FORM 10–K
INDEVUS PHARMACEUTICALS INC – IDEV
Filed: December 07, 2006 (period: September 30, 2006)
Annual report which provides a comprehensive overview of the company for the past year
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Indevus Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

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

33 Hayden Avenue
Lexington, MA 02421−7966
(Address of principal executive offices) (Zip Code)

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

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

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

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

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 ☑

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 ☑ NO □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non−accelerated filer. See definition of “accelerated filer and large accelerated filer” in Rule 12b−2 of the Exchange Act. (Check one):

Large accelerated filer □ Accelerated filer ☑ Non−accelerated filer □

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

The aggregate market value of the voting and non−voting common equity (excluding preferred stock convertible into 622,000 shares of Common Stock and having voting rights on certain matters equivalent to 568,750 shares of Common Stock) held by non−affiliates of the registrant was approximately $289,000,000, based on the last sales price of the Common Stock as of March 31, 2006. Shares of Common Stock held by each executive officer and director and each person who beneficially owns 10% or more of the outstanding Common Stock and individuals or entities related to such persons have been excluded. This determination of affiliate status may not be conclusive for other purposes.

As of December 1, 2006, 56,065,456 shares of Common Stock, $.001 par value per share, of the registrant were issued and outstanding.
DOCUMENTS INCORPORATED BY REFERENCE

See Part III hereof with respect to incorporation by reference from the registrant’s definitive proxy statement for the fiscal year ended September 30, 2006 to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 and the Exhibit Index beginning on page number 59 hereto.

PART I

Note Regarding Forward Looking Statements

Statements in this Form 10−K that are not statements or descriptions of historical facts are “forward looking” statements under Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward−looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA® (trospium chloride tablets), SANCTURA XR™ (once−daily SANCTURA) and NEBIDO® (testosterone undecanoate); our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux™−related litigation. The words “believe,” “expect,” “anticipate,” “intend,” “plan,” “estimate” or other expressions which predict or indicate future events and trends and do not relate to historical matters identify forward−looking statements. Readers are cautioned not to place undue reliance on these forward−looking statements as they involve risks and uncertainties and such forward−looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under “Risk Factors” and elsewhere in, or incorporated by reference into, this Form 10−K. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR, and NEBIDO; the early stage of product candidates under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR and NEBIDO; risks associated with contractual agreements, particularly for the manufacture and co−promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO; dependence on third parties for manufacturing, marketing and clinical trials; competition; need for additional funds and corporate partners, including for the development of our products; failure to acquire and develop additional product candidates; history of operating losses and expectation of future losses; product liability and insurance uncertainties; risks relating to the Redux−related litigation; our reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity; valuation of our common stock; risks related to repayment of debts; risks related to increased leverage; and other risks. The forward−looking statements represent our judgment and expectations as of the date of this Form 10−K. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward looking statements. See “Risk Factors.”

Unless the context indicates otherwise, “Indevus”, the “Company”, “we”, “our” and “us” refer to Indevus Pharmaceuticals, Inc., and “Common Stock” refers to the common stock, $.001 par value per share, of Indevus. Our registered trademark “SANCTURA” is assigned in the U.S. to Esprit Pharma, Inc. (subject to our co−exclusive right to use it) and “NEBIDO” is a registered trademark of Schering AG, Germany that we exclusively license in the United States. “DELATESTRYL” is our registered trademark for our DELATESTRYL® product. We have pending trademark applications for SANCTURA XR. Other trademarks, trade names and service marks used in this Form 10−K are the property of their respective owners.

Where You Can Find More Information

We are subject to the information and reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, under which we file periodic reports, proxy and information statements and other information with the SEC. Copies of the reports, proxy statements and other information may be examined without charge at
ITEM 1. Business

Overview

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

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

In addition to our core urology, gynecology and men’s health portfolio, we are preparing to begin a Phase III development program for pagoclone, a GABA (gamma amino butyric acid) receptor modulator which we are developing for the treatment of persistent developmental stuttering. Our product portfolio also contains aminocandin, an echinocandin for systemic fungal infections for which we recently licensed worldwide rights to Novexel S.A. (“Novexel”). We also are receiving royalties under a patent we licensed to Eli Lilly & Company (“Lilly”) based on net sales of Sarafem® in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual dysphoric disorder.

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

Our Strategy

Our goal is to become a leading biopharmaceutical company focused in urology, gynecology and men’s health. The key elements of our strategy that we employ in our efforts to achieve our goal include:

1. Identifying and acquiring products, product candidates, or products that have differentiating features and defined specialty markets within our core focus area.

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

3. Commercializing products independently with our specialty sales force or in collaboration with corporate partners in order to help ensure broader penetration of target markets.
Core Focus Area—Urology, Gynecology, Men’s Health

In the urology, gynecology and men’s health markets, we believe we have developed strong capabilities in product development based on our research and development organization and in sales and marketing based on our approximately 85 person specialty sales force.

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

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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Indication/Use</th>
<th>Status</th>
<th>Commercial Rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>SANCTURA</td>
<td>Overactive bladder</td>
<td>Marketed</td>
<td>U.S.</td>
</tr>
<tr>
<td>SANCTURA XR</td>
<td>Overactive bladder</td>
<td>NDA submitted</td>
<td>Worldwide</td>
</tr>
<tr>
<td>DELATESTRYL</td>
<td>Hypogonadism</td>
<td>Marketed</td>
<td>U.S.</td>
</tr>
<tr>
<td>NEBIDO</td>
<td>Hypogonadism</td>
<td>Phase III</td>
<td>U.S.</td>
</tr>
<tr>
<td>PRO 2000</td>
<td>HIV and STD prevention</td>
<td>Phase III</td>
<td>Worldwide</td>
</tr>
<tr>
<td>IP 751</td>
<td>Interstitial cystitis/pain</td>
<td>Phase I</td>
<td>Worldwide</td>
</tr>
</tbody>
</table>

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

SANCTURA

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

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

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

OAB is a medical condition whose symptoms include urinary frequency, urgency, and urge incontinence, the accidental loss of urine that occurs after the strong, sudden urge to urinate. An estimated 33 million Americans suffer from OAB. In 2005, the market for drugs to treat OAB was approximately $1.4 billion in the United States. OAB represents a significant clinical problem with potential medical, hygienic, and social consequences. When untreated, this condition can lead to disability, dependence, and isolation from the community. It is most prevalent among the elderly and strikes women twice as frequently as men.

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

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
Development Program. On May 28, 2004, the FDA approved the NDA for SANCTURA. The NDA included data from 34 clinical studies conducted in the U.S. and Europe involving approximately 3,000 subjects.

Our development program for SANCTURA has included two randomized, double-blind, placebo-controlled Phase III trials conducted in the U.S. that were submitted in the NDA. The first trial included 523 patients who were studied at 51 sites. The second trial included 658 patients who were studied at 52 sites. Both trials were three-month trials and measured the effects of 20 milligrams (mg) of SANCTURA versus placebo, twice-daily, on symptoms of OAB. Patients treated with SANCTURA experienced statistically significantly fewer toilet voids per day at the end of the three-month trial than did patients on placebo. SANCTURA treated patients also experienced statistically significantly fewer episodes of urge urinary incontinence per day at the end of the three-month trial than did placebo patients. Treatment with SANCTURA also led to a significant improvement (decrease) in average urgency severity, another key symptom of OAB.

Across the two Phase III trials, the most common adverse events considered possibly related to treatment were dry mouth (20.1% for SANCTURA vs. 5.8% for placebo), constipation (9.6% for SANCTURA vs. 4.6% for placebo) and headache (4.2% for SANCTURA vs. 2.0% for placebo). Like other products in this class, SANCTURA is contraindicated in patients with or at risk for urinary retention, gastric retention, uncontrolled narrow-angle glaucoma and in patients who have demonstrated hypersensitivity to the drug or its ingredients.

Commercialization. We currently co-promote SANCTURA in the U.S. with Esprit. To support the commercialization of SANCTURA and as a platform for future growth, we have a sales and marketing infrastructure which includes a specialty sales force consisting of 85 sales representatives who call on urologists and other prescribers specializing in treating patients with OAB. Effective July 1, 2005, Esprit acquired the rights to market SANCTURA in the U.S. from Odyssey Pharmaceuticals, Inc. ("Odyssey"), a specialty-branded subsidiary of PLIVA d.d. ("PLIVA"). See “AGREEMENTS.”

SANCTURA XR

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

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

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

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

Our development program for SANCTURA XR included two randomized, double-blind, placebo-controlled Phase III trials conducted in the U.S. that were submitted in the NDA. We announced positive data from the first Phase III trial in June 2006 and positive data from the second Phase III trial in July 2006. The first trial included 601 patients who were studied at 55 sites. The second trial included 564 patients who were studied at 62 sites. Both trials were 12-week trials and measured the effects of 60 mg of SANCTURA XR versus placebo, once-daily, on symptoms of OAB. Patients treated with SANCTURA XR experienced statistically significantly fewer
toilet voids per day at the end of the 12-week trial than did patients on placebo. SANCTURA XR treated patients also experienced statistically significantly fewer episodes of urge urinary incontinence per day at the end of the 12-week trial than did placebo patients. Treatment with SANCTURA XR also led to a statistically significant improvement (decrease) in average urgency severity, another key symptom of OAB. Additionally, SANCTURA XR had a rapid onset of action and achieved a statistically significant difference from placebo as early as Week 1 of therapy for key efficacy endpoints. The most common anticholinergic side effects were dry mouth (10.7% of the SANCTURA XR treated patients compared to 3.7% of the placebo treated patients) and constipation (8.5% of the SANCTURA XR treated patients compared to 1.5% of the placebo treated patients).

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

NEBIDO

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

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

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

Development Program. Schering has obtained approvals throughout Europe (by Mutual Recognition Procedure with Finland as Reference Member State, including first national approval November 25, 2003, EU approval July 7, 2004; new EU member states approval March 27, 2005). Subsequently, this formulation of testosterone undecanoate depot injection has been approved in over 80 countries under the trade names NEBIDO and Reandron.

As part of our development program we are conducting a pharmacokinetic study following a minimum of 100 hypogonadal men for 48 weeks to supplement the existing Schering clinical database. We completed enrollment in the trial in June 2006 and expect to complete the trial in the second quarter of calendar 2007. Assuming positive results, we anticipate submitting an NDA in mid-2007. The existing database from Schering’s clinical development program contains over 300 patients that have been treated for up to eight years in five clinical trials. These studies assessed the pharmacokinetic parameters of various dosing regimens of NEBIDO. These studies determined that dosing every 12 weeks following a loading interval between the first two injections of 6–8 weeks provides effective testosterone replacement in patients with hypogonadism. The Company may conduct additional trials for marketing purposes. If approved, we intend to commercialize NEBIDO in the U.S. utilizing our specialty sales force.

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
**DELATEGYRL**

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

**PRO 2000**

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

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

HIV infection usually leads to AIDS, a life-threatening impairment of the immune system. The World Health Organization estimates that over four million new adult HIV infections will occur worldwide in 2006 with the majority of the infections arising from heterosexual intercourse. Other STDs, such as genital herpes, chlamydia and gonorrhea, can lead to serious complications, especially in women, and can increase the risk of HIV infection. The Kaiser Family Foundation and the World Health Organization have estimated that there are approximately 15 million new STD cases each year in the U.S. and more than 340 million worldwide.

**Development Program.** PRO 2000 is being studied, as the only agent, in a large, multi-national Phase III trial sponsored by the Microbicides Development Programme (“MDP”), an international partnership to develop and test vaginal microbicides. The MDP was established in February 2002 with funding of approximately $22,700,000 from the United Kingdom’s Department for International Development. The program is administered by the Clinical Trials Unit of the Medical Research Council (“MRC”) and Imperial College in London, and involves researchers in the U.K., Cameroon, South Africa, Tanzania, Uganda and Zambia. This trial commenced in October 2005, and is designed to examine the safety and efficacy of PRO 2000 in preventing HIV infection and transmission of other STDs in women. An estimated 10,000 women will be enrolled in this trial that is expected to last approximately three to four years and include interim analyses of safety and efficacy data conducted by an independent data safety monitoring board. As of September 30, 2006, approximately 2,600 women have been enrolled in the trial.

PRO 2000 is also being studied, as one of two investigational topical microbicides, in a large, multi-national Phase II/III clinical trial sponsored by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (“NIH”). The trial, which commenced in February 2005, is designed to examine the safety and effectiveness of two candidate topical microbicides, including PRO 2000, in preventing HIV infection and transmission of other STDs in women. Approximately 3,200 women will be enrolled in the study at multiple sites in Africa and the U.S. and is expected to last 30 months and include interim analyses of safety and efficacy data conducted by an independent data safety monitoring board. As of September 30, 2006, approximately 1,700 women have been enrolled in the trial.

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
Also in February 2005, findings from a study performed at the Mount Sinai School of Medicine were presented at the 12th Conference on Retroviruses and Opportunistic Infections. These data demonstrated that PRO 2000 retains activity against HIV and the herpes simplex virus following intervaginal administration to HIV–infected women. The study, funded by the NIH, marks the first time that the anti–viral activity of a microbicide has been demonstrated following human application.

Prior to the initiation of the Phase III trials in 2005, a number of pre–clinical and early clinical studies with PRO 2000 had been completed under the sponsorship of government agencies and research organizations in the U.S., Europe, Africa and India. Pre–clinical development with PRO 2000 included an NIH–funded study with 28 female macaque monkeys, divided equally into one control group and three treatment groups that received gels with 0.5% PRO 2000, 2% PRO 2000, and 4% PRO 2000 concentrations. All of the control animals were infected within two weeks after receiving the simian human immunodeficiency virus, and went on to develop AIDS symptoms. Of the treated animals, none in the 0.5% group, and one each in the 2% and 4% groups became infected and developed disease.

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

**IP 751**

*General.* IP 751 is believed to be a non–psychoactive synthetic derivative of tetrahydrocannabinol (THC) and is in pre–clinical development to treat interstitial cystitis. IP 751 appears to suppress various inflammatory cytokines which are implicated in pain and inflammation.

We believe IP 751 also has a broad potential to treat other pain and inflammatory conditions such as arthritis, post–operative pain, and musculoskeletal injuries. In addition, IP 751 may be useful in treating non–inflammatory conditions such as headache and neuropathic pain, as well as other specialty–focused indications. Pre–clinical studies suggest that IP 751 may lack the gastrointestinal ulceration associated with NSAIDs (non–steroidal anti–inflammatory agents) and the cardiovascular effects seen with cyclooxygenase–2 (COX–2) inhibitors.

Interstitial cystitis is an extremely painful and often debilitating condition that results in recurring discomfort or pain in the bladder and the surrounding pelvic region. Interstitial cystitis is far more common in women than in men. Of the estimated one million Americans with interstitial cystitis, approximately 90% are women.

*Development Program.* In March 2005, we announced the results of a study conducted at the University of Pittsburgh that showed that administration of IP 751 significantly reduces the bladder overactivity observed in an animal model of interstitial cystitis. IP 751 suppressed the overactivity in a dose dependent manner and at the highest doses completely reversed the excessive bladder contractility to normal function. In addition, IP 751 appeared to have no effect on the normal voiding mechanism of the bladder. We have now completed additional studies confirming these results.

We also believe that IP 751 will have significant applications in multiple areas of chronic and acute pain, including neuropathic and inflammatory pain. An Investigational New Drug Application (“IND”) has been filed with the FDA, and an initial Phase I clinical trial designed to assess the safety of IP 751 showed that it was well tolerated, with no clinically significant adverse events and no evidence of psychotropic activity. In December 2002, we successfully completed a Phase II trial for IP 751 in neuropathic pain. In this trial, patients experienced significantly less pain when treated with IP 751 compared with placebo, and showed no significant differences in adverse events in comparison to placebo. Most notably, the lack of psychoactive properties related to IP 751 was confirmed in this study. We are currently considering strategic partners for future development and commercialization of IP 751.
Our Other Products

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

The following table summarizes the status of our other products:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Indication/Use</th>
<th>Status1</th>
<th>Commercial Rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sarafem</td>
<td>Premenstrual Dysphoric Disorder</td>
<td>Marketed</td>
<td>Worldwide²</td>
</tr>
<tr>
<td>Pagoclone</td>
<td>Stuttering</td>
<td>Phase III</td>
<td>Worldwide</td>
</tr>
<tr>
<td>Aminocandin</td>
<td>Systemic fungal infections</td>
<td>Phase I</td>
<td>Worldwide³</td>
</tr>
</tbody>
</table>

1 See “Government Regulation.”
2 Licensed to Lilly
3 Know−how licensed to Novexel

Sarafem

We receive royalties under a patent we licensed to Lilly based on net sales of Sarafem in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre−menstrual syndrome (“PMS”). In January 2003, Galen Holdings PLC (“Galen”) announced the completion of the acquisition of the sales and marketing rights to Sarafem from Lilly. Our patent on Sarafem expires in November 2007 unless additional extensions are applicable.

Pagoclone

General. Pagoclone is under development as a treatment for persistent developmental stuttering. Pagoclone is a novel, non−benzodiazepine, GABA−A receptor modulator. Clinical targets to date have included panic and generalized anxiety disorders (“GAD”). In early 2005, we were granted a new method of use patent in the U.S. that covers the use of pagoclone as a therapeutic agent for stuttering. Stuttering is a disease of uncertain etiology that affects approximately three million adults and children in the United States. The treatment for stuttering consists mainly of behavioral modification and speech therapy. There are currently no drugs approved in the U.S. for the treatment of stuttering.

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

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

The primary endpoints evaluated in the double−blind phase of the study were the Frequency and Duration Subscale of the Stuttering Severity Instrument Version 3 (SSI−3), the Stuttering Severity Scale (SEV) and the Subjective Screening of Stuttering (SSS) Severity Subscore. The secondary endpoints evaluated in the study included the Clinician Global Impression−Improvement (CGI−I), the Liebowitz Social Anxiety Scale (LSAS) and the Speech Naturalness Scale (SNS). Given that this was an exploratory study, pre−specified analyses utilized 1−tailed tests of significance.
In September 2006, we announced that following an End of Phase II meeting with the FDA, we had established a clinical plan towards regulatory approval of pagoclone for the treatment of persistent developmental stuttering. Specifically, the FDA advised us to: 1) pursue pediatric studies in parallel with adult studies so that if pagoclone is effective and safe in both populations, the NDA could be approvable for the broadest possible stuttering population; 2) conduct the next adult and pediatric placebo-controlled trials as fixed dose-response studies to determine the minimally-effective dose; and 3) pursue Phase III trials under special protocol assessments (“SPA”) to allow the FDA to formally sign-off on trial designs.

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

Prior to the initiation of the Phase II stuttering trial, over 1,500 patients had participated in clinical studies with pagoclone, including three Phase II trials that demonstrated statistically significant efficacy, two in panic disorder conducted by us and one in GAD conducted by Pfizer Inc. (“Pfizer”), then our licensee. Pfizer then conducted two Phase II GAD trials and one Phase III panic disorder trial that did not show statistically significant efficacy. In all of the clinical trials, pagoclone was well-tolerated, with no clinically significant differences with respect to adverse events, such as sedation and withdrawal effects as compared with placebo.

As a result of the prior clinical programs, we have an extensive database for pagoclone including toxicology, pharmacology and manufacturing packages. We are currently evaluating commercialization options for pagoclone in parallel with our ongoing development program and preliminary market development activities.

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

**Aminocandin**

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

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

Aminocandin has shown *in vitro* and *in vivo* activity against a number of candida and aspergillus fungal species. The worldwide market for anti-fungal agents that target invasive fungal infections is currently estimated at $3.5 billion.

**Development Program.** In October 2004, we commenced a multi−dose Phase I trial of aminocandin. During dose escalation, we saw some local vein irritation as doses and concentrations increased causing us to interrupt the trial. We believe we have identified the formulation issues that caused such vein irritation and we have developed new formulations which we believe address these issues.

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

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

We believe aminocandin has a favorable systemic safety profile as well as certain differentiating properties. In December 2006, we outlicensed the know−how relating to aminocandin to Novexel.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
AGREEMENTS

SANCTURA and SANCTURA XR. In November 1999, we entered into an agreement with Madaus under which we licensed exclusive rights under Madaus’ patents and know−how to develop and market certain products, including SANCTURA in the United States. In exchange for these rights, we agreed to pay Madaus potential regulatory and sales milestone payments and royalties on net sales of the licensed products or, if sublicensed by us, a portion of royalties received by us from our sublicensee on net sales of the licensed product by the sublicensee, in lieu of royalty payments. We are responsible for all clinical development and regulatory activities and costs related to licensed products in the United States. In December 2002, we entered into a manufacturing agreement with Madaus under which Madaus produces and sells to us commercial quantities of SANCTURA in bulk form.

In March 2003, we signed a development and license agreement with Supernus under which Supernus developed once−daily, extended release formulations of SANCTURA (SANCTURA XR) and granted us exclusive worldwide rights under Supernus related patents and know−how. The agreement includes potential future development and commercialization milestone payments from us to Supernus, as well as royalties based on potential future sales of SANCTURA XR. We are responsible for all development costs and the commercialization of SANCTURA XR under this agreement.

In April 2004, we entered into a license, commercialization and supply agreement with PLIVA through its specialty−branded subsidiary, Odyssey, for the U.S. commercialization of SANCTURA for OAB (the “SANCTURA Agreement”). In May 2005, we, PLIVA and Esprit entered into an Amendment and Consent Agreement (the “Amendment and Consent Agreement”), which became effective as of July 1, 2005, pursuant to which we amended certain provisions of the SANCTURA Agreement and consented to the acquisition by Esprit of the rights to market SANCTURA in the U.S. from PLIVA and the assumption by Esprit of PLIVA’s obligations under the SANCTURA Agreement. Upon the effectiveness of the Amendment and Consent, the effective royalty rates increased and we became entitled to annual minimum royalties of $5,600,000, $7,900,000, and $10,500,000 for the first three years of the Amendment and Consent Agreement, respectively. Additionally, the annual sales force subsidy was increased to $8,800,000 from $7,700,000 through December 31, 2007, and extended for one additional year at an annual rate of $4,400,000. Further, Esprit is not subject to minimum detail and sales force requirements. Except if the context indicates otherwise, all references to the SANCTURA Agreement shall mean the agreement as amended by the Amendment and Consent.

Under the SANCTURA Agreement, we received $30,000,000 upon the initial signing, $120,000,000 upon the approval of SANCTURA by the FDA in May 2004, $10,000,000 upon initiation of the SANCTURA XR Phase III clinical trial program in September 2005, and $10,000,000 upon submission of the NDA in October 2006. In addition, we are eligible to receive an approximately $35,000,000 future payment contingent upon the approval of the NDA for SANCTURA XR, as well as a payment of $20,000,000 related to the achievement of a long−term commercialization milestone in 2013. Esprit will not have an obligation to pay the milestone of approximately $35,000,000 related to the FDA approval of the NDA for SANCTURA XR or the $20,000,000 long−term commercialization milestone and the rights to SANCTURA XR will revert to us if Esprit provides notice to us no later than the approval date that it does not intend to proceed with the launch of SANCTURA XR.

For the six months following the approval of SANCTURA, called the co−promotion period, we received a commission based on net sales of SANCTURA, a portion of which funded our own sales force and certain advertising and promotional costs. We were co−promoting SANCTURA with PLIVA through a joint sales force of approximately 500 sales representatives. We established a sales force initially numbering approximately 280 representatives promoting SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians. We exercised our right to convert the SANCTURA Agreement into a royalty−bearing structure effective November 29, 2004 (the “Conversion”). Upon the Conversion, approximately 200 of our primary care sales representatives became PLIVA employees and PLIVA became responsible for promotional,
advertising and sales force−related costs. Effective upon the Conversion, we began receiving royalties on net sales of SANCTURA and a sales force subsidy.

Under the SANCTURA Agreement, we supply SANCTURA to Esprit, which is responsible for product distribution. We are responsible for conducting and funding the development of SANCTURA XR.

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

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

NEBIDO. In July 2005, we licensed exclusive U.S. rights from Schering to market NEBIDO, a long−acting injectable testosterone preparation for the treatment of male hypogonadism (the “Schering Agreement”). We will be responsible for the development and commercialization of NEBIDO in the United States. Schering will be responsible for manufacturing and supplying us with finished product. We agreed to pay to Schering up to $30,000,000 in up−front, regulatory milestone, and commercialization milestone payments, including a $7,500,000 up−front payment paid in August 2005 and a $5,000,000 payment due upon approval by the FDA to market the product. We also agreed to pay to Schering 25% of net sales of NEBIDO to cover both the cost of finished product and royalties.

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

DELATESTRYL. In January 2006, we acquired DELATESTRYL, an injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient, for a total purchase price of $6,800,000 and accounted for the transaction as the purchase of an asset. Upon closing, we paid Savient $5,600,000 and we owe Savient an additional $1,300,000 which is payable in two installments of approximately $644,000 on the first and second anniversary of the closing. Additionally, we assumed Savient’s previous obligation to purchase approximately $1,100,000 of additional DELATESTRYL inventory. We believe the supplier defaulted on its
obligation to provide DELATESTRYL in the time required and we believe we are no longer obligated to purchase this inventory. However, in the event the supplier was able to demonstrate compliance with the agreement and we were obligated to purchase such inventory, we may be required to provide a reserve for at least a portion of the value of this inventory.

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

**PRO 2000.** In June 2000, we licensed exclusive, worldwide rights from Paligent, Inc. (formerly HeavenlyDoor.com and Procept, Inc.) (“Paligent”) to develop and market PRO 2000, in exchange for an up-front payment, future milestone payments, and royalties on net sales. We are responsible for all remaining development and commercialization activities for PRO 2000.

In April 2003, we amended the terms of the PRO 2000 licensing agreement. Paligent agreed to relinquish a potential future $500,000 milestone payment and provide us with an option to acquire all rights to PRO 2000 by a certain future date in exchange for an immediate $500,000 payment and an optional buyout payment. In September 2004, we exercised this option and made a $500,000 buyout payment to Paligent for the acquisition of all rights to PRO 2000.

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

**IP 751.** In June 2002, we licensed exclusive, worldwide rights to IP 751 from Manhattan Pharmaceuticals, Inc. (formerly known as Atlantic Technology Ventures, Inc.) (“Manhattan”), in exchange for an up-front licensing payment, potential development milestones and royalty payments. In August 2003, we terminated the license and acquired from Manhattan all its intellectual property rights to IP 751 in exchange for a combination of cash and equity payments from us to Manhattan. In August 2003, we also entered into an agreement with Sumner Burstein, Ph.D., the owner of certain intellectual property rights related to IP 751 under which Dr. Burstein granted to us an exclusive, worldwide license to these rights in exchange for up-front, milestone and royalty payments. We are responsible for the clinical development, regulatory review activities and commercialization of this compound.

**Pagoclone.** In February 1994, we licensed from Rhone-Poulenc Rorer, S.A., now Aventis, S.A. (“Aventis”), exclusive, worldwide rights for the manufacture, use and sale of pagoclone under patent rights and know-how related to the drug, except that we granted Aventis an option to sublicense from us, under certain conditions, rights to market pagoclone in France. In exchange, we paid Aventis a license fee and agreed to make milestone payments based on clinical and regulatory developments, and to pay royalties based on net sales through the expiration of the composition of matter patent. If sublicensed by us, we would pay to Aventis a portion of receipts from the sublicensee in lieu of payments. Under the terms of our agreement with Aventis, we are responsible for all costs of developing, manufacturing, and marketing pagoclone.

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
Aminocandin. We licensed exclusive, worldwide rights to aminocandin from Aventis in April 2003 (the “Aminocandin Agreement”). In exchange for these rights and for Aventis’ inventory of aminocandin, we made an up-front payment to Aventis and are obligated to pay potential milestone payments and royalties on future sales. Under the Aminocandin Agreement, we are responsible for all development and commercialization activities for both intravenous and oral formulations of aminocandin. Aventis has agreed to manufacture the key component of aminocandin, using its proprietary fermentation technology.

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

Sarafem. In June 1997, we entered into an agreement with Lilly, under which we sublicensed to Lilly exclusive, worldwide rights under a Massachusetts Institute of Technology ("MIT") patent that was licensed exclusively by MIT to us and which is directed to the use of fluoxetine to treat certain conditions and symptoms associated with PMS. In July 2000, Lilly received approval for fluoxetine, which is marketed under the trade name Sarafem, to treat a severe form of PMS. Lilly’s composition of matter patent on fluoxetine expired in July 2001. The Lilly agreement provided for milestone payments and royalties based on net sales of fluoxetine attributable to the approved indication in the U.S. up to an annual maximum limit. In December 2002, we entered into a renegotiated licensing agreement with Lilly providing us an initial payment upon the signing of the agreement and future royalty payments from Lilly based on net sales of Sarafem in the U.S. from October 2002 until the November 2007 expiration of our patent related to Sarafem unless additional extensions are applicable. In addition, the agreement includes other potential milestone payments to us from Lilly. In January 2003, Galen Holdings PLC announced the completion of the acquisition of the sales and marketing rights to Sarafem from Lilly. Pursuant to our agreement with Lilly, the remaining milestone payments were accelerated and received by us from Lilly.

Citicoline. Effective January 2004, we entered into a new agreement with Ferrer International, S.A. (“Ferrer”) superseding our January 1993 agreement and covering the development, manufacture, and marketing of citicoline in the U.S. and Canada. Under the terms of the new agreement, we have granted Ferrer exclusive rights to our patents and know−how related to citicoline. In exchange, Ferrer agreed to assume all future development, manufacturing, and commercialization costs of citicoline. Indevus will receive 50% of all milestone payments made to Ferrer by a third party and royalties on net sales of the product. In October 2004, IVAX Corporation (“IVAX”) announced a licensing agreement between Ferrer and IVAX for citicoline. Under the terms of this agreement, IVAX will be responsible for fulfilling the requirements for FDA approval of citicoline for acute stroke and for commercializing citicoline in the United States.

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
MANUFACTURING AND MARKETING

General. We currently have no direct manufacturing capabilities. For both clinical trials and commercialized products, we rely on third parties to manufacture our products. We expect to market our products ourselves or through co-promotion or exclusive marketing arrangements with other pharmaceutical companies.

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

SANCTURA and SANCTURA XR. Pursuant to the SANCTURA Agreement, Esprit is responsible for all advertising and promotional costs and for subsidizing our sales force at specified annual amounts through 2008. We are co-promoting SANCTURA and expect to co-promote SANCTURA XR with our sales force consisting of approximately 85 sales representatives through 2008. The combined sales forces of Indevus and Esprit are promoting SANCTURA and intend to co-promote SANCTURA XR to urology specialists, obstetricians and gynