to the initiation of the Phase II stuttering trial, over 1,500 patients had participated in clinical studies with pagoclone, including three Phase II trials that demonstrated statistically significant efficacy, two in panic disorder conducted by us and one in GAD conducted by Pfizer Inc. ( Pfizer ), then our licensee. Pfizer then conducted two Phase II GAD trials and one Phase III panic disorder trial that did not show statistically significant efficacy. In all of the clinical trials, pagoclone was well-tolerated, with no clinically significant differences with respect to adverse events, such as sedation and withdrawal effects as compared with placebo. As a result of the prior clinical programs, we have an extensive database for pagoclone including toxicology, pharmacology and manufacturing packages.

***HYDRON Polymer Technology***

*General.* The HYDRON Polymer Implant is a proprietary, non-biodegradable, reservoir-based drug delivery device designed to be inserted under a patient s skin. The technology underlying the HYDRON Polymer Implant evolved from similar technology used in soft contact lenses, resulting in flexible material which can be adapted to deliver many types of drugs. The HYDRON Polymer Technology serves as the foundation for two currently marketed, FDA approved products being VANTAS and SUPPRELIN LA. We will need to obtain approval for each product we develop, including products using HYDRON Polymer Technology. Our implant is designed to allow release of drugs continuously, at even, controlled rates for periods up to 12 months. We believe such predictable release over a period of 12 months has not been achieved by most other drug delivery systems, including sustained release injections, biodegradable implants and transdermal devices. In addition, implants utilizing HYDRON Polymer Technology are generally smaller, softer and more flexible than other implants.

Utilizing HYDRON Polymer Technology, we are able to manufacture implants to the exact chemical and physical specifications required by the particular drugs to be released. By modifying the geometric characteristics (wall thickness, diameter and length) and the polymer make-up of the implants, we can vary the release rates of a broad spectrum of drugs according to the therapeutic levels required for a particular indication. Once filled with an active ingredient, sealed and sterilized, the implant is inserted into a patient in a minor outpatient procedure generally performed in a physician s office. The procedure to insert the implant takes approximately 7 to 10 minutes.

***Bucindolol***

*General.* CPEC LLC, an entity jointly owned 65% by us and 35% by Aeolus Pharmaceuticals, Inc. ( Aeolus ) (formerly Incara Pharmaceuticals, Inc.) was developing bucindolol, a nonselective beta-blocker for treatment of congestive heart failure. In October 2003, CPEC LLC licensed its bucindolol development and marketing rights to ARCA Discovery, Inc. ( ARCA ) in exchange for potential future milestone and royalty payments. In fiscal 2008, ARCA filed an NDA for bucindolol with the FDA. See Agreements.

***ALKS 27***

*General.* In January 2007, we announced our joint collaboration with Alkermes for the development of ALKS 27, an inhaled formulation of trospium chloride for the treatment of COPD using Alkermes proprietary AIR® pulmonary delivery system. Trospium chloride is a muscarinic receptor antagonist that relaxes smooth muscle tissue and has the potential to improve airflow in patients with COPD. The formulation under development for ALKS 27 is specifically designed for inhalation utilizing Alkermes proprietary AIR pulmonary delivery system. Pursuant to the collaboration agreement, we and Alkermes share equally in all costs of the development and commercialization of ALKS 27 on a worldwide basis.

COPD is characterized by airflow obstruction and loss of expiratory force and comprises mostly smoking-related diseases such as emphysema and chronic bronchitis. COPD is the fourth largest cause of death in the U.S. and is projected to be the third leading cause of death for both males and females by 2020. It is estimated that over 12 million adults in the U.S. have been diagnosed with COPD and there is no known cure at the present time. The total U.S. market for COPD product sales is over $3 billion and worldwide sales are over $6 billion.

*Development.* In January 2007, we announced results of our Phase I trial for ALKS 27 in healthy volunteers. The Phase I randomized, double-blind, placebo-controlled study was designed to assess the safety, tolerability, and pharmacokinetics of ALKS 27 in 20 healthy, non-smoking adults. Subjects were given single escalating inhaled administrations of ALKS 27 at dose levels ranging from 50 mcg to 800 mcg. The study results showed that ALKS 27 was well tolerated over a wide dose range, with no dose-limiting effects observed. Evaluation of the pharmacokinetic data indicated that exposure was dose-related.

In September 2007, we announced results of our Phase IIa trial for ALKS 27 in COPD. The Phase IIa randomized, double-blind, placebo-controlled crossover study was designed to assess the safety, tolerability, pharmacokinetics and efficacy of ALKS 27 in 24 patients with moderate to severe COPD. During the study, patients received a single administration of two different dose levels of ALKS 27 and placebo, with each dose separated by a wash out period. The primary objective of the study was to assess the effect of ALKS 27 as measured by the area under the curve ( AUC ) of FEV1 over a 24-hour time period. FEV1 is an important clinical measure of lung function defined as the amount (volume) of air expelled during the initial second of forced exhalation. In the study, patients treated with a single dose of ALKS 27 showed a statistically significant improvement in lung function ($p<0.0001$) compared to placebo. The onset of action of ALKS 27 was rapid and observed as early as 15 minutes post-treatment. ALKS 27 was well tolerated, and all 24 enrolled patients completed the study. No treatment-related adverse events were reported in this study.

In April 2008, we received from Alkermes, Inc. a letter purporting to terminate the Feasibility Agreement dated as of February 4, 2005, between us and Alkermes. We and Alkermes have been engaged in discussions with several third parties relating to the further development and commercialization of this product and with each other to provide for further development by us and Alkermes. We dispute Alkermes position that this agreement has terminated and intend to pursue vigorously our rights and remedies under this agreement and applicable law. We own or have an exclusive license to various know-how, and own the IND, relating to the product that has been under development by us and Alkermes. We also have certain rights to joint intellectual property.

Alkermes has agreed to submit to the dispute resolution procedures set forth in the Feasibility Agreement to reach a resolution of these contractual issues.

***Aminocandin***

*General.* In December 2006, we licensed the know-how to aminocandin to Novexel. Aminocandin is a member of a new class of anti-fungal compounds, known as echinocandins, in development for the treatment of a broad spectrum of systemic, invasive fungal infections. Echinocandins function by inhibiting a key component of the cell wall of fungi, and lack cross-resistance with older antifungal agents. Echinocandins are the first new class of anti-fungal agents to be developed and introduced in approximately 30 years. They are designed to be fungicidal, that is, to destroy fungi rather than simply to inhibit their growth, and to have broad-spectrum activity against multiple fungi that cause serious systemic infections. Examples of such infections include aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, cryptococcosis and zycomycosis.

Aminocandin has shown *in vitro* and *in vivo* activity against a number of candida and aspergillus fungal species. The worldwide market for anti-fungal agents that target invasive fungal infections is currently estimated at $4.1 billion.

*Development*. We conducted two Phase I trials for aminocandin prior to licensing the compound to Novexel. Novexel is responsible for all future development and commercialization of aminocandin. See Agreements.

**AGREEMENTS**

***SANCTURA and SANCTURA XR***

**Allergan and Esprit**

In September 2007, we entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit, which re-defined the obligations of each party and superseded all previous agreements, (the Allergan Agreement ). On October 16, 2007, the effective date of the Allergan Agreement, Allergan also acquired Esprit resulting in Esprit being a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, we received an up-front license fee, partially creditable by Allergan against future payments to us, of $25,000,000, and $8,000,000 as payment of the supply price for future deliveries of SANCTURA XR, subject to purchase orders issued by Allergan. The Allergan Agreement also grants us the right to receive a fixed percentage of net sales for the term of this Agreement, subject to increasing annual minimum royalties aggregating up to approximately $123,000,000 for the first seven years of this Agreement, provided there is no product adverse event, as defined in the Allergan Agreement. Commencing January 1, 2010, or earlier in the case of generic competition, Allergan has the right to reduce, subject to quarterly and annual restrictions, royalty payments by $20,000,000. In addition, we received approximately $9,000,000 in annual sales force subsidy in fiscal year 2008 and extended our copromotion through December 31, 2008 and subsequently have extended our copromotion to March 31, 2009 at an annual rate of approximately $9,000,000. We may also receive a payment of $20,000,000 related to a long-term commercialization milestone related to generic competition. Lastly, all third-party royalties paid by us as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR as of October 16, 2007 will be reimbursed to us by Allergan. Pursuant to the Allergan Agreement, on August 13, 2008, Allergan assumed responsibility to manufacture SANCTURA XR for its use (the Processing Assumption Date ) and we assigned to Allergan certain agreements and purchase orders relating to the manufacture SANCTURA XR. We manufactured and supplied SANCTURA XR to Allergan at our cost through the Processing Assumption Date and will manufacture and supply SANCTURA through September 30, 2012. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of SANCTURA XR or the last to expire patent covering SANCTURA XR in the United States. Either party may also terminate the Allergan Agreement under certain customary conditions of breach.

In August 2008, we assigned our rights to receive a fixed percentage of net sales and $20,000,000 related to a long-term commercialization milestone related to generic competition to investors pursuant to our private placement of the Non-recourse Notes. See Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations, Liquidity and Capital Resources Cash, Cash Equivalents and Marketable Securities for additional details regarding the Non-recourse Notes.

The Allergan Agreement superseded all previous agreements with Esprit or its predecessors pertaining to SANCTURA and SANCTURA XR. In April 2004, we entered into a license, commercialization and supply agreement with PLIVA d.d. ( PLIVA ), through its specialty-branded subsidiary, Odyssey, for the U.S. commercialization of SANCTURA for OAB (the SANCTURA Agreement ). In May 2005, we, PLIVA and Esprit entered into an Amendment and Consent Agreement (the Amendment and Consent Agreement ), which became effective as of July 1, 2005, pursuant to which we amended certain provisions of the SANCTURA Agreement and consented to the acquisition by Esprit of the rights to market SANCTURA in the U.S. from PLIVA and the assumption by Esprit of PLIVA s obligations under the SANCTURA Agreement. Collectively through September 30, 2008 and pursuant to all agreements between us and PLIVA, Esprit and Allergan, we have received approximately $364,000,000 in the form of up front and milestone payments, royalties, sales force reimbursements and payments for product shipped to our marketing partners at our cost to manufacture.

Except if the context indicates otherwise, all references in this Form 10-K to the SANCTURA Agreement shall mean the SANCTURA Agreement, as amended by the Amendment and Consent.

**Madaus**

In November 1999, we entered into an agreement with Madaus under which we licensed exclusive rights under Madaus patents and know-how to develop and market certain products, including SANCTURA in the United States. In exchange for these rights, we agreed to pay Madaus potential regulatory and sales milestone payments and royalties on net sales of the licensed products or, if sublicensed by us, a portion of royalties received by us from our sublicensee on net sales of the licensed product by the sublicensee, in lieu of royalty payments. We are responsible for all clinical development and regulatory activities and costs related to licensed products in the United States. The agreement expires on the tenth annual anniversary of the launch of SANCTURA XR provided either party may also terminate this agreement under certain customary conditions of breach. The term of the agreement continues for ten years from the first commercial sale of each licensed product, after which the license is fully paid for that licensed product. In December 2002, we entered into a manufacturing agreement with Madaus under which Madaus produces and sells to us commercial quantities of SANCTURA in bulk form.

In November 2006, we entered into (i) a License and Supply Agreement and (ii) an amendment to our original license agreement with Madaus (collectively, the Madaus Agreements ). Under the Madaus Agreements, we agreed to (a) purchase from Madaus all required trospium active pharmaceutical ingredient for production of SANCTURA XR through November 2007, (b) license Madaus the rights to sell SANCTURA XR in all countries outside of the U.S. (the Madaus Territory ) except Canada, Japan, Korea and China (the Joint Territory ), (c) pay to Madaus a fee based on the number of capsules of SANCTURA XR sold by us in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share, (d) supply SANCTURA XR to Madaus for a specified period of time, (e) provide development committee support for a defined period, and (f) provide future know-how to Madaus. In exchange, Madaus (a) waived all rights to manufacture SANCTURA XR, (b) will purchase SANCTURA XR from us at cost plus a fee based on the number of SANCTURA XR capsules sold in the Madaus Territory, and (c) will make payments upon the achievement of certain commercial milestones and royalties based on future sales of SANCTURA XR in the Madaus Territory. Certain of the milestone and royalty payments we will receive represent royalty and milestone payments due to Supernus from Indevus under the Supernus Agreement. We and Madaus will share the economics of development and commercialization in the countries in the Joint Territory. If either party decides not to pursue development and commercialization of SANCTURA XR in any country in the Joint Territory, the other party has the right to develop and commercialize SANCTURA XR in that country. Madaus is also due a portion of royalties we receive for SANCTURA and SANCTURA XR subject to a minimum of 4% of net sales, which is offsetable by any third party royalties owed by us. There is $1,200,000 of potential additional milestone payments due to us, from Madaus, pursuant to these agreements. As of September 30, 2008 we have received $700,000 from Madaus under the Madaus Agreement for SANCTURA XR. The term of the Madaus Agreement for SANCTURA XR extends until the expiration, on a country-by-country basis, of all royalty obligations to us from Madaus which ceases upon the last to expire applicable patent in the Madaus territory. Either party may also terminate this agreement under certain customary conditions of breach. Through September 30, 2008, we have paid Madaus approximately $33,400,000 pursuant to these agreements. There are no other milestones due pursuant to all Madaus Agreements.

In May 2008, together with Madaus, we also licensed to Allergan the exclusive right to develop, manufacture, and commercialize SANCTURA XR in Canada. In exchange, the Company received an upfront payment of $7,000,000 and could receive milestone payments totaling $2,000,000 upon achievement of certain sales thresholds. In addition, third-party royalties owed by us on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation, after which Allergan will have a fully-paid license. The $7,000,000 payment represents the aggregate amounts paid to us pursuant to this Agreement through September 30, 2008. Additionally, either party may terminate this agreement under certain customary conditions of breach.

**Supernus**

In March 2003, we signed a development and license agreement with Supernus under which Supernus developed SANCTURA XR and granted us exclusive, worldwide rights under Supernus-related patents and know-how. The agreement includes payments from us to Supernus, including royalties based on sales of SANCTURA XR as well as potential future development and commercialization milestone payments for up to an aggregate of $2,400,000 pertaining to the launch of SANCTURA XR in certain geographic areas. In addition, the agreement includes potential future development and commercialization milestone payments for up to an aggregate of $4,500,000 pertaining to the launch of new formulations and over-the-counter products. We are responsible for all development costs and the commercialization of SANCTURA XR under this agreement. This agreement continues until the earlier of, in any particular country, (i) the last date on which the manufacture, use or sale of licensed product in such country would infringe a valid claim of a licensed patent in such country but for the license granted by the agreement; or (ii) 12 years from the date of first commercial sale of licensed product in such country. Either party may also terminate this agreement under certain customary conditions of breach or by mutual consent. As of September 30, 2008 we have paid approximately $5,600,000 to Supernus pursuant to the agreement.

**Helsinn Chemicals SA and Helsinn Advanced Synthesis SA**

In November 2006, we entered into the API Supply Agreement with Helsinn Chemicals SA and Helsinn Advanced Synthesis SA ( Helsinn ) (the Helsinn Agreement ) whereby Helsinn agreed to supply trospium active pharmaceutical ingredient to us. Trospium active pharmaceutical ingredient is used in the production of SANCTURA XR and ALKS 27. The term of the Helsinn Agreement is seven years and contained certain minimum purchase requirements which would cease after we purchased a certain aggregate quantity. As of September 30, 2008, we have paid approximately $1,900,000 to Helsinn pursuant to this agreement. This minimum purchase requirement has been transferred to Allergan pursuant to the Processing Assumption Date. Either party may also terminate the Helsinn Agreement under certain customary conditions of breach, and we may terminate the agreement if regulatory actions prohibit or materially restrict the manufacture, sale or use if the product in the United States. While retaining rights under this agreement, we also assigned certain rights and obligations under this agreement to Allergan, including the minimum purchase requirements, pursuant to the Processing Assumption Date.

**Catalent Pharma Solutions, Inc.**

In September 2007, we entered into a Manufacturing and Supply Agreement with Catalent Pharma Solutions, Inc. (now Catalent Pharma Solutions, LLC), ( Catalent ), to manufacture SANCTURA XR bulk capsules and to package them in bottles for sale and blister packages to be used as samples in the United States. In August 2008, pursuant to the Processing Assumption Date, Allergan entered into a separate agreement to manufacture and package SANCTURA XR, and we entered into a new agreement to manufacture SANCTURA XR bulk capsules. Our agreement with Catalent terminates in September 2012, subject to earlier termination by either party under certain customary conditions of breach. We may terminate this agreement at any time if regulatory actions prohibit or materially restrict the manufacture, sale or use of the product in the United States. We supply to Catalent the active pharmaceutical ingredient used to manufacture the SANCTURA XR capsules sold to Madaus.

***VANTAS and SUPPRELIN LA***

**The Population Council**

We market our products utilizing the HYDRON Polymer Technology pursuant to our agreement with the Population Council. Subject to earlier termination by either party under certain customary conditions of breach, the term of the agreement is the shorter of twenty-five years from October 1997 or until the date on which The Population Council receives approximately $40,000,000 in payments from us. We are required to pay to The Population Council 3% of our net sales of VANTAS and any polymer implant containing an LHRH analog. The Population Council is also entitled to receive royalties ranging from 0.5% of net sales to 4% of net sales under

certain conditions. The Population Council is entitled to 30% of certain profits and payments in certain territories received by us from the licensing of VANTAS or any other polymer implant containing an LHRH analog and 5% for other implants.

**Shire Pharmaceuticals Group plc**

Until April 2008, we had been marketing VANTAS pursuant to a license agreement and a related manufacturing and supply agreement with Shire plc ( Shire ). Royalties were payable to Shire for ten years from the date of the first commercial sale of VANTAS in November of 2004 and we were paying Shire approximately 2% of net sales of VANTAS. In April 2008, the Company entered into an agreement to terminate its manufacturing and supply agreement with Shire related to VANTAS. Under this termination agreement, Shire relinquished its right to receive royalties on net sales of VANTAS or a percentage of royalties and other consideration received by the Company relative to a sublicense of our VANTAS selling and marketing rights granted by Shire. In exchange, the termination agreement provided for the Company to pay Shire a total of $5,000,000 consisting of an immediate payment of $1,000,000 and the balance of $4,000,000 in three annual installments commencing in January 2009.

**Orion Corporation**

In April 2008, we entered into a License, Supply and Distribution Agreement with Orion granting them the rights to market VANTAS throughout Europe as well as in certain other countries (the Orion Agreement ). VANTAS is currently approved for the treatment of advanced prostate cancer in certain European countries. VANTAS is currently undergoing the mutual recognition procedure for further European approvals. We received a $7,000,000 up-front payment and could receive certain additional contingent payments related to approvals and sales thresholds aggregating up to $14,000,000. The $7,000,000 payment represents the aggregate amounts paid to us pursuant to this Agreement through September 30, 2008. Additionally, we have agreed to supply VANTAS to Orion at a pre-determined transfer price subject to annual minimum purchase requirements beginning in 2009. The agreement expires in April 2023, subject to earlier termination by either party under certain customary conditions of breach. The Orion Agreement will automatically renew for one-year periods at a time, subject to the right of either party to terminate the agreement at any time effective at the end of the initial 15-year term or any subsequent one-year renewal period thereafter with at least six months prior written notice to the other party.

***DELATESTRYL***

**Savient**

In January 2006, we acquired DELATESTRYL, an injectable testosterone therapy for the treatment of hypogonadism, from Savient. Under the terms of the acquisition, we are obligated to pay royalties to Savient for three years from January 2006 based upon the cumulative net sales of DELATESTRYL. Through September 30, 2008, we have paid approximately $6,600,000 to Savient in connection with this arrangement.

***NEBIDO***

**BayerSchering**

In July 2005, we licensed exclusive U.S. rights from BayerSchering to market NEBIDO, a long-acting injectable testosterone preparation for the treatment of hypogonadism (the BayerSchering Agreement ). We are responsible for the development and commercialization of NEBIDO in the United States. BayerSchering is responsible for manufacturing and supplying us with finished product. We agreed to pay to BayerSchering up to $30,000,000 in up-front, regulatory milestone, and commercialization milestone payments, including a $7,500,000 up-front payment paid in August 2005 and a $5,000,000 payment due upon approval by the FDA to market the product. Through September 30, 2008, we have paid in aggregate approximately $9,500,000 under this agreement. We also agreed to pay to BayerSchering 25% of net sales of NEBIDO to cover both the cost of finished product and royalties. This agreement extends to ten years from the first commercial sale of NEBIDO.

Either party may also terminate this agreement under certain customary conditions of breach, and BayerSchering may terminate this agreement if there was a change in control of Indevus, as defined in the agreement.

In October 2006, we entered into a supply agreement with BayerSchering under which we finalized terms of our July 2005 license for the manufacture and the supply of NEBIDO from BayerSchering. Pursuant to the terms of this agreement, BayerSchering agreed to manufacture and supply us with all of our requirements for NEBIDO for a supply price based on net sales of NEBIDO. The BayerSchering Agreement (including the supply agreement) contains certain minimum purchase requirements that would commence after the second year of sales of NEBIDO and would be determined after the second year of sales based on a percent of purchases made during the year. The supply price is applied against the 25% of net sales owed to BayerSchering pursuant to the BayerSchering Agreement. We do not know what our purchases will be in the second year of sales of NEBIDO, and accordingly, as of September 30, 2008, we are unable to estimate its minimum purchase requirements of NEBIDO. This agreement expires ten years from the first commercial sale of NEBIDO.

***VALSTAR***

**Plantex**

We have a supply agreement with Plantex USA Inc. ( Plantex ), whereby Plantex will supply us with the active pharmaceutical ingredient for VALSTAR called Valrubicin. The Agreement will expire ten years after the date of the first commercial sale of VALSTAR provided we receive approval by June 30, 2009. Beginning in the calendar year following the year in which we receive regulatory approval for VALSTAR in the U.S., we will have annual minimum purchase requirements of $1,000,000. This agreement may be terminated by either party under certain customary conditions of breach, by mutual agreement of the parties, or by Plantex if Valrubicin is not approved by June 30, 2009.

***PAGOCLONE***

**Sanofi-aventis**

In February 1994, we licensed from Rhone-Poulenc Rorer, S.A., now sanofi-aventis, ( sanofi-aventis ), exclusive, worldwide rights for the manufacture, use and sale of pagoclone under patent rights and know-how related to the drug, except that we granted sanofi-aventis an option to sublicense from us, under certain conditions, rights to market pagoclone in France. In exchange, we paid sanofi-aventis a license fee and agreed to make milestone payments based on clinical and regulatory developments, and to pay royalties based on net sales through the expiration of the composition of matter patent. If sublicensed by us, we would pay to sanofi-aventis a portion of receipts from the sublicensee in lieu of payments. Under the terms of our agreement with sanofi-aventis, we are responsible for all costs of developing, manufacturing, and marketing pagoclone. This agreement expires with respect to each country upon the date of the last to expire applicable patent. Additionally, either party may also terminate this agreement under certain customary conditions of breach. Through September 30, 2008, we have paid approximately $3,800,000 pursuant to this agreement. We would owe an additional $5,500,000 if we successfully achieve remaining development milestones, as well as royalties on net sales or a percentage of royalties we receive if the product is sublicensed.

**Teva**

On September 25, 2008, we entered into a Development, License and Commercialization Agreement with Teva (the Teva Agreement ) for the exclusive, worldwide rights to pagoclone. Under the terms of the Teva Agreement, we will conduct and Teva will reimburse us for our expenses for a Phase IIb study for stuttering. Following the completion of a successful Phase IIb study, the Teva Agreement provides for us to participate on a 50/50 basis with Teva in the U.S., sharing development and marketing costs, and splitting future profits, in addition to receiving milestone payments. Under certain circumstances, either party may convert the Teva Agreement from the 50/50 arrangement to a royalty structure where Teva will be responsible for all development and commercial costs in the U.S., and we would receive royalties on net sales, in addition to milestones. In either

case, if the arrangement continues, Teva will be responsible for the conduct of the Phase III program. For territories outside of the U.S., Teva will be responsible for all future development and commercialization and we will receive milestones and royalties on net sales.

Under the 50/50 participation, we could receive up to $92,500,000 (including the Phase IIb study expenses) in U.S. and European development milestones and Research and Development reimbursement. In the event of a conversion to the royalty structure, in addition to the $92,500,000 of milestones and reimbursements, we could receive up to $50,000,000 in U.S.-based sales threshold milestones. The Teva Agreement became effective in November 2008 and continues in effect until the later of 12 years from first commercial sale or the last valid claim in a country in the territory.

Teva may terminate the Teva Agreement (i) by giving notice within a certain time frame from the completion of the Phase IIb study (the Next Trial ), and (ii) anytime with a specified advance notice, except no such termination will be effective until the completion of any ongoing clinical trial. If Teva terminates the Teva Agreement after a product is approved, we will pay Teva royalties on our revenues up to an aggregate of certain amounts expended by Teva on development and commercialization. Either party may terminate the Teva Agreement upon certain customary conditions of breach.

***PRO 2000***

**Paligent, Inc.**

In June 2000, we licensed exclusive, worldwide rights from Paligent, Inc. (formerly HeavenlyDoor.com and Procept, Inc.) to develop and market PRO 2000, in exchange for an up-front payment, future milestone payments, and royalties on net sales. In April 2003, we amended the terms of the PRO 2000 licensing agreement and purchased all rights to PRO 2000.

**MRC**

In July 2005, we entered into the Collaborative Research and Licensing Agreement with the MRC, an agency of the United Kingdom. In exchange for the right to have PRO 2000 included in the MRC s approximately 10,000 person Phase III clinical trial studying the prevention of the transmission of HIV and other sexually-transmitted diseases to be conducted primarily in Africa and India and the right to use the results of this trial, we agreed to grant to the MRC a non-exclusive license to PRO 2000 solely for its use in the Phase III trial and also to supply, at no cost to the MRC, all PRO 2000 and placebo required for the Phase III trial. The MRC will be responsible for all other trial costs. Additionally, we agreed to make PRO 2000 available in developing countries with high need under a license agreement to be negotiated in good faith, or to supply to the MRC PRO 2000 to be distributed in these developing countries at our cost plus a markup pursuant to a supply agreement to be negotiated. We will pay the MRC a minimal royalty on sales of PRO 2000 in developed countries. The term of this agreement will extend to ten years from the date of the first commercial sale of PRO 2000 in a developed country.

***HYDRON POLYMER TECHNOLOGY***

In November 1989, GP Strategies Corporation ( GP Strategies ), then known as National Patent Development Corporation, entered into an agreement (the Hydron Agreement ) with Dento-Med Industries, Inc., now known as Hydron Technologies, Inc. In June 2000, Valera entered into a contribution agreement with GP Strategies, pursuant to which Valera acquired the assets of GP Strategies drug delivery business, including all intellectual property, the Hydron Agreement, and certain other agreements with The Population Council, Inc. and Shire US, Inc.

Pursuant to the Hydron Agreement, we have the exclusive right to manufacture, sell or distribute any prescription drug or medical device and certain other products made with the Hydron polymer, while Hydron Technologies was granted an exclusive, worldwide license to manufacture, market or use products composed of, or produced with the use of, the Hydron polymer in certain consumer and oral health fields. Neither party is prohibited from manufacturing, exploiting, using or transferring the rights to any new non-prescription drug product containing the Hydron polymer, subject to certain exceptions, for limited exclusivity periods. Subject to certain conditions and exceptions, we are obligated to supply certain types of Hydron polymers if Hydron Technologies elects to purchase them from us. In the event we withdraw from the business of manufacturing the Hydron polymer, we will assign all of our right and interest in the Hydron trademark to Hydron Technologies. The agreement continues indefinitely, unless terminated earlier by the parties. Each party may owe royalties up to 5% to the other party on certain products under certain conditions.

***AMINOCANDIN***

**Sanofi-aventis**

We licensed exclusive, worldwide rights to aminocandin from sanofi-aventis in April 2003 (the Aminocandin Agreement ). In exchange for these rights and for sanofi-aventis inventory of aminocandin, we made an up-front payment to sanofi-aventis and are obligated to pay potential milestone payments and royalties on future sales. As of September 30, 2008, we have paid approximately $2,175,000 to sanofi-aventis pursuant to this agreement.

**Novexel**

In December 2006, we licensed our know-how related to aminocandin to Novexel (the Novexel Agreement ) for an up-front payment and potential future development and sales milestones aggregating approximately $44,500,000 for injectable and oral formulations of the product, and royalties on net sales. sanofi-aventis assigned the Aminocandin Agreement to Novexel. Effective as of the date of the Novexel Agreement, we entered into a termination agreement with Novexel terminating the Aminocandin Agreement. Pursuant to the Novexel Agreement, Novexel now is responsible for all future development, manufacturing, marketing and financial obligations relating to aminocandin. The Novexel Agreement will terminate on a country-by-country basis, at the later of the date of the last to expire Novexel patent relating to aminocandin existing as of the date of the agreement, or ten years from the first commercial sale of the product. Either party may terminate the Novexel Agreement upon certain customary conditions of breach. Also, Novexel may terminate the agreement following certain notice periods, (a) upon the occurrence of a material adverse change relating to the compound or product, or (b) after the earlier of (i) the commencement of the first Phase II clinical trial for the compound or product, or (ii) fifteen months after the date of the agreement. As of September 30, 2008, we have received approximately $1,500,000 from Novexel pursuant to this agreement.

***SARAFEM***

**Lilly**

In June 1997, we entered into an agreement with Eli Lilly ( Lilly ) under which we sublicensed to Lilly exclusive, worldwide rights under a Massachusetts Institute of Technology ( MIT ) patent that was licensed exclusively by MIT to us and which is directed to the use of fluoxetine to treat certain conditions and symptoms associated with premenstrual syndrome ( PMS ). In July 2000, Lilly received approval for fluoxetine, which is marketed under the trade name Sarafem, to treat a severe form of PMS. We will receive royalties on net sales of Sarafem until the expiration of our patent related to Sarafem. In January 2003, Galen Holdings PLC acquired the sales and marketing rights to Sarafem from Lilly. Through September 30, 2008, we have received approximately $19,600,000 from Lilly and paid approximately $3,700,000 of this amount to MIT. Royalties ceased during fiscal 2008.

***ALKS 27***

**Alkermes**

In January 2007, we announced our joint collaboration with Alkermes, Inc. for the development of ALKS 27, an inhaled formulation of trospium chloride for the treatment of COPD using Alkermes proprietary AIR® pulmonary delivery system. Pursuant to the collaboration agreement, we and Alkermes shared equally in all costs of the development and commercialization of ALKS 27 on a worldwide basis. Alkermes performed all formulation work and manufacturing. We conducted the clinical development program. This agreement will continue in effect until both parties have met to review the results of the feasibility study and decide whether to continue development and enter into a new collaboration agreement, seek a commercialization partner or terminate the agreement. Certain provisions apply if either one party does not wish to continue. Also, either party may terminate this agreement under certain customary conditions of breach.

In April 2008, we received from Alkermes a letter purporting to terminate the Feasibility Agreement dated as of February 4, 2005, between us and Alkermes. We and Alkermes have been engaged in discussions with several third parties relating to the further development and commercialization of this product and with each other to provide for further development by us and Alkermes. We dispute Alkermes position that this agreement has terminated and intend to pursue vigorously our rights and remedies under this agreement and applicable law. We own or have an exclusive license to various know-how, and own the IND, relating to the product that has been under development by us and Alkermes. We also have certain rights to joint intellectual property.

Alkermes has agreed to submit to the dispute resolution procedures set forth in the Feasibility Agreement to reach a resolution of these contractual issues.

***BUCINDOLOL***

**CPEC**

CPEC LLC, an entity 65% owned by us and 35% owned by Aeolus Pharmaceuticals, Inc. ( Aeolus ) (formerly Incara Pharmaceuticals, Inc.) was developing bucindolol, a nonselective beta-blocker for treatment of congestive heart failure. In October 2003, CPEC LLC licensed its bucindolol development and marketing rights to ARCA in exchange for potential future milestone and royalty payments (the ARCA Agreement ). In fiscal 2006, we amended our agreement with ARCA resulting in $1,266,000 of license fee revenue, $1,000,000 of which was received in cash. In fiscal 2008, CPEC LLC received from ARCA a $500,000 milestone related to ARCA s filing of an NDA for bucindolol. As a result of the FDA s acceptance of the bucindolol for filing, we incurred a liability of $750,000 to be paid in Indevus Common Stock to the original licensor to us of bucindolol. Aeolus is liable to us for 55% of this liability which it may pay in the form of Aeolus common stock. If the bucindolol NDA is approved, we would have a similar liability that could range from $750,000 to $1,875,000 in value depending upon the price of Indevus Common Stock to be issued at the time the payment is due. CPEC LLC or ARCA may terminate the ARCA Agreement under certain customary conditions of breach.

***IP 751***

**Manhattan Pharmaceuticals**

In June 2002, we licensed exclusive, worldwide rights to IP 751 from Manhattan Pharmaceuticals, Inc. (formerly known as Atlantic Technology Ventures, Inc.), ( Manhattan ), in exchange for an up-front licensing payment, potential development milestones, and royalty payments. In August 2003, we terminated the license and acquired from Manhattan all its intellectual property rights to IP 751 in exchange for a combination of cash and equity payments from us to Manhattan. In August 2003, we also entered into an agreement with Sumner Burstein, Ph.D., the owner of certain intellectual property rights related to IP 751 under which Dr. Burstein granted to us an exclusive, worldwide license to these rights in exchange for up-front milestone payments and other consideration totaling approximately $4,300,000, of which approximately $3,600,000 pertains to potential

future milestone payments, as well as potential future royalty payments on product sales, if any. The term of the Burstein License continues in effect on a country-by-country basis until the date of the expiration of the last to expire Burstein patent in such country, subject to earlier termination by either party. In November 2008, we issued our notice of termination.

**Cervelo Pharmaceuticals**

In October 2007, we licensed our worldwide rights to IP 751 to Cervelo Pharmaceuticals, Inc. and received an upfront payment of $1,000,000. Cervelo is responsible for the development and marketing of IP 751. In November 2008, we issued our notice of termination.

## MANUFACTURING AND MARKETING

*General.* We have a specialty sales force of approximately 100 people who promote or copromote our products throughout the U.S. We currently manufacture VANTAS, SUPPRELIN LA and other product candidates that utilize our HYDRON Polymer Technology using a patented and proprietary process and proprietary equipment. We have no direct manufacturing capabilities beyond our capabilities for VANTAS, SUPPRELIN LA and other candidates that utilize our HYDRON Polymer Technology. For both clinical trials and commercialized products, we rely on third parties to manufacture our products and product candidates. We expect to market our products ourselves or through co-promotion or exclusive marketing arrangements with other pharmaceutical companies.

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

*SANCTURA and SANCTURA XR*. Pursuant to the Allergan Agreement, Allergan is responsible for all advertising and promotional costs. Allergan is also responsible for subsidizing our sales force at specified annual amounts through March 2009. We are co-promoting SANCTURA and SANCTURA XR with our sales force.

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

We are manufacturing SANCTURA XR though a contract manufacturer. After August 2008, Allergan became responsible for manufacturing SANCTURA XR for their own use in the U.S. and Canada. We rely on third-party manufacturing to produce SANCTURA XR, including the manufacture of the active pharmaceutical ingredient as well as finishing and packaging the product.

*VANTAS*. We currently market VANTAS directly through our sales force. We manufacture VANTAS at our facility in Cranbury, NJ.

*SUPPRELIN LA*. We currently market SUPPRELIN LA directly through our sales force. We manufacture SUPPRELIN LA at our facility in Cranbury, NJ.

*VALSTAR.* If approved, we intend to market VALSTAR directly through our sales force. We rely on third-party manufacturing to produce VALSTAR, including the manufacture of the active pharmaceutical ingredient as well as finishing and packaging the product.

*NEBIDO*. Pursuant to the BayerSchering Agreement, we are responsible for the commercialization and marketing of NEBIDO in the U.S., either independently or with marketing partners. BayerSchering is exclusively responsible for the manufacture and supply of finished product to us. BayerSchering currently manufactures NEBIDO for sale in Europe. The manufacturing facility expected to be used for the manufacture of commercial product for sale in the U.S. had a successful pre-approval inspection by FDA in April 2008.

*DELATESTRYL.* We currently market DELATESTRYL directly through our sales force. Indevus purchased the U.S. marketing rights of Delatestryl from Savient Pharmaceuticals. The product is manufactured and supplied by Sandoz Canada.

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

*OCTREOTIDE*. We manufacture octreotide at our facility in Cranbury, NJ. We rely on a third-party manufacturer for the active pharmaceutical ingredient for octreotide.

*PAGOCLONE*. We currently use third-parties to manufacture pagoclone.

**COMPETITION**

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

*SANCTURA and SANCTURA XR.* Current therapy for OAB includes anticholinergics, such as Detrol and Detrol LA (tolterodine) by Pfizer, Ditropan and Ditropan XL (oxybutynin) by Johnson & Johnson, Inc., Oxytrol (oxybutynin transdermal patch) by Watson Pharmaceuticals, Vesicare (solifenacin) by Astellas Pharma US, Inc. and Glaxo Smith Kline, Enablex (darifenacin) by Novartis A.G., generic oxybutynin, and generic oxybutynin extended release. Many of the products on the market for the treatment of OAB, including SANCTURA XR, are available in once-daily formulations, whereas SANCTURA is a twice-daily formulation. We believe there are other products in various stages of development for the treatment of OAB, which may lead to further competition. Toviaz, (fesoterodine fumarate) developed by UCB and licensed to Pfizer, has been approved in the EU, and was approved in the U.S. in November 2008 with a predicted launch during the first half of 2009. Toviaz is a once-daily, sustained release, antimuscarinic agent. YM-178, a Selective ß3-Adrenoceptor Agonist by Astellas, is currently in Phase III trials.

*NEBIDO and DELATESTRYL.* Current preferred methods for treating hypogonadism are topical and injectable treatments. Topical treatments include gels, such as AndroGel by Solvay and Testim by Auxilium, and transdermal patch systems, such as AndroDerm by Watson. There are several additional gel products in development and two of these products, Fortigel from ProStrakan and Androgel 1.62% from Solvay, have

completed clinical development and are pending registration. We anticipate that both of these products will gain marketing approval in 2009. Acrux is developing MD Lotion, a topical testosterone applied with a no touch applicator to the axilla, and has recently initiated a Phase III trial in the United States. There are multiple injectable products currently marketed in the U.S., including DELATESTRYL, which require more frequent injections than NEBIDO. The majority of the injectable treatments are generic. Testosterone is also available in oral dose forms, however, they are not widely prescribed for use in the United States. Two new oral agents are currently being evaluated as oral treatments for men with secondary hypogonadism in Phase II clinical trials, Androxal (Oral Enclomiphene Citrate) by Repros Therapeutics and fispemifene by QuatRx Pharmaceuticals, Inc.

*VANTAS.* The most common dosage forms for the administration of LHRH agonists for the palliative treatment of prostate cancer involve three- and four-month injection formulations such as Lupron marketed by Abbott Laboratories and Eligard marketed by sanofi-aventis, each of which delivers leuprolide. Eligard is also marketed as a six-month formulation and Abbott is developing a six-month formulation of Lupron. Two additional agents are also currently marketed, Trelstar by Watson, delivers triptorelin, and Zoladex marketed by AstraZeneca, a biodegradable rod, that contains goserelin. Viadur, a 12-month implant marketed by Bayer Healthcare is no longer commercially available. Trelstar, a six-month formulation, is currently in registration with an expected approval date during the third quarter of 2009.

*SUPPRELIN LA.* There are three currently approved agents to treat CPP, Lupron Depot-PED, which is manufactured and marketed by Abbott Laboratories, Synarel (nafarelin acetate) an intra nasal formulation marketed by Pfizer, and SUPPRELIN LA. CPP treatment using Lupron Depot-PED consists of intramuscular injections of leuprolide every three to four weeks to hormonally suppress patients. Synarel is administered intra-nasally b.i.d to induce gonadotropin suppression. Synarel is typically used as a second-line agent if leuprolide proves difficult to administer.

*VALSTAR.* There are no products other than VALSTAR approved by the FDA for therapy of BCG-refractory CIS of the urinary bladder; however, VALSTAR is not covered by any patents and its orphan drug status has expired in the United States. Bioniche Life Sciences, Inc. announced that Urocidin, for patients with non-muscle invasive bladder cancer that is refractory to BCG, has started Phase III clinical trials. According to Bioniche, Urocidin has limited efficacy and is associated with a number of treatments with limited side effects.

*PRO 2000.* Other than condoms, we are not aware of any product to prevent sexually-transmitted infections having been approved for use anywhere in the world. We believe there are several dozen new substances being evaluated for this indication, but we believe only a few have reached the stage of development of PRO 2000. Advanced clinical stage topical microbicides include BufferGel by Reprotect, Inc.

*OCTREOTIDE IMPLANT.* There are currently two somatostatin analogues approved and marketed to treat acromegaly. These products include Sandostatin LAR Depot (octreotide/IM injection) by Novartis A.G., and Somatuline Depot (lanreotide acetate) by Tercica Inc. Both products require injections every four weeks. We are currently aware of three somatostatin analogues in clinical development; two of these products are in advanced clinical stage development. These products, Octreotide (C2L) and Pasireotide LAR, are being developed by Ambrilia Biopharma and Novartis, respectively, Ambrillia has recently announced that it plans to sell our out-license C2L before the end of the year.

**PATENTS AND PROPRIETARY RIGHTS**

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

*SANCTURA and SANCTURA XR*. There are no existing U.S. compositions of matter patents covering the active pharmaceutical ingredient (trospium chloride), which is used in SANCTURA. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, provides for a new chemical entity ( NCE ) period of market exclusivity in the U.S. for SANCTURA for five years following the date of FDA approval, which was May 28, 2004. This NCE period of exclusivity is granted for drugs containing an active pharmaceutical ingredient not previously approved by the FDA. We have acted to seek more extensive market exclusivity protection for the SANCTURA brand through the development of SANCTURA XR, a once-daily formulation of the drug. Our licensor, Supernus, has filed patent applications directed to various aspects of the once-a-day formulation, including but not limited to the use of various types of polymers and drug release characteristics. One of these patent applications has matured to a granted patent, U.S. Patent No. 7,410,978, which is not scheduled to expire until February 1, 2025. Foreign counterparts are also being pursued in major markets outside the United States, such as Europe and Japan.

*NEBIDO*. We licensed from BayerSchering rights under a U.S. patent application covering composition of matter for NEBIDO and methods of treating diseases or symptoms associated with deficient endogenous levels of testosterone with NEBIDO. If granted, the corresponding U.S. patent would have a patent term extending into early 2024.

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

*PRO 2000*. We own intellectual property relating to PRO 2000, including five issued U.S. patents: two covering compositions of matter issued in June 2000 and April 2002, two covering the use of PRO 2000 to inhibit, treat, or prevent HIV infection, which were issued in May and October 1997, respectively, and one covering the use of PRO 2000 to prevent pregnancy issued in September 1999. These U.S. patents are slated to expire as early as November 2013 to as late as June 2017. Foreign counterparts to the domestic composition and methods patents for the treatment of HIV have been granted in Japan and in numerous countries across Europe. A Canadian patent application remains pending. Foreign counterpart patents to the domestic method patent for the prevention of pregnancy have been granted in Australia, China, Hong Kong, Mexico, New Zealand, Russian Federation, South Africa, and South Korea and the European Patent Office, including 23 member states. Patent applications remain pending in Brazil, Canada, and Japan.

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

*Pagoclone*. We licensed from sanofi-aventis rights under U.S. and foreign patents and patent applications covering compositions of matter, processes, and metabolites of pagoclone. A U.S. composition of matter patent was issued in October 1990 and four related U.S. patents were issued in February and March 1996 and February

and October 1997. In addition, we own certain patent rights, which were assigned to us by Warner Lambert, which are directed to many uses of pagoclone, including the treatment of obsessive compulsive disorder and social anxiety disorder, and certain methods of manufacture of pagoclone. The U.S. patent rights assigned to us by Warner Lambert are set to expire as early as April 2022 to as late as March 2023. We have also filed a patent application that covers a transdermal patch including pagoclone, which, if granted, would enjoy a patent term extending into early 2025. We also own U.S. Patent No. 6,855,721, which covers a method of alleviating stuttering by the administration of a therapeutically effective dose of pagoclone or a pharmaceutically acceptable salt thereof. This last patent is scheduled to expire in July 2020.

*HYDRON Polymer Technology*. We have three patent families that cover different aspects of our HYDRON Polymer Technology, including two U.S. patents that generally cover our approved products, VANTAS and SUPPRELIN LA, and our implant products under development. These two U.S. patents, which are directed to methods of manufacture, articles of manufacture and devices for drug delivery, are scheduled to expire on November 30, 2010 and March 8, 2011, respectively. Foreign counterparts exist in a number of countries, including Australia, Canada, Europe and Japan. In addition, a separate patent family is being pursued, which is specifically directed to SUPPRELIN LA and a method for treating central precocious puberty. If granted, patent protection in the U.S. for SUPPRELIN LA would extend to mid-2025. Still another patent family is being pursued, which is specifically directed to our octreotide implant and a method of treating acromegaly. To that end, U.S. Patent No. 7,452,868 was granted on November 18, 2008, which is scheduled to expire on March 18, 2026 We also own a U.S. patent and corresponding foreign counterparts, which are directed to an implanting device, or trocar, that is used to insert an implant beneath the skin. The United States trocar patent is scheduled to expire on April 3, 2023. The Company also owns a design patent on the design features of the trocar, which is scheduled to expire on July 13, 2018.

## GOVERNMENT REGULATION

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

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

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

Clinical trials are normally done in three phases, although the phases may overlap. Phase I trials are concerned primarily with the safety and pharmacokinetics of the product. Phase II trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These

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

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

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

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

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

SANCTURA, approved for marketing in the U.S. on May 28, 2004, was granted five years of market exclusivity under the Hatch-Waxman Act. VANTAS, approved for marketing in the U.S. on October 12, 2004, was granted five years of market exclusivity. SUPPRELIN LA, approved for marketing in the U.S. on May 3, 2007 with an orphan designation, was granted seven years of market exclusivity. SANCTURA XR was approved for patent protection in August 2008. The patent extends through February 1, 2025.

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

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

*Reimbursement*. Section 303(c) of the Medicare Modernization Act of 2003 ( MMA ) revised the payment methodology for Part B covered drugs (such as VANTAS and SUPPRELIN LA) that are not paid on a cost or prospective payment basis. In particular, section 303(c) of the MMA amended Title XVIII of the Act by adding section 1847A, which established a new average sales price ( ASP ) drug payment system. Beginning January 1, 2005, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on the ASP methodology, and payment to the providers will be 106 percent of the ASP. There are exceptions to this general rule which are listed in the latest ASP quarterly change request ( CR ) document. The ASP methodology uses quarterly drug pricing data submitted to the CMS by drug manufacturers. CMS will supply contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis.

In addition, rebates must be paid to government organizations under the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, and under amendments of that law that became effective in 1993 and discounted pricing is required for purchases by authorized users of the Federal Supply Schedule of the General Services Administration. Since 1993, as a result of the Veterans Health Care Act of 1992, including the Veterans Administration, the Department of Defense, Coast Guard, and the PHS, including the Indian Health Service.

**EMPLOYEES**

As of September 30, 2008, we had 246 full-time employees. None of our employees are represented by a labor union and we believe our employee relations are satisfactory. We are highly dependent upon certain key personnel and believe our future success will depend in large part on our ability to retain such individuals and attract other highly skilled management, marketing and scientific personnel.

**Item 1A.** ***Risk Factors***

*A restated description of the risk factors associated with our business is set forth below. The following factors should be reviewed carefully, in conjunction with the other information contained in this Report and our consolidated financial statements. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this Form 10-K and presented elsewhere by our management from time to time. See Part I Note Regarding Forward Looking Statements.*

**Risks Relating to Our Business**

***We will be dependent on our marketed products and the ability of Allergan to perform its obligations with respect to SANCTURA and SANCTURA XR.***

We derived a substantial portion of our revenue in fiscal 2008 from only four products. Two of our products SANCTURA and SANCTURA XR are treatments for overactive bladder, which we co-promote with our marketing partner, Allergan. The others are VANTAS, a product for the treatment of advanced prostate cancer, and SUPPRELIN LA, for the treatment of central precocious puberty. We believe that revenues derived under our agreement with Allergan and from the sale of VANTAS and SUPPRELIN LA will continue to account for a substantial portion of our revenue for the foreseeable future.

In October 2007, Allergan became our new partner with respect to SANCTURA and SANTURA XR in connection with its acquisition of Esprit. Our agreement with Allergan is referred to herein as the Allergan Agreement. We are highly dependent on Allergan for the commercialization and marketing of SANCTURA and SANCTURA XR in the U.S. and for performance of its obligations under the Allergan Agreement. Under the terms of the Allergan Agreement, Allergan will be responsible for all U.S. marketing and sales activities relating to SANCTURA and SANCTURA XR (we have the right to co-promote SANCTURA XR through March 2009). As such, we will depend on Allergan to devote sufficient resources to effectively market SANCTURA and SANCTURA XR. The failure of Allergan to effectively market SANCTURA or SANCTURA XR or perform its obligations under the Allergan Agreement, could materially adversely affect our business, financial condition and results of operations.

We currently market VANTAS and SUPPRELIN LA ourselves through our approximately 100-person specialty sales force. Our specialty sales force may not be able to successfully market and sell such products. Moreover, because our marketing resources are limited, we may be unable to devote sufficient resources to our marketed products to maintain, or achieve increasing, market acceptance of such products in their highly competitive marketplaces. If we are unable to successfully market and sell such products, it will have a material adverse effect on our business and results of operations.

***Our product candidates may not be successfully developed or achieve market acceptance.***

We currently have multiple compounds or products which are in various stages of development and have not been approved by the FDA. These product candidates are subject to the risk that any or all of them are found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances or receive such clearances on a timely basis.

In June 2008, the FDA required that we respond to certain clinical deficiencies related to NEBIDO. While we reached an agreement with regard to the additional data and risk management strategy that will lead to re-submission (complete response) of the NDA for NEBIDO, we are still unable to predict when or if we will be able to adequately address the issues raised by the FDA and cannot predict when or if NEBIDO will be approved for marketing by the FDA. The FDA could require additional testing prior to FDA approval. In addition, if approved, the FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of NEBIDO. Even if NEBIDO receives regulatory clearance, there can be no assurance that it will achieve or maintain market acceptance. If NEBIDO does not achieve market acceptance it will have a material adverse effect on our business and results of operations.

We are unable to predict whether any of our other product candidates, such as VALSTAR and the octreotide implant, will receive regulatory clearances or will be successfully manufactured or marketed. On December 19, 2007 we announced that we had received a non-approvable letter from the FDA for VALSTAR due to manufacturing deficiencies identified during an FDA pre-approval inspection of our third-party manufacturing facility. Due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frames for commercialization of any products are long and uncertain. Even if these product candidates receive regulatory clearance, there can be no assurance that such products will achieve or maintain market acceptance which could have a material adverse effect on our business and results of operations.

The product candidates that we are attempting to develop differ from established treatment methods and will compete with a number of more established drugs and therapies manufactured and marketed by major pharmaceutical companies. If any of our products or product candidates fails to achieve market acceptance, we may not be able to market and sell the products successfully, which would limit our ability to generate revenue and could harm our business.

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

We believe that our existing cash resources will be sufficient to fund our planned operations into the first calendar quarter of 2010. Our cash requirements and cash resources will vary significantly depending upon the following principal factors:

- marketing success of SANCTURA, SANCTURA XR, VANTAS and SUPPRELIN LA;
- approval, launch and marketing success of NEBIDO and VALSTAR;
- the costs and progress of our research and development programs;
- the timing and cost of obtaining regulatory approvals; and
- the timing and cash flows of in-licensing or out-licensing products.

In addition, we continue to expend substantial funds for research and development, marketing, general and administrative expenses and manufacturing. We expect to continue to use substantial cash for operating activities in fiscal 2009 as we continue to fund our development activities for NEBIDO, pagoclone pursuant to the Teva Agreement, the octreotide implant and other product candidates, as well as sales and marketing activities related to VANTAS and SUPPRELIN LA and premarketing and potential marketing activities related to VALSTAR and NEBIDO. We are also co-promoting SANCTURA and SANCTURA XR at least until March 2009.

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

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

***Leverage as a result of our outstanding convertible notes may harm our financial condition and results of operations.***

At September 30, 2008, we had $71,925,000 of outstanding debt reflected on our balance sheet relating to the Convertible Senior Notes. These Notes have a maturity date of July 15, 2009.

The noteholders may decide not to convert the Notes. If the price of our common stock at the time the Notes become due does not exceed $8.50 for a specified period, then we may not be able to redeem the Notes to cause a conversion, and then we may be obligated to repay the holders of the Notes in cash on the July 2009 due date.

We may incur additional indebtedness in the future and the Notes do not restrict our future issuance of indebtedness. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

- a portion of our cash flow from operations will be dedicated to the payment of any interest required with respect to outstanding indebtedness;
- increases in our outstanding indebtedness and leverage will increase our vulnerability to adverse changes in general economic and industry conditions, as well as to competitive pressure; and
- depending on the levels of our outstanding debt, our ability to obtain additional financing for working capital, capital expenditures, general corporate and other purposes may be limited.

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

- to seek additional financing in the debt or equity markets;
- to refinance or restructure all or a portion of our indebtedness, including the Notes or any other notes that may be issued;
- to sell selected assets; or
- to reduce or delay planned expenditures on clinical trials, and development and commercialization activities.

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

***In certain circumstances, we may lose the potential to receive future royalty payments after the Non-recourse Notes are repaid in full or we may be required to pay damages for breaches of representations, warranties or covenants under certain of the Non-recourse Note financing agreements.***

In August 2008, through a wholly-owned subsidiary, we issued $105 million in aggregate principal amount of Non-recourse Notes, which are secured principally by royalty payments from future sales of SANCTURA and SANCTURA XR in the U.S., and by a pledge by us of all the outstanding equity interest in our subsidiary. If the SANCTURA and SANCTURA XR royalty payments are insufficient to repay the Non-recourse Notes or if an event of default occurs under the indenture governing the Non-recourse Notes, in certain circumstances, the royalty payments and our equity interest in our subsidiary may be foreclosed upon and we would lose the potential to receive future royalty payments after the Non-recourse Notes are repaid in full. In addition, in connection with the issuance of the Non-recourse Notes, we have made certain representations, warranties and covenants to our subsidiary and the holders of the Non-recourse Notes, or the Non-recourse Noteholders. If we breach these representations, warranties or covenants, such breach could trigger an event of default under the

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indenture and we could also be liable to our subsidiary or the Non-recourse Noteholders for substantial damages in respect of any such breach, which could harm our financial condition and ability to conduct our business as currently planned. See Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations, Liquidity and Capital Resources Cash, Cash Equivalents and Marketable Securities for additional details regarding the Non-recourse Notes.

***Allergan s failure to successfully market and commercialize SANCTURA and SANCTURA XR would harm sales of SANCTURA and SANCTURA XR and, therefore, would delay or prevent repayment of the Non-recourse Notes, which would delay or prevent us from receiving future revenue from sales of SANCTURA and SANCTURA XR.***

The Non-recourse Notes issued by our subsidiary will be repaid solely from royalties on net sales of SANCTURA and SANCTURA XR in the United States by Allergan under the Allergan Agreement. Royalty payments in respect of net sales of SANCTURA and SANCTURA XR in the U.S. will be entirely dependent on the actions, efforts and success of Allergan, over whom neither we nor our subsidiary have control. Neither we nor our subsidiary can ensure that Allergan effectively maximizes the potential sales of SANCTURA and SANCTURA XR. Our subsidiary s ability to pay amounts due on the Non-recourse Notes may be materially harmed to the extent Allergan fails or is unable to successfully market and sell SANCTURA and SANCTURA XR. Our ability to receive future revenue from sales of SANCTURA and SANCTURA XR is dependent on our subsidiary repaying the Non-recourse Notes in a timely fashion. If our subsidiary takes longer than anticipated to repay the Non-recourse Notes, or if it defaults on the Non-recourse Notes, in each case due to lower sales of SANCTURA and SANCTURA XR by Allergan, we may not receive future revenue from SANCTURA and SANCTURA XR as currently planned, or at all. See Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations, Liquidity and Capital Resources Cash, Cash Equivalents and Marketable Securities for additional details regarding the Non-recourse Notes.

***Royalties under the Allergan Agreement may not be sufficient for our subsidiary to meet its payment obligations under the Non-recourse Notes.***

While our subsidiary will be entitled to certain minimum royalties under the Allergan Agreement, such minimum royalties may not be sufficient for our subsidiary to meet its payment obligations under the Non-recourse Notes and, therefore, it will be dependent on Allergan s successful sales and marketing efforts for SANCTURA and SANCTURA XR in order for it to receive royalties in excess of these minimum amounts. In addition, Allergan s obligation to pay minimum royalties may be reduced, suspended or eliminated following certain adverse events pertaining to regulatory non-compliance, generic competition, lack of product supply and other events. Any such royalty modifications would result in our subsidiary receiving significantly reduced or no royalties under the Allergan Agreement, which would delay repayment of the Non-recourse Notes, or result in a default under the Non-recourse Notes. In such circumstances we may not receive future revenue relating to SANCTURA or SANCTURA XR as currently planned, or at all.

***We may not compete successfully in the urology and endocrinology markets, including for sales of our products as well as the acquisition of additional compounds.***

Our products compete in the urology and endocrinology markets. The competition in the urology and endocrinology markets is intense and is expected to increase. Our products compete with many current drug therapies or with new drugs which may reach the market in the future. Launches of other competitive products may occur in the near future, and we cannot predict with accuracy the timing or impact of the introduction of competitive products or their possible effect on our sales.

We compete against biotechnology companies, universities, government agencies, and other research institutions. Many of the 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.

In addition, although we are seeking proprietary protection for NEBIDO and other products we are developing, we could face competition from generic substitutes of these products and our other marketed products, such as SANCTURA and SANCTURA XR. Because generic manufacturers are not exposed to development risks for such generic substitutes, these manufacturers can capture market share by selling generic products at lower prices, which can reduce markedly the market share held by the original product.

Sales of competing products may cause a decrease in the selling price or units sold for our products, and could have a material adverse effect on our net product sales, gross margin and cash flows from operations. In the event our products were unable to be sold at a rate we anticipate, we could potentially have excess inventory, resulting in an impairment charge that could have a material adverse effect on our financial statements.

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

In particular, our marketed products and near term product candidates compete against the following products:

- SANCTURA and SANCTURA XR compete against anticholinergics, such as Detrol and Detrol LA (tolterodine) by Pfizer, Ditropan and Ditropan XL (oxybutynin) by Johnson & Johnson, Inc., Oxytrol (oxybutynin transdermal patch) by Watson Pharmaceuticals, Vesicare (solifenacin) by Astellas Pharma US, Inc. and Glaxo Smith Kline, Enablex (darifenacin) by Novartis A.G., generic oxybutynin, and generic oxybutynin extended release;

- VANTAS competes against TAP Pharmaceutical Products Lupron and sanofi aventis Eligard, both multiple injection formulations that deliver leuprolide; Watson Pharmaceuticals Trelstar, a multiple injection formulation that delivers triptorelin; AstraZeneca s Zoladex, a biodegradable rod that delivers goserelin for up to three months;

- SUPPRELIN LA competes against Abbott Laboratories Products Lupron Depot-PED; and

- NEBIDO, if approved and launched, will compete against gels, such as AndroGel by Solvay and Testim by Auxilium, transdermal patch systems, such as AndroDerm by Watson, and multiple injectable products currently marketed in the U.S. which require more frequent injections than NEBIDO.

Physicians may not prescribe, and patients may not accept, our products if we do not promote our products effectively. Factors that could affect our success in marketing our products include:

- the adequacy and effectiveness of our sales force and that of any co-promotion partners;

- the adequacy and effectiveness of our production, distribution and marketing capabilities;

- the success of competing products, including generics; and

- the availability and extent of reimbursement from third-party payors.

In addition, we do not conduct our own research to discover new drug compounds. Instead, we depend on the acquisition of compounds from others for development through licensing, partnerships, corporate collaborations, strategic corporate transactions or company acquisitions.

Therefore, in order to grow, we must

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

***We rely on third parties with respect to manufacturing, distribution and commercialization of certain of our products as well as products we have out-licensed.***

We are currently dependent on third parties to manufacture SANCTURA XR, Madaus GmbH ( Madaus ) to manufacture SANCTURA, and Bayer Schering Pharma AG, Germany ( BayerSchering ) to manufacture NEBIDO. Allergan is responsible for manufacturing SANCTURA XR for their own use. In addition, we will be dependent on third parties for manufacturing of VALSTAR. We are dependent on third parties in the supply chain, for the manufacture of trospium chloride, the active pharmaceutical ingredient in SANCTURA and SANCTURA XR, as well as for the packaging of SANCTURA. If any of these third parties were unable to achieve or maintain compliance with FDA requirements for manufacturers of drugs sold in the U.S., we would need to seek alternative sources of supply, which could create disruptions in the supply of SANCTURA, SANCTURA XR or NEBIDO. In addition, we are reliant on third parties for manufacturing relating to our non-core product candidates, such as PRO 2000 and pagoclone. Reliance on third-party manufacturers for the manufacture of most of our products, entails risks to which we would not be subject if we manufactured these products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us.

Any manufacturing facilities for any of our compounds are subject to FDA inspection both before and after NDA approval to determine compliance with U.S. current Good Manufacturing Practices ( cGMP ) requirements. There are a limited number of contract manufacturers that operate under cGMP that are capable of manufacturing our products. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or commercialize them. Facilities used to produce our compounds may not have complied, or may not be able to maintain compliance, with cGMP. For example, our third-party manufacturer of VALSTAR failed to pass a recent cGMP compliance inspection and as a result, we received a non-approvable letter for VALSTAR which has delayed the approval and launch of this product. The cGMP regulations are complex and failure to be in compliance could lead to non-approval or delayed approval of an NDA which would delay product launch or, if approval is obtained, may result in remedial action, penalties and delays in production of material acceptable to the FDA.

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

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

We have out-licensed to third parties the development and commercialization efforts of many of our non-core products and product candidates such as aminocandin. We are dependent on such third parties with respect to development and commercialization of such products and product candidates and we have limited or no influence over their efforts and activities. Reliance on third parties for such efforts entails risks, many of which we would not be subject if we developed these products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the licensing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us. In addition, the occurrence of any such events or any other failure by these third parties to adequately develop or commercialize these products or product candidates could materially adversely affect our operations and financial condition.

***As a manufacturer of some of our products, we are subject to risks of reliance on single suppliers, interruptions on the manufacturing process and regulatory requirements.***

As a manufacturer of some of our products and product candidates, we are subject to a variety of risks, including risks pertaining to reliance on single suppliers, interruptions on the manufacturing process and regulatory requirements.

We currently rely on single suppliers for some of our products and product candidates, including in particular histrelin, the active ingredient in VANTAS and SUPPRELIN LA and octreotide acetate for the octreotide implant. Any alternate sources of these raw materials and services may not be immediately available to us and may not meet specifications or requirements of us or the FDA. Consequently, if any of our suppliers are unable or unwilling to supply us with these raw materials in sufficient quantities with the correct specifications, or provide services on commercially acceptable terms, we may not be able to manufacture our products or our product candidates in a timely manner or at all, which could materially adversely affect our operations and financial condition.

Any interruption in the supply or manufacturing of our products or product candidates may adversely impact sales of our products or the development of our product candidates. Any lack of supply during such period of interruption may have an adverse impact on our future sales because physicians may have elected to use alternative treatments during this time frame or may, as a result of this interruption, permanently switch to another product. For example, prior to the merger with Indevus, Valera experienced two separate disruptions in its manufacturing of VANTAS due to issues caused by its supply of histrelin. These difficulties delayed the manufacturing of VANTAS for several weeks and directly impacted Valera s supply of VANTAS in 2005. Also, VALSTAR was withdrawn from the market in 2002 due to a manufacturing problem. In the future, we may experience other disruptions in our manufacturing process for these and our products and product candidates which may adversely impact sales and development.

Pharmaceutical products are required to be manufactured under regulations known as current good manufacturing practice, or cGMP. Before commercializing a new product, manufacturers must demonstrate compliance with the applicable cGMP regulations, which include quality control and quality assurance requirements, as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products generated through the use of their technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems or the failure to maintain compliance with existing or new regulatory requirements may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and civil or criminal sanctions.

We may also encounter problems with the following:

- production yields;
- raw materials;
- shortages of qualified personnel;
- compliance with FDA regulations, including the demonstration of purity and potency;
- changes in FDA requirements;
- controlling production costs; and
- development of advanced manufacturing techniques and process controls.

In addition, we are required to register our manufacturing facilities with the FDA and other regulatory authorities. The facilities are subject to inspections confirming compliance with cGMP or other regulations. If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, or revocation of pre-existing approval for a product, such as VANTAS or SUPPRELIN LA, which would eliminate a substantial source of our revenue and could materially adversely affect our operations and financial condition.

We also currently contract with third parties for most of our manufacturing needs and do not manufacture any of our own products or product candidates, except for VANTAS, SUPPRELIN LA and the octreotide implant. We do not currently have any substitute manufacturing facilities and arrangements in place with respect to our manufacturing facility now used for VANTAS and SUPPRELIN LA. As such, if we are unable to continue to use our current manufacturing facility for any reason, including regulatory non-compliance or otherwise, it could materially adversely affect our operations and financial condition. In addition, we cannot be certain that alternative manufacturing sources will be available on reasonable terms or at all.

To continue to develop products, apply for regulatory approvals and commercialize products, we will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. Certain of our requirements for supplies or clinical compounds are filled by purchase orders on an as-requested basis and are not the subject of long-term contracts. As a result, we cannot be certain that manufacturing sources will continue to be available or that we can continue to outsource the manufacturing of these products or product candidates on reasonable terms or at all.

***We rely on the protection provided by our intellectual property and have limited patent protection on some of our products and we are dependent on market exclusivity for some of our products.***

Our future success will depend to a significant extent on our ability to:

- obtain and enforce patent protection on our products and technologies;
- maintain trade secrets; and

operate and commercialize products without infringing on the patents or proprietary rights of others.

There can be no assurance that patent applications filed by us or others, in which we have an interest as assignee, licensee or prospective licensee, will result in patents being granted or that, if granted, any of such patents will afford protection against competitors with similar technology or products, or could not be circumvented or challenged.

In addition, certain products we are developing or selling are not covered by any patents and, accordingly, we will be dependent on obtaining market exclusively under the Hatch-Waxman Act for such products. Under the Hatch-Waxman Act, a company may obtain five years of market exclusivity if the FDA determines such

compound to be a chemical entity that has not been the subject of an approved NDA in the past. The period of market exclusivity under the Hatch-Waxman Act is considerably shorter than the exclusivity period afforded by patent protection, which, in the case of some patents, may last up to twenty years from the earliest priority date of the patent directed to the product, our approved use or method of manufacture. If we are unable to obtain strong proprietary rights protection of our products after obtaining regulatory clearance, competitors may be able to market competing generic products by obtaining regulatory clearance, by demonstrating equivalency to our product, without being required to conduct the lengthy and expensive clinical trials required of us. Certain of our agreements provide for reduced royalties, or forgo royalties altogether, in the event of generic competition.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a product candidate can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing any advantage of the patent.

Our license for SANCTURA, a product approved for use in the treatment of overactive bladder, does not include any patents that cover the commercialization of the product. We do not otherwise currently own or have a license to issued patents that cover our SANCTURA product. Our ability to successfully commercialize SANCTURA in the U.S. or have it successfully commercialized through a marketing partner will depend on the continued availability of market exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, which provides protections for certain new products. The Hatch-Waxman Act provides for a period of market exclusivity in the U.S. for SANCTURA for five years from the date of FDA approval, May 28, 2004. The marketing of SANCTURA could be materially adversely affected if the period of market exclusivity is shortened. After this time, there may be generic versions of trospium chloride available to treat overactive bladder at significantly lower prices than SANCTURA, in which case sales of SANCTURA will likely decrease significantly.

Our licensor, Supernus, has one patent granted in the United States (U.S. Patent No. 7,410,978) and several related patent applications, which are directed to the once-a-day formulation of trospium chloride, which is SANCTURA XR. The patent applications continue to be pending, but we cannot predict whether any additional patents will issue from any of these pending patent applications. There can be no assurance that the granted patent or any other patents, which may be granted in the future, can or will preclude eventual market erosion from new technologies, competing products generic competition.

Further, we will not have exclusive rights with respect to the sale of VALSTAR because the product candidate is not covered by any patents or orphan drug exclusivity. As a result, competitors may compete with us by, among other things, introducing a generic version of the product or a similar product that contains the active ingredient, valrubicin.

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

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

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

obtain a license, which may not be available, in order to continue to manufacture or market the affected product or use the affected process. If a license is not available to us, we may be forced to abandon the related product. In still other situations, others may be able to pursue an action seeking a declaratory judgment that one or more of the patents, which we own or control, are invalid, unenforceable, or not infringed. If successful, such actions may severely curtail our ability to maintain the exclusivity of a market, which is targeted by an affected product, thus adversely affecting our business. The outcome of any litigation may be uncertain. Any litigation may also result in significant use of management and financial resources.

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

To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the attribution of proprietary rights to such information which may not be resolved in a manner favor to us. Most of our consultants are employed by or have consulting agreements with third parties, and the ability of such consultants to assign to us any inventions discover may be impaired. 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.

***The successful commercialization of our products will depend on obtaining reimbursement at adequate levels from government authorities, private health insurers and Medicare/Medicaid for patient use of these products.***

Sales of pharmaceutical products largely depend on the reimbursement of patients medical expenses by government healthcare programs, such as Medicare and Medicaid, and private health insurers. These third party payors control healthcare costs by limiting both coverage and the level of reimbursement for healthcare products. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services and altering reimbursement levels. The levels at which government authorities and private health insurers reimburse physicians or patients for the price they pay for our current marketed products or products we may develop could affect the extent to which we are able to commercialize these products.

We cannot be sure that reimbursement in the United States or elsewhere will be available for any pharmaceutical products we may develop or, if already available, in particular VANTAS, will not be decreased in the future. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our drug products. Any reduction in demand would adversely affect our business.

Significant uncertainty generally exists as to the reimbursement status of newly approved healthcare products. Our ability to achieve acceptable levels of reimbursement for product candidates will affect our ability to successfully commercialize, and attract collaborative partners to invest in the development of, our product candidates. Reimbursement may not be available for products that we may develop and reimbursement or coverage levels may reduce the demand for, or the price of products that we may develop. If we cannot maintain coverage for our existing marketed products or obtain adequate reimbursement for other products we develop, the market for those products may be limited.

Acceptable levels of reimbursement will also have an effect on our ability to attract collaborative partners to invest in the development of, our products and product candidates. If reimbursement is not available or is

available only at limited levels, we may not be able to obtain collaborative partners to manufacture and commercialize our products and product candidates, and may not be able to obtain a satisfactory financial return on our own manufacturing and commercialization of any future products.

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

Our business is dependent on market acceptance of our products by physicians, healthcare payors, patients and the medical community. Medical doctors willingness to prescribe, and patients willingness to accept, our products depend on many factors, including:

- perceived safety and efficacy of our products;
- convenience and ease of administration;
- prevalence and severity of adverse side effects in both clinical trials and commercial use;
- availability of alternative treatments;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of our products;
- publicity concerning our products or competing products; and
- our ability to obtain third-party coverage or reimbursement.

If our products are not accepted by physicians, healthcare payors, patients and the medical community, it will have a material adverse effect on our business and results of operations.

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

Before obtaining regulatory approval for the commercial sale of any of the pharmaceutical product candidates we are developing, we or our licensees must demonstrate that the product is safe and efficacious for use in each target indication. The process of obtaining FDA and other regulatory approvals is lengthy and expensive. If clinical trials do not demonstrate the safety and efficacy of certain products under development, we will be materially adversely affected. The results of pre-clinical studies and early clinical trials may not predict results that will be obtained in large-scale testing or use. Clinical trials of products we are developing may not demonstrate the safety and efficacy of such products.

Regardless of clinical trial results, the FDA may not approve marketing of the product. The costs to obtain regulatory approvals are considerable and the failure to obtain, or delays in obtaining, regulatory approval could have a significant negative effect on our business performance and financial results. For example, in June 2008 the delays in obtaining regulatory approval of NEBIDO resulting from the FDA s approvable letter relating to clinical deficiencies resulted in a material adverse impact on our stock price.

Even if a product is approved, the FDA is authorized to impose post-marketing requirements. A number of companies in the pharmaceutical industry, including Indevus, have suffered significant setbacks in advanced clinical trials or have not received FDA approval, even after promising results in earlier trials. For example, while there were multiple clinical trials of pagoclone that demonstrated statistically significant efficacy for panic and generalized anxiety disorders, other trials of pagoclone were unsuccessful for these indications. These unsuccessful trials prompted Pfizer (our previous licensee of this compound) to elect not to pursue further development of the compound and to return to us all rights to pagoclone which resulted in a material adverse impact on our stock price.

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***We rely on third parties to conduct certain of the clinical trials for our product candidates, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for or commercialize our product candidates.***

We design the clinical trials for our product candidates, but we rely on academic institutions, private physician offices, corporate partners, contract research organizations and other third parties to assist in the conduct and management of these trials. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted the trials entirely on our own. For example, we are conducting certain clinical trials for the octreotide implant in Europe; however, we have employed a contract research organization to monitor the trials. We will also contract with a third party to handle the data management for these trials.

Although we rely on, and will continue to rely on, third parties to manage the data from our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. Moreover, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practice, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trials plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

***We have regulatory guidelines and related pricing risks.***

Although our marketed products have been approved by the FDA, the FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of these products. In addition, although these products have thus far demonstrated an acceptable safety profile in clinical trials, there can be no assurance that the safety profile of the drugs would not change when assessed in future trials or when used by a larger patient population.

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

Government health care cost-containment measures can significantly affect our sales and profitability. These include federal, state, and foreign laws and regulations that negatively affect pharmaceutical pricing, such as Medicaid and Medicare, pharmaceutical importation laws, and other laws and regulations that, directly or indirectly, impose governmental controls on the prices at which our products are sold.

Government agencies promulgate regulations and guidelines directly applicable to us and our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our products.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to profitably sell our marketed products and any other products that we may develop. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for certain

medical treatments or subject the pricing of drugs to government control. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has been enacted by Congress and signed by the President. Additionally, Medicare regulations implementing the prescription drug benefit became effective as of January 1, 2006. These and other regulatory and legislative changes or proposals may affect our ability to raise capital, obtain additional collaborators and market our existing products and any other products that we may develop. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subject the price of our products to governmental control, our ability to sell our current marketed products and other products we may develop in commercially acceptable quantities at profitable prices may be harmed.

Third-party payors are increasingly challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any products that may be offered by us in the future. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that we successfully develop and are approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

***The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of our products in those jurisdictions.***

We have worldwide rights to market many of our products and product candidates. We intend to seek approval of and market our products outside of the U.S. For example, we have agreements to license VANTAS in Canada, South Africa, Asia and Argentina. To market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country ensure approval by regulatory authorities in other foreign countries or the FDA. Other than the approval of VANTAS for marketing in the European Union and certain other foreign jurisdictions, we may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market. If we fail to comply with these regulatory requirements or obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue from abroad will be adversely affected.

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

The use of products in clinical trials and the marketing of products may expose us to substantial product liability claims and adverse publicity. Certain of our agreements require us to obtain specified levels of insurance coverage, naming the other party as an additional insured. We currently maintain product liability and clinical trial insurance in the amount of $40,000,000. We may obtain additional coverage for products that may be marketed in the future. We may not be able to maintain or obtain insurance coverage, or to obtain insurance in amounts sufficient to protect us or other named or additionally insured parties against liability, at a reasonable cost, or at all. In addition, any insurance obtained may not cover any particular liability claim. We have indemnified certain licensors, licensees and contractors and may be required to indemnify additional licensors,

licensees or contractors against product liability claims incurred by them as a result of products we develop or market. If uninsured or insufficiently insured product liability claims arise, or if a successful indemnification claim was made against us, our business and financial condition could be materially adversely affected. In addition, any payments made by us in connection with product liability litigation could result in significant charges to operations and would materially adversely affect our results of operations and financial condition.

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

On September 15, 1997, we announced a market withdrawal of our first commercial prescription product, the weight loss medication Redux, which had been launched by American Home Products Corporation, now Wyeth, our licensee, in June 1996. Following the withdrawal, we have been named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. The existence of such litigation may materially adversely affect our business. In addition, although we are unable to predict the outcome of any such litigation, if successful uninsured or insufficiently insured claims, or if a successful indemnification claim, were made against us, our business, financial condition and results of operations could be materially adversely affected. In addition, the uncertainties associated with these legal actions have had, and may continue to have, an adverse effect on the market price of our common stock and on our ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, and to obtain product liability insurance for other products at costs acceptable to us, or at all, any or all of which may materially adversely affect our business, financial condition and results of operations.

On May 30, 2001, we entered into an Indemnity and Release Agreement with Wyeth, which provides for indemnification of Redux-related claims brought by plaintiffs who initially elected not to stay in the AHP national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension, a serious disease involving the blood vessels in the lungs. This agreement also provides for funding of all defense costs related to all Redux-related claims and provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the AHP indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. We are unable to predict whether the existence of such litigation may adversely affect our business.

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

***We 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 product candidate or risk loss of the license or incur penalties. Depending upon the importance to us of the product that is subject to any such agreement, this could materially adversely affect our business. In particular, termination of our agreements with Allergan, Madaus, or Helsinn Chemicals SA and Helsinn Advanced Synthesis SA, related to SANCTURA and SANCTURA XR, our agreements with BayerSchering, under which we license NEBIDO, or our agreement with sanofi-aventis, under which we license pagoclone, would materially harm us. The agreements with Allergan, Madaus, sanofi-aventis or BayerSchering may be terminated by any of them if we are in material breach of our agreements with them or if

we become insolvent or file for bankruptcy protection. Termination of the supply agreement with Plantex USA Inc. for the supply of valrubicin, the active pharmaceutical ingredient for VALSTAR, could significantly hinder the potential to commercialize VALSTAR.

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

We have incurred substantial net losses over the past five fiscal years, including net losses of approximately $68,200,000, $53,200,000, $50,600,000, $103,800,000 and $65,600,000 for fiscal years 2004, 2005, 2006, 2007, and 2008, respectively. At September 30, 2008 we had an accumulated deficit of approximately $642,100,000.

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

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

We may never achieve or sustain profitability in the future. We expect to continue to experience fluctuations in revenue as a result of the timing of regulatory filings or approvals, product launches, license fees, royalties, product shipments, and milestone payments. We also continue to expect fluctuations in expense from the timing of clinical trials, payments to licensors for development milestones, and in licensing fees for new product candidates.

***We may be adversely impacted if our controls over external financial reporting fail or are circumvented.***

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes Oxley Act of 2002 to report annually on our internal control over financial reporting. If we, or our independent registered public accounting firm, determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees and as executive officers.

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

We may acquire companies, businesses and products that complement or augment our existing business. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Integrating any newly acquired business or product could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management s attention and any delay or difficulties encountered in connection with any future acquisitions we

may consummate could result in the disruption of our on-going business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness.

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

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

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

We have a small number of employees and are dependent on certain executive officers and scientific personnel, including Glenn L. Cooper, our Chief Executive Officer, Noah D. Beerman, our Chief Business Officer, Mark S. Butler, our Chief Administrative Officer and General Counsel, Michael W. Rogers, our Chief Financial Officer, and Bobby W. Sandage, Jr., our Chief Scientific Officer. Our business could be adversely affected by the loss of any of these individuals. In addition, we rely on the assistance of independent consultants to design and supervise clinical trials and prepare FDA submissions.

Competition for qualified employees, including sales people, among pharmaceutical and biotechnology companies is intense. If key employees terminate their employment, or insufficient numbers of employees are retained to maintain effective operations, our sales, marketing or development activities and prospects might be adversely affected. In addition, we might not be able to locate suitable replacements for any key employees that leave Indevus or offer employment to potential replacements on reasonable terms.

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

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

Our board of directors has the authority, without further approval of our stockholders, to fix the rights and preferences, and to issue up to 5,000,000 shares of preferred stock. In addition, vesting of shares of our common stock subject to awards under our 2004 Equity Incentive Plan accelerates, and outstanding options under our stock option plans become immediately exercisable, upon certain changes in control of Indevus, 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 Indevus 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.

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

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

***The price for our securities is volatile.***

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

- market success of SANCTURA, SANCTURA XR, VANTAS and SUPPRELIN LA;
- results of clinical studies and regulatory reviews;
- marketing approval of NEBIDO;
- marketing approval of VALSTAR;
- sales by Valera s former stockholders of significant amounts of Indevus common stock they received in the merger or upon conversion of any contingent stock rights;
- partnerships, corporate collaborations and company acquisitions;
- announcements by our corporate collaboration partners concerning our products, about which we generally have very limited control, if any, over the timing, substance or content;
- changes in the levels we spend to develop, market, acquire or license new compounds;

market conditions in the pharmaceutical and biotechnology industries;

competitive products;

sales, the possibility of sales, or buybacks of Indevus common stock or other financings, including resales of stock, stock issued upon conversion of the contingent stock rights issued in connection with the merger with Valera, issuance of additional debt and entering into credit facilities;

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

changes in proprietary rights of our, or our competitor s, products;

Redux-related litigation developments;

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

general economic conditions.

The high and low sales prices of our common stock as reported by the NASDAQ Global Market were: $10.25 and $4.86 for fiscal 2004, $7.45 and $2.41 for fiscal 2005, $6.75 and $2.50 for fiscal 2006, $8.06 and $5.58 for fiscal 2007 and $8.22 and $1.19 for fiscal 2008. Our common stock is subject to possible delisting if our stock price drops below the bid price of $1.00 per share. If we fail to meet any of the continued listing requirements for the NASDAQ Global Market, our common stock could be delisted from the NASDAQ Global Market, the effects of which could include limited release of a market price of our common stock, limited liquidity for stockholders and limited news coverage and could result in an adverse effect on the market for our common stock. Further, if our common stock is delisted, we may have difficulties in raising, or may be unable to raise, additional funds with which to operate our business by selling our common stock.

The stock markets also experience significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of our common stock.

***Impairment charges pertaining to goodwill, identifiable intangible assets or other long-lived assets from our merger with Valera could have an adverse impact on our results of operations and the market value of our common stock.***

The total purchase price pertaining to our merger with Valera has been allocated to Valera s net tangible assets, identifiable intangible assets, in process research and development and goodwill. To the extent the value of goodwill or identifiable intangible assets or other long-lived assets become impaired, we will be required to incur material charges relating to the impairment. Any impairment charges could have a material adverse impact on our results of operations and the market value of our common stock.

***The price for our common stock could be negatively affected if we issue additional shares.***

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 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1998 Employee Stock Option Plan, 2000 Stock Option Plan, and 2004 Equity Incentive Plan. In addition, shares of our common stock may be issued upon conversion of the contingent stock rights issued in connection with the merger with Valera. The possibility of sales of such shares, private sales of securities or the possibility of resale of such shares in the public market may adversely affect the market price of our common stock.

***Our stockholders could be diluted if we issue our shares subject to options, warrants, convertible notes, stock awards or other arrangements.***

As of September 30, 2008, we had reserved the following shares of our common stock for issuance:

10,806,040 shares issuable upon conversion of the Convertible Senior Notes issued in August 2007, which are due in July 2009;

15,986,135 shares issuable upon exercise of outstanding options, performance stock awards and deferred stock units, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if Indevus issues additional securities below certain prices;

5,000,000 shares of Common Stock reserved for issuance upon conversion of our authorized but unissued Preferred Stock; and

2,927,546 shares reserved for grant and issuance under our stock option, stock purchase and equity incentive plans.

We may grant additional options, warrants or stock awards. To the extent such shares are issued, the interest of holders of our common stock will be diluted.

In addition, we are obliged to issue shares of common stock upon achievement of development milestones related to contingent stock rights, or CSRs, issued in connection with the merger with Valera. As a result of the May 3, 2007 FDA approval of SUPPRELIN LA and our possession of a specified amount of inventory of commercially sellable units, approximately 2,300,000 shares were issued. The achievement of future milestones related to two other outstanding CSRs could result in the issuance of shares totaling approximately $40,600,000.

***Our convertible senior notes may not be rated or may receive a lower rating than anticipated.***

If one or more rating agencies rates our outstanding convertible senior notes, collectively referred to herein as the Notes, assigns the Notes a rating lower than the rating expected by investors, or reduces its rating in the future, the market price of the Notes would be harmed.

***The price of our convertible senior notes may fluctuate significantly as a result of the volatility of the price for our common stock.***

Because our convertible senior notes are convertible into shares of our common stock, volatility or depressed prices for our common stock could have a similar effect on the trading price of the convertible senior notes.

***Fluctuations in the price of our common stock may prevent the holders of our convertible senior notes from being able to convert such notes.***

The ability of holders of our outstanding convertible notes to convert the notes is conditioned on the closing price of our common stock reaching a specified threshold or the occurrence of other specified events, such as a change of control. As of December 1, 2008, the closing sales price of our common stock was $2.26, which is below the current conversion price threshold of $6.656. Due to the numerous factors impacting the trading price of our common stock, such as our results of operations and the volatility in securities prices relating to the recent disruption in the financial markets, concerns about inflation, and slower economic activity, it is likely that the trading price of our common stock will not exceed the current conversion price threshold prior to the final maturity date of the convertible senior notes. If such closing price threshold is not satisfied and the other specified events that would permit a holder to convert such notes do not occur, it is likely that holders would not convert the notes and the notes would be become due and payable in full on the maturity date of July 15, 2009. If such conversion does not occur, there can be no assurance that we will have sufficient cash to repay the notes on the maturity date.

***The recent volatility in the financial markets could adversely affect us or our partners, customers or suppliers***

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in securities prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Among other risks we face, the current tightening of credit in financial markets may adversely affect our ability to obtain financing in the future, including, if necessary, to fund a product or strategic acquisition. In addition, current economic conditions could harm the liquidity or financial position of our partners, customers or suppliers, which could in turn cause such parties to fail to meet their contractual or other obligations to us.

In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we cannot be assured that we will not experience losses on these deposits.

***If we are unable to pay all of our debts, the noteholders will receive payment on the Notes only if we have funds remaining after we have paid any future secured indebtedness.***

The convertible senior notes are unsecured and are effectively subordinated in right of payment to any future secured indebtedness that we may incur to the extent of the value of the pledged assets. If some or all of our assets are pledged to secure other obligations, there may not be sufficient assets remaining to pay amounts due on any or all of the outstanding convertible senior notes. In addition, we may be unable to fulfill our obligations to offer to repurchase the convertible senior notes upon a change of control.

***The convertible senior notes will effectively be subordinated to the debt of our subsidiaries.***

Our right to receive any assets of any of our subsidiaries upon their liquidation or reorganization, and therefore the right of the holders of the convertible senior notes to participate in those assets, will be effectively subordinated to the claim of that subsidiary s creditors, including trade creditors. In addition, even if we were a creditor of any of our subsidiaries, our rights as a creditor would be subordinate to any security interest in the assets of our subsidiaries and any indebtedness of our subsidiaries senior to that held by us. Our subsidiaries have no obligation to pay any amounts due on the convertible senior notes or to provide us with funds for our payment obligations, whether by dividends, distributions, loans or other payments. Furthermore, we are not limited in or prohibited from transferring cash or other assets to our subsidiaries from time to time.

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

None.

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

We lease our corporate headquarters of approximately 53,200 square feet in Lexington, Massachusetts under two leasing agreements with total annual base rent of approximately $1,330,000. The initial terms for these leases expire in 2010 and 2012. We also lease two facilities in Cranbury, New Jersey consisting of a total of approximately 51,000 square feet with total annual base rent of approximately $1,278,000. The initial terms of these leases expire in 2015. We manufacture VANTAS and SUPPRELIN LA at our New Jersey facilities.

In October 2007, we entered into a sub-lease agreement with Nano-Ditech Corporation to sub-lease 7,400 square feet of excess space located in our 7 Clarke Drive, Cranbury, New Jersey, facility. This sub-lease will provide annual rental income of approximately $156,000 through 2015.

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

*Product Liability Litigation.* On September 15, 1997, we announced a market withdrawal of our first prescription product, the weight loss medication Redux (dexfenfluramine hydrochloride capsules) C-IV, which had been launched by Wyeth (formerly American Home Products Corporation), our licensee, in June 1996. The withdrawal of Redux was based on a preliminary analysis by the FDA of potential abnormal echocardiogram findings associated with certain patients taking Redux or the combination of fenfluramine with phentermine. After the withdrawal of Redux, we were named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purported to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. To date, there have been no judgments against us, nor have we paid any amounts in settlement of any of these claims.

On May 30, 2001, we entered into an indemnity and release agreement with Wyeth pursuant to which Wyeth agreed to indemnify us against certain classes of product liability cases filed against us involving Redux. Our indemnification covers plaintiffs who initially opted out of Wyeth s national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth agreed to fund all future

legal costs related to our defense of Redux- related product liability cases. The agreement also provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. We believe this total insurance coverage is sufficient to address our potential remaining Redux product liability exposure.

Up to the date of the AHP indemnity and release agreement, our defense costs were paid by, or subject to reimbursement to us from, our product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by us or our insurers.

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

*General*. Although we maintain certain product liability and director and officer liability insurance and intend to defend these and similar actions vigorously, we have been required and may continue to be required to devote significant management time and resources to these legal actions. In the event of successful uninsured or insufficiently insured claims, or in the event a successful indemnification claim were made against us and our officers and directors, our business, financial condition and results of operations could be materially adversely affected. The uncertainties and costs associated with these legal actions have had, and may continue to have an adverse effect on the market price of our common stock and on our ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, or to obtain product liability insurance for other products at costs acceptable to us, or at all, any or all of which may materially adversely affect our business, financial condition and results of operations.

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

Not applicable.

**EXECUTIVE OFFICERS OF THE REGISTRANT**

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

| Name | Age | Position |
|---|---|---|
| Glenn L. Cooper, M.D | 55 | Chief Executive Officer and Chairman |
| Noah D. Beerman | 46 | Executive Vice President, Chief Business Officer |
| Mark S. Butler | 62 | Executive Vice President, Chief Administrative Officer and General Counsel |
| Michael W. Rogers | 48 | Executive Vice President, Chief Financial Officer and Treasurer |
| Bobby W. Sandage, Jr., Ph.D. | 55 | Executive Vice President, Research and Development and Chief Scientific Officer |

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

*Noah D. Beerman* is our Executive Vice President and Chief Business Officer, a position he has held since September 2004. Mr. Beerman joined us in June 1997 as Director of Business Development and subsequently was appointed Executive Director in June 1998, Vice President in January 2000, and Senior Vice President in August 2000. Prior to joining us, Mr. Beerman was Vice President in charge of healthcare at Technology Management and Funding ( TMF ), a venture firm, from June 1995 to June 1997, where he developed and executed commercialization and business development strategies for TMF s biotechnology portfolio. He previously served in a variety of business development and scientific capacities at Creative BioMolecules from January 1994 to June 1995, Sandoz AG from January 1988 to December 1993, and Repligen from June 1984 to December 1987. Mr. Beerman received an M.B.A. from Northeastern University s High Technology Program and a B.S. in molecular genetics from the University of Rochester.

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

*Michael W. Rogers* is our Executive Vice President, Chief Financial Officer and Treasurer, a position he has held since joining us in February 1999. From February 1998 to December 1998, Mr. Rogers was Executive Vice President and Chief Financial and Corporate Development Officer at Advanced Health Corporation, a publicly-traded healthcare 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 served in the Investment Banking Division of PaineWebber, Inc., most recently as Vice President. Mr. Rogers received an M.B.A. from the Darden School at the University of Virginia and a B.A. from Union College.

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

**PART II**

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

**Price Range of Securities**

Our Common Stock trades on the NASDAQ Global Market under the symbol IDEV . The table below sets forth the high and low sales prices of our Common Stock as reported by the NASDAQ Global 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, 2008: | | |
| July 1 through September 30, 2008 | $ 3.80 | $ 1.57 |
| April 1 through June 30, 2008 | 5.10 | 1.19 |
| January 1 through March 31, 2008 | 7.09 | 4.17 |
| October 1 through December 31, 2007 | 8.22 | 6.88 |
| Fiscal Year Ended September 30, 2007: | | |
| July 1 through September 30, 2007 | $ 7.48 | $ 6.00 |
| April 1 through June 30, 2007 | 7.85 | 6.10 |
| January 1 through March 31, 2007 | 7.48 | 6.18 |
| October 1 through December 31, 2006 | 8.06 | 5.58 |

**Approximate Number of Equity Security Holders**

The number of holders of record of our Common Stock as of September 30, 2008 was approximately 578.

We have never paid a cash dividend on our Common Stock and anticipate that for the foreseeable future any earnings will be retained for use in our business; any dividends on our Common Stock will be subject to dividends payable on any preferred stock that we may issue.

**Stock Performance Graph**

This performance graph shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act ), or incorporated by reference into any filing of Indevus under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

The following graph compares the cumulative 5-year total return to shareholders on Indevus Pharmaceuticals common stock with the cumulative total returns of the NASDAQ Composite index and a peer group index consisting of companies reporting under SIC Code 2834 Pharmaceutical Preparations. The graph assumes that the value of the investment in the company s common stock, in the peer group, and the index (including reinvestment of dividends) was $100 on 9/30/2003 and tracks it through 9/30/2008.

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

The following selected financial data should be read together with the information under Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the notes to those financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the years ended September 30, 2008, 2007 and 2006 and balance sheet data as of September 30, 2008 and 2007 set forth below have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the years ended September 30, 2005 and 2004 and balance sheet data as of September 30, 2006, 2005 and 2004 set forth below have been derived from the audited financial statements for such years not included in this Annual Report on Form 10-K. The historical results presented here are not necessarily indicative of future results.

| | Fiscal Years Ended September 30, | | | | |
|---|---|---|---|---|---|
| | 2008 | 2007 | 2006 | 2005 | 2004 |
| | (Amounts in thousands except per share) | | | | |
| Statement of Operations Data: | | | | | |
| Revenues: | | | | | |
| Product revenue | $ 32,642 | $ 25,033 | $ 26,738 | $ 14,269 | $ 9,740 |
| Contract and license fees | 45,149 | 41,034 | 23,714 | 19,067 | 8,986 |
| Total revenues | 77,791 | 66,067 | 50,452 | 33,336 | 18,726 |
| Cost of revenues | 30,835 | 14,640 | 19,692 | 8,593 | 7,950 |
| Research and development | 24,964 | 41,927 | 43,203 | 30,597 | 23,303 |
| Marketing, general and administrative | 75,854 | 60,185 | 36,009 | 41,983 | 51,916 |
| Acquired in-process research and development | | 50,000 | | | |
| Amortization of intangible assets | 2,267 | 910 | | | |
| Restructuring | 2,980 | | | | |
| Loss from operations | (59,109) | (101,595) | (48,452) | (47,837) | (64,443) |
| Investment income | 2,692 | 3,354 | 3,505 | 3,142 | 1,396 |
| Interest expense | 8,958 | 5,492 | 5,170 | 5,170 | 5,170 |
| Minority interest and other | 176 | 93 | 437 | 182 | (5) |
| Loss before income taxes | (65,551) | (103,826) | (50,554) | (50,047) | (68,212) |
| Provision for income taxes | | | | (3,171) | |
| Net loss [1,2] | (65,551) | (103,826) | (50,554) | (53,218) | (68,212) |
| Preferred stock dividends | 17 | 35 | 35 | 35 | 35 |
| Net loss attributable to common stockholders | $ (65,568) | $ (103,861) | $ (50,589) | $ (53,253) | $ (68,247) |
| Net loss per common share-basic and diluted | $ (0.86) | $ (1.61) | $ (1.02) | $ (1.13) | $ (1.43) |
| Weighted average common shares-basic and diluted | 76,565 | 64,679 | 49,411 | 46,977 | 47,542 |

| | September 30, | | | | |
|---|---|---|---|---|---|
| | 2008 | 2007 | 2006 | 2005 | 2004 |
| | (Amounts in thousands) | | | | |
| Balance Sheet Data: | | | | | |
| Working capital | $ 19,156 | $ 38,648 | $ 54,876 | $ 79,233 | $ 131,288 |
| Total assets | 263,002 | 183,050 | 92,307 | 112,531 | 173,838 |
| Convertible Notes, current | 70,187 | 75 | | | |
| Convertible Notes, long-term | | 68,037 | 72,000 | 72,000 | 72,000 |
| Non-recourse Notes, long-term | 105,000 | | | | |
| Total liabilities including deferred revenue | 393,188 | 257,388 | 216,511 | 227,667 | 236,868 |
| Accumulated deficit | (642,052) | (576,501) | (472,675) | (422,121) | (368,903) |
| Total stockholders deficit | (130,186) | (74,338) | (124,330) | (115,142) | (63,038) |

(1) We adopted SFAS 123R on a prospective basis beginning in fiscal 2006. See Note M of the Notes to Consolidated Financial Statements.
(2)

We acquired Valera effective April 18, 2007. The acquisition was accounted for under the purchase method of accounting and the results of operations of Valera have been included in our consolidated results as of the acquisition date. See Note C of the Notes to Consolidated Financial Statements.

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

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

**Our Business**

We are a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Our approved products include SANCTURA® and SANCTURA XR for overactive bladder ( OAB ), co-promoted with our partner Allergan, Inc. ( Allergan ), VANTAS® for advanced prostate cancer, SUPPRELIN® LA for central precocious puberty ( CPP ), and DELATESTRYL® for the treatment of hypogonadism. We market our products through an approximately 100-person specialty sales force.

Our core urology and endocrinology portfolio contains multiple compounds in development in addition to our approved products. Our most advanced compounds are VALSTAR for bladder cancer, NEBIDO® for hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted diseases, the octreotide implant for acromegaly and cardinoid syndrome.

In addition to our core urology and endocrinology portfolio, there are multiple compounds outside of our core focus area which we either currently outlicense for development and commercialization, or intend to outlicense in the future. These compounds include pagoclone for stuttering which we have recently licensed worldwide rights to Teva Pharmaceutical Industries Ltd. ( Teva ), ALKS 27 for chronic obstructive pulmonary disease ( COPD ) which we have been jointly developing with Alkermes, Inc. ( Alkermes ), and aminocandin for systemic fungal infections for which we licensed worldwide rights to Novexel S.A. ( Novexel ).

**Issuance of Non-recourse Notes**

On August 26, 2008, Ledgemont Royalty Sub LLC ( Royalty Sub ), our wholly-owned subsidiary, closed a private placement to institutional investors of $105,000,000 in aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due November 5, 2024 (the Non-recourse Notes ). In connection with the issuance of the Non-recourse Notes, we entered into a Purchase and Sale Agreement with Royalty Sub, through which we sold to Royalty Sub our rights to receive royalty payments from Allergan arising under the Allergan Agreement. The Non-recourse Notes are secured by royalties payable to us from Allergan for sales in the U.S. of SANCTURA and SANCTURA XR and by a pledge by us of all the outstanding equity interest in our subsidiary. The Non-recourse Notes are non-recourse and non-convertible and have not been guaranteed by us. Our subsidiary will receive all royalties payable to us from Allergan for sales in the U.S. of SANCTURA and SANCTURA XR until the Non-recourse Notes have been repaid in full; therefore, future royalties, until the Non-recourse Notes are fully paid, will not be available to fund our operations. See Liquidity and Capital Resources Cash, Cash Equivalents and Marketable Securities for additional details regarding the Non-recourse Notes.

**Product Developments**

***VANTAS***

In April 2008, we entered into an agreement to terminate our manufacturing and supply agreement with Shire plc ( Shire ) related to VANTAS. Under this termination agreement, Shire relinquished its right to receive future royalties on net sales of VANTAS or a percentage of royalties and other consideration received by us relative to a sublicense of our VANTAS selling and marketing rights granted by Shire. In exchange, the termination agreement provided for us to pay Shire a total of $5,000,000 consisting of an immediate payment of $1,000,000 and the balance of $4,000,000 in three annual installments commencing in January 2009. We capitalized the net present value of the total $5,000,000 payment using a discount rate of 17.5%, resulting in a

$3,932,000 intangible asset. The intangible asset is being amortized from the date of the transaction over the remaining term of the original license agreement, which is approximately 6.5 years. After consideration of the $1,000,000 payment, there is approximately $1,000,000 classified as a short-term obligation and $2,100,000 classified as a long-term obligation in the consolidated September 30, 2008 balance sheet. This remaining obligation will be accreted up to its face value over the payment term through charges to interest expense.

In April 2008, we entered into a License, Supply and Distribution Agreement with Orion Corporation ( Orion ) granting Orion the rights to market VANTAS throughout Europe as well as in certain other countries (the Orion Agreement ). VANTAS is currently approved for the treatment of advanced prostate cancer in Denmark and the United Kingdom. VANTAS is currently undergoing the mutual recognition procedure for further European approvals. We received a $7,000,000 up-front payment and could receive certain additional contingent payments related to approvals and sales thresholds aggregating up to $14,000,000. Additionally, we have agreed to supply VANTAS to Orion at a pre-determined transfer price subject to annual minimum purchase requirements beginning in 2009. Commencing on the first sale of product to Orion, we will recognize the $7,000,000 up-front payment as revenue over the 15-year term of the Orion Agreement in accordance with the proportional performance method using the minimum supply quantities to estimate completion of the earnings process. Expected performance will be assessed quarterly to incorporate changes in estimates and payments received.

***PAGOCLONE***

On September 25, 2008, we entered into a Development, License and Commercialization Agreement with Teva (the Teva Agreement ) for the exclusive, worldwide rights to pagoclone. Under the terms of the Teva Agreement, which became effective in November 2008, we will conduct and Teva will reimburse us for our expenses for a Phase IIb study. Following the completion of a successful Phase IIb study, the Teva Agreement provides for us to participate on a 50/50 basis with Teva in the U.S., sharing development and marketing costs, and splitting future profits, in addition to receiving milestone payments. Under certain circumstances, either party may convert the Teva Agreement from the 50/50 arrangement to a royalty structure where Teva will be responsible for all development and commercial costs in the U.S. and we would receive royalties on net sales, in addition to milestones. In either case, if the arrangement continues, Teva will be responsible for the conduct of the Phase III program. For territories outside of the U.S., Teva will be responsible for all future development and commercialization and we will receive milestones and royalties on net sales.

Under the 50/50 participation, we could receive up to $92,500,000 (including the Phase IIb study expenses) in U.S. and European development milestones and Research and Development reimbursement. In the event of a conversion to the royalty structure, in addition to the $92,500,000 of milestones and reimbursements, we could receive up to $50,000,000 in U.S. based sales threshold milestones.

***SANCTURA XR***

In September 2007, we entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc. ( Esprit ), which re-defined the obligations of each party and superseded all previous agreements pertaining to SANCTURA and SANCTURA XR (the Allergan Agreement ). The Allergan Agreement became effective on October 16, 2007. Simultaneously, Allergan acquired Esprit resulting in Esprit becoming a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, we received an up-front license fee, partially creditable by Allergan against future payments to us, of $25,000,000 and $8,000,000 as payment of the supply price for future deliveries of SANCTURA XR, subject to purchase orders issued by Allergan. The Allergan Agreement also grants us the right to receive a fixed percentage of net sales for the term of the Allergan Agreement, subject to increasing annual minimum royalties totaling approximately $123,000,000 over the first seven years of the Agreement, provided there is no product adverse event, as defined in the Agreement. Commencing January 1, 2010, or earlier in the case of generic competition, Allergan has the right to reduce, subject to quarterly and annual restrictions, royalty payments by $20,000,000. In addition, we

received approximately $9,000,000 in annual sales force subsidy for fiscal year 2008 which can be extended for up to six months at our option. Third-party royalties paid by us as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR will be reimbursed to us by Allergan. Pursuant to the Allergan Agreement, on August 13, 2008, Allergan assumed responsibility to manufacture SANCTURA XR for its use (the Processing Assumption Date ) and we assigned to Allergan certain agreements and purchase orders relating to the manufacture SANCTURA XR. We manufactured and supplied SANCTURA XR to Allergan at our cost through the Processing Assumption Date and will manufacture and supply SANCTURA through September 30, 2012. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of SANCTURA XR or the last to expire patent covering SANCTURA XR in the United States. Either party may also terminate the Allergan Agreement under certain customary conditions of breach. In August 2008, we assigned our rights to receive certain royalties and milestone payments related to generic competition to investors pursuant to our private placement of $105,000,000 Non-recourse Notes (see Issuance of Non-recourse Notes above).

In May 2008, together with Madaus, we licensed to Allergan the exclusive right to develop, manufacture, and commercialize SANCTURA XR in Canada. In exchange, we received an upfront payment of $7,000,000 and could receive milestone payments totaling $2,000,000 upon achievement of certain sales thresholds. In addition, third-party royalties owed by us on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation, after which Allergan will have a fully-paid license. The performance period continues through September 30, 2012. All consideration received from Allergan during the term will be recognized using the CAPM.

Collectively through September 30, 2008 and pursuant to all agreements between us and PLIVA d.d. ( PLIVA ), Esprit and Allergan, we have received approximately $364,000,000 in the form of up front and milestone payments, royalties, sales force reimbursements and payments for product shipped to our marketing partners at our cost to manufacture.

***NEBIDO***

In January 2008, we announced the final results of an additional Phase III pharmacokinetic trial for NEBIDO. The data from the trial showed that NEBIDO met its primary endpoints, including a responder analysis based on an average testosterone concentration during the steady state dosing interval and an outlier analysis based on the maximum testosterone concentration during the steady state closing interval. In addition, the drug was well-tolerated.

As part of our development program we conducted a pharmacokinetic trial which enrolled 237 hypogonadal men to supplement the existing BayerSchering clinical database. The trial was a randomized open-label (unblinded) study that included the evaluation of the pharmacokinetics of NEBIDO dosed as either 1000 mg every 12 weeks or as 750 mg every 12 weeks, both via intramuscular injection. We announced positive data from the trial in June 2007. Of the 97 patients in the 1000 mg arm receiving their fourth injection, 94% had a Cavg over the course of the 12-week injection period that was within the normal range, demonstrating that treatment with NEBIDO was sufficient to maintain clinically therapeutic testosterone levels in hypogonadal men with injections given only once every 12 weeks. Further, no patients in the 1000 mg arm exceeded a testosterone concentration of 2500 ng/dL; four of 97 (4.1%) patients had a peak level over 1800 ng/dL; and 11 of 97 (11.3%) patients had a peak level exceeding 1500 ng/dL. Of the 102 patients in the 750 mg arm receiving their fourth injection, 86% had a Cavg within the normal range. No patients in the 750 mg arm exceeded a testosterone level of either 2500 ng/dL or 1800 ng/dL, and only four of 102 (3.9%) patients had a peak level exceeding 1500 ng/dL. Both treatment arms demonstrated improvements from baseline in the key secondary clinical outcome variables. Both doses of the drug were well-tolerated as indicated by the analysis of the safety measurements collected and the persistence with study treatment. Furthermore, the spectrum of adverse events reported were comparable to other injectable hypogonadism treatments reported in the literature. There were no significant adverse changes in laboratory parameters with NEBIDO treatment.

The existing combined database from BayerSchering and Indevus clinical development program contains over 2,500 patients, which includes over 500 patients from Indevus US studies and over 2,000 patients from BayerShering s European studies. Some of these patients have been treated for up to eight years in five clinical trials. These studies assessed the pharmacokinetic parameters of various dosing regimens of NEBIDO. In addition, the database contains post-marketing data from safety data reporting through June 2007 reflecting over 260,000 injections.

On June 4, 2008, we announced that after a discussion with the FDA that we expected the FDA to request that we provide additional safety data prior to its approval of NEBIDO. We believed at the time that this request would result in approximately a 24-month delay in approval. We also believed the FDA s concern related to a reaction immediately following the injection and is a known, rare complication of oil-based depot injections. The reaction is characterized by short-term coughing episodes, urge to cough or a shortness of breath. In rare cases, the reaction has been classified as serious or the patient experiences other symptoms such as dizziness, flushing or fainting. In addition, we believed the FDA s safety concerns were related to spontaneous post-marketing adverse event reports from the European experience using NEBIDO 1000 mg dose. In our U.S. clinical trials, using the 750 mg dose, which include approximately 500 patients, there was a single, non-serious, instance of this reaction. The patient did not require medical intervention and the event resolved without issue within 10 minutes.

On June 30, 2008, we announced that we had received an approvable letter for NEBIDO from the FDA. The letter confirmed our previously-announced indications from the FDA. The FDA expressed a concern about the relatively small number of patients who experienced respiratory symptoms immediately following the intramuscular injection of NEBIDO 1000 mg. The FDA also indicated that four of the cases in the European post-marketing database may have had an allergic, anaphylactoid reaction. We believe the each of the four cases were improperly classified and represent the same oil-based reaction. The FDA requested that we address these clinical deficiencies by providing additional safety information to determine the precise incidence of serious post-injection oil-based reactions and allergic reactions. Specifically, the FDA has requested follow-up data from the on-going U.S. and European studies in which patients are being treated with NEBIDO on an extended basis. A majority of these trials are scheduled to be completed within twelve months. The FDA at the time stated that depending on the findings, the number of subjects and the number of injections of testosterone undecanoate, the safety database may need to include data from additional clinical studies. Additionally, the FDA has requested that we provide a plan to minimize the risks associated with the clinical use of testosterone undecanoate intramuscular injection to reduce the incidence and/or severity of the serious oil-based reactions. Additionally, they requested certain data to exclude an allergic component to the drug or some of its excipients.

On September 26, 2008, we announced that we had reached an agreement with the FDA regarding additional data and risk management strategy that will lead to a re-submission of the NDA for NEBIDO in the first quarter of calendar 2009. The re-submission will include over 14,000 injections in more than 2,600 patients, all of which come from existing clinical trials conducted in the U.S. and in Europe.

FDA also agreed on an education plan to minimize the risks associated with the clinical use of NEBIDO. This plan is intended to reduce the incidence and/or severity of the serious oil-based reactions. Additionally, we have agreed to gather skin-testing data to characterize an allergic component to the drug or any of its excipients in certain patients. We have also agreed to conduct a large, simple post-marketing study of the safety of NEBIDO in approximately 10,000 patients.

We are conducting additional trials for marketing and if applicable, regulatory purposes. If approved, we intend to commercialize NEBIDO in the U.S. utilizing our specialty sales force. We may expand our existing 100-person sales force for the launch of NEBIDO, if approved.

***VALSTAR***

In August 2007, we received an approvable letter from the FDA asking for clarification regarding manufacturing validation protocols and for additional data on the manufacturing process. We submitted a response to the approvable letter in October 2007. In December 2007, we received a non-approvable letter from the FDA for VALSTAR related to its chemistry, manufacturing and controls ( CMC ) NDA supplement submitted to the FDA in May 2007. The letter was received following our response to an August 2007 approvable letter.

We believe the VALSTAR-specific issues that caused the 2002 withdrawal of the product from the market have been satisfactorily resolved. However, based on the December 2007 non-approvable letter deficiencies were identified with respect to our third-party manufacturing facility for VALSTAR that require resolution prior to approval. We believe that successfully addressing the deficiencies at the manufacturing plant is the only remaining item for product approval. Upon resolution, which we expect to occur within several months, we will respond to the FDA and request re-inspection of the facility.

We anticipate resolving these manufacturing issues during the first half of calendar 2009. If marketing clearance is received, we intend to commercialize VALSTAR in the U.S. utilizing our specialty sales force. Additionally, we are evaluating opportunities for the use of VALSTAR in other indications and potential clinical development requirements of such opportunities.

***PRO 2000***

In February 2008, we were advised by the United Kingdom s Medical Research Council ( MRC ) that after review of data from the Phase III clinical trial of PRO 2000, our candidate vaginal microbicide for HIV prevention, the Independent Data Monitoring Committee ( IDMC ) has recommended that the low-dose arm (0.5%) continue to be tested for safety and effectiveness in the trial. The IDMC, a group of independent experts providing oversight to the MDP 301 trial, also recommended the high-dose arm (2.0%) be closed as there is no more than a small chance of the high dose showing protection against HIV infection compared to placebo gel. The trial is sponsored by the MRC and conducted by the Microbicides Development Programme, an international partnership of researchers established to develop microbicides for the prevention of HIV transmission. The 0.5% dose of PRO 2000 is also being tested for safety and effectiveness in an additional Phase III trial sponsored by the National Institute of Allergy and Infectious Diseases ( NIAID ), part of the National Institutes of Health. The NIAID trial, which has completed enrollment, is expected to be completed this summer.

***ALKS 27***

On April 28, 2008, we received from Alkermes, Inc. a letter purporting to terminate the Feasibility Agreement dated as of February 4, 2005 between us and Alkermes relating to the development of an inhaled formulation of a pharmaceutical product that includes trospium chloride for the treatment of chronic obstructive pulmonary disease. We and Alkermes have been engaged in discussions with several third parties relating to the further development and commercialization of this product and with each other to provide for further development by us and Alkermes. We dispute Alkermes position that this agreement has terminated and we intend to pursue vigorously all its rights and remedies under this agreement and applicable law. We own or have an exclusive license to various know-how, and own the IND, relating to the product that has been under development by us and Alkermes. We also have certain rights to joint intellectual property.

Alkermes has agreed to submit to the dispute resolution procedures set forth in the Feasibility Agreement to reach a resolution of these contractual issues.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements that have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reported periods. These items are regularly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from these estimates.

*Goodwill and Other Intangible Assets*

Our intangible assets consist primarily of goodwill, VANTAS, our patented HYDRON® Polymer Technology (the HYDRON Polymer Technology ), and the Shire asset. SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, requires that an intangible asset subject to amortization be reviewed for impairment whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. We did not record any impairment charges related to intangible assets during the year ended September 30, 2008. SFAS 142, *Goodwill and Other Intangible Assets,* requires that periodic tests of goodwill for impairment be performed and that the other intangibles be amortized over their useful lives unless those lives are determined to be indefinite. SFAS 142 requires that goodwill be tested for impairment under a two-step impairment process at least annually or more frequently whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. We did not record any impairment charges during the fiscal year ended September 30, 2008.

We amortize the carrying value of the VANTAS and the HYDRON Polymer Technology assets using the straight-line method over useful lives of 14 years for VANTAS, 17 years for the HYDRON Polymer Technology and approximately 6.5 years for the Shire asset. Annual amortization expense is expected to be approximately $2,500,000 for each of the next 5 years. For the fiscal years ended September 30, 2008 and 2007, we recognized $2,267,000 and $910,000, respectively of amortization expense.

*Revenue Recognition Policy*

We classify all revenue as product revenue or contract and license fee revenue. Any consideration received in advance of revenue recognition is recorded as deferred revenue. Product revenue consists primarily of revenues from sales of products, royalties and reimbursements for royalties owed by us. Product sales are generally recognized as revenue upon the later of shipment or title transfer to our customers. Sales of SUPPRELIN LA, VANTAS and DELATESTRYL are recorded net of reserves for returns, rebates and allowances. Where chargebacks, insurance reimbursement or refunds cannot be reasonably estimated, revenue is deferred until such amounts are known and recorded as product revenue net of reserves for rebates and allowances. Until October 16, 2007, the effective date of the Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharmaceuticals Inc., which was simultaneously acquired by Allergan, Inc., (the Allergan Agreement ), we recorded sales of SANCTURA to our marketing partner as product sales. Subsequent to the Allergan Agreement, we determined that the arrangement represented a single unit of accounting and began aggregating all of the proceeds from sales of SANCTURA and SANCTURA XR with all of the other consideration received from Allergan, recording it all as deferred revenue and recognizing it as contract and license fee revenue using the appropriate revenue recognition model.

Royalty revenue consists of payments received from licensees for a portion of the sales proceeds from products that utilize our licensed technologies. Royalties are generally reported to us in a royalty report on a specified periodic basis and recognized in the period in which the sales of the product or technology on which the

royalties are based occurred. If the royalty report for such period is received subsequent to the time when we are required to report our results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received and when the amount of and basis for such royalty payments are reported to us in accurate and appropriate form and in accordance with the related license agreement.

Contract and license fee revenue consists of sales force subsidies, grants from agencies supporting research and development activities, and contractual initial and milestone payments received from partners, as well as amortization of deferred revenue from contractual payments, and since October 2007, sales of SANCTURA. Our business strategy includes entering into collaborative license, development, supply and co-promotion agreements with strategic partners for the development and commercialization of our products or product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments resulting from the achievement of certain milestones and royalties on net product sales.

Many of our agreements contain multiple elements and require evaluation pursuant to Emerging Issues Task Force ( EITF ) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as we complete our performance obligations, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered elements in the arrangement. In the case of an arrangement where it is determined that there is a single unit of accounting, all cash flows from the arrangement are aggregated and recognized as revenue over the term of the arrangement as we complete our performance obligations. We record such revenue as contract and license fee revenue.

Certain multiple element arrangements include provisions for us to participate on various committees, such as steering committees, development committees, and commercialization committees. We evaluate the facts and circumstances of the arrangement to determine if our participation is protective of our interests or if it constitutes a deliverable to be included in our evaluation of the arrangement under EITF 00-21. Additionally, pursuant to the guidance in Securities and Exchange Commission Bulletin ( SAB ) No. 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected period of the arrangements during which we have continuing performance obligations.

We have elected to use the proportional performance model to determine recognition of revenue related to multiple element arrangements determined to be single units of accounting where we have continuing performance obligations and can estimate the completion of our earnings process. Under the Allergan Agreement, because we cannot determine the total amount of expected revenue or the pattern by which we will complete our obligations, all consideration is recognized as contract and license fee revenue using the Contingency-Adjusted Performance Model ( CAPM ). Under this model, when a portion of the consideration under the arrangement is earned, revenue is immediately recognized on a pro-rata basis in the period we achieve the milestone based on the time elapsed from inception of the Allergan Agreement to the time the milestone is earned over the estimated performance period of the Allergan Agreement. Thereafter, the remaining portion of the consideration is recognized on a straight-line basis over the remaining estimated performance period of the Allergan Agreement. In other multiple element arrangements where we can estimate our expected revenue and measure our completion of the earnings process, we utilize the proportional performance model.

In multiple element arrangements, where we have separate units of accounting, revenues from milestone payments are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. Determination as to whether a milestone meets the aforementioned conditions involves management s

judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

*Expected Terms of the Agreements regarding SANCTURA and SANCTURA XR and Deferred Revenue*

We executed the Allergan Agreement effective on October 16, 2007, the terms and conditions of which required an assessment of the expected term over which we have continuing performance obligations. We assessed the Allergan Agreement pursuant to Emerging Issues Task Force ( EITF ) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Based on this assessment, we determined that we had multiple deliverables, however the delivered elements did not have stand-alone value and there was no objective, reliable evidence of fair value for the undelivered elements. Thus, we concluded that the arrangement represented a single unit of accounting. Our obligations are expected to cease no later than September 30, 2012. Accordingly, commencing on the effective date of the Allergan Agreement, we commenced recognizing the deferred revenue balances that existed on the effective date, as well as the initial license payment of $25,000,000, over the approximately 5-year performance period. All future payments received from Allergan during the performance period, including royalties, sales force reimbursement and product revenue will be amortized using the CAPM. All payments received after the performance period will be recognized as revenue when earned.

Prior to the October 16, 2007 effective date of the Allergan Agreement, we were recording the initial and milestone payments received from PLIVA and Esprit as deferred revenue and recognizing such payments as revenue using the CAPM over the estimated twelve year term of the original agreement with PLIVA, commencing on the date such payments were received.

After consideration of the estimated performance periods as noted above, we amortized $42,317,000, $29,939,000 and $13,417,000 of deferred revenue into contract and license fee revenue during the fiscal years ended September 30, 2008, 2007 and 2006, respectively. The balance of deferred revenue related to the Allergan Agreement at September 30, 2008 was $174,967,000.

In May 2008, together with Madaus, we licensed to Allergan the exclusive right to develop, manufacture, and commercialize SANCTURA XR in Canada. In exchange, we received an upfront payment of $7,000,000 and could receive milestone payments totaling $2,000,000 upon achievement of certain sales thresholds. In addition, third-party royalties owed by us on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation, after which Allergan will have a fully-paid license. The performance period continues through September 30, 2012. All consideration received from Allergan during the performance period will be recognized using the CAPM. We amortized $538,000 of deferred revenue into contract and license fee revenue during the year ended September 30, 2008. The balance of deferred revenue related to this license at September 30, 2008 was $6,462,000.

In November 2006, we entered into several agreements with Madaus relative to SANCTURA and SANCTURA XR in certain non U.S. territories (the Madaus Agreements ). The Madaus Agreements have been combined for accounting purposes and we evaluated the multiple deliverables in accordance with the provisions of EITF 00-21. We were unable to demonstrate that the delivered items had stand alone value or that the undelivered elements had verifiable objective evidence of fair value, and thus we concluded that the arrangement represented a single unit of accounting. Initially, upon execution of the Madaus Agreements, we were unable to determine the term of our obligation to provide future know-how to Madaus. Subsequent to the Allergan Agreement, we reevaluated this performance obligation and determined that it was analogous to a performance obligation we have to provide know-how to Allergan. Per the Allergan Agreement, our know-how obligations are expected to cease no later than September 30, 2012. Accordingly, we will recognize all payments received from Madaus through September 30, 2012 using the CAPM and will reflect the recognition of such payments as contract and license fee revenue over the approximately 6-year performance period. All payments received after

the approximately 6-year performance period will be recognized as revenue when earned. In addition, we have evaluated payments to be made by us to Madaus under the Madaus Agreements in accordance with the provisions of EITF 01-9, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products) , and have determined that we are receiving a separable benefit for each payment and each benefit has objective evidence of fair value.

*Redux-Related Liabilities*

At September 30, 2008, we have an accrued liability of approximately $400,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ significantly from the amount currently accrued at September 30, 2008. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

*Insurance Claim Receivable*

As of September 30, 2008, we had an outstanding insurance claim of approximately $3,300,000, consisting of payments made by us to the group of law firms defending us in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of our current outstanding insurance claim is made pursuant to our product liability policy issued to us by Reliance Insurance Company ( Reliance ). In fiscal 2008, we received a partial payment of $400,000 from Reliance pertaining to this claim. Based upon discussions with our attorneys and other consultants regarding the amount and timing of potential collection of our claim on Reliance, we previously recorded a reserve against our outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $858,000 reflecting our best estimate given the available facts and circumstances. We believe our reserve of approximately $2,400,000 against the insurance claim on Reliance as of September 30, 2008 is a significant estimate reflecting management s judgment. Subsequent to September 30, 2008, we received an additional $300,000 payment. It is uncertain when, if ever, we will collect any of our remaining $3,000,000 of claims. If we incur additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the $5,000,000 limit of the policy, we will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments. To the extent we do not collect the insurance claim receivable of $858,000 we would be required to record additional charges. Alternatively, if we collect amounts in excess of the current receivable balance, we would record a credit for the additional funds received in the statement of operations.

*Inventory Capitalization Policy*

Inventories are stated at the lower of cost or market with cost determined under the first in, first out ( FIFO ) method. Included in inventory costs are materials, drug costs, direct labor and manufacturing overheads that include facility costs and indirect manufacturing costs. We expense costs related to inventory until such time as we receive approval from the FDA to market a product, at which time we commence capitalization of costs relating to that product.

*Debt Issuance Costs*

We incurred financing costs associated with the issuance of debt securities. We amortize those costs over the contractual or estimated expected life of the related debt issuance to result in a constant rate of interest when applied to the amount outstanding at the beginning or ending period or other methods where the results would not be materially different as set forth in Accounting Principles Board ( APB ) 21, *Interest on Receivables and Payables* , paragraph 15.

*Accounting for Stock-Based Compensation*

We have several stock-based employee compensation plans. On October 1, 2005, we adopted SFAS 123R Accounting for Stock-Based Compensation ( SFAS 123R ). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. We are required to make significant estimates related to

SFAS 123R. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the fiscal years ended September 30, 2008, 2007, and 2006, we used an expected stock-price volatility of 46% to 76%, 46% to 61%, and 65%, respectively. For stock option grants to executives during the fiscal years ended September 30, 2008, 2007, and 2006, we used a weighted average expected stock-price volatility of 75%, 63.0% and 73%, respectively. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. We also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the fiscal years ended September 30, 2008, 2007 and 2006, we used a weighted-average expected option life assumption of 6.0 to 6.5 years, 6.25 to 6.5 years, and 6.25 years, respectively, for non-executives. For stock option grants made during the fiscal years ended September 30, 2008, 2007 and 2006, we used a weighted-average expected option life assumption of 7.5, 8.0 and 8.0 years, respectively, for executives. During the fiscal years ended September 30, 2008, 2007 and 2006, we recognized, in aggregate, $6,452,000, $7,330,000 and $4,535,000, respectively, in stock based compensation.

*Use of Estimates*

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

**Results of Operations**

Fiscal Year Ended September 30, 2008 Compared to Fiscal Year Ended September 30, 2007

Our net loss decreased $38,275,000, or 37%, to $(65,551,000) in fiscal 2008 from $(103,826,000) in fiscal 2007. In April 2007, we completed our acquisition of Valera Pharmaceuticals, Inc. ( Valera ), and incurred a non-recurring charge of $50,000,000 for in-process research and development related to the portion of the purchase price assigned to the value of Valera s unapproved product candidates. In addition, we recognized reduced margins on revenues, increased interest expense related to our Convertible and Non-recourse Notes and restructuring charges recorded in fiscal 2008. During 2008, increased selling, marketing and administrative expenses were offset by reduced research and development expenses.

Total revenues in fiscal 2008 were $77,791,000, an increase of $11,724,000, or 18%, from the $66,067,000 reported in fiscal 2007. Historically, product revenue included shipments of SANCTURA and SANCTURA XR to our marketing partner, as well as royalty payments whereas amortization of deferred revenue from the upfront and milestone payments resulting from our collaboration agreement was recorded as contract and license fee revenue. We assessed the accounting model for the Allergan Agreement and determined that as of October 16, 2007, all payments received from Allergan under this new arrangement, including upfront fees, sales force payments, product sales and royalties would be accounted for as a single unit of accounting and reflected as contract and license fee revenue in our income statement using the CAPM. Previously, the estimated term of the marketing arrangement related to SANCTURA and SANCTURA XR was twelve years. Commencing October 16, 2007, the estimated term of the Allergan Agreement was approximately five years.

Product revenue in fiscal 2008 was $32,642,000, an increase of $7,609,000, or 30%, from the $25,033,000 in fiscal 2007. Net sales of SUPPRELIN LA and VANTAS increased approximately $12,800,000 and $10,700,000, respectively. Sales of SANCTURA to our marketing partner of approximately $4,100,000 in fiscal 2007 and approximately $10,700,000 of royalties received from our marketing partner in fiscal 2007 were also included in 2007 product revenue. In fiscal 2008, such receipts were recorded as deferred revenue and recognized as contract and license fee revenue using the CAPM. Contract and license fee revenue for the year ended

September 30, 2008 was $45,149,000, an increase of $4,115,000, or 10%, from the $41,034,000 reported for the year ended September 30, 2007. In the year ended September 20, 2008, we recognized $42,317,000 of contract and license fee revenue related to the Allergan Agreement using the CAPM, an increase of $12,378,000 compared to $29,939,000 recognized during the year ended September 30, 2007. Additionally, the balance of deferred revenue prior to the effective date of the Allergan Agreement, as well as all new receipts, are now being amortized over the new five year term causing an increase in the annual recognition rate. Offsetting this $12,378,000 increase is a reduction from approximately $8,700,000 of sales force subsidy from our SANCTURA marketing partner which was recognized in fiscal 2008 using the CAPM. We believe that reserves for returns and allowances are not material to our net income.

Cost of product revenue for fiscal 2008 was $30,835,000, an increase of $16,195,000, or 111% from $14,640,000 in fiscal 2007. Cost of SANCTURA and SANCTURA XR product sales increased approximately $9,600,000 from sales of finished SANCTURA XR to Allergan and inventory pursuant to the Processing Assumption Date. Cost of VANTAS sold increased approximately $7,100,000 primarily due to increased sales and unabsorbed overhead costs resulting from production at a rate less than normal capacity. We expect our manufacturing facility to be running at normal capacity in fiscal 2009. We expect a significant decrease in cost of product revenue sold to Allergan in fiscal 2009 because Allergan became responsible for manufacturing SANCTURA XR in August 2008. We will continue to manufacture and sell SANCTURA to Allergan through September 2012.

Research and development expense for the year ended September 30, 2008 was $24,964,000, a decrease of $16,963,000, or 40%, from $41,927,000 in fiscal 2007. This decrease includes a reduction in external product development costs of $10,400,000 related to trospium which was approved in August 2007, $7,900,000 related to NEBIDO for which we submitted an NDA in October 2007, and $2,700,000 related to pagoclone for which we curtailed development activities until a partner could be identified. Partially offsetting these decreases were increases of external product development costs of $3,400,000 for Octreotide for which we initiated a Phase III in the fiscal quarter ended September 30, 2008 and $1,000,000 related to VALSTAR. As a result of the Teva Agreement, we have commenced in November 2008 a Phase IIb clinical trial program estimated to cost approximately $10,000,000 that will extend through fiscal 2010 and for which we will be reimbursed by Teva.

Marketing, general and administrative expense for fiscal 2008 was $75,854,000, an increase of $15,669,000, or 26%, from $60,185,000 in fiscal 2007. Marketing expense for the year ended September 30, 2008 was $49,349,000, an increase of $14,069,000, or 40%, from $35,280,000 in fiscal 2007. Approximately $6,500,000 of this increase is the result of increased external marketing or pre-marketing costs related to NEBIDO, VANTAS and VALSTAR. In addition, costs related to field sales increased approximately $5,100,000 due to the recognition of expense for an entire year of Valera-related costs, in addition to increased commissions, training and travel expenses for the promotion of VANTAS and SUPPRELIN LA. Also, sales and marketing operating costs increased approximately $3,000,000 due to increased staffing and compensation and external costs related to marketing information and data.

General and administrative expense for the year ended September 30, 2008 was $26,505,000, an increase of $1,600,000, or 6%, from $24,905,000 in fiscal 2007. This increase is primarily related to increased external costs including consulting and product evaluation and identification.

We amortize our VANTAS and the HYDRON Polymer Technology intangible assets, acquired from Valera, over fourteen to seventeen years and the Shire asset purchased in fiscal 2008 over approximately 6.5 years. We have recorded amortization expense of $2,267,000 and $910,000 related to these intangible assets during the fiscal years ended 2008 and 2007, respectively.

As discussed in Note N of the Notes to Consolidated Financial Statements, we announced a restructuring of operations to more appropriately align our cost structure to revenue projections and development opportunities. As a result of this restructuring, we recorded a charge of $2,980,000 including separation costs of approximately

$1,780,000 and an impairment charge of approximately $1,200,000 associated with the disposal of capital assets. As of September 30, 2008, the accrued restructuring balance is $713,000 and is expected to be paid through June 30, 2009.

Investment income for fiscal 2008 of $2,692,000 decreased $662,000, or 20%, from $3,354,000 in fiscal 2007. The decrease in investment income is primarily the result of decreased weighted average cash balances and decreasing interest returns in fiscal 2008.

Interest expense relates to our convertible notes and Non-recourse Notes. In fiscal 2008, we recorded approximately $1,633,000 of interest expense related to our Non-recourse Notes. We expect to record approximately $16,514,000 of interest expense, including amortization of offering costs, related to our Non-recourse Notes in fiscal 2009. Interest expense of $4,499,000 and $5,492,000 in fiscal 2008 and 2007, respectively, related to our convertible notes. Our $71,925,000 outstanding convertible notes are due in July 2009.

We expect to incur a net loss in fiscal 2009.

Fiscal Year Ended September 30, 2007 Compared to Fiscal Year Ended September 30, 2006

Our net loss increased $53,272,000, or 105%, to $(103,826,000) in fiscal 2007 from $(50,554,000) in fiscal 2006. In April 2007, we completed our acquisition of Valera and incurred significant charges relating specifically to the transaction. We recorded a non-recurring charge of $50,000,000 for in-process research and development related the portion of the purchase price assigned to the value of Valera s unapproved product candidates. We reflected $910,000 of expense relating to the amortization of intangible assets acquired in the acquisition in fiscal 2007.

Total revenues increased $15,615,000, or 31%, to $66,067,000 in fiscal 2007 from $50,452,000 in fiscal 2006. Product revenue includes sales of product to our customers and royalties received from our partners. The decrease in product sales to our customers of $1,705,000, or 6%, to $25,033,000 in fiscal 2007 from $26,738,000, in fiscal 2006 is due primarily to a $10,915,000 decrease in sales of SANCTURA to our marketing partner, Esprit. Esprit reduced its orders of SANCTURA in fiscal 2007 as it managed its SANCTURA inventory in anticipation of the FDA s approval of our once-daily product, SANCTURA XR. Partially offsetting this decrease is a $2,930,000 increase in SANCTURA royalties, reflecting an increase in the minimum royalties due pursuant to the SANCTURA Agreement. In addition, fiscal 2007 product revenue included $6,266,000 of VANTAS sales as a result of our acquisition of Valera in April, 2007.

The increase in contract and license fee revenue of $17,320,000, or 73%, to $41,034,000 in fiscal year 2007 from $23,714,000 in fiscal 2006 is due to an increase of $16,523,000 in the amortization of deferred revenue related to milestone payments received from Esprit in fiscal 2007. We received a $10,000,000 milestone in October 2006 pursuant to our filing the SANCTURA XR NDA and a $49,900,000 milestone in August 2007 pursuant to the FDA s approval of the product. These milestones were accounted for consistently with our prior milestones received from Esprit. We applied the CAPM to these types of milestone payments. In addition, we recognized license fee revenue from Novexel of approximately $1,500,000 pursuant to the Novexel Agreement. This was offset by a decrease of $1,266,000 due to a payment we received in fiscal 2006 related to our amended bucindolol license agreement. Sales force support remained relatively consistent for the years ended September 30, 2007 and September 30, 2006 at $9,065,000 and $8,811,000, respectively.

Cost of product revenue decreased $5,052,000, or 26%, to $14,640,000 in fiscal 2007 from $19,692,000 in fiscal 2006. Cost of SANCTURA product sales decreased $10,822,000 which is consistent with decreased sales of SANCTURA product to Esprit. Partially offsetting this decrease was an increase in costs of $4,314,000 related to sales of VANTAS. Additionally, a $1,100,000 reserve was established in our first fiscal quarter of 2007 for excess DELATESTRYL inventory.

Research and development expense decreased $1,276,000, or 3%, to $41,927,000 in fiscal 2007 from $43,203,000 in fiscal 2006. This decrease reflects a reduction in development costs of $12,200,000 for SANCTURA XR, $1,200,000 for pagoclone, and $1,300,000 for IP 751. Partially offsetting these decreases were increases in development costs of $7,700,000 for NEBIDO and approximately $2,000,000 for products acquired from Valera. Total research and development expense for fiscal 2007 substantially relates to our major compounds being developed as follows: NEBIDO $15,330,000, SANCTURA XR $12,600,000, pagoclone $5,260,000, PRO 2000 $2,730,000, the octreotide implant $1,070,000, VALSTAR $1,040,000, the biodegradable ureteral stent $930,000, SUPPRELIN LA $920,000, naltrexone $790,000, VANTAS $680,000, and IP 571 $590,000.

Marketing, general and administrative expense increased $24,176,000, or 67%, to $60,185,000 in fiscal 2007 from $36,009,000 in fiscal 2006. Marketing expense increased $14,749,000, or 72%, to $35,280,000 in fiscal 2007 from $20,531,000 in fiscal 2006. This increase primarily reflected external costs related to SUPPRELIN LA, VANTAS and pre-launch activities related to NEBIDO. In addition, employee related expense increased approximately $4,000,000 due primarily to higher staffing levels as a result of our acquisition of Valera in April of 2007. Adding to these were increased noncash stock-based compensation expense of $700,000 and other marketing and sales related activities. Partially offsetting these increases was approximately $1,200,000 of decreased promotion and advertising expense related to SANCTURA.

General and administrative expense increased $9,427,000, or 61%, to $24,905,000 in fiscal 2007 from $15,478,000 in fiscal 2006. Included in the fiscal 2007 general and administrative expense is increased compensation expense of approximately $2,754,000 related primarily to higher staffing levels, $1,541,000 for increased noncash stock-based compensation expense, and increased outside services expense of approximately $850,000 related primarily to our acquisition of Valera and increased business development activities. Also included in fiscal 2007 is $1,400,000 of expense related to the disposition of our investment in Spepharm Holdings B.V., a company specializing in urology products in the European Union.

On April 18, 2007, we acquired 100% of the outstanding stock of Valera. The acquisition was accounted for under the purchase method. Of the $80,100,000 of acquired intangible assets, $50,000,000 was allocated to in-process research and development ( IPR&D ) and was reflected as expense in the fiscal year ended September 30, 2007 because the products to which it relates had not received regulatory approval prior to the acquisition date. The value assigned to IPR&D relates to the following products: SUPPRELIN LA, $24,000,000, the octreotide implant, $14,000,000 and a ureteral stent, $12,000,000. We believe that this charge represents a reasonable estimate of the future benefits attributed to the purchased IPR&D. The valuation was determined using an income approach. Cash flows were projected through a date commensurate with management s expectation of patent protection. The discounted cash flow method was applied to the projected cash flows, adjusted for the probability of success using a discount rate of approximately 22%. The discount rate takes into consideration the uncertainty surrounding successful development and commercialization of the IPR&D. Given the risks inherent in the clinical development and regulatory approval process, it is possible, with the exception of SUPPRELIN LA which was recently approved, that no commercial product will ever result from these product candidates.

In connection with the Valera acquisition, we recorded amortization expense of $910,000 during the year ended September 30, 2007 related to VANTAS and the HYDRON Polymer Technology intangible assets. Investment income decreased $151,000, or 4%, to $3,354,000 in fiscal 2007 from $3,505,000 in fiscal 2006. The decrease in investment income is primarily the result of average cash balances decreasing throughout 2007.

Interest expense relates to our $71,925,000 of Convertible Notes 2009 and $75,000 of 6.25% Convertible Senior Notes due in 2008 (the Convertible Notes 2008 ) (See Note I of Notes to Consolidated Financial Statements). Interest expense of approximately $5,500,000 in fiscal 2007 includes $4,500,000 of interest to be paid, approximately $700,000 of amortization of original debt issuance costs, and approximately $300,000 from accretion of the discounted carrying value of the Convertible Notes 2009 and their face value.

**Liquidity and Capital Resources**

Cash, Cash Equivalents and Marketable Securities

At September 30, 2008 we had consolidated cash and cash equivalents of $131,306,000 compared to consolidated cash and cash equivalents of $71,142,000 at September 30, 2007. This increase of $60,164,000 is primarily the result of the issuance of $100,701,000, net of issuance costs, in Non-recourse Notes, offset by net cash used in operating activities of $29,753,000. We had several significant sources of cash in fiscal 2008 that contributed to funding our business. Receipts from Allergan since the October 16, 2007 effective date of the Allergan Agreement and which are subject to CAPM treatment totaled approximately $63,000,000. Increased net sales of VANTAS and SUPPRELIN LA additionally contributed to funding our business. The closing of the Non-recourse Notes in August 2008 provided us with approximately $90,700,000 of net proceeds that is expected to be available to fund our business going forward (see Analysis of Cash Flows ).

We are continuing to invest substantial amounts in the ongoing development of our product candidates and sales activities related to our marketed products SANCTURA and SANCTURA XR, SUPPRELIN LA and VANTAS. If approved by the FDA, we expect to invest in launch and marketing activities related to VALSTAR. We are continuing to invest in the development of NEBIDO. We believe our current and expected cash resources are sufficient to fund our operations. We will need to obtain additional funding through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available to us. The failure to raise such funds would result in the need to significantly curtail our operating activities and delay development efforts, which would have a material adverse effect on us.

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

We have $71,925,000 of our Convertible Notes 2009 outstanding which are due in July 2009. If these notes do not convert into common stock by July 15, 2009, we will be required to redeem these notes for cash.

There remain 1,950,000 shares issuable pursuant to a shelf registration statement on Form S-3 we filed with the SEC in December 2005. The registration statement remains effective and the remaining shares of our common stock may be offered from time to time through one or more methods of distribution, subject to market conditions and our capital needs. The terms of any offerings would be established at the time of the offering. Currently, we do not have any commitments to sell such shares remaining under the registration statement which expires in February 2009.

In August 2008, Royalty Sub, our wholly-owned subsidiary, closed the private placement to institutional investors of $105,000,000 in aggregate principal amount of the Non-recourse Notes. Royalty Sub is obligated to make quarterly debt service payments, beginning on November 5, 2008. These payments will be funded by the quarterly royalty payments received by Royalty Sub from Allergan. Applicable royalties received for any quarter that exceed the interest payments and expenses due for that quarter, will be applied to the repayment of principal of the Non-recourse Notes until the Notes have been paid in full. Any portion of the principal amount of the Non-recourse Notes not repaid on or before the legal final maturity date of November 5, 2024, will be payable on that date. In addition, the Non-recourse Notes may be redeemed at our option on any quarterly payment date, subject to the payment of a redemption premium if repaid on or before November 5, 2012. After November 5, 2012, the Non-recourse Notes may be redeemed without premium.

The royalty receipts from Allergan continue to represent consideration for the completion of our performance obligations under the U.S. Allergan Agreement. Thus, royalty receipts will continue to be recorded as deferred revenue and recognized over the performance period under the CAPM.

In connection with the transaction, a $10,000,000 interest reserve was established to fund potential interest shortfalls, or if none, for repayment of principal due under the Non-recourse Notes. Approximately $4,850,000 of this reserve is classified as non-current in our consolidated balance sheet as of September 30, 2008. These funds came out of the debt proceeds and are restricted. Deferred financing costs of approximately $4,300,000 were paid by Royalty Sub to complete the transaction. These came out of the debt proceeds and will be expensed over the expected term of 6.2 years.

In April 2008, the holder of our issued and outstanding 239,425 shares of Series B Convertible Preferred Stock and 5,000 shares of Series C Convertible Preferred Stock exercised its conversion rights and converted all shares of issued and outstanding preferred stock into 622,220 shares of our Common Stock.

Product Development

There can be no assurance that results of any ongoing or future pre-clinical or clinical trials will be successful, that additional trials will not be required, that any drug or product under development will receive FDA approval in a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with U.S. current Good Manufacturing Practices, or successfully marketed in a timely manner, or at all, or that we will have sufficient funds to develop or commercialize any of our products.

Total research and development expenses incurred by us through September 30, 2008 on our core development products for which an NDA has not been filed, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: $26,000,000 for PRO 2000 and $8,000,000 for the octreotide implant. We have not included compounds in development for which we do not expect to incur additional material research and development costs. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA.

Given the above uncertainties, and other risks, variables and considerations related to each compound and regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from September 30, 2008 through the preparation of an NDA for our core development compounds as follows: approximately $10,000,000 for PRO 2000 and $9,000,000 for the octreotide implant. Actual costs to complete any of our products may differ significantly from the estimates. We expect to file an NDA for PRO 2000 in 2011. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development. We are currently considering strategic partners for future development and commercialization of PRO 2000.

Analysis of Cash Flows

Net cash (used in) operating activities

For the year ended September 30, 2008, our primary source of funds was related to our agreement with Allergan. On the effective date of the Allergan Agreement, we received an up-front fee of $25,000,000. Cash was expended primarily in the normal operations of our business by the various functions as represented in the

statement of operations. Net cash used in operating activities in the twelve month period ended September 30, 2008 of $29,753,000 consisted primarily of (i) the net loss of $65,551,000, (ii) a decrease in accrued expenses and other liabilities of $7,863,000, (iii) an increase in accounts receivable of $7,263,000 primarily due to increased sales of VANTAS and SUPPRELIN LA and an increase in sales force reimbursement from Allergan because these are now paid quarterly compared to monthly in the prior year, partially offset by (i) a $30,554,000 increase in deferred revenue primarily due to payments from Allergan, net of amortization, and (ii) $15,447,000 of noncash charges for stock-based compensation, depreciation and amortization, note discount amortization, loss on disposals of property and equipment and inventory impairment.

For the year ended September 30, 2007, our primary source of funds was related to SANCTURA and the Esprit Agreement. We received $59,900,000 from Esprit related to milestones in fiscal 2007, $49,900,000 related to the FDA approval of SANCTURA XR and $10,000,000 related to submission of the SANCTURA NDA to the FDA. In addition, we received approximately $11,000,000 in royalties and $9,000,000 for sales force reimbursement from Esprit. Cash was expended primarily in the normal operations of our Company by the various functions as represented in the statement of operations. Net cash used in operating activities in the twelve month period ended September 30, 2007 of $8,717,000 consisted primarily of the net loss of $103,826,000 offset primarily by (i) a noncash charge of $50,000,000 for acquired IPR&D pursuant to the Valera acquisition, (ii) a $30,887,000 increase in deferred revenue from milestone payments from Esprit as described above, offset by amortization, and (iii) $9,135,000 of noncash stock-based compensation, depreciation and amortization.

Net cash used in operating activities of $(29,753,000) for the year ended September 30, 2008 increased $21,036,000 from $(8,717,000) for the year ended September 30, 2007. The change in accrued expenses and other liabilities decreased $12,204,000 primarily related to contractual payments made to Madaus and a reduction in research and development costs associated with NEBIDO, pagoclone and SANCTURA XR. In addition, our net loss in fiscal year 2008 increased from the net loss in fiscal 2007, excluding the noncash charge of $50,000,000 for acquired IPR&D pursuant to the Valera acquisition, by approximately $11,725,000.

Net cash (used in) provided by investing activities

For the year ended September 30, 2008, net cash used in investing activities of $(3,932,000) resulted from (i) purchases of property, plant and equipment of $2,932,000 and (ii) purchases of intangible assets of $1,000,000.

For the year ended September 30, 2007, net cash provided by investing activities of $7,977,000 is primarily comprised of (i) net proceeds from maturities and sales of marketable securities of $5,956,000 which represents a transfer of funds from marketable securities to cash and cash equivalents and (ii) cash acquired, net of business acquisition costs, of $3,372,000 related to the Valera acquisition.

Net cash used in investing activities of $(3,932,000) for the year ended September 30, 2008 increased $11,909,000 from net cash provided by investing activities of $7,977,000 for the year ended September 30, 2007. During fiscal 2007, we acquired Valera, including their cash balances, in addition to sales or maturity of our marketable securities resulting in cash equivalents.

Net cash provided by financing activities

For the year ended September 30, 2008, net cash provided by financing activities of $93,849,000 resulted from net proceeds related to the issuance of the Non-recourse Notes of $100,701,000 and common stock issued from employee exercises of stock options and employee participation in our employee stock purchase plan of $3,223,000, offset by $10,000,000 of proceeds from the Non-recourse Notes reflected as restricted cash.

For the year ended September 30, 2007, net cash provided by financing activities of $1,713,000 was the result of common stock issued from employee exercises of stock options and employee participation in our employee stock purchase plan during the year ended September 30, 2007. We cannot predict if or when stock options will be exercised in the future.

Net cash provided by financing activities of $93,849,000 for the year ended September 30, 2008 increased $92,136,000 from $1,713,000 for the year ended September 30, 2007 due primarily to the issuance of the Non-recourse Notes.

Contractual Obligations and Off-Balance Sheet Arrangements

The following chart summarizes our contractual payment obligations as of September 30, 2008. The notes, (including the Convertible Notes 2009 and Non-recourse Notes) are reflected as liabilities on our Balance Sheet as of September 30, 2008. Operating leases are accrued and paid pursuant to the lease arrangement. Purchase obligations relate to research and development agreements and arrangements and sales and marketing agreements; portions of these amounts are reflected as accrued expenses on our Balance Sheet as of September 30, 2008. We lease approximately 125 automobiles for our field sales force. The lease requires a minimum term of 12 months per automobile. We expect monthly lease expense related to this operating lease to be approximately $60,000. We are responsible for certain disposal costs in case of termination.

| | Payments due by Period | | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Less than 1 Year** | **1-3 Years** | **3-5 Years** | **Greater than 5 Years** | **Total** |
| Convertible Notes 2009 (1) | $ 71,925,000 | $ | $ | $ | $ 71,925,000 |
| Interest on convertible notes (1) | 3,562,000 | | | | 3,562,000 |
| Non-recourse Notes (1) | | 18,292,000 | 65,098,000 | 21,610,000 | 105,000,000 |
| Interest on Non-recourse Notes (1) | 15,820,000 | 31,873,000 | 21,668,000 | 4,049,000 | 73,410,000 |
| Purchase obligations (2) | 15,543,000 | 8,635,000 | 1,986,000 | 333,000 | 26,497,000 |
| Operating leases (3) | 2,800,000 | 4,543,000 | 3,138,000 | 2,226,000 | 12,707,000 |
| Total | $ 109,650,000 | $ 63,343,000 | $ 91,890,000 | $ 28,218,000 | $ 293,101,000 |

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

Pursuant to certain of our in-licensing arrangements, we will owe payments to our licensors upon achievement of certain development, regulatory and licensing milestones. We generally cannot predict if or when such events will occur. In particular, we will owe BayerSchering $5,000,000 if FDA approval of our NDA for NEBIDO is obtained. Additionally, we could owe BayerSchering up to $17,500,000 for achievement of certain commercial milestones if NEBIDO is approved for marketing by the FDA.

The BayerSchering Agreement contains certain minimum purchase requirements that would commence after the second year of sales of NEBIDO, if approved. Such minimums will be determined to be a percent of purchases we would make in the second year of sales. After the second year of sales, we will be able to determine such minimum purchase requirements.

We have a supply agreement for valrubicin, the active ingredient of VALSTAR. The Agreement will expire ten years after the date of the first commercial sale of VALSTAR provided VALSTAR is approved by June 30, 2009. Beginning in the calendar year following the year in which it receives regulatory approval for VALSTAR in the United States, we will have annual minimum purchase requirements of $1,000,000. This agreement may be terminated by either party under certain customary conditions of breach, by mutual agreement of the parties, or by Plantex if VALSTAR is not approved by June 30, 2009.

Pursuant to the Teva Agreement, we will conduct, and Teva will reimburse expenses for, a Phase IIb study for stuttering. We are committed to perform this study and incur approximately $10,000,000 of external expenses over the next two fiscal years.

There remains outstanding CSRs and CSR Equivalents issued by us pursuant to Valera acquisition which will become payable in shares of Indevus common stock only if the applicable milestones for the biodegradable ureteral stent and octreotide implant are achieved within five years of the closing of the merger. If both remaining CSR and CSR Equivalent milestones are achieved, we will issue common stock totaling approximately $40,600,000 in value.

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

**Other**

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

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS 159 ). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are evaluating the implications of this standard.

In June 2007, the EITF reached a consensus on EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-03 ). EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. This consensus is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier adoption is not permitted. The effect of applying the consensus will be prospective for new contracts entered into on or after that date. We do not expect the adoption of EITF 07-03 to have a material effect on our results of operations and financial condition.

On December 12, 2007, EITF 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property,* or EITF 07-01, was issued. EITF 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaboration relationship. EITF 07-01 is effective for all of our collaborations existing after January 1, 2009. We are evaluating the impact, if any, this Standard will have on our financial statements.

In December 2007, the FASB issued SFAS 141(R), *Business Combinations* ( SFAS 141R ). SFAS 141R replaces SFAS 141, *Business Combinations* ( SFAS 141 ). SFAS 141R retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R also establishes principles and requirements for how the acquirer: a) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the

acquiree; b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase and c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R will apply prospectively to business combinations for which the acquisition date is on or after our fiscal year beginning October 1, 2009. While we have not yet evaluated this statement for the impact that SFAS 141R will have on our consolidated financial statements, we will be required to expense costs related to any acquisitions after September 30, 2009.

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements* ( SFAS 160 ). SFAS 160 amends Accounting Research Bulletin 51 to establish accounting and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. We have not yet determined the impact that SFAS 160 will have on our consolidated financial statements. SFAS 160 is effective for our fiscal year beginning October 1, 2009.

In March 2008, the FASB issued SFAS 161, *Disclosures About Derivative Instruments and Hedging Activities* ( SFAS 161 ). SFAS 161 enhances the disclosure requirements for derivative instruments and hedging activities. This Standard is effective January 1, 2009. Since SFAS 161 requires only additional disclosures concerning derivatives and hedging activities, adoption of SFAS 161 will not affect our financial condition, results of operations or cash flows.

In April 2008, the FASB Staff Position ( FSP ) issued SFAS No. 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP SFAS 142-3 ). FSP SFAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. The intent of FSP SFAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141 (revised 2007), *Business Combinations*, and other U.S. generally accepted accounting principles ( GAAP ). FSP SFAS 142-3 is effective for fiscal years beginning after December 15, 2008 and we will adopt it in the first quarter of fiscal year 2009. We are currently evaluating the effect that the adoption of FSP SFAS 142-3 will have on our results of operation and financial position or cash flows, but do not expect it to have a material impact.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Principles* ( SFAS 162 ). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy). SFAS 162 will become effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU 411, *the Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not expect the adoption of SFAS 162 to have a material effect on our results of operations and financial condition.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ). FSP ABP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and (conversion option) components of the instrument in a manner that reflects the issuer s non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 on a retroactive basis and we will adopt it in the first quarter of fiscal year 2009. We are currently evaluating the potential impact, if any, of the adoption of FSP APB 14-1 on our results of operations and financial condition.

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

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

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

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

Risk related to the Convertible Notes 2009

The fair value of our Convertible Notes 2009 is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Convertible Notes 2009 are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Convertible Notes 2009. For example on a very simplified basis, a decrease of 10% of the market value of our Common Stock could reduce the value of a $1,000 Note by approximately $0. An increase in market interest rates could result in a decrease in the fair value of the Convertible Notes 2009. For example on a very simplified basis, an interest rate increase of 1% could reduce the value of a $1,000 Note by approximately $10. The two examples provided above are only hypothetical and actual changes in the value of the Convertible Notes 2009 due to fluctuations in market value of our Common Stock or interest rates could vary substantially from these examples.

Risk related to the Non-recourse Notes

A 10% increase or decrease in market interest rates pertaining to the Non-recourse Notes would not have a material impact on our consolidated financial statements.

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

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

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

Not applicable.

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

**Evaluation of Disclosure Controls and Procedures**

We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of September 30, 2008, of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2008 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed,

summarized and reported, within the time periods specified in the SEC s rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

**Management s Report on Internal Control Over Financial Reporting**

We are responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles in the United States. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ). Based upon that evaluation, management has concluded that our internal control over financial reporting was effective as of September 30, 2008.

The effectiveness of our internal control over financial reporting as of September 30, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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

**Changes in Internal Control Over Financial Reporting**

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal year ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

**PART III**

The information required by Item 10: Directors, Executive Officers, and Corporate Governance; Item 11: Executive Compensation; Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters; Item 13: Certain Relationships and Related Transactions, and Director Independence; and Item 14: Principal Accounting Fees and Services will be included in and is incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation l4A within 120 days after the close of our fiscal year.

**PART IV**

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

A) Documents filed as a part of this report:

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

(2) Financial Statement Schedule: All financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.

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

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| 2.1 | - Agreement and Plan of Merger, dated as of December 11, 2006, by and among Indevus, Hayden Merger Sub, Inc. and Valera Pharmaceuticals, Inc. (71) |
| 3.4 | - Restated Certificate of Incorporation of Registrant, as amended (63) and (75) |
| 3.5 | - By-Laws of Registrant, as amended and restated December 4, 2007 (50) |
| 4.1 | - Indenture dated as of July 16, 2003 between the Registrant, Lehman Brothers Inc. and Wachovia Capital Markets, LLC (51) |
| 4.2 | - Registration Rights Agreement dated as of July 16, 2003 between the Registrant, Lehman Brothers Inc. and Wachovia Capital Markets, LLC (51) |
| 4.8 | - 1997 Equity Incentive Plan and Form of Restricted Stock Award Agreement there under (25) (64) |
| 4.9 | - Form of Notice of Grant of Stock Options issued under the Registrant s 2004 Equity Incentive Plan (64) |
| 4.10 | - Form of Option Agreement relating to Incentive Stock Options issued under the Registrant s 2004 Equity Incentive Plan (64) |
| 4.11 | - Form of Option Agreement relating to Non-Qualified Stock Options issued under the Registrant s 2004 Equity Incentive Plan (64) |
| 4.12 | - Form of Restricted Stock Award issued under the Registrant s 2004 Equity Incentive Plan (64) |
| 4.13 | - Indenture dated as of August 6, 2007 between the Registrant and The Bank of New York Trust Company, N.A, as trustee (77) |
| 10.6 | - Assignment of Invention and Agreement between Richard Wurtman, M.D., Judith Wurtman and the Registrant (1) |
| 10.9 | - Restated and Amended 1989 Stock Option Plan (4) |
| 10.11 | - Restated Amendment to MIT Option Agreement (1) |
| 10.12(a) | - Patent and Know-How License Agreement between the Registrant and Les Laboratories Servier ( Servier ) dated February 7, 1990 with Revised Appendix A (1) |
| 10.12(b) | - Amendment Agreement between Registrant and Servier, Orsem and Oril Produits Chimiques dated November 19, 1992 (2) (6) |
| 10.12(c) | - Amendment Agreement dated April 28, 1993 between Registrant and Servier (9) |
| 10.12(d) | - Consent and Amendment Agreement among Servier, American Home Products Corp. and Registrant (17) |

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| 10.13 | - Trademark License Agreement between the Registrant and Orsem dated February 7, 1990 (1) |
| 10.14 | - Supply Agreement between the Registrant and Oril Produits Chimiques dated February 7, 1990 (1) (2) |
| 10.16 | - Assignment of Invention by Richard Wurtman, M.D. (1) |
| 10.25 | - License Agreement between the Registrant and the Massachusetts Institute of Technology (3) |
| 10.37 | - License Agreement dated as of February 15, 1992 between the Registrant and Massachusetts Institute of Technology (5) |
| 10.40 | - Patent and Know-How Sublicense and Supply Agreement between Registrant and American Cyanamid Company dated November 19, 1992 (2) (6) |
| 10.41 | - Equity Investment Agreement between Registrant and American Cyanamid Company dated November 19, 1992 (6) |
| 10.42 | - Trademark License Agreement between Registrant and American Cyanamid Company dated November 19, 1992 (6) |
| 10.44 | - Consent Agreement between Registrant and Servier dated November 19, 1992 (12) |
| 10.45 | - Agreement between Registrant and PAREXEL International Corporation dated October 22, 1992 (as of July 21, 1992) (2) (7) |
| 10.46 | - License Agreement dated February 9, 1993 between the Registrant and Massachusetts Institute of Technology (2) (8) |
| 10.52 | - License Agreement dated February 18, 1994 between Registrant and Rhone-Poulenc Rorer, S.A. (11) |
| 10.55 | - Patent License Agreement between Registrant and Massachusetts Institute of Technology dated March 1, 1994 (11) |
| 10.59 | - Exhibit D to Agreement between Registrant and Parexel International Corporation dated as of March 15, 1994 (2) (12) |
| 10.60(a) | - Acquisition Agreement dated as of May 13, 1994 among the Registrant, Intercardia, Inc., Cardiovascular Pharmacology Engineering Consultants, Inc. (CPEC), Myocor, Inc. and the sellers named therein (13) |
| 10.60(b) | - Amendment dated June 15, 1994 to Acquisition Agreement referenced in Exhibit 10.60(a) (13) |
| 10.61 | - License Agreement dated December 6, 1991 between Bristol-Myers Squibb and CPEC, as amended (2) (13) |
| 10.61(a) | - Letter Agreement dated November 18, 1994 between CPEC and Bristol-Myers Squibb (4) |
| 10.65(a) | - 1994 Long-Term Incentive Plan, as amended (23) |
| 10.68(a) | - 1995 Employee Stock Purchase Plan, as amended (19) (57) (73) |
| 10.78 | - Contract Manufacturing Agreement dated November 20, 1995 between Registrant and Boehringer Ingelheim Pharmaceuticals, Inc. (2) (l7) |
| 10.83 | - Co-promotion Agreement effective June 1, 1996 between Wyeth-Ayerst Laboratories and Interneuron Pharmaceuticals, Inc. (2) (18) |
| 10.87 | - Lease dated February 5, 1997 between Registrant and Ledgemont Realty Trust (21) |
| 10.93 | - Form of Indemnification Agreement between Registrant and each director, executive officer and certain officers of the Registrant entered into as of October 6, 1997 (26) |

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| 10.94 | - 1998 Employee Stock Option Plan (27) |
| 10.96 | - Assignment and Assumption and Royalty Agreement between Intercardia and Registrant dated May 8, 1998 (29) |
| 10.102 | - Employment Agreement between Interneuron Pharmaceuticals, Inc. and Michael W. Rogers dated and effective as of February 23, 1999 (34) (*) |
| 10.103 | - Employment Agreement between Interneuron Pharmaceuticals, Inc. and Bobby W. Sandage, Jr. dated and effective as of March 15, 1999 (34) (*) |
| 10.104 | - Employment Agreement between Interneuron Pharmaceuticals, Inc. and Mark S. Butler dated and effective as of March 15, 1999 (34) (*) |
| 10.105 | - Employment Agreement between Internmeuron Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated and effective as of May 1, 1999 (34) (*) |
| 10.108 | - Exchange Agreement dated July 15, 1999 between Intercardia, Inc. and Interneuron Pharmaceuticals, Inc. (35) |
| 10.109 | - Amended and Restated Limited Liability Company Agreement of CPEC LLC dated July 15, 1999 among CPEC LLC, Interneuron Pharmaceuticals, Inc. and Intercardia, Inc. (35) |
| 10.110 | - Assignment, Assumption and License Agreement dated July 15, 1999 by and between CPEC LLC and Intercardia, Inc. (35) |
| 10.113 | - License Agreement effective as of November 26, 1999 between Madaus AG and Interneuron Pharmaceuticals, Inc. (37) (2) |
| 10.116(a) | - 2000 Stock Option Plan (39) |
| 10.119 | - License Agreement by and between Charles S. Lieber, M.D. and Interneuron Pharmaceuticals, Inc. dated December 26, 2000 (42) (2) |
| 10.120 | - Indemnity and Release Agreement between American Home Products Corporation and Interneuron Pharmaceuticals, Inc. dated as of May 30, 2001 (43) (2) |
| 10.124 | - Form of Stock Purchase Agreement dated December 20, 2001 between Indevus Pharmaceuticals, Inc. and the Investors named on Schedule A attached thereto (45) |
| 10.127 | - Employment Agreement dated and effective as of October 1, 2002 by and between Indevus Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. (47) (*) |
| 10.128 | - Amendment No. 1 to Licensing Agreement by and between Registrant and Eli Lilly and Company and Eli Lilly S.A. (48) (2) |
| 10.129 | - Supply Agreement between Registrant and Madaus AG dated December 16, 2003 (48) (2) |
| 10.130 | - Development and License Agreement between Registrant and Shire Laboratories Inc. dated March 11, 2003 (49) (2) |
| 10.131 | - Amendment to the License Agreement by and between Registrant and Paligent Inc. dated April 10, 2003 (49) |
| 10.132 | - License Agreement by and between Registrant and Aventis Pharma SA dated April 18, 2003 (51) (2) |
| 10.133 | - License Agreement by and between Registrant and Sumner Burstein dated August 22, 2003 (52) (2) |
| 10.134 | - Assignment and Termination Agreement by and between Registrant and Manhattan Pharmaceuticals, Inc. dated August 22, 2003 (52) (2) |

10.136 - Agreement by and between the Registrant and Ferrer Internacional S.A. dated January 22, 2004 (53) (2)

10.138 - 2004 Equity Incentive Plan, as amended (54) (63) (73)

10.139 - License, Commercialization and Supply Agreement dated April 6, 2004 between the Registrant and Odyssey Pharmaceuticals Inc. (55) (2)

10.142 - Indenture of Lease dated December 20, 2004 between the Registrant and Mortimer B. Zuckerman and Edward H. Linde, Trustees of Hayden Office Trust (56)

10.143 - Amendment No. 1 to License, Commercialization and Supply Agreement dated April 30, 2005 between the Registrant and Odyssey Pharmaceuticals, Inc. (58)

10.144 - Amendment and Consent Agreement dated May 14, 2005 between the Registrant, Odyssey Pharmaceuticals, Inc., and Saturn Pharmaceuticals, Inc (59)

10.145 - License Agreement dated July 28, 2005 between the Registrant and Schering Aktiengesellschaft (60)

10.148 - Collaborative Research and Licensing Agreement dated July 26, 2005 between the Registrant and Medical Research Counsel (61) (2)

10.149 - Form of Indemnification Agreement between Registrant and certain directors, executive officers and officers of the Registrant (61) (*)

10.150 - Asset Purchase Agreement dated December 12, 2005 by and between Savient Pharmaceuticals, Inc. and the Registrant (62) (2)

10.151 - Form of Employment Agreement by and between the Registrant and Noah D. Beerman, dated March 31, 2006 (65) (*)

10.152 - Form of Employment Agreement by and between the Registrant and John H. Tucker, dated March 31, 2006 (65) (*)

10.153 - Form of Underwriting Agreement, dated June 28, 2006; by and between the Registrant and UBS Securities LLC, as representative of the several underwriters named therein (66)

10.154 - A copy of the Fiscal Year 2007 CEO Bonus Plan of Registrant (67) (*)

10.155 - A copy of the Fiscal Year 2007 Senior Executive Bonus Plan of Registrant (67) (*)

10.156 - Form of Employment Agreement by and between the Registrant and Thomas Farb dated on or about October 16, 2006 (68) (*)

10.157 - Form of Indemnification Agreement with Thomas Farb dated on or about October 16, 2006 (62) (*)

10.158 - Manufacturing and Supply Agreement by and between the Registrant and Schering AG, Germany dated on or about October 20, 2006 (69) (2)

10.159 - License and Supply Agreement by and between the Registrant and Madaus GmbH dated on or about November 3, 2006 (69) (2)

10.160 - Amendment and Agreement by and between the Registrant and Madaus GmbH dated on or about November 3, 2006 (69) (2)

10.161 - Know-How License Agreement by and between the Registrant and Novexel SA dated December 4, 2006 (69) (2)

10.162 - API Supply Agreement by and between the Registrant and Helsinn Chemicals SA and Helsinn Advanced Synthesis SA dated on or about November 22, 2006 (69) (2)

10.163 - Voting Agreement, dated as of December 11, 2006, by and among the Registrant, Hayden Merger Sub, Inc. and certain affiliated funds of Sanders Morris Harris, Inc. (70)

10.164 - Voting Agreement, dated as of December 11, 2006, by and among the Registrant, Hayden Merger Sub, Inc. and Psilos Group Partners II-S, L.P. (70)

10.165 - Copromotion and Marketing Services Agreement by and between the Registrant and Valera Pharmaceuticals, Inc. dated December 11, 2006 (71) (2)

10.166 - Supprelin Contingent Stock Rights Agreement, dated as of April 17, 2007, between the Registrant and American Stock Transfer & Trust Company (73)

10.167 - Stent Contingent Stock Rights Agreement, dated as of April 17, 2007, between the Registrant and American Stock Transfer & Trust Company (73)

10.168 - Octreotide Contingent Stock Rights Agreement, dated as of April 17, 2007, between the Registrant and American Stock Transfer & Trust Company (73)

10.169 - Grant of Deferred Stock Units on April 30, 2007 to each non-employee member of the Board of Directors of the Registrant (75) (*)

10.170 - Amended and Restated License, Commercialization and Supply Agreement executed September 18, 2007 between the Registrant and Esprit Pharma, Inc. (77) (2)

10.171 - A copy of the Fiscal Year 2008 CEO Bonus Plan of Registrant (78) (*)

10.172 - A copy of the Fiscal Year 2008 COO and Executive VP Bonus Plan of Registrant (78) (*)

10.173 - Asset Purchase Agreement between Valera Pharmaceuticals, Inc. and Anthra Pharmaceuticals, Inc. dated as of September 28, 2005 (2) (88)

10.174 - Credit Agreement between Valera Pharmaceuticals, Inc. and Merrill Lynch Capital dated October 20, 2005 (80)

10.175 - Distribution Agreement between Valera Pharmaceuticals, Inc. and Teva-Tuteur dated December 9, 2005 (80)

10.176 - Form of Change in Control Agreement between Valera Pharmaceuticals, Inc. and certain of its Executive Officers (81) (*)

10.177 - License and Distribution Agreement between Hydro Med Sciences, Inc. and Paladin Labs, Inc. dated October 3, 2002 (80)

10.178 - Investment Agreement between Hydro Med Sciences, Inc. and Paladin Labs, Inc. dated October 3, 2002 (80)

10.179 - License and Distribution Agreement between Valera Pharmaceuticals, Inc. and Key Oncologics dated September 17, 2003 (80)

10.180 - Collaboration and Development Agreement between Valera Pharmaceuticals, Inc. and Alpex Pharma S.A. dated April 6, 2005 (88) (2)

10.181 - Termination Agreement, License Back and Option between Hydro Med Sciences, Inc. and Shire US Inc. dated December 21, 2001 (82)

10.182 - Termination of Agreement dated September 12, 1990 between National Patent Development Corporation and The Population Council, Inc. dated October 1, 1997 (82)

10.183 - Amendment to the Termination of the Joint Development Agreement between GP Strategies Corporation and The Population Council, Inc. dated November 29, 2001 (82)

10.184 - Amendment No. 2 to Termination Agreement between Valera Pharmaceuticals, Inc. and The Population Council, Inc. dated August 31, 2004 (82)

10.185 - Lease Agreement between National Patent Development Corporation and Cedar Brook Corporate Center, L.P. dated October 6, 1997 (82)

10.186 - Amendment to Lease between Valera Pharmaceuticals, Inc. and Cedar Brook Corporate Center, L.P. dated January 7, 2004 (82)

10.187 - Lease Agreement between Valera Pharmaceuticals, Inc. and Cedar Brook 7 Corporate Center, L.P. dated March 8, 2005 (82)

10.188 - Contribution Agreement between Hydro Med Sciences, Inc. and GP Strategies Corporation dated June 30, 2000 (82)

10.189 - License and Distribution Agreement between Valera Pharmaceuticals, Inc. and BioPro Pharmaceutical, Inc. dated January 28, 2005 (82)

10.190 - 2002 Equity Incentive Plan of Valera Pharmaceuticals, Inc. (82)

10.191 - Agreement between National Patent Development Corporation and Dento-Med Industries, Inc. dated November 30, 1989 (82)

10.192 - Amended and Restated Executive Employment Agreement by and between Valera Pharmaceuticals, Inc. and David S. Tierney, M.D. dated July 5, 2006 (83) (*)

10.193 - Supply Agreement by and between Valera Pharmaceuticals, Inc. and Plantex USA Inc. (84)

10.194 - Investment and Shareholders Agreement of Valera Pharmaceuticals, Inc. with Spepharm Holding B.V. (85)

10.195 - License and Distribution Agreement between Valera Pharmaceuticals, Inc. and Spepharm Holding B.V. (85)

10.196 - Revised Research and Development Proposal dated April 27, 2005, between Valera Pharmaceuticals, Inc. and Poly-Med, Inc. (86)

10.197 - Advanced Development and Pilot Production Outline issued by the Company and Poly-Med on March 24, 2006 and revised on April 10, 2006. (86)

10.198 - Letter Agreement dated December 4, 2006, between Valera Pharmaceuticals, Inc. and Poly-Med, Inc. (86)

10.199 - Form of Letter Agreement dated December 21, 2006 to Amend Change in Control Agreements by and between Valera Pharmaceuticals, Inc. and certain officers (87) (*)

10.200 - Letter Agreement dated December 21, 2006 to Amend Amended and Restated Executive Employment Agreement by and between Valera Pharmaceuticals, Inc. and David S. Tierney (87) (*)

10.201 - Form of Amended and Restated Employment Agreement by and between the Registrant and Glenn L. Cooper, M.D. effective as of October 1, 2007 (79) (*)

10.202 - Form of Amended and Restated Employment Agreement by and between the Registrant and Thomas F. Farb. effective as of October 1, 2007 (79) (*)

10.203 - Form of Amended and Restated Employment Agreement by and between the Registrant and Bobby W. Sandage, Jr. effective as of October 1, 2007 (79) (*)

10.204 - Form of Amended and Restated Employment Agreement by and between the Registrant and Michael W. Rogers effective as of October 1, 2007 (79) (*)

10.205 - Form of Amended and Restated Employment Agreement by and between the Registrant and Mark S. Butler effective as of October 1, 2007 (79) (*)

10.206 - Form of Amended and Restated Employment Agreement by and between the Registrant and Noah D. Beerman effective as of October 1, 2007 (79) (*)

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| 10.207 | - Executive Retirement Agreement by and between Indevus Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated March 3, 2008, as amended (89) (*) |
| 10.208 | - Form of License, Supply and Distribution Agreement by and between Indevus Pharmaceuticals, Inc. and Orion Corporation dated April 2, 2008 (93) (2) |
| 10.209 | - Retention Agreement by and between Indevus Pharmaceuticals, Inc. and Noah D. Beerman dated April 11, 2008 (90) (*) |
| 10.210 | - Retention Agreement by and between Indevus Pharmaceuticals, Inc. and Michael W. Rogers dated April 11, 2008 (90) (*) |
| 10.211 | - Retention Agreement by and between Indevus Pharmaceuticals, Inc. and Bobby W. Sandage, Jr. dated April 11, 2008 (90) (*) |
| 10.212 | - Grant of Deferred Stock Units on March 11, 2008 to each non-employee member of the Board of Directors of Indevus (91) (*) |
| 10.213 | - A copy of the Fiscal Year 2009 CEO Bonus Plan (92) (*) |
| 10.214 | - A copy of the Fiscal Year 2009 EVP s Bonus Plan (92) (*) |
| 10.215 | - Form of Purchase and Sale Agreement by and between Ledgemont Royalty Sub LLC and the Registrant dated August 26, 2008 (93) |
| 10.216 | - Form of Note Purchase Agreement by and among Ledgemont Royalty Sub LLC, the Registrant and the purchasers named therein dated August 26, 2008 (93) |
| 10.217 | - Form of Indenture by and between Ledgemont Royalty Sub LLC and U.S. Bank National Association dated August 26, 2008 (93) |
| 10.218 | - Form of Pledge and Security Agreement made by the Registrant to U.S. Bank National Association, as Trustee, dated August 26, 2008 (93) |
| 10.219 | - Form of Development, License and Commercialization Agreement made by and between the Registrant and Teva Pharmaceutical Industries Ltd., dated September 25, 2008 (93) (2) |
| 21 | - List of Subsidiaries (93) |
| 23 | - Consent of PricewaterhouseCoopers LLP (93) |
| 31.1 | - Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (93) |
| 31.2 | - Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (93) |
| 32.1 | - Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer (93) |
| 32.2 | - Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Michael W. Rogers, Chief Financial Officer (93) |

(*) Management contract or compensatory plan or arrangement.
(1) Incorporated by reference to the Registrant s Registration Statement on Form S-1 (File No. 33-32408) declared effective on March 8, 1990.
(2) Confidential Treatment requested for a portion of this Exhibit.
(3) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the year ended September 30, 1990.

(4) Incorporated by reference to Post-Effective Amendment No. 2 to the Registrant s Registration Statement on Form S-1 (File No. 33-32408) filed December 18, 1991.
(5) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1992.
(6) Incorporated by reference to the Registrant s Form 8-K dated November 30, 1992.
(6a) Incorporated by reference to Post-Effective Amendment No. 5 to the Registrant s Registration Statement on Form S-1 (File No. 33-32408) filed on December 21, 1992.
(7) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1992.
(8) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 1992.
(9) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1993.
(10) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 1993.
(11) Incorporated by reference to the Registrant s Registration Statement on Form S-3 or Amendment No. I (File no. 33-75826).
(12) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1994.
(13) Incorporated by reference to the Registrant s Form 8-K dated June 20, 1994.
(14) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1994.
(15) Incorporated by reference to the Registrant s Report on Form 8-K dated June 2, 1995.
(16) Incorporated by reference to the Registrant s Report on Form 8-K dated August 16, 1995.
(17) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1995.
(18) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q or 10-Q/A for the period ended June 30. 1996.
(19) Incorporated by reference to Amendment No. 1 to Registrant s Registration Statement on Form S-3 (File No. 333-1273) filed March 15, 1996.
(20) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1996.
(21) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 1996.
(22) Incorporated by reference to Exhibit 3.5 of the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1997.
(25) Incorporated by reference to the Registrant s Form S-8 (File No. 333-40315) filed November 14, 1997.
(26) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1997.
(27) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 1997.
(28) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1998.
(29) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 1998.
(30) Incorporated by reference as to Exhibit 99.1 of Registrant s Form 8-K dated September 3, 1998.
(31) Incorporated by reference as to Exhibit 99.2 of Registrant s From 8-K dated September 28, 1998.
(32) Incorporated by reference as to Exhibit 99.3 of Registrant s Form 8-K dated September 28, 1998.
(34) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 1999.
(35) Incorporated by reference to Registrant s Form 8-K dated July 27, 1999.

(37) Incorporated by reference to the Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 1999.
(38) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 1999.
(39) Incorporated by reference to Registrant s Definitive Proxy Statement filed January 28, 2000.
(40) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 2000.
(41) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2000.
(42) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 2000.
(43) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 2001.
(44) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2001.
(45) Incorporated by reference to Exhibit 10.124 of Registrant s Form 8-K dated December 21, 2001.
(46) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 1998.
(47) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2002.
(48) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 2003.
(49) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2003.
(50) Incorporated by reference to Registrant s Form 8-K filed December 7, 2007.
(51) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 2003.
(52) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2003.
(53) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2004.
(54) Incorporated by reference to Registrant s Definitive Proxy Statement filed January 28, 2004.
(55) Incorporated by reference to Registrant s Form 8-K filed April 19, 2004.
(56) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 2004.
(57) Incorporated by reference to Registrant s Definitive Proxy Statement filed January 28, 2005.
(58) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2005.
(59) Incorporated by reference to Registrant s Form 8-K filed May 17, 2005.
(60) Incorporated by reference to Registrant s Form 8-K filed August 2, 2005.
(61) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2005.
(62) Incorporated by reference to Registrant s Form 8-K filed December 16, 2005.
(63) Incorporated by reference to Registrant s Definitive Proxy Statement filed January 30, 2006.
(64) Incorporated by reference to Registrant s Form 8-K filed March 6, 2006.
(65) Incorporated by reference to Registrant s Form 8-K filed April 6, 2006.
(66) Incorporated by reference to Registrant s Form 8-K filed June 30, 2006.
(67) Incorporated by reference to Registrant s Form 8-K filed September 18, 2006.
(68) Incorporated by reference to Registrant s Form 8-K filed October 20, 2006.
(69) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2006.
(70) Incorporated by reference to Registrant s Form 8-K filed December 12, 2006.

(71) Incorporated by reference to Registrant s Annual Report on Form 10-K/A filed January 26, 2007 for the fiscal year ended September 30, 2006.
(72) Incorporated by reference to Registrant s Registration Statement on Form S-4 (File No. 333-140271) filed on March 12, 2007
(73) Incorporated by reference to Registrant s Form 8-K filed April 17, 2007.
(74) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2007.
(75) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended June 30, 2007.
(76) Incorporated by reference to Registrant s Form 8-K filed August 7, 2007.
(77) Incorporated by reference to Registrant s Form 8-K filed September 21, 2007.
(78) Incorporated by reference to Registrant s Form 8-K filed November 2, 2007.
(79) Incorporated by reference to Registrant s Form 8-K filed November 30, 2007.
(80) Incorporated by reference to Amendment No. 4 to Registration Statement on Form S-1 of Valera (File No. 333-123288) filed on December 9, 2005 by Valera.
(81) Incorporated by reference to Amendment No. 2 to Registration Statement on Form S-1 of Valera (File No. 333-123288) filed on April 20, 2005 by Valera.
(82) Incorporated by reference to Registration Statement on Form S-1 of Valera (File No. 333-123288) filed on March 14, 2005 by Valera.
(83) Incorporated by reference to Current Report on Form 8-K of Valera (File No. 000-51768) filed on July 10, 2006 by Valera.
(84) Incorporated by reference to Quarterly Report on Form 10-Q of Valera (File No. 000-51768) filed on August 9, 2006 by Valera.
(85) Incorporated by reference to Quarterly Report on Form 10-Q of Valera (File No. 000-51768) filed on November 9, 2006 by Valera.
(86) Incorporated by reference to Current Report on Form 8-K of Valera (File No. 000-51768) filed on December 11, 2006 by Valera.
(87) Incorporated by reference to Current Report on Form 8-K of Valera (File No. 000-51768) filed on December 27, 2006 by Valera.
(88) Incorporated by reference to Registrant s Annual Report on Form 10-K for the fiscal year ended September 30, 2006.
(89) Incorporated by reference to Registrant s Form 8-K filed March 7, 2008 and Form 8-K filed June 16, 2008.
(90) Incorporated by reference to Registrant s Form 8-K filed April 15, 2008.
(91) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2008.
(92) Incorporated by reference to Registrant s Form 8-K filed September 30, 2008.
(93) Filed with this report.

**SIGNATURES**

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

Date: December 10, 2008

INDEVUS PHARMACEUTICALS, INC.

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

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

| Name | Title | Date |
|---|---|---|
| /s/ GLENN L. COOPER<br>**Glenn L. Cooper, M.D.** | Chief Executive Officer and Chairman (Principal Executive Officer) | December 10, 2008 |
| /s/ ANDREW FERRARA<br>**Andrew Ferrara** | Director | December 10, 2008 |
| /s/ JAMES C. GALE<br>**James C. Gale** | Director | December 10, 2008 |
| /s/ MICHAEL E. HANSON<br>**Michael E. Hanson** | Director | December 10, 2008 |
| /s/ STEPHEN C. MCCLUSKI<br>**Stephen C. McCluski** | Director | December 10, 2008 |
| /s/ MALCOLM MORVILLE<br>**Malcolm Morville** | Director | December 10, 2008 |
| /s/ CHERYL P. MORLEY<br>**Cheryl P. Morley** | Director | December 10, 2008 |
| /s/ MICHAEL W. ROGERS<br>**Michael W. Rogers** | Executive Vice President, Chief Financial Officer, and Treasurer (Principal Financial Officer) | December 10, 2008 |
| /s/ DALE RITTER<br>**Dale Ritter** | Senior Vice President, Finance, (Principal Accounting Officer) | December 10, 2008 |

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**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, statements of stockholders deficit and statements of cash flows present fairly, in all material respects, the financial position of Indevus Pharmaceuticals, Inc. and its subsidiaries at September 30, 2008 and September 30, 2007, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management s Report on Internal Control Over Financial Reporting appearing in Item 9A. Our responsibility is to express opinions on these financial statements and on the Company s internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

**PricewaterhouseCoopers LLP (signed)**

**Boston, Massachusetts**

**December 10, 2008**

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED BALANCE SHEETS**

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

| | September 30, 2008 | September 30, 2007 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 131,306 | $ 71,142 |
| Restricted cash | 5,150 | |
| Accounts receivable, net | 14,512 | 7,249 |
| Inventories, net | 6,179 | 7,729 |
| Prepaid and other current assets | 4,998 | 4,708 |
| Total current assets | 162,145 | 90,828 |
| Property, plant and equipment, net | 9,224 | 9,771 |
| Inventories, net | | 682 |
| Restricted cash | 4,850 | |
| Goodwill | 48,244 | 48,244 |
| Intangible assets, net | 30,855 | 29,190 |
| Other assets | 7,684 | 4,335 |
| Total assets | $ 263,002 | $ 183,050 |
| **LIABILITIES** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,338 | $ 4,505 |
| Accrued expenses | 16,116 | 24,704 |
| Accrued interest | 2,582 | 950 |
| Deferred revenue | 46,766 | 21,946 |
| Convertible notes | 70,187 | 75 |
| Total current liabilities | 142,989 | 52,180 |
| Convertible notes | | 68,037 |
| Non-recourse notes | 105,000 | |
| Deferred revenue | 142,249 | 136,515 |
| Other | 2,950 | 656 |
| **STOCKHOLDERS DEFICIT** | | |
| Convertible Preferred Stock, $.001 par value, 5,000,000 shares authorized: | | |
| Series B, 0 and 239,425 shares issued and outstanding at September 30, 2008 and 2007, respectively | | 3,000 |
| Series C, 0 and 5,000 shares issued and outstanding at September 30, 2008 and 2007, respectively | | 500 |
| Common Stock, $.001 par value, 200,000,000 shares authorized; 78,151,809 and 76,360,039 shares issued and outstanding at September 30, 2008 and September 30, 2007, respectively | 78 | 76 |
| Additional paid-in capital | 511,788 | 498,587 |
| Accumulated deficit | (642,052) | (576,501) |
| Total stockholders deficit | (130,186) | (74,338) |
| Total liabilities and stockholders deficit | $ 263,002 | $ 183,050 |

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

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**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

| | For the years ended September 30, | | |
|---|---|---|---|
| | **2008** | **2007** | **2006** |
| Revenues: | | | |
| Product revenue | $ 32,642 | $ 25,033 | $ 26,738 |
| Contract and license fees | 45,149 | 41,034 | 23,714 |
| Total revenues | 77,791 | 66,067 | 50,452 |
| Costs and expenses: | | | |
| Cost of revenues | 30,835 | 14,640 | 19,692 |
| Research and development | 24,964 | 41,927 | 43,203 |
| Marketing, general and administrative | 75,854 | 60,185 | 36,009 |
| Acquired in-process research and development | | 50,000 | |
| Amortization of intangible assets | 2,267 | 910 | |
| Restructuring | 2,980 | | |
| Total costs and expenses | 136,900 | 167,662 | 98,904 |
| Loss from operations | (59,109) | (101,595) | (48,452) |
| Investment income | 2,692 | 3,354 | 3,505 |
| Interest expense | (8,958) | (5,492) | (5,170) |
| Other | (176) | (93) | (437) |
| Net loss | $ (65,551) | $ (103,826) | $ (50,554) |
| Net loss per common share, basic and diluted | $ (0.86) | $ (1.61) | $ (1.02) |
| Weighted average common shares outstanding, basic and diluted | 76,565 | 64,679 | 49,411 |

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

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT**

**(Dollar amounts in thousands)**

| | Common Stock | | Preferred Stock | | Additional |
|---|---|---|---|---|---|
| | Number of Shares | Par Value Amount | Number of Shares | Amount | Paid-in Capital |
| Balance at September 30, 2005 | 47,825,896 | $ 48 | 244,425 | $ 3,500 | $ 307,435 |
| Public offering of common stock, net of issuance costs of $2,405 | 8,050,000 | 8 | | | 35,020 |
| Proceeds from exercise of stock options | 86,562 | | | | (923) |
| Proceeds from offering of Employee Stock Purchase Plan | 68,067 | | | | (114) |
| Dividends on preferred stock | | | | | (35) |
| Stock-based compensation and other | 9,931 | | | | 3,406 |
| Comprehensive loss: | | | | | |
| Net loss | | | | | |
| Unrealized gain on marketable and equity securities | | | | | |
| Total comprehensive loss | | | | | |
| Balance at September 30, 2006 | 56,040,456 | 56 | 244,425 | 3,500 | 344,789 |
| Issuance of common stock for settlement of contingent stock rights from acquisition of business | 19,896,136 | 20 | | | 140,487 |
| Proceeds from exercise of stock options | 224,210 | | | | 908 |
| Proceeds from offering of Employee Stock Purchase Plan | 144,459 | | | | 805 |
| Dividends on preferred stock | | | | | (35) |
| Stock-based compensation and other | 54,778 | | | | 7,365 |
| Convertible notes valuation | | | | | 4,268 |
| Comprehensive loss: | | | | | |
| Net loss | | | | | |
| Unrealized gain on marketable and equity securities | | | | | |
| Total comprehensive loss | | | | | |
| Balance at September 30, 2007 | 76,360,039 | 76 | 244,425 | 3,500 | 498,587 |
| Proceeds from exercise of stock options | 545,474 | 1 | | | 2,512 |
| Proceeds from offering of Employee Stock Purchase Plan | 199,733 | | | | 704 |
| Dividends on preferred stock | | | | | (17) |
| Stock-based compensation and other | 424,343 | | | | 6,503 |
| Conversion of preferred stock | 622,220 | 1 | (244,425) | (3,500) | 3,499 |
| Comprehensive loss: | | | | | |
| Net loss | | | | | |
| Unrealized gain on marketable and equity securities | | | | | |
| Total comprehensive loss | | | | | |
| Balance at September 30, 2008 | 78,151,809 | $ 78 | | $ | $ 511,788 |

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

**INDEVUS PHARMACEUTICALS, INC.**

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

**(Dollar amounts in thousands)**

| | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Treasury Stock Number of Shares | Treasury Stock Amount | Total Equity | Comprehensive Income (Loss) |
|---|---|---|---|---|---|---|
| Balance at September 30, 2005 | (422,121) | (4) | 660,607 | (4,000) | (115,142) | |
| Public offering of common stock, net of issuance costs of $2,405 | | | | | 35,028 | |
| Proceeds from exercise of stock options | | | (323,376) | 2,082 | 1,159 | |
| Proceeds from offering of Employee Stock Purchase Plan | | | (125,666) | 754 | 640 | |
| Dividends on preferred stock | | | | | (35) | |
| Stock-based compensation and other | | | (211,565) | 1,164 | 4,570 | |
| Comprehensive loss: | | | | | | |
| Net loss | (50,554) | | | | (50,554) | (50,554) |
| Unrealized gain on marketable and equity securities | | 4 | | | 4 | 4 |
| Total comprehensive loss | | | | | | $ (50,550) |
| Balance at September 30, 2006 | (472,675) | | | | (124,330) | |
| Issuance of common stock for settlement of contingent stock rights from acquisition of business | | | | | 140,507 | |
| Proceeds from exercise of stock options | | | | | 908 | |
| Proceeds from offering of Employee Stock Purchase Plan | | | | | 805 | |
| Dividends on preferred stock | | | | | (35) | |
| Stock-based compensation and other | | | | | 7,365 | |
| Convertible notes valuation | | | | | 4,268 | |
| Comprehensive loss: | | | | | | |
| Net loss | (103,826) | | | | (103,826) | (103,826) |
| Unrealized gain on marketable and equity securities | | | | | | |
| Total comprehensive loss | | | | | | $ (103,826) |
| Balance at September 30, 2007 | (576,501) | | | | (74,338) | |
| Proceeds from exercise of stock options | | | | | 2,513 | |
| Proceeds from offering of Employee Stock Purchase Plan | | | | | 704 | |
| Dividends on preferred stock | | | | | (17) | |
| Stock-based compensation and other | | | | | 6,503 | |
| Conversion of preferred stock | | | | | | |
| Comprehensive loss: | | | | | | |
| Net loss | (65,551) | | | | (65,551) | (65,551) |
| Unrealized gain on marketable and equity securities | | | | | | |
| Total comprehensive loss | | | | | | $ (65,551) |

| | | | | |
|---|---|---|---|---|
| Balance at September 30, 2008 | $ (642,052) | $ | $ | $ (130,186) |

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

**INDEVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(Amounts in thousands)**

| | For the years ended September 30, | | |
|---|---|---|---|
| | **2008** | **2007** | **2006** |
| Cash flows from operating activities: | | | |
| Net loss | $ (65,551) | $ (103,826) | $ (50,554) |
| Adjustments to reconcile net loss to net cash (used in) operating activities: | | | |
| Depreciation and amortization | 4,581 | 1,805 | 447 |
| Note discount amortization | 2,495 | 1,025 | 660 |
| Loss on disposal of property and equipment | 1,165 | | |
| Minority interest in net income of consolidated subsidiary | | (51) | 435 |
| Acquired in-process research and development | | 50,000 | |
| Inventory impairment | 415 | 1,100 | |
| Noncash stock-based compensation | 6,452 | 7,330 | 4,535 |
| Noncash exchange of asset | | 1,100 | |
| Noncash consideration | | | (266) |
| Impairment and loss on equity securities | | 144 | |
| Lease abandonment | 339 | | |
| Changes in assets and liabilities, net of assets and liabilities acquired: | | | |
| Accounts receivable | (7,263) | (1,708) | (314) |
| Inventories | 1,818 | 1,842 | (3,950) |
| Prepaid and other assets | 272 | (1,390) | (1,221) |
| Accounts payable | 2,833 | (1,316) | 620 |
| Deferred revenue | 30,554 | 30,887 | (14,834) |
| Accrued expenses and other liabilities | (7,863) | 4,341 | 2,743 |
| Net cash (used in) operating activities | (29,753) | (8,717) | (61,699) |
| Cash flows from investing activities: | | | |
| Purchases of property, plant and equipment | (2,932) | (1,351) | (224) |
| Purchases of marketable securities | | | (5,956) |
| Purchases of intangible assets | (1,000) | | |
| Proceeds from maturities and sales of marketable securities | | 5,956 | 16,123 |
| Cash acquired, net of business acquisition costs | | 3,372 | |
| Net cash (used in) provided by investing activities | (3,932) | 7,977 | 9,943 |
| Cash flows from financing activities: | | | |
| Net proceeds from issuance of common stock | | | 35,028 |
| Net proceeds from issuance of Non-recourse Notes | 100,701 | | |
| Restricted cash from issuance of Non-recourse Notes | (10,000) | | |
| Maturity of Convertible Notes 2008 | (75) | | |
| Proceeds from exercise of stock options and stock issued under employee stock purchase plan | 3,223 | 1,713 | 1,799 |
| Net cash provided by financing activities | 93,849 | 1,713 | 36,827 |
| Net change in cash and cash equivalents | 60,164 | 973 | (14,929) |
| Cash and cash equivalents at beginning of period | 71,142 | 70,169 | 85,098 |
| Cash and cash equivalents at end of period | $ 131,306 | $ 71,142 | $ 70,169 |

Supplemental disclosures of cash flow information and noncash transactions:

| | | | |
|---|---|---|---|
| Issuance of common stock related to acquisition (see Note C) | $ | $ 140,508 | $ |
| Modification of notes payable (see Note I) | $ | $ 72,000 | $ |
| Payable to Shire for manufacturing and supply agreement termination (see Note Q) | $ 3,198 | $ | $ |
| Cash paid for interest | $ 4,500 | $ 4,500 | $ 4,500 |

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

**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**A. Nature of the Business**

Indevus is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. The Company s approved products include SANCTURA® and SANCTURA XR for overactive bladder ( OAB ), co-promoted with its partner Allergan, Inc. ( Allergan ), VANTAS® for advanced prostate cancer, SUPPRELIN® LA for central precocious puberty ( CPP ), and DELATESTRYL® for the treatment of hypogonadism. The Company markets its products through an approximately 100-person specialty sales force.

The Company s core urology and endocrinology portfolio contains multiple compounds in development in addition to its approved products. The Company s most advanced compounds are VALSTAR™ for bladder cancer, NEBIDO® for hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and the octreotide implant for acromegaly and carcinoid syndrome.

In addition to the Company s core urology and endocrinology portfolio, there are multiple compounds outside of its core focus area which the Company either currently outlicenses for development and commercialization, or intends to outlicense in the future. These compounds include pagoclone for stuttering for which we recently licensed to Teva Pharmaceutical Industries Ltd. ( Teva ), ALKS 27 for chronic obstructive pulmonary disease ( COPD ) which the Company has been jointly developing with Alkermes, Inc. ( Alkermes ), and aminocandin for systemic fungal infections for which the Company licensed worldwide rights to Novexel S.A. ( Novexel ).

**B. Summary of Significant Accounting Policies**

*Basis of Presentation:* The consolidated financial statements include the accounts of the Company and its wholly- and majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. For an entity that is not a variable interest entity under FIN 46, Consolidation of Variable Interest Entities, the Company s policy is to consolidate a subsidiary when the Company owns greater than 50% of the voting interest in the subsidiary and/or controls it.

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

*Cash, Cash Equivalents and Marketable Securities:* The Company invests available cash primarily in short-term bank deposits, money market funds, repurchase agreements, domestic and foreign commercial paper and government securities. Cash and cash equivalents include investments with original maturities of three months or less at date of purchase. Marketable securities consist of investments purchased with maturities greater than three months and are classified as noncurrent if they mature one year or more beyond the balance sheet date and are not considered available to fund current operations. Investments are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income or loss until realized. The fair value of these securities is based on quoted market prices. At September 30, 2008 and September 30, 2007, the Company had no marketable securities.

*Accounts Receivable:* Trade accounts receivable are recorded at the invoiced amount and do not bear interest. At September 30, 2008 and 2007, the Company has recorded an allowance for doubtful accounts of approximately $222,000, and $241,000, respectively, related to product trade receivables.

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

To date, the Company s revenues have been generated from a limited number of sources. The Company s revenue was primarily generated pursuant to the Allergan Agreement or predecessor agreements related to SANCTURA and SANCTURA XR (see Note Q). Total revenues generated in accordance with the Allergan Agreement or predecessor agreements were approximately $42,855,000 or 55%, of total revenues in fiscal 2008, $53,728,000, or 81%, of total revenues in fiscal 2007 and $44,937,000, or 89%, of total revenue in fiscal 2006. Allergan also represented approximately 35.5% of accounts receivable at September 30, 2008. The Company believes credit risk associated with Allergan is not significant.

*Inventory:* Inventories are stated at the lower of cost or market with cost determined under the first in, first out ( FIFO ) method. Included in inventory costs are materials, drug costs, direct labor and manufacturing overheads that include facility costs and indirect manufacturing costs. The Company expenses costs related to inventory until such time as it receives approval from the FDA to market a product, at which time the Company commences capitalization of costs relating to that product.

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

| | |
|---|---|
| Manufacturing and office equipment | 2 to 7 years |
| Leasehold improvements | 5 to 10 years |

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

*Goodwill and Other Intangible Assets*: The Company s intangible assets consist of goodwill, VANTAS, the patented HYDRON® Polymer Technology (the HYDRON Polymer Technology ), and the Shire asset. SFAS 142, *Goodwill and Other Intangible Assets*, requires that periodic tests of goodwill for impairment be performed and that the other intangibles be amortized over their useful lives unless those lives are determined to be indefinite. SFAS 142 requires that goodwill be tested for impairment under a two-step impairment process at least annually or more frequently whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

The Company amortizes the carrying value of the VANTAS and the HYDRON Polymer Technology assets using the straight-line method over useful lives of 14 years for VANTAS and 17 years for the HYDRON Polymer Technology. The Shire intangible asset is being amortized over the remaining term of the original license agreement, which is approximately 6.5 years.

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

*Revenue Recognition:* The Company classifies all revenue as product revenue or contract and license fee revenue. Any consideration received in advance of revenue recognition is recorded as deferred revenue. Product

revenue consists primarily of revenues from sales of products, royalties and reimbursements for royalties owed by the Company. Product sales are generally recognized as revenue upon the later of shipment or title transfer to the Company s customers. Sales of SUPPRELIN LA, VANTAS and DELATESTRYL are recorded net of reserves for returns, rebates and allowances. Where chargebacks, insurance reimbursement or refunds cannot be reasonably estimated, revenue is deferred until such amounts are known and recorded as product revenue net of reserves for rebates and allowances. Until October 16, 2007, the effective date of the Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharmaceuticals Inc., which was simultaneously acquired by Allergan, (the Allergan Agreement ), the Company recorded sales of SANCTURA to its marketing partner as product sales. Subsequent to the Allergan Agreement, the Company determined that the arrangement represented a single unit of accounting and began aggregating all of the proceeds from sales of SANCTURA and SANCTURA XR with all other consideration received from Allergan, recording it all as deferred revenue and recognizing it as contract and license fee revenue using the appropriate revenue recognition model.

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

Contract and license fee revenue consists of sales force subsidies, grants from agencies supporting research and development activities, and contractual initial and milestone payments received from partners, as well as amortization of deferred revenue from contractual payments, and since October 2007, sales of SANCTURA product. The Company s business strategy includes entering into collaborative license, development, supply and co-promotion agreements with strategic partners for the development and commercialization of the Company s products or product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments resulting from the achievement of certain milestones and royalties on net product sales.

Many of the Company s agreements contain multiple elements and require evaluation pursuant to Emerging Issues Task Force ( EITF ) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where the Company has continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as the Company completes its performance obligations, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered elements in the arrangement. In the case of an arrangement where it is determined that there is a single unit of accounting, all cash flows from the arrangement are aggregated and recognized as revenue over the term of the arrangement as the Company completes its performance obligations. The Company records such revenue as contract and license fee revenue.

Certain multiple element arrangements include provisions for the Company to participate on various committees, such as steering committees, development committees, and commercialization committees. The Company evaluates the facts and circumstances of the arrangement to determine if its participation is protective of the Company s interests or if it constitutes a deliverable to be included in the Company s evaluation of the arrangement under EITF 00-21. Additionally, pursuant to the guidance in Securities and Exchange Commission Bulletin ( SAB ) No. 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected period of the arrangements during which the Company has continuing performance obligations.

The Company has elected to use the proportional performance model to determine recognition of revenue related to multiple element arrangements determined to be single units of accounting where the Company has continuing performance obligations and can estimate the completion of its earnings process. Under the Allergan Agreement, because the Company cannot determine the total amount of expected revenue or the pattern by which it will complete its obligations, all consideration is recognized as contract and license fee revenue using the Contingency-Adjusted Performance Model ( CAPM ). Under this model, when a portion of the consideration under the arrangement is earned, revenue is immediately recognized on a pro-rata basis in the period the Company achieves the milestone based on the time elapsed from inception of the Allergan Agreement to the time the milestone is earned over the estimated performance period of the Allergan Agreement. Thereafter, the remaining portion of the consideration is recognized on a straight-line basis over the remaining estimated performance period of the Allergan Agreement. In other multiple element arrangements where the Company can estimate its expected revenue and measure its completion of the earnings process, the Company utilizes the proportional performance model.

In multiple element arrangements, where the Company has separate units of accounting, revenues from milestone payments are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. Determination as to whether a milestone meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

*Debt Issuance Costs:* The Company incurs financing costs associated with its issuance of debt securities. The Company amortizes those costs over the contractual or estimated expected life of the related debt issuance to result in a constant rate of interest when applied to the amount outstanding at the beginning or ending period or other methods where the results would not be materially different as set forth in Accounting Principles Board ( APB ) 21, *Interest on Receivables and Payables* , paragraph 15.

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

*Advertising:* Costs associated with advertising are expensed in the period incurred and are included in marketing, general and administrative expenses.

*Income Taxes:* Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management s review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax asset will not be realized. The Company s historical losses from operations represent significant negative evidence that indicates the need for a valuation allowance. Accordingly, a valuation allowance has been established for the full amount of the deferred tax asset. If it is determined, based on future profitability, that these deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate material income tax benefit in the period of decrease and material income tax provisions in future periods.

*Accounting for Stock-Based Compensation:* The Company has several stock-based employee compensation plans. On October 1, 2005, the Company adopted SFAS 123R, *Accounting for Stock-Based Compensation* ( SFAS 123R ). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is

measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. The Company is required to make significant estimates related to SFAS 123R. The Company s expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the fiscal years ended September 30, 2008, 2007 and 2006, the Company used an expected stock-price volatility of 46% to 76%, 46% to 61%% and 65%, respectively. For stock option grants issued to executives during the fiscal years ended September 30, 2008, 2007 and 2006, the Company used a weighted average expected stock-price volatility of 75%, 63% and 73%, respectively. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. The Company also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the fiscal years ended September 30, 2008, 2007 and 2006, the Company used a weighted-average expected option life assumption of 6.0 to 6.5 years, 6.25 to 6.5 years and 6.25 years, respectively, for non-executives. For stock option grants made during the fiscal years ended September 30, 2008, 2007 and 2006, the Company used a weighted-average expected option life assumption of 7.5, 8.0 and 8.0 years for executives. During the fiscal years ended September 30, 2008, 2007 and 2006, the Company recognized, in aggregate, $6,452,000, $7,330,000 and $4,535,000, respectively, in stock based compensation.

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

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

*Recent Accounting Pronouncements:*

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS No. 159 ). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is evaluating the impact that the adoption of SFAS No. 159 will have on its consolidated results of operations and financial condition.

On June 27, 2007, the FASB reached a final consensus on Emerging Issues Task Force Issue 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-03 ). Currently, under FASB Statement No. 2, Accounting for Research and Development Costs , nonrefundable advance payments for future research and development activities for materials, equipment, facilities, and purchased intangible assets that have no alternative future use are expensed as incurred. EITF 07-03 addresses whether such non-refundable advance payments for goods or services that have no alternative

future use and that will be used or rendered for research and development activities should be expensed when the advance payments are made or when the research and development activities have been performed. The consensus reached by the FASB requires companies involved in research and development activities to capitalize such non-refundable advance payments for goods and services pursuant to an executory contractual arrangement because the right to receive those services in the future represents a probable future economic benefit. Those advance payments will be capitalized until the goods have been delivered or the related services have been performed. Entities will be required to evaluate whether they expect the goods or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment will be charged to expense. The consensus on EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. Entities are required to recognize the effects of applying the guidance in EITF 07-03 prospectively for new contracts entered into after the effective date. The Company does not expect the adoption of EITF 07-03 to have a material effect on its results of operations and financial condition.

On December 12, 2007, EITF 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property,* or EITF 07-01, was issued. EITF 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaboration relationship. EITF 07-01 is effective for all of the Company s collaborations existing after January 1, 2009. The Company is evaluating the impact, if any, this Standard will have on its financial statements.

In December 2007, the FASB issued SFAS 141(R), *Business Combinations* ( SFAS 141R ). SFAS 141R replaces SFAS 141, *Business Combinations* ( SFAS 141 ). SFAS 141R retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R also establishes principles and requirements for how the acquirer: a) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree; b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase and c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R will apply prospectively to business combinations for which the acquisition date is on or after our fiscal year beginning October 1, 2009. While the Company has not yet evaluated this statement for the impact that SFAS 141R will have on its consolidated financial statements, it will be required to expense costs related to any acquisitions after September 30, 2009.

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements* ( SFAS 160 ). SFAS 160 amends Accounting Research Bulletin 51 to establish accounting and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. The Company has not yet determined the impact that SFAS 160 will have on its consolidated financial statements. SFAS 160 is effective for the Company s fiscal year beginning October 1, 2009.

In March 2008, the FASB issued SFAS 161, *Disclosures About Derivative Instruments and Hedging Activities* ( SFAS 161 ). SFAS 161 enhances the disclosure requirements for derivative instruments and hedging activities. This Standard is effective January 1, 2009. Since SFAS 161 requires only additional disclosures concerning derivatives and hedging activities, adoption of SFAS 161 will not affect the Company s financial condition, results of operations or cash flows.

In April 2008, the FASB Staff Position ( FSP ) issued SFAS No. 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP SFAS 142-3 ). FSP SFAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. The intent of FSP SFAS 142-3 is to improve the

consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141 (revised 2007), *Business Combinations*, and other U.S. generally accepted accounting principles ( GAAP ). FSP SFAS 142-3 is effective for fiscal years beginning after December 15, 2008 and will be adopted by the Company in the first quarter of fiscal year 2009. The Company is currently evaluating the effect that the adoption of FSP SFAS 142-3 will have on its results of operation and financial position or cash flows, but does not expect it to have a material impact.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Principles* ( SFAS 162 ). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy). SFAS 162 will become effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU 411, *the Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not expect the adoption of SFAS 162 to have a material effect on its results of operations and financial condition.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ). FSP ABP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and (conversion option) components of the instrument in a manner that reflects the issuer s non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 on a retroactive basis and will be adopted by the Company in the first quarter of fiscal year 2009. The Company is currently evaluating the potential impact, if any, of the adoption of FSP APB 14-1 on its results of operations and financial condition.

**C. Valera Acquisition**

On April 18, 2007, the Company completed its acquisition of Valera Pharmaceuticals, Inc. ( Valera ). The Company acquired 100% of the outstanding stock of Valera in a tax-free stock-for-stock merger valued at approximately $128,544,000 plus contingent stock rights ( CSRs ) related to three of Valera s product candidates in development at the time of the Valera Acquisition. At the date of acquisition, each share of Valera common stock was exchanged for 1.1337 shares of Indevus common stock. As a result, approximately 17,693,000 shares of Indevus common stock were issued.

Valera common stockholders received three CSRs for each share of Valera common stock and the option holders who consented to the proposed treatment of such options received three unfunded and unsecured promises to receive shares of Indevus common stock ( CSR Equivalents ). The CSRs convert to $1.00, $1.00 and $1.50, respectively, worth of Indevus common stock upon the FDA approval to market SUPPRELIN LA (treatment for CPP), a biodegradable stent and an octreotide implant (treatment for acromegaly), respectively. The CSRs and CSR Equivalents related to SUPPRELIN LA became payable on May 3, 2007, upon the regulatory approval of SUPPRELIN LA, and 2,251,000 shares of Indevus common stock became issuable. The additional purchase price related to achievement of this milestone was $16,522,000 and was recorded as an increase to goodwill. The remaining CSRs and CSR Equivalents will become payable in shares of Indevus common stock only if the applicable milestones for the biodegradable ureteral stent and octreotide implant are achieved within five years of the closing of the merger. If both remaining CSR milestones are achieved, the Company will issue common stock totaling approximately $40,600,000 in value, which will have the effect of increasing recorded goodwill by an equivalent amount.

The aggregate purchase price pertaining to the Valera acquisition consisted of approximately $140,508,000 of the Company s common stock and $4,211,000 of transaction costs consisting primarily of fees paid for financial advisory, legal, valuation and accounting services. As of September 30, 2008 and 2007, approximately $347,000 of Indevus Common Stock was owed to those Valera stockholders and option holders who had not converted their SUPPRELIN LA CSRs and CSR Equivalents, respectively.

The Valera acquisition was accounted for under the purchase method of accounting and the results of operations of Valera have been included in the consolidated results of the Company from the acquisition date. The purchase price of the acquisition was allocated to tangible and intangible assets and liabilities assumed based on their estimated fair values at the date of acquisition. The purchase price exceeded the amounts allocated to the tangible and intangible assets acquired and liabilities assumed by $48,244,000, which was classified as goodwill. The goodwill is not deductible for tax purposes.

The following table presents the allocation of the purchase price for the acquisition of Valera, including the value of the SUPPRELIN CSRs and CSR Equivalents:

| | |
|---|---|
| Current assets | $ 18,084,000 |
| Property and equipment | 8,434,000 |
| Intangible assets: | |
| Developed technology | 30,100,000 |
| Acquired in-process research and development | 50,000,000 |
| Total intangible assets | 80,100,000 |
| Goodwill | 48,244,000 |
| Other assets | 1,227,000 |
| Accrued expenses and other current liabilities | (10,196,000) |
| Long-term liabilities | (827,000) |
| Total consideration paid | $ 145,066,000 |

Of the $80,100,000 of acquired intangible assets, $50,000,000 was allocated to in-process research and development ( IPR&D ) and was reflected as expense in the fiscal year ended September 30, 2007 because the products to which it relates had not received regulatory approval prior to the acquisition date. The value assigned to IPR&D relates to the following product candidates: SUPPRELIN LA, $24,000,000, the octreotide implant, $14,000,000 and a ureteral stent, $12,000,000. The Company believes that this charge represents a reasonable estimate of the future benefits attributed to the purchased IPR&D. The valuation was determined using an income approach. Cash flows were projected through a date commensurate with management s expectation of patent protection. The discounted cash flow method was applied to the projected cash flows, adjusted for the probability of success using a discount rate of approximately 22%. The discount rate takes into consideration the uncertainty surrounding successful development and commercialization of the IPR&D. Given the risks inherent in the clinical development and regulatory approval process, it is possible, with the exception of SUPPRELIN LA which was approved in May 2007, that no commercial product will ever result from these product candidates.

The following represents the unaudited pro forma results of the ongoing operations for Indevus and Valera as though the acquisition of Valera had occurred at the beginning of each of the years ended September 30, 2007 and September 30, 2006. As a result, the pro forma financial information for each of the years ended September 30, 2007 and September 30, 2006 includes non-recurring adjustments of $50,000,000 for IPR&D expense and $1,227,000 for stock compensation expense for the acceleration of vesting of Valera stock options. The unaudited pro forma information, however, is not necessarily indicative of the results that would have resulted had the acquisition occurred at the beginning of the periods presented, nor is it necessarily indicative of future results.

| | **September 30, 2007** | **September 30, 2006** |
|---|---|---|
| Revenue | $ 73,239,000 | $ 70,400,000 |
| Net loss | $ (123,964,000) | $ (115,802,000) |
| Net loss per common share (basic and diluted) | $ (1.63) | $ (1.68) |

In December 2006, the Company entered into a co-promotion and marketing services agreement with Valera pursuant to which the Company s sales force and Valera co-promoted VANTAS in the United States. This agreement terminated concurrent with the Company s acquisition of Valera effective April 18, 2007. The Company recorded approximately $536,000 of revenue pursuant to the agreement in the year ended September 30, 2007.

**D. Goodwill and Intangible Assets**

The carrying amount of goodwill is $48,244,000 at September 30, 2008 and was recorded in connection with the Valera acquisition and the subsequent conversion of CSRs and CSR Equivalents issued to the former shareholders of Valera relating to FDA approval of SUPPRELIN LA on May 3, 2007.

The Company s net intangible assets at September 30, 2008 totaled $30,855,000. Approximately $27,204,000 of the Company s net intangible assets was obtained as a result of the Valera acquisition. In April 2008, the Company entered into an agreement to terminate its existing manufacturing and supply agreement with Shire. In exchange for upfront and installment payments aggregating $5,000,000, the Company is no longer obligated to pay future royalties to Shire. Upon termination of the agreement, the Company capitalized the net present value of the total $5,000,000 payment using a discount rate of 17.5%, resulting in an intangible asset of approximately $3,932,000. The intangible asset is being amortized on a straight line basis from the date of the transaction over the remaining term of the original license agreement, which is approximately 6.5 years (see Note Q). After consideration of the initial $1,000,000 payment, there is approximately $1,077,000 classified as a short-term obligation and $2,121,000 classified as a long-term obligation in the consolidated balance sheet as of September 30, 2008. Approximately $1,068,000 will be accreted through interest expense over the payment term, which is approximately 3 years.

Amortization expense for intangible assets totaled approximately $2,267,000 and $910,000 during the years ended September 30, 2008 and 2007, respectively. The Company did not have any intangible assets and therefore did not record amortization expense for intangible assets during the year ended September 30, 2006. The annual amortization expense for each of the next five years for the intangible assets is expected to be approximately $2,500,000.

**E. Inventories**

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

The components of inventory at September 30, 2008 and 2007 are as follows:

| | September 30, 2008 | September 30, 2007 |
|---|---|---|
| Raw materials | $ 1,424,000 | $ 771,000 |
| Work in process | 3,215,000 | 4,405,000 |
| Finished goods | 1,540,000 | 3,235,000 |
| | $ 6,179,000 | $ 8,411,000 |

All of the Company s inventories at the balance sheet date relate to commercially approved products: SANCTURA, VANTAS, SUPPRELIN LA and DELATESTRYL. The Company established a reserve for the DELATESTRYL inventory that it believes is in excess of what can be sold before reaching a shelf life limitation and recorded the charge to cost of revenues. The balance of the reserve at September 30, 2008 and 2007 is $1,515,000 and $1,100,000, respectively. The Company has classified $0 and $682,000 of DELATESTRYL inventory, net of the reserve, as noncurrent as of September 30, 2008 and 2007, respectively.

**F. Property, Plant and Equipment**

At September 30, 2008 and 2007, property, plant and equipment consisted of the following:

| | Useful Lives | September 30, 2008 | September 30, 2007 |
|---|---|---|---|
| Manufacturing and office equipment | 2 - 7 years | $ 6,366,000 | $ 4,373,000 |
| Leasehold improvements | 5 - 10 years | 6,830,000 | 6,309,000 |
| Construction in progress | | 124,000 | 1,011,000 |
| | | 13,320,000 | 11,693,000 |
| Less: accumulated depreciation and amortization | | (4,096,000) | (1,922,000) |
| Property, plant and equipment, net | | $ 9,224,000 | $ 9,771,000 |

Included in construction in process at September 30, 2008 and 2007 were costs associated with new manufacturing equipment, supply chain management systems and leasehold improvements. These assets will begin to depreciate once they are placed in service or, in the case of the leasehold improvements, once the space is occupied.

Depreciation and amortization expense for property, plant and equipment for the three years ended September 30, 2008, 2007, and 2006 was $2,314,000, $895,000 and $447,000, respectively. Approximately $6,773,000 of the $9,224,000 of net property, plant and equipment as of September 30, 2008 relates to the fair value of property, plant and equipment acquired as part of the Valera acquisition. Approximately $8,148,000 of the $9,771,000 of net property, plant and equipment as of September 30, 2007 relates to the fair value of property, plant and equipment acquired as part of the Valera acquisition. During 2008, the Company recorded a fixed asset impairment charge of approximately $1,068,000 associated with the disposal of capital assets in connection with its restructuring plan.

**G. Accrued Expenses**

At September 30, 2008 and 2007, accrued expenses consisted of the following:

| | September 30, 2008 | September 30, 2007 |
|---|---|---|
| Compensation related | $ 6,975,000 | $ 5,351,000 |
| Manufacturing and production costs | 731,000 | 2,243,000 |
| Clinical and sponsored research | 1,788,000 | 9,048,000 |
| Sales and marketing | 699,000 | 2,903,000 |
| Professional fees | 1,107,000 | 895,000 |
| Milestone payment | | 1,500,000 |
| Other | 4,816,000 | 2,764,000 |
| | $ 16,116,000 | $ 24,704,000 |

**H. Commitments**

The Company leases its facilities, as well as certain office equipment under non-cancelable operating leases. Rent expense under these leases was approximately $2,952,000, $1,583,000, and $1,188,000 for the years ended September 30, 2008, 2007, and 2006, respectively. Rent expense for fiscal 2007 includes rent expense from Valera leases from the acquisition date of April 18, 2007 to September 30, 2007. The Company leases approximately 125 automobiles for its field sales force. The lease requires a minimum term of 12 months per automobile. Monthly lease expense related to this operating lease is expected to be approximately $60,000. The Company is responsible for certain disposal costs in case of termination. The average term of these leases is approximately three years.

At September 30, 2008, the Company s future minimum payments under non-cancelable lease arrangements are as follows:

| Fiscal Year | Operating Lease |
|---|---|
| 2009 | $ 2,800,000 |
| 2010 | 2,708,000 |
| 2011 | 1,835,000 |
| 2012 | 1,654,000 |
| 2013 | 3,710,000 |
| Thereafter | |
| Total Lease Payments | $ 12,707,000 |

Pursuant to certain in-licensing arrangements, the Company will owe payments to its licensors upon achievement of certain development, regulatory and licensing milestones. The Company generally cannot predict if or when such events will occur. In particular, the Company will owe Bayer Schering Pharma AG ( BayerSchering ) $5,000,000 if FDA approval of the NDA for NEBIDO is obtained. Additionally, the Company could owe BayerSchering up to $17,500,000 for achievement of certain commercial milestones if NEBIDO is approved for marketing by the FDA.

The BayerSchering Agreement contains certain minimum purchase requirements that would commence after the second year of sales of NEBIDO, upon approval. Such minimums will be determined to be a percent of purchases the Company would make in the second year of sales. After the second year of sales, the Company will be able to determine such minimum purchase requirements.

The Company has a supply agreement for valrubicin, the active ingredient of VALSTAR. The Agreement will expire ten years after the date of the first commercial sale of VALSTAR provided VALSTAR is approved by June 30, 2009. Beginning in the calendar year following the year in which it receives regulatory approval for VALSTAR in the United States, the Company will have annual minimum purchase requirements of $1,000,000. This agreement may be terminated by either party under certain customary conditions of breach, by mutual agreement of the parties, or by Plantex if VALSTAR is not approved by June 30, 2009.

Pursuant to the Teva Agreement, the Company will conduct, and Teva will reimburse expenses for, a Phase IIb study for stuttering. The Company is committed to perform this study and incur approximately $10,000,000 of external expenses over the next two fiscal years for reimbursement (see Note Q).

There remains outstanding CSRs and CSR Equivalents issued by the Company pursuant to Valera acquisition which will become payable in shares of Indevus common stock only if the applicable milestones for the biodegradable ureteral stent and octreotide implant are achieved within five years of the closing of the merger. If both remaining CSR and CSR Equivalent milestones are achieved, the Company will issue common stock totaling approximately $40,600,000 in value.

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

*Guarantees*

The Company s charter provides for indemnification, to the fullest extent permitted under Delaware law, of any person who is made a party to any action or threatened with any action as a result of such person s serving or having served as one of its officers or directors. The Company has separate indemnification agreements with certain officers, directors and employees. The indemnification obligation survives termination of the indemnified

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

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

**I. Convertible Notes and Non-recourse Notes**

**Convertible Notes**

On August 6, 2007, the Company completed its offer to exchange all $72,000,000 of its outstanding 6.25% Convertible Senior Notes due July 2008 (the Convertible Notes 2008 ), for an equal amount of the Company s 6.25% Convertible Senior Notes due July 2009 (the Convertible Notes 2009 ) (the Exchange Offer ). Holders of $71,925,000 of the Convertible Notes 2008 accepted the Exchange Offer. Consequently, the Company has $71,925,000 of the Convertible Notes 2009 as a component of current liabilities as of September 30, 2008. The Convertible Notes 2008 balance of $75,000 was paid in July 2008. The Convertible Notes 2008 and Convertible Notes 2009 are collectively referred to herein as the Convertible Notes.

The terms of the Convertible Notes 2009 and the Convertible Notes 2008 differ as follows:

(i) Maturity Date: The maturity date of the Convertible Notes 2009 is July 15, 2009, which is one year later than the maturity date of the Convertible Notes 2008, which was July 15, 2008. Similar to the Convertible Notes 2008, the maturity date of the Convertible Notes 2009 will continue to be subject to conversion at an earlier date at the discretion of the holders at a conversion price of $6.656 per share, as well as redemption by the Company at its option upon satisfaction of the market-based redemption condition.

(ii) Provisional Redemption Period: The Company cannot redeem the Convertible Notes 2009 in whole or in part at any time prior to July 15, 2008, whereas the Convertible Notes 2008 were redeemable at the Company s option in whole or in part since July 20, 2006. Similar to the Convertible Notes 2008, the Company s redemption option under the Convertible Notes 2009 is subject to certain notice requirements and remains subject to a condition related to the current market value of the Company s common stock. As discussed in (iii) below, this condition has been modified in the Convertible Notes 2009.

(iii) Stock Price Condition for Provisional Redemption: A condition to the Company s redemption of the Convertible Notes 2009 and the Convertible Notes 2008 is that the current market value of its common stock equals or exceeds a certain threshold for at least 20 trading days in any consecutive 30 trading day period ending on the trading day prior to the date the notice of the provisional redemption is mailed. Under the Convertible Notes 2009 this threshold is fixed at $8.50. Under the Convertible Notes 2008 this threshold was 150% of the $6.656 conversion price, or $9.984.

The Company concluded in accordance *with ETIF 96-19: Debtors Accounting for a Modification or Exchange of Debt Instruments* and *EITF 06-6: Debtor s Accounting for a Modification for a Modification (or Exchange) of Convertible Debt,* the exchange of the Convertible Notes 2008 should be accounted for as a

modification as opposed to an extinguishment and reissuance as the Convertible Notes 2009 were not deemed to be *substantially different* from the Convertible Notes 2008. As such, the unamortized existing bond issuance costs of approximately $700,000, as of the date of modification, related to the Convertible Notes 2008 offering, are being amortized through the new term of July 2009. Costs of approximately $100,000 related to issuance of the Convertible Notes 2009 have been expensed as incurred. The Company also concluded that none of the embedded derivatives as defined by *FASB 133: Accounting for Derivative Instruments and Hedging Activities* require bifurcation from the note payable. These embedded derivatives consist of the conversion feature allowing conversion into the Company s common stock, the Company s redemption provision based upon stock price conditions, and the put provision allowing the note holders to force repayment in the event of a change in control. EITF 06-6 also required the Company to calculate the fair value of the conversion feature immediately before and after the conversion. The Company performed a Monte Carlo simulation method to quantify the value of the conversion features immediately before and after the conversion. The result of that valuation indicated an increase in value of the conversion features of $4,267,000. This increase in value was accounted for as a decrease in the carrying value of the Convertible Notes 2009 and an increase in additional paid in capital. Accordingly, the carrying value of the Convertible Notes 2009 was $67,658,000 as of the exchange date and will be accreted to the $71,925,000 face value of the Convertible Notes 2009 over the period from the exchange date through the due date of July 15, 2009. Approximately $2,149,000 was accreted into the Convertible Notes 2009, and reflected as interest expense for the twelve month period ended September 30, 2008.

**Non-recourse Notes**

On August 26, 2008, the Company closed a private placement to institutional investors of $105,000,000 in aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due 2024 ( Non-recourse Notes ). The Non-recourse Notes were issued by Ledgemont Royalty Sub LLC ( Royalty Sub ), a wholly-owned subsidiary of the Company. In connection with the issuance of the Non-recourse Notes, the Company and Royalty Sub entered into a Purchase and Sale Agreement through which the Company sold to Royalty Sub its rights to receive royalty payments from Allergan arising under the U.S. Allergan Agreement for sales in the U.S. of SANCTURA and SANCTURA XR and by a pledge by the Company of all the outstanding equity interest in Royalty Sub. The Non-recourse Notes have not been guaranteed by the Company.

Principal and interest on the Non-recourse Notes issued by Royalty Sub will be repaid solely from the royalties from Allergan. Payments may also be made from the interest reserve account and certain other accounts established in accordance with the Indenture. Principal on the Non-recourse Notes is required to be paid in full by the final legal maturity date of November 5, 2024, unless repaid or redeemed earlier. In the event the Non-recourse Notes are repaid or redeemed prior to November 5, 2024, the noteholders will be entitled to a redemption premium. The interest rate applicable to the Non-recourse Notes is 16% per year and is payable quarterly in arrears commencing on November 5, 2008. These payments will be funded by the quarterly royalty payments received by Royalty Sub from Allergan. Royalty Sub will receive all royalties payable to the Company until the Non-recourse Notes have been repaid in full.

The royalty receipts from Allergan continue to represent consideration for the completion of the Company s performance obligations under the U.S. Allergan Agreement. Thus, royalty receipts will continue to be recorded as deferred revenue and recognized over the performance period under the CAPM.

In connection with the transaction, a $10,000,000 interest reserve was established to fund potential interest shortfalls, or if none, for repayment of principal due under the notes. Approximately $4,850,000 of this reserve is classified as non-current in the Company s consolidated balance sheet as of September 30, 2008. These funds came out of the debt proceeds and are restricted.

Deferred financing costs of approximately $4,300,000 were paid by Royalty Sub to complete the transaction. These also came out of the debt proceeds and are included in other assets in the consolidated balance sheet at September 30, 2008. The debt issuance costs are amortized based on the effective interest method over

the term of the related debt issuance. The Company determined that the term of the related debt is approximately 6.2 years, based upon the estimated repayment of the Non-recourse Notes. The amortization expense related to the debt issuance costs is included in interest expense on the consolidated statement of operations for the year ended September 30, 2008.

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

In May 2001, the Company entered into the AHP Indemnity and Release Agreement pursuant to which Wyeth agreed to indemnify the Company against certain classes of product liability cases filed against the Company related to Redux (dexfenfluramine hydrochloride capsules) C-IV, a prescription anti-obesity compound withdrawn from the market in September 1997. This indemnification covers plaintiffs who initially opted out of Wyeth s national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth has agreed to fund all future legal costs related to the Company s defense of Redux-related product liability cases. Also, pursuant to the agreement, Wyeth has funded additional insurance coverage to supplement the Company s existing product liability insurance. The Company believes this total insurance coverage is sufficient to address its potential remaining Redux product liability exposure. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which the Company is not otherwise indemnified or covered under the AHP Indemnity and Release Agreement will not have a material adverse effect on the Company s future business, results of operations or financial condition or that the potential of any such claims would not adversely affect the Company s ability to obtain sufficient financing to fund operations. Up to the date of the AHP Indemnity and Release Agreement, the Company s defense costs were paid by, or subject to reimbursement to the Company from, the Company s product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to Indevus by Wyeth, the Company agreed to dismiss its suit against Wyeth filed in January 2000, its appeal from the order approving Wyeth s national class action settlement of diet drug claims, and its cross-claims against Wyeth related to Redux product liability legal actions.

At September 30, 2008, the Company has an accrued liability of approximately $400,000 for Redux-related expenses, including legal expenses. The amount the Company ultimately pays could differ significantly from the amount currently accrued at September 30, 2008. To the extent the amount paid differs from the amount accrued, the Company will record a charge or credit to the statement of operations.

As of September 30, 2008, the Company had an outstanding insurance claim of approximately $3,300,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company s current outstanding insurance claim is made pursuant to the Company s product liability policy issued to the Company by Reliance Insurance Company ( Reliance ). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. In fiscal 2008, the Company received a partial payment of $400,000 from Reliance pertaining to this claim. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $858,000 reflecting the Company s best estimate given the available facts and circumstances. The amount the Company collects could differ from the $858,000 reflected as a noncurrent insurance claim receivable at September 30, 2008. Subsequent to September 30, 2008, the Company received an additional $300,000 payment. It is uncertain when, if ever, the Company will collect any of its remaining $3,000,000 of claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the $5,000,000 limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

**K. Stockholders Equity**

*Issuance of shares upon acquisition:* In fiscal 2007, the Company completed the Valera acquisition (see Note C). Approximately 19,900,000 shares of common stock were issued as consideration for the acquisition.

*Common Stock Offering:* In July 2006, the Company completed an underwritten public offering of common stock. The Company issued 8,050,000 shares including 1,050,000 shares to cover underwriter over allotments, at a price to the public of $4.65 per share. Net proceeds, after underwriting commissions and expenses of $2,405,000, was approximately $35,000,000. This offering of common stock was made pursuant to an effective shelf registration statement filed with the SEC on December 28, 2005.

*Preferred Stock:* The Certificate of Incorporation of the Company authorizes the issuance of 5,000,000 shares of preferred stock. The Board of Directors has the authority to issue preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions, including the dividend, conversion, voting, redemption (including sinking fund provisions), and other rights, liquidation preferences, and the number of shares constituting any series and the designations of such series, without any further vote or action by the stockholders of the Company. In fiscal 1993, the Company issued shares of Series B and Series C Convertible Preferred Stock in connection with an agreement with Wyeth. In April 2008, the issued and outstanding 239,425 shares of Series B Convertible Preferred Stock and 5,000 shares of Series C Convertible Preferred Stock converted into 622,220 shares of the Company s Common Stock.

*Treasury Stock:* In fiscal 2004, the Company s Board of Directors approved the repurchase from time to time by the Company of up to 2,500,000 shares of Indevus Common Stock in the open market and the Company repurchased an aggregate of 1,166,000 shares for $7,319,000. As of September 30, 2006, the Company reissued all 1,166,000 of those shares primarily pursuant to its employee stock option and purchase plans.

*Other:* In addition to the 78,151,809 shares of Common Stock outstanding at September 30, 2008, there were approximately 31,792,000 shares of Common Stock reserved for issuance ( Reserved Common Shares ). Included in the number of Reserved Common Shares are the following: (i) 10,806,000 shares reserved for issuance upon conversion of the Convertible Notes 2009; (ii) 15,986,000 shares issuable upon exercise of outstanding options, performance stock awards and deferred stock units, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if Indevus issues additional securities below certain prices; (iii) 5,000,000 shares of Common Stock reserved for issuance upon conversion of the Company s authorized but unissued Preferred Stock.

**L. Basic and Diluted Loss per Share**

During the year ended September 30, 2008, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 7,363,000 shares of Common Stock at prices ranging from $8.72 to $4.74 with expiration dates ranging up to May 6, 2018. Additionally, during the year ended September 30, 2008, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) the Convertible Notes 2009, which are convertible into 10,806,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2009; (ii) options to purchase 6,307,000 shares of Common Stock at prices ranging from $1.22 to $4.54 with expiration dates ranging up to September 25, 2018; (iii) unvested restricted stock with service-based vesting criteria of 540,230 shares and unvested restricted stock awards with service and market-based vesting criteria of 640,900 to 1,108,900 contingently issuable shares; (iv) vested deferred stock units with service vesting criteria of 13,000 shares of common stock; and (v) unvested deferred stock units with service vesting criteria of 86,667 shares of common stock.

During the year ended September 30, 2007, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 1,580,000 shares of Common Stock at prices ranging from $6.93 to $8.72 with expiration dates ranging up to August 9, 2017. Additionally, during the year ended September 30, 2007, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) the Convertible Notes, which are convertible into 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008 with respect to the Convertible Notes 2008 and through July 15, 2009 with respect to the Convertible Notes 2009; (ii) options to purchase 11,218,000 shares of Common Stock at prices ranging from $1.22 to $6.91 with expiration dates ranging up to September 4, 2017; (iii) Series B and C preferred stock convertible into 622,222 shares of Common Stock; (iv) unvested restricted stock with service-based vesting criteria of 237,100 shares and unvested restricted stock awards with service and market-based vesting criteria of 227,650 to 379,500 contingently issuable shares; and (v) unvested deferred stock units with service vesting criteria of 48,000 shares of common stock.

During the year ended September 30, 2006, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 4,927,874 shares of Common Stock at prices ranging from $5.18 to $20.13 with expiration dates ranging up to September 26, 2016. The Convertible Notes 2008, which prior to the exchange were convertible into 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008, are also excluded from dilutive earnings per share as they would have been anti-dilutive following the if converted method. Additionally, during the year ended September 30, 2006, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 6,965,399 shares of Common Stock at prices ranging from $1.22 to $5.08 with expiration dates ranging up to June 28, 2016 and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock and (iii) unvested restricted stock with service-based vesting criteria of 215,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 210,750 to 351,400 contingently issuable shares.

**M. Stock Plans and Stock-Based Compensation**

*Stock Plans*

The Company has several stock-based employee compensation plans, including (i) the 1994 Long-Term Incentive Plan (the 1994 Plan ) that expired in 2004; and (ii) the 1998 stock option plan (the 1998 plan ), that expired in 2005. Incentive and non-qualified options granted to employees, officers, directors and consultants pursuant to the 1994 Plan which was outstanding as of the date the 1994 Plan expired may be exercised until cancelled or expired. Under the 2000 Stock Option Plan (the 2000 Plan ), incentive and non-qualified options to purchase 3,500,000 shares may be granted. Under the Company s 2004 Equity Incentive Plan (the 2004 Plan ), incentive and non-qualified options to purchase 9,000,000 shares may be granted. Under the 2000 Plan, the 2004 Plan, and under the 1994 and 1998 Plans prior to their expiration (collectively the Option Plans ), employees and officers may be granted incentive and nonqualified options and directors and consultants may be granted non-qualified options. Persons who were executive officers or directors of the Company as of the date of adoption of the 1998 Plan were not eligible to receive grants under the 1998 Plan. The duration of each Option Plan is ten years. The term of each grant under the 1994, 2000, and 2004 Plans cannot exceed ten years and the term of each grant under the 1998 Plan cannot exceed seven years.

The Company s 1995 Employee Stock Purchase Plan (the 1995 Plan ) covers an aggregate of 1,050,000 shares of Common Stock which is offered in one-year offerings. Each offering is divided into two six-month Purchase Periods (the Purchase Periods ). Stock is purchased at the end of each Purchase Period with employee contributions at the lower of 85% of the closing sale price of the Company s Common Stock on the first day of an Offering or the last day of the related Purchase Period. The last purchases under the 1995 Plan were made on September 30, 2008, after which the 1995 Plan expired as all shares allowable under the 1995 Plan were issued.

In fiscal 2008, the Company established a new 2008 Employee Stock Purchase Plan (the 2008 Plan ) covering an aggregate of 1,500,000 shares offered in six month offerings. Stock is purchased at the time of each offering with employee contributions at the lower of 85% of the closing sale price of the Company s Common Stock on the first and last day of the offering. The 2008 Plan was approved by the Company s Board of Directors on September 25, 2008 and will be proposed to the stockholders for approval at the annual meeting in March 2009.

*Stock-Based Compensation*

On October 1, 2005, the Company adopted SFAS No. 123R Accounting for Stock-Based Compensation ( SFAS 123R ) using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. Stock-based employee compensation expense, excluding portions related to modifications and restricted stock, was approximately $4,477,000, $4,572,000, and $3,331,000 for the fiscal years ended September 30, 2008, 2007, and 2006, respectively. Previously the Company had followed APB Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, which resulted in the accounting for employee share options at their intrinsic value in the consolidated financial statements.

*Stock Option and Plan Modifications*

During the fiscal years ended September 30, 2008 and 2007, the Board of Directors approved modifications to extend the term of certain outstanding fully-vested stock options, and the Company recorded approximately $554,000 and $530,000, respectively, of noncash compensation expense related to these modifications. Pursuant to FAS 123R, the Company is required to record a charge for the change in fair value measured immediately prior and subsequent to the modification of the stock options. Approximately $1,227,000 of noncash compensation expense was recorded during the fiscal year ended September 30, 2007, due to acceleration of vesting of Valera options on April 18, 2007, in connection with the Valera acquisition.

During the fiscal year ended September 30, 2006, the Board of Directors adopted a modification to the Company s stock option plans relating to the retirement of employees and directors who are also reporting persons pursuant to Section 16 of the Securities Exchange Act of 1934. This provision stipulates that awards to such persons who retire after meeting certain age and service requirements may have an extended period of time after retirement to exercise options that were vested at the date of retirement. In the fiscal year ended September 30, 2006, the Company recorded $300,000 of noncash compensation expense related to this modification. During the fiscal year ended September 30, 2006, the Board of Directors approved modifications to extend the term of certain outstanding stock options and the Company recorded $472,000 of noncash compensation expense related to these modifications.

*Deferred Stock Units*

Subject to the discretion of the Compensation Committee of the Board of Directors, on the date following each annual meeting of the stockholders, each non-employee director of the Company may receive annual grants of a number of deferred stock units determined by the Committee at the time of grant based on current market conditions and the fair market value of the Company s common stock. In accordance with this policy, during fiscal years 2008 and 2007, each of the five non-employee members of the Board of Directors of the Company was granted 10,000 and 8,000, respectively, Deferred Stock Units ( DSUs ) pursuant to the Company s 2004 Equity Incentive Plan. Compensation expense for these awards is recognized over the three year vesting period and is recorded as a component of general and administrative expense. As such, during the two years ended September 30, 2008 and 2007, $146,000 and $56,000, respectively, of noncash compensation expense related to these DSUs was recognized, respectively. Each DSU represents the right to receive one share of the Company s

common stock. The DSUs vest in three equal annual increments from the date of the grant, and the vested portion of the award is distributable after the earlier of the Director s retirement from the Board or five years from the date of grant. The Company will recognize the remaining $389,000 of noncash compensation expense related to these DSUs over the remaining vesting period.

*Other Stock Award Grants*

During fiscal years ended September 30, 2008, 2007 and 2006, the Company granted certain restricted and performance-based common stock awards to the Company s executive officers pursuant to the Company s 2004 Equity Incentive Plan. Compensation expense for these awards is recognized over the service period and is recorded as a component of marketing, general and administrative and research and development expense, as appropriate. During the fiscal years ended September 30, 2008, 2007 and 2006, $1,275,000, $945,000 and $432,000, respectively, of noncash compensation expense related to these stock awards was recognized.

Calculation of the fair value of these performance-based common stock awards was determined using a binomial valuation model that utilizes the assumptions shown in the table below. For certain of these stock awards that vest based upon market-based vesting criteria, a Monte Carlo Simulation technique and the lattice model were used to value these awards. Restricted stock awards were valued under the intrinsic value method.

| | Fiscal Year Ended September 30, 2008 | Fiscal Year Ended September 30, 2007 |
|---|---|---|
| Expected volatility | 89.00% | 56.00% |
| Risk-free interest rate | 2.42% | 4.78% |
| Dividend rate | 0.00% | 0.00% |

*Stock-Based Compensation*

The Company recognized the full impact of its share-based payment plans, including the impact of the charges related to the modifications and restricted stock explained above, in the consolidated statements of income for the fiscal years ended September 30, 2008, 2007 and 2006 under SFAS 123R and did not capitalize any such costs on the consolidated balance sheets, as such costs that qualified for capitalization were not material. In the fiscal years ended September 30, 2008, 2007 and 2006, the Company recorded $6,452,000, $7,330,000 and $4,535,000 of these noncash expenses, respectively. There was no impact in any of the fiscal years ended September 30, 2008, 2007 or 2006, on cash flows from operations, investing or financing activities in connection with the adoption of SFAS 123R. In the fiscal year ended September 30, 2008, the Company allocated $352,000, $1,416,000 and $4,684,000 to cost of goods sold, research and development and marketing, and general and administrative expense, respectively. In the fiscal year ended September 30, 2007, the Company allocated $200,000, $1,438,000 and $5,692,000 to cost of goods sold, research and development and marketing, general and administrative expense, respectively. In the fiscal year ended September 30, 2006, the Company allocated $851,000 and $3,684,000 to research and development and marketing, general and administrative expense, respectively.

Below are the factors used to determine the value of options granted pursuant to SFAS 123R:

| | Fiscal Years Ended September 30, | | | | | |
|---|---|---|---|---|---|---|
| | 2008 | | 2007 | | 2006 | |
| | Executives | Non-executives | Executives | Non-executives | Executives | Non-executives |
| Option life | 7.5 years | 6.0 to 6.5 years | 8 years | 6.25 to 6.5 years | 8 years | 6.25 years |
| Risk-free interest rate | 3.60% | 2.78% to 3.54% | 4.70% | 4.38% to 4.98% | 4.95% | 4.61% |
| Stock volatility | 74.5% | 46.2% to 75.5% | 62.8% | 45.7% to 60.6% | 73.0% | 65.0% |
| Dividend rate | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

As of September 30, 2008, there remained approximately $9,610,000 of compensation costs related to non-vested stock options to be recognized as expense over a weighted average period of approximately 1.49 years.

Presented below is the Company s stock option activity:

| | Stock Options | |
|---|---|---|
| | Shares | Weighted Average Exercise Price |
| Outstanding at September 30, 2007 | 13,303,246 | $ 4.91 |
| Granted | 1,670,000 | $ 4.39 |
| Exercised | (545,469) | $ 4.61 |
| Cancelled | (1,023,017) | $ 6.05 |
| Outstanding at September 30, 2008 | 13,404,760 | $ 4.71 |
| Options exercisable at end of period | 10,637,283 | $ 4.59 |

The weighted average fair value of options granted during the twelve months ended September 30, 2008, 2007 and 2006 was $2.35, $4.03, and $3.25, respectively.

At September 30, 2008, stock options were outstanding and exercisable as follows:

| Outstanding | | | Exercisable | |
|---|---|---|---|---|
| Number | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number | Weighted Average Exercise Price |
| 3,481,250 | 3.3 years | $2.21 | 2,808,814 | $2.33 |
| 3,517,347 | 3.8 years | $3.94 | 3,073,091 | $3.86 |
| 3,354,329 | 2.4 years | $6.06 | 3,153,422 | $6.07 |
| 3,051,834 | 7.6 years | $6.98 | 1,601,956 | $7.02 |
| 13,404,760 | 4.2 years | $4.71 | 10,637,283 | $4.59 |

The aggregate intrinsic value of outstanding options as of September 30, 2008 was $4,054,000, of which $2,967,000 was related to exercisable options. The intrinsic value of options exercised during the fiscal years ended September 30, 2008, 2007 and 2006 was $671,000, $646,000, and $1,431,000, respectively. The intrinsic value of options vested during the fiscal years ended September 30, 2008, 2007 and 2006 was $98,000, $2,043,000, and $1,327,000, respectively. The weighted average contractual life for total options exercisable at September 30, 2008 was approximately 2.9 years. The weighted average contractual life for total options outstanding at September 30, 2008 was approximately 4.2 years.

Presented below is the Company s restricted stock and performance award activity:

| | Restricted Stock Awards Service-Based | | Performance Awards Service and Market-Based | | |
|---|---|---|---|---|---|
| | Shares | Weighted Average Grant Date Fair Value | Share Range | | Weighted Average Grant Date Fair Value |
| Nonvested at September 30, 2006 | 215,900 | | 210,750 | to 351,400 | |
| Granted | 50,000 | $ 6.32 | 45,000 | to 75,000 | $ 5.88 |
| Vested | | | | | |
| Forfeited | (28,800) | | (28,100) | (46,900) | |
| Nonvested at September 30, 2007 | 237,100 | | 227,650 | to 379,500 | |
| Granted | 495,160 | $ 2.80 | 484,420 | 807,330 | $ 2.56 |
| Vested | (141,400) | | | | |
| Forfeited | (50,630) | | (61,800) | (103,000) | |
| Nonvested at September 30, 2008 | 540,230 | | 650,270 | 1,083,830 | |

The aggregate intrinsic value of restricted stock awards with service-based vesting outstanding at September 30, 2008 was $1,810,000. The value of performance awards with service and market-based vesting criteria ranged from $2,147,000 to $3,715,000 at September 30, 2008. At September 30, 2008, there remained approximately $2,523,000 of compensation expense related to restricted stock and performance awards to be recognized as expense over approximately 3.0 years.

**N. Restructuring**

On June 30, 2008, the Company announced a restructuring of its operations to more appropriately align its cost structure to revenue projections and development opportunities. During fiscal 2008, the Company recorded charges, aggregating $2,980,000 related to the restructuring plan. The charges incurred include: (i) separation costs of approximately $1,780,000 and (ii) asset impairment charges and other non-cash charges of approximately $1,200,000 associated with the disposal of capital assets. The accrued restructuring balance was approximately $713,000 as of September 30, 2008, consisting primarily of unpaid separation costs, which are expected to be paid by June 30, 2009.

The following table summarizes the charges and spending during fiscal 2008 relating to the restructuring plan:

| | Separation Costs |
|---|---|
| Balance at June 30, 2008 | $ 2,313,000 |
| Payments | (1,100,000) |
| Estimate revisions | (500,000) |
| Balance at September 30, 2008 | $ 713,000 |

The Company records restructuring activities in accordance with SFAS 144, *Accounting for the Impairment and Disposal of Long-Lived Assets* and SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*.

**O. Income Taxes**

The provision for income taxes for the fiscal years ended September 30, 2008, 2007 and 2006 consist of the following:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| Current tax expense (benefit): | | | |
| Federal | $ | $ | $ |
| State | | | |
| Deferred tax expense: | | | |
| Federal | 20,295,000 | 20,245,000 | 14,841,000 |
| State | 2,942,000 | 2,677,000 | 682,000 |
| Change in Valuation Allowance | (23,237,000) | (22,922,000) | (15,523,000) |
| | $ | $ | $ |

The Company files consolidated tax returns. For each of the years ended September 30, 2008, 2007 and 2006, the Company s United States Federal statutory tax rate was 34% and its effective tax rate was 0%, 0%, and 0%, respectively. The Company s effective tax rate varies from its statutory tax rate for the years ended September 30 principally due to the following:

| Fiscal Years Ended September 30, | 2008 | 2007 | 2006 |
|---|---|---|---|
| U.S. statutory rate | (34.0)% | (34.0)% | (34.0)% |
| State taxes | (4.4) | (2.6) | (1.4) |
| Permanent differences | | 17.3 | 2.9 |
| Credit generation | | (2.5) | 1.3 |
| Expiration of credit | 1.1 | 0.5 | 0.5 |
| Valuation allowance | 37.3 | 21.3 | 30.7 |
| | % | % | % |

Included in the effective tax rate for the year ended September 30, 2007 is the permanent difference that resulted from the $50,000,000 in process research and development charge related to the Company s acquisition of Valera, which is not deductible for tax purposes. Under EITF 96-7, Accounting for Deferred Taxes on In-Process Research and Development Activities Acquired in a Purchase Business Combination, a deferred tax liability was not recorded in the initial purchase accounting for in-process research and development.

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management s review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax asset will not be realized. The Company s historical losses from operations represent significant negative evidence that indicates the need for a valuation allowance. Accordingly, a valuation allowance has been established for the full amount of the deferred tax asset. If it is determined, based on future profitability, that these deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate material income tax benefit in the period of decrease and material income tax provisions in future periods.

At September 30, 2008 and 2007, the significant components of the Company s deferred taxes consisted of the following:

| | 2008 | 2007 |
|---|---|---|
| Assets | | |
| Federal and state net operating loss carryforwards | $ 130,609,000 | $ 122,288,000 |
| Federal and state tax credit carryforwards | 13,375,000 | 13,451,000 |
| Capital loss carryforwards | 13,335,000 | 15,772,000 |
| Accrued expenses | 14,647,000 | 12,802,000 |
| Investment in CPEC LLC | 4,640,000 | 5,697,000 |
| Deferred revenue | 58,920,000 | 44,004,000 |
| Liabilities | | |
| Purchase accounting | (10,882,000) | (12,607,000) |
| Valuation allowance | (224,644,000) | (201,407,000) |
| Net deferred tax asset | $ | $ |

At September 30, 2008, the Company had consolidated Federal net operating loss carryforwards of approximately $353,523,000, which expire at various dates from 2018 through 2027, and consolidated state tax net operating loss carryforwards of approximately $230,696,000, which expire at various dates from 2008 through 2015. At September 30, 2008, the Company had approximately $8,203,000 of Federal tax credit carryforwards, which expire at various dates through 2027, and approximately $5,301,000 of state tax credit carryforwards, which expire at various dates through 2023. In addition, the Company had Federal capital loss carryforwards of approximately $34,835,000, which expire at various dates through 2012. Approximately $20,437,000 of the net operating loss carryforwards available for federal income tax purposes relate to exercises of non-qualified stock options and disqualifying dispositions of incentive stock options, the tax benefit from which, if realized, will be credited to additional paid-in capital. Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, use of the Company s historical net operating loss and tax credit carryforwards may be subject to annual limitations due to a change in ownership of more than 50%.

On April 17, 2007, the Company completed a merger with Valera. For tax purposes, this merger was treated as a tax-free reorganization under Section 368 of the Internal Revenue Code of 1986, as amended. As a result, Valera s tax basis and tax attributes remained unchanged and transferred to the Company. Included in these tax attributes were Federal net operating loss carryforwards of approximately $43,245,000, state tax net operating loss carryforwards of approximately $38,198,000, Federal tax credit carryforwards of $1,704,000 and state tax credit carryforwards of $647,000. At the date of acquisition, Valera s net deferred tax asset was approximately $20,590,000 immediately prior to the Company s recognition of $13,574,000 of deferred tax liabilities related to the basis differences related to the acquired intangible assets and other purchase accounting adjustments. In accordance with SFAS 109, Accounting for Income Taxes and SFAS 141, Business Combinations, the Company recorded such deferred tax liabilities in accounting for the acquisition, and recorded an incremental valuation allowance of $7,016,000. Pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, use of Valera s net operating loss carryforwards as of April 17, 2007 are subject to an annual limitation of $4,700,000 due to a change in ownership of more than 50%.

The Company adopted FIN 48 on October 1, 2007. The implementation of FIN 48 did not have a material impact on the Company s consolidated financial statements or results of operations. The Company does not have any unrecognized tax benefits. As of September 30, 2008, the Company had federal and state net operating loss carryforwards and federal and state research and development ( R&D ) credit carryforwards, which may be available to offset future federal and state income tax liabilities. The Company has not completed a formal R&D credit study, however, no amounts related to R&D credit carryforwards are being presented as an uncertain tax position under FIN 48.

The Company files tax returns in the U.S. Federal jurisdiction and in various state and local jurisdictions. The Company currently does not have any federal, state or local audits in progress. With limited exceptions, the Company is no longer subject to federal, state or local examinations for years prior to 2004, however, carryforward attributes that were generated prior to 2004 may still be adjusted upon examination by state or local tax authorities if they either have been or will be used in a future period.

The Company will recognize accrued interest and penalties related to unrecognized tax benefits as a component of tax expense. This policy did not change as a result of the adoption of FIN 48. For the year ended September 30, 2008, the Company did not recognize any accrued interest and penalties in its consolidated statement of operations or its consolidated balance sheet.

**P. Related Party Transactions**

The Company s Corporate Secretary is not a director, executive officer or employee of the Company, but is merely a statutory officer. The Company has engaged a law firm to provide legal and other consulting services and the Company s Corporate Secretary is associated with such law firm. Total amounts due or paid pursuant to the arrangement with such law firm were approximately $395,000, $858,000, and $357,000 in fiscal 2008, 2007 and 2006, respectively.

**Q. Product Agreements**

**SANCTURA and SANCTURA XR**

**Allergan/Esprit**

In September 2007, the Company entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit, which re-defined the obligations of each party and superseded all previous agreements, (the Allergan Agreement ). On October 16, 2007, the effective date of the Allergan Agreement, Allergan also acquired Esprit resulting in Esprit being a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, the Company received an up-front license fee, partially creditable by Allergan against future payments to the Company, of $25,000,000, and $8,000,000 as payment of the supply price for future deliveries of SANCTURA XR, subject to purchase orders issued by Allergan. The Allergan Agreement also grants the Company the right to receive a fixed percentage of net sales for the term of this Agreement, subject to increasing annual minimum royalties aggregating up to approximately $123,000,000 for the first seven years of this Agreement, provided there is no product adverse event, as defined in the Allergan Agreement. Commencing January 1, 2010, or earlier in the case of generic competition, Allergan has the right to reduce, subject to quarterly and annual restrictions, royalty payments by $20,000,000. In addition, the Company received approximately $9,000,000 in annual sales force subsidy in fiscal year 2008 and extended its copromotion through December 31, 2008 and subsequently has extended its copromotion to March 31, 2009 at an annual rate of approximately $9,000,000. The Company may also receive a payment of $20,000,000 related to a long-term commercialization milestone related to generic competition. Lastly, all third-party royalties paid by the Company as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR as of October 16, 2007 will be reimbursed to the Company by Allergan. Pursuant to the Allergan Agreement, on August 13, 2008, Allergan assumed responsibility to manufacture SANCTURA XR for its use (the Processing Assumption Date ), and the Company assigned to Allergan certain agreements and purchase orders relating to the manufacture SANCTURA XR. The Company manufactured and supplied SANCTURA XR to Allergan at its cost through the Processing Assumption Date and will manufacture and supply SANCTURA through September 30, 2012. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of SANCTURA XR or the last to expire patent covering SANCTURA XR in the United States. Either party may also terminate the Allergan Agreement under certain customary conditions of breach.

In August 2008, the Company assigned its rights to receive a fixed percentage of net sales and $20,000,000 related to a long-term commercialization milestone related to generic competition to investors pursuant to the Company s private placement of Non-recourse Notes (see Note I).

The Allergan Agreement superseded all previous agreements with Esprit or its predecessors pertaining to SANCTURA and SANCTURA XR.

Commencing on the effective date of the Allergan Agreement, the Company began recognizing the deferred revenue balances that existed on the effective date and the upfront license payment of $25,000,000 on a straight-line basis over the approximately 5 year obligation period of the agreement. All subsequent payments received from Allergan during the 5 year obligation period of the agreement, including royalties, sales force reimbursement and product revenues, will be recognized using the CAPM. All payments received after the 5 year obligation period of the agreement will be recognized as revenue when earned, provided that there are no remaining obligations.

In May 2008, together with Madaus, the Company also licensed to Allergan the exclusive right to develop, manufacture, and commercialize SANCTURA XR in Canada. In exchange, the Company received an upfront payment of $7,000,000 and could receive milestone payments totaling $2,000,000 upon achievement of certain sales thresholds. In addition, third-party royalties owed by the Company on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation, after which Allergan will have a fully-paid license. The $7,000,000 payment represents the aggregate amounts paid to the Company pursuant to this Agreement through September 30, 2008. Additionally, either party may terminate this agreement under certain customary conditions of breach.

All consideration received from Allergan during the term will be recognized using the CAPM.

**Esprit/PLIVA**

In April 2004, the Company entered into a license, commercialization and supply agreement with PLIVA d.d. ( PLIVA ) through its specialty-branded subsidiary, Odyssey, for the U.S. commercialization of SANCTURA for OAB (the SANCTURA Agreement ). In May 2005, the Company, PLIVA and Esprit entered into an Amendment and Consent Agreement (the Amendment and Consent Agreement ), which became effective as of July 1, 2005, pursuant to which the Company amended certain provisions of the SANCTURA Agreement and consented to the acquisition by Esprit of the rights to market SANCTURA in the U.S. from PLIVA and the assumption by Esprit of PLIVA s obligations under the SANCTURA Agreement.

Commencing July 1, 2005, the effective royalty rates increased and the Company became entitled to annual minimum royalties of $5,625,000, $7,875,000, and $10,500,000 for the first three years of the Amendment and Consent Agreement, respectively. Third-party royalties paid by the Company as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR were also reimbursed to the Company. Additionally, the annual sales force subsidy was increased to $8,750,000 through December 31, 2007. Further, Esprit would not be subject to minimum detail and sales force requirements. The Company recorded all royalties and reimbursements of third party royalties as product revenue and sales force reimbursements as contract and license fee revenue when earned.

Through October 15, 2007, the Company recognized as contract and license fee revenue the amortization of these payments under the contingency-adjusted performance model over the estimated term of the SANCTURA Agreement of twelve years. Sales of SANCTURA to the Company s marketing partners were recorded as product revenue.

Collectively through September 30, 2008 and pursuant to all agreements between the Company and PLIVA, Esprit and Allergan, the Company has received approximately $364,000,000 in the form of up front and milestone payments, royalties, sales force reimbursements and payments for product shipped to the Company s marketing partners at its cost to manufacture.

**Madaus**

In November 1999, the Company entered into an agreement with Madaus under which the Company licensed exclusive rights under Madaus patents and know-how to develop and market certain products, including SANCTURA in the United States. In exchange for these rights, the Company agreed to pay Madaus potential regulatory and sales milestone payments and royalties on net sales of the licensed products or, if sublicensed by the Company, a portion of royalties received from its sublicensee on net sales of the licensed product by the sublicensee, in lieu of royalty payments. The Company is responsible for all clinical development and regulatory activities and costs related to licensed products in the United States. The agreement expires on the tenth annual anniversary of the launch of SANCTURA XR provided either party may also terminate this agreement under certain customary conditions of breach. The term of the agreement continues for ten years from the first commercial sale of each licensed product, after which the license is fully paid for that licensed product. In December 2002, the Company entered into a manufacturing agreement with Madaus under which Madaus produces and sells to the Company commercial quantities of SANCTURA in bulk form.

In November 2006, the Company entered into (i) a License and Supply Agreement and (ii) an amendment to its original license agreement with Madaus (collectively, the Madaus Agreements ). Under the Madaus Agreements, the Company agreed to (a) purchase from Madaus all required trospium active pharmaceutical ingredient for production of SANCTURA XR through November 2007, (b) license Madaus the rights to sell SANCTURA XR in all countries outside of the U.S. (the Madaus Territory ) except Canada, Japan, Korea and China (the Joint Territory ), (c) pay to Madaus a fee based on the number of capsules of SANCTURA XR sold by the Company in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share, (d) supply SANCTURA XR to Madaus for a specified period of time, (e) provide development committee support for a defined period, and (f) provide future know-how to Madaus. In exchange, Madaus (a) waived all rights to manufacture SANCTURA XR, (b) will purchase SANCTURA XR from the Company at cost plus a fee based on the number of SANCTURA XR capsules sold in the Madaus Territory, and (c) will make payments upon the achievement of certain commercial milestones and royalties based on future sales of SANCTURA XR in the Madaus Territory. Certain of the milestone and royalty payments the Company will receive represent royalty and milestone payments due to Supernus from Indevus under the Supernus Agreement. The Company and Madaus will share the economics of development and commercialization in the countries in the Joint Territory. If either party decides not to pursue development and commercialization of SANCTURA XR in any country in the Joint Territory, the other party has the right to develop and commercialize SANCTURA XR in that country. Madaus is also due a portion of royalties the Company receives for SANCTURA and SANCTURA XR subject to a minimum of 4% of net sales, which is offsetable by any third party royalties owed by the Company. There is $1,200,000 of potential additional milestone payments due to us, from Madaus, pursuant to these agreements. As of September 30, 2008 the Company had received $700,000 from Madaus under the Madaus Agreement for SANCTURA XR. The term of the Madaus Agreement for SANCTURA XR extends until the expiration, on a country-by-country basis, of all royalty obligations owed to the Company from Madaus which ceases upon the last to expire applicable patent in the Madaus territory. Either party may also terminate this agreement under certain customary conditions of breach.

The Madaus Agreements have been combined for accounting purposes and the Company evaluated the multiple deliverables in accordance with the provisions of EITF 00-21. The Company was unable to demonstrate that the delivered items had stand alone value or that the undelivered elements had verifiable objective evidence of fair value, and thus concluded that the arrangement represented a single unit of accounting. Initially, upon execution of the Madaus Agreements, the Company was unable to determine the term of its obligation to provide future know-how to Madaus. Subsequent to the Allergan Agreement, the Company reevaluated this performance obligation and determined that it was analogous to its performance obligation to provide know-how to Allergan. Per the Allergan Agreement, the Company s know-how obligations are expected to cease no later than September 30, 2012. Accordingly, the Company will recognize all payments received from Madaus through September 30, 2012 using the CAPM and will reflect the recognition of such payments as contract and license fee revenue over the approximately 6-year performance period. All payments received after the approximately

6-year performance period will be recognized as revenue when earned. In addition, the Company has evaluated its payments to be made to Madaus under the Madaus Agreements in accordance with the provisions of EITF 01-9, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products) , and has determined that it is receiving a separable benefit for each payment and each benefit has objective evidence of fair value. Through September 30, 2008, the Company has paid Madaus approximately $33,400,000 pursuant to these agreements. There are no other milestones due pursuant to all Madaus Agreements.

**Supernus**

In March 2003, the Company signed a development and license agreement with Supernus under which Supernus developed SANCTURA XR and granted exclusive, worldwide rights under Supernus-related patents and know-how to the Company. The agreement includes potential future development and commercialization milestone payments from the Company to Supernus, including royalties based on sales of SANCTURA XR, and potential future development and commercialization milestone payments for up to an aggregate of $2,400,000 pertaining to the launch of SANCTURA XR in certain geographic areas. In addition, the agreement includes potential future development and commercialization milestone payments for up to an aggregate of $4,500,000 pertaining to the launch of new formulations and over-the-counter products. The Company is responsible for all development costs and the commercialization of SANCTURA XR under this agreement. This agreement continues until the earlier of, in any particular country, (i) the last date on which the manufacture, use or sale of licensed product in such country would infringe a valid claim of a licensed patent in such country but for the license granted by the agreement; or (ii) 12 years from the date of first commercial sale of licensed product in such country. Either party may also terminate this agreement under certain customary conditions of breach or by mutual consent. As of September 30, 2008 the Company has paid approximately $5,600,000 to Supernus pursuant to the agreement.

**Helsinn Chemicals SA and Helsinn Advanced Synthesis SA**

In November 2006, the Company entered into the API Supply Agreement with Helsinn Chemicals SA and Helsinn Advanced Synthesis SA ( Helsinn ) (the Helsinn Agreement ) whereby Helsinn agreed to supply trospium active pharmaceutical ingredient to the Company. Trospium active pharmaceutical ingredient is used in the production of SANCTURA XR and ALKS 27. The term of the Helsinn Agreement is seven years and contained certain minimum purchase requirements which would cease after the Company purchased a certain aggregate quantity based on the current supply price. As of September 30, 2008, the Company has paid approximately $1,900,000 to Helsinn pursuant to this agreement. This minimum purchase requirement has been transferred to Allergan pursuant to the Processing Assumption Date. Either party may also terminate this agreement under certain customary conditions of breach, and the Company may terminate the agreement if regulatory actions prohibit or materially restrict the manufacture, sale or use if the product in the United States. While retaining rights under this agreement, the Company also assigned certain rights and obligations under this agreement to Allergan, including the minimum purchase requirements, pursuant to the Processing Assumption Date.

**Catalent Pharma Solutions, Inc.**

In September 2007, the Company entered into a Manufacturing and Supply Agreement with Catalent Pharma Solutions, Inc. (now Catalent Pharma Solutions, LLC) ( Catalent ), to manufacture SANCTURA XR bulk capsules and to package them in bottles for sale and blister packages to be used as samples in the United States. In August 2008, pursuant to the Processing Assumption Date, Allergan entered into a separate agreement to manufacture and package SANCTURA XR, and the Company entered into a new agreement to manufacture SANCTURA XR bulk capsules. The agreement with Catalent terminates in September 2012, subject to earlier termination by either party under certain customary conditions of breach. The Company may terminate this agreement at any time if regulatory actions prohibit or materially restrict the manufacture, sale or use of the product in the United States.

The Company supplies Catalent the active pharmaceutical ingredient used to manufacture the SANCTURA XR capsules sold to Madaus.

**VANTAS**

**The Population Council**

The Company markets its products utilizing the Hydron Polymer Technology pursuant to its agreement with the Population Council. Subject to earlier termination by either party under certain customary conditions of breach, the term of the agreement is the shorter of twenty-five years from October 1997 or until the date on which The Population Council receives approximately $40,000,000 in payments from the Company. The Company is required to pay to The Population Council 3% of its net sales of VANTAS and any polymer implant containing an LHRH analog. The Population Council is also entitled to receive royalties ranging from 0.5% of net sales to 4% of net sales under certain conditions. The Population Council is entitled to 30% of certain profits and payments in certain territories received by the Company from the licensing of VANTAS or any other polymer implant containing an LHRH analog and 5% for other implants.

**Shire Pharmaceuticals Group plc**

Until April 2008, the Company had been marketing VANTAS pursuant to a license agreement and a related manufacturing and supply agreement with Shire plc ( Shire ). Royalties were payable to Shire for ten years from the date of the first commercial sale of VANTAS in November of 2004, and the Company was paying Shire approximately 2% of net sales of VANTAS. In April 2008, the Company entered into an agreement to terminate its manufacturing and supply agreement with Shire related to VANTAS. Under this termination agreement, Shire relinquished its right to receive royalties on net sales of VANTAS or a percentage of royalties and other consideration received by the Company relative to a sublicense of VANTAS selling and marketing rights granted by Shire. In exchange, the termination agreement provided for the Company to pay Shire a total of $5,000,000 consisting of an immediate payment of $1,000,000 and the balance of $4,000,000 in three annual installments commencing in January 2009. The Company capitalized the net present value of the total $5,000,000 payment using a discount rate of 17.5%, resulting in a $3,932,000 intangible asset. The intangible asset is being amortized from the date of the transaction over the remaining term of the original license agreement, which is approximately 6.5 years. After consideration of the $1,000,000 payment, there is approximately $1,077,000 classified as a short-term obligation and $2,121,000 classified as a long-term obligation in the consolidated September 30, 2008 balance sheet. This remaining obligation will be accreted up to its face value over the payment term through charges to interest expense.

**Orion Corporation**

In April 2008, the Company entered into a License, Supply and Distribution Agreement with Orion Corporation ( Orion ) granting Orion the rights to market VANTAS throughout Europe as well as in certain other countries. VANTAS is currently approved for the treatment of advanced prostate cancer in Denmark, the United Kingdom and other European countries. VANTAS is currently undergoing the mutual recognition procedure for further European approvals. The Company received a $7,000,000 up-front payment and could receive certain additional contingent payments related to approvals and sales thresholds aggregating up to $14,000,000. The $7,000,000 payment represents the aggregate amounts paid to the Company pursuant to this Agreement through September 30, 2008. Additionally, the Company has agreed to supply VANTAS to Orion at a pre-determined transfer price subject to annual minimum purchase requirements beginning in 2009. The agreement expires in April 2023, subject to earlier termination by either party under certain customary conditions of breach. The Agreement will automatically renew for one-year periods at a time, subject to the right of either party to terminate the agreement at any time effective at the end of the initial 15-year term or any subsequent one-year renewal period thereafter with at least six months prior written notice to the other party. Commencing on the first sale of product to Orion, the Company will recognize the $7,000,000 up-front payment as revenue over the 15-year term of the agreement in accordance with the proportional performance method using the minimum supply quantities to estimate completion of the earnings process. Expected performance will be assessed quarterly to incorporate changes in estimates and payments received.

**DELATESTRYL**

**Savient**

In January 2006, the Company acquired DELATESTRYL, an injectable testosterone therapy for the treatment of hypogonadism, from Savient. Under the terms of the acquisition, the Company is obligated to pay royalties to Savient for three years from January 2008 based upon the cumulative net sales of DELATESTRYL. Through September 30, 2008, the Company has paid approximately $6,600,000 to Savient in connection with this arrangement.

**NEBIDO**

**BayerSchering**

In July 2005, the Company licensed exclusive U.S. rights from BayerSchering to market NEBIDO, a long-acting injectable testosterone preparation for the treatment of hypogonadism (the BayerSchering Agreement ). The Company is responsible for the development and commercialization of NEBIDO in the United States. BayerSchering is responsible for manufacturing and supplying the Company with finished product. The Company agreed to pay to BayerSchering up to $30,000,000 in up-front, regulatory milestone, and commercialization milestone payments, including a $7,500,000 up-front payment paid in August 2005 and a $5,000,000 payment due upon approval by the FDA to market the product. Through September 30, 2008, the Company has paid in aggregate approximately $9,500,000 under this agreement. The Company also agreed to pay to BayerSchering 25% of net sales of NEBIDO to cover both the cost of finished product and royalties. This agreement extends to ten years from the first commercial sale of NEBIDO. Either party may also terminate this agreement under certain customary conditions of breach, and BayerSchering may terminate this agreement if there was a change in control of Indevus, as defined in the agreement.

In October 2006, the Company entered into a supply agreement with BayerSchering under which the Company finalized terms of its July 2005 license for the manufacture and the supply of NEBIDO from BayerSchering. Pursuant to the terms of this agreement, BayerSchering agreed to manufacture and supply the Company with all of its requirements for NEBIDO for a supply price based on net sales of NEBIDO. The supply price is applied against the 25% of net sales owed to BayerSchering pursuant to the BayerSchering Agreement. This agreement expires ten years from the first commercial sale of NEBIDO.

**VALSTAR**

**Plantex**

The Company has a supply agreement with Plantex USA Inc. ( Plantex ), whereby Plantex will supply the Company with the active pharmaceutical ingredient for VALSTAR called Valrubicin. The Agreement will expire ten years after the date of the first commercial sale of VALSTAR provided VALSTAR is approved by June 30, 2009. Beginning in the calendar year following the year in which it receives regulatory approval for VALSTAR in the U.S., the Company will have annual minimum purchase requirements of $1,000,000. This agreement may be terminated by either party under certain customary conditions of breach, by mutual agreement of the parties, or by Plantex if Valrubicin is not approved by June 30, 2009.

**PAGOCLONE**

**Sanofi-aventis**

In February 1994, the Company licensed from Rhone-Poulenc Rorer, S.A., now sanofi-aventis, ( sanofi-aventis ), exclusive, worldwide rights for the manufacture, use and sale of pagoclone under patent rights and know-how related to the drug, except that the Company granted sanofi-aventis an option to sublicense, under certain conditions, rights to market pagoclone in France. In exchange, the Company paid sanofi-aventis a license

fee and agreed to make milestone payments based on clinical and regulatory developments, and to pay royalties based on net sales through the expiration of the composition of matter patent. If sublicensed, the Company would pay to sanofi-aventis a portion of receipts from the sublicensee in lieu of payments. Under the terms of the agreement with sanofi-aventis, the Company is responsible for all costs of developing, manufacturing, and marketing pagoclone. This agreement expires with respect to each country upon the last to expire applicable patent. Additionally either party may also terminate this agreement under certain customary conditions of breach. Through September 30, 2008, the Company has paid approximately $3,800,000 pursuant to this agreement. The Company would owe an additional $5,500,000 if the Company successfully achieves remaining development milestones, as well as royalties on net sales or a percentage of royalties it receives if the product is sublicensed.

**Teva**

In September 2008, the Company entered into a development, license and commercialization agreement with Teva Pharmaceutical Industries Ltd. ( Teva ) for the exclusive, worldwide rights to pagoclone (the Teva Agreement ). Under the terms of the Teva Agreement, the Company will conduct, and Teva will reimburse expenses for, a Phase IIb study for stuttering.

Following the completion of a successful Phase IIb study, the Teva Agreement provides for the parties to share equally development and marketing costs and future profits for the U.S., and the Company would receive certain potential milestone payments. Under certain circumstances, either party may convert the Teva Agreement from the equal sharing arrangement to a royalty structure where Teva will be responsible for all development and commercial costs in the U.S., and the Company would receive royalties on potential net sales, in addition to milestones. In either case, if the arrangement continues, Teva will be responsible for the conduct of all remaining development, including the Phase III program.

Under the equal sharing arrangement, the Company could receive up to $92,500,000 in U.S. and European development milestones and payments, including approximately $10,000,000 of contractual payments to be received during the first thirteen months after the commencement date. In the event of a conversion to the royalty structure, in addition to the $92,500,000 of milestones and payments, the Company could receive up to $50,000,000 in U.S.-based sales threshold milestones. For territories outside of the U.S., Teva will be responsible for all future development and commercialization, and the Company will receive milestones and royalties on net sales.

The Teva Agreement became effective in November 2008. The term will extend on a country-by-country basis from the effective date to the later of 12 years from first commercial sale or the last valid claim in a country in the territory. Teva may terminate the Teva Agreement (i) by giving notice within a certain time frame from the completion of the Phase IIb study (the Next Trial ), and (ii) anytime with a specified advance notice, except no such termination will be effective until the completion of any ongoing clinical trial. If Teva terminates the Teva Agreement after a product is approved, the Company will pay Teva royalties on its revenues up to an aggregate of certain amounts expended by Teva on development and commercialization. Either party may terminate the Teva Agreement upon certain customary conditions of breach.

**PRO 2000**

**Paligent, Inc.**

In June 2000, the Company licensed exclusive, worldwide rights from Paligent, Inc. (formerly HeavenlyDoor.com and Procept, Inc.) to develop and market PRO 2000, in exchange for an up-front payment, future milestone payments, and royalties on net sales. In April 2003, the Company amended the terms of the PRO 2000 licensing agreement and purchased all rights to PRO 2000.

**MRC**

In July 2005, the Company entered into the Collaborative Research and Licensing Agreement with the MRC, an agency of the United Kingdom. In exchange for the right to have PRO 2000 included in the MRC s approximately 10,000 person Phase III clinical trial studying the prevention of the transmission of HIV and other sexually-transmitted diseases to be conducted primarily in Africa and India and the right to use the results of this trial, the Company agreed to grant to the MRC a non-exclusive license to PRO 2000 solely for its use in the Phase III trial and also to supply, at no cost to the MRC, all PRO 2000 and placebo required for the Phase III trial. The MRC will be responsible for all other trial costs. Additionally, the Company agreed to make PRO 2000 available in developing countries with high need under a license agreement to be negotiated in good faith, or to supply to the MRC PRO 2000 to be distributed in these developing countries at its cost plus a markup pursuant to a supply agreement to be negotiated. The Company will pay the MRC a minimal royalty on sales of PRO 2000 in developed countries. The term of this agreement will extend to ten years from the date of first commercial sale in a developed country.

**HYDRON POLYMER TECHNOLOGY**

In November 1989, GP Strategies Corporation ( GP Strategies ), then known as National Patent Development Corporation, entered into an agreement (the Hydron Agreement ) with Dento-Med Industries, Inc., now known as Hydron Technologies, Inc. In June 2000, Valera entered into a contribution agreement with GP Strategies, pursuant to which Valera acquired the assets of GP Strategies drug delivery business, including all intellectual property, the Hydron Agreement, and certain other agreements with The Population Council, Inc. and Shire US, Inc.

Pursuant to the Hydron Agreement, the Company has the exclusive right to manufacture, sell or distribute any prescription drug or medical device and certain other products made with the Hydron polymer, while Hydron Technologies was granted an exclusive, worldwide license to manufacture, market or use products composed of, or produced with the use of, the Hydron polymer in certain consumer and oral health fields. Neither party is prohibited from manufacturing, exploiting, using or transferring the rights to any new non-prescription drug product containing the Hydron polymer, subject to certain exceptions, for limited exclusivity periods. Subject to certain conditions and exceptions, the Company is obligated to supply certain types of Hydron polymers if Hydron Technologies elects to purchase them from the Company. In the event the Company withdraws from the business of manufacturing the Hydron polymer, the Company will assign all of its right and interest in the Hydron trademark to Hydron Technologies. The agreement continues indefinitely, unless terminated earlier by the parties. Each party may owe royalties up to 5% to the other party on certain products under certain conditions.

**AMINOCANDIN**

**Sanofi-aventis**

The Company licensed exclusive, worldwide rights to aminocandin from sanofi-aventis in April 2003 (the Aminocandin Agreement ). In exchange for these rights and for sanofi-aventis inventory of aminocandin, the Company made an up-front payment to sanofi-aventis and is obligated to pay potential milestone payments and royalties on future sales. As of September 30, 2008, the Company has paid approximately $2,175,000 to sanofi-aventis pursuant to this agreement.

**Novexel**

In December 2006, the Company licensed its know-how related to aminocandin to Novexel (the Novexel Agreement ) for an up-front payment and potential future development and sales milestones aggregating approximately $44,500,000 for injectable and oral formulations of the product, and royalties on net sales

(the Novexel Agreement ) and. sanofi-aventis assigned the Aminocandin Agreement to Novexel. Effective as of the date of the Novexel Agreement, the Company entered into a termination agreement with Novexel terminating the Aminocandin Agreement. Pursuant to the Novexel Agreement, Novexel now is responsible for all future development, manufacturing, marketing and financial obligations relating to aminocandin. The Novexel Agreement will terminate on a country-by-country basis, at the later of the last to expire Novexel patent relating to aminocandin existing as of the date of the agreement or ten years from the first commercial sale of the product. Either party may terminate the Novexel Agreement upon certain customary conditions of breach. Also, Novexel may terminate the agreement following certain notice periods, (a) upon the occurrence of a material adverse change relating to the compound or product, or (b) after the earlier of (i) the commencement of the first Phase II clinical trial for the compound or product, or (ii) fifteen months after the date of the agreement. As of September 30, 2008, the Company has received approximately $1,500,000 from Novexel pursuant to this agreement.

***SARAFEM***

**Lilly**

In June 1997, the Company entered into an agreement with Eli Lilly ( Lilly ), under which it sublicensed to Lilly exclusive, worldwide rights under a Massachusetts Institute of Technology ( 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 premenstrual syndrome ( PMS ). In July 2000, Lilly received approval for fluoxetine, which is marketed under the trade name Sarafem, to treat a severe form of PMS. The Company will receive royalties on net sales of Sarafem until the expiration of its patent related to Sarafem. In January 2003, Galen Holdings PLC acquired the sales and marketing rights to Sarafem from Lilly. Through September 30, 2008, the Company has received approximately $19,600,000 from Lilly and paid approximately $3,700,000 of this amount to MIT. Royalties ceased during fiscal 2008.

***ALKS***

**Alkermes**

In January 2007, the Company announced its joint collaboration with Alkermes for the development of ALKS 27, an inhaled formulation of trospium chloride for the treatment of COPD using Alkermes proprietary AIR® pulmonary delivery system. Pursuant to the collaboration agreement, the Company and Alkermes shared equally in all costs of the development and commercialization of ALKS 27 on a worldwide basis. Alkermes performed all formulation work and manufacturing. The Company conducted the clinical development program. This agreement will continue in effect until both parties have met to review the results of the feasibility study and decide whether to continue development and enter into a new collaboration agreement, seek a commercialization partner or terminate the agreement. Certain provisions apply if either one party does not wish to continue. Also, either party may terminate this agreement under certain customary conditions of breach.

In April 2008, the Company received from Alkermes, Inc. a letter purporting to terminate the Feasibility Agreement dated as of February 4, 2005 between the Company and Alkermes. The Company and Alkermes have been engaged in discussions with several third parties relating to the further development and commercialization of this product and with each other to provide for further development by the Company and Alkermes. The Company disputes Alkermes position that this agreement has terminated and intends to pursue vigorously its rights and remedies under this agreement and applicable law. The Company owns or has an exclusive license to various know-how, and owns the IND, relating to the product that has been under development by the Company and Alkermes. The Company also has certain rights to joint intellectual property.

Alkermes has agreed to submit to the dispute resolution procedures set forth in the Feasibility Agreement to reach a resolution of these contractual issues.

**IP 751**

**Manhattan Pharmaceuticals**

In June 2002, the Company licensed exclusive, worldwide rights to IP 751 from Manhattan Pharmaceuticals, Inc. (formerly known as Atlantic Technology Ventures, Inc.), ( Manhattan ), in exchange for an up-front licensing payment, potential development milestones, and royalty payments. In August 2003, the Company terminated the license and acquired from Manhattan all its intellectual property rights to IP 751 in exchange for a combination of cash and equity payments from us to Manhattan. In August 2003, the Company also entered into an agreement with Sumner Burstein, Ph.D., the owner of certain intellectual property rights related to IP 751 under which Dr. Burstein granted to it an exclusive, worldwide license to these rights in exchange for up-front milestone payments and other consideration totaling approximately $4,300,000, of which approximately $3,600,000 pertains to potential future milestone payments, as well as potential future royalty payments on product sales, if any. The term of the Burstein License continues in effect on a country-by-country basis until the date of the expiration of the last to expire Burstein patent in such country, subject to earlier termination by either party. In November 2008, the Company issued its notice of termination.

**Cervelo Pharmaceuticals**

In October 2007, the Company licensed its worldwide rights to IP 751 to Cervelo Pharmaceuticals, Inc. and received an upfront payment of $1,000,000. Cervelo is responsible for the development and marketing of IP 751. In November 2008, the Company issued its notice of termination.

**R. Subsidiary**

CPEC LLC is owned 65% by the Company and 35% by Aeolus Pharmaceuticals, Inc. ( Aeolus ) (formerly Incara Pharmaceuticals, Inc.) and was developing bucindolol, a nonselective beta-blocker for treatment of congestive heart failure. In October 2003, CPEC LLC licensed its bucindolol development and marketing rights to ARCA Discovery, Inc. ( ARCA ) in exchange for potential future milestone and royalty payments (the ARCA Agreement ). In fiscal 2006, the Company amended its agreement with ARCA resulting in $1,266,000 of license fee revenue, $1,000,000 of which was received in cash. In fiscal 2008, CPEC LLC received from ARCA a $500,000 milestone related to ARCA s filing of an NDA for bucindolol. As a result of the FDA s acceptance of the bucindolol for filing, the Company incurred a liability of $750,000 to be paid in Indevus Common Stock to the original licensor to the Company of bucindolol. Aeolus is liable to Indevus for 55% of this liability which it may pay in the form of Aeolus common stock. If the bucindolol NDA is approved, the Company would have a similar liability that could range from $750,000 to $1,875,000 in value depending upon the price of Indevus Common Stock to be issued at the time the payment is due. CPEC LLC or ARCA may terminate the ARCA Agreement under certain customary conditions of breach. The accounts of CPEC LLC are included in the Company s consolidated financial statements.

**S. Liquidity**

The Company is subject to risks common to companies in the specialty pharmaceutical industry including, but not limited to, development by its competitors of new technological innovations, dependence on key personnel, its ability to protect proprietary technology, reliance on corporate collaborators and licensors to successfully research, develop and commercialize products based on the Company s technologies, its ability to comply with FDA government regulations and approval requirements, its ability to grow its business and its ability to obtain adequate financing to fund its current and planned operations. The Company expects to continue to incur substantial expenditures for the development, commercialization and marketing of its products. In addition, the Company s Convertible Notes 2009 of $71,925,000 will become due in July 2009. The Company believes its current and expected cash resources are sufficient to fund its operations through approximately the first calendar quarter of 2010. The Company will need to obtain additional funding through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of

financing. There can be no assurance that such funds will be available to the Company. The failure to raise such funds would result in the need to significantly curtail the Company s operating activities and delay development efforts, which would have a material adverse effect on the Company.

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

| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| **Fiscal 2008** | | | | |
| Total revenues | $ 16,398,000 | $ 17,643,000 | $ 20,419,000 | $ 23,331,000 |
| Net loss | (14,703,000) | (17,906,000) | (18,964,000) | (13,978,000) |
| Net loss per common share, basic and diluted | $ (0.19) | $ (0.23) | $ (0.25) | $ (0.18) |
| **Fiscal 2007** | | | | |
| Total revenues | $ 13,151,000 | $ 11,224,000 | $ 12,225,000 | $ 29,467,000 |
| Net loss | (10,299,000) | (12,439,000) | (72,335,000) | (8,753,000) |
| Net loss per common share, basic and diluted | $ (0.18) | $ (0.22) | $ (1.02) | $ (0.12) |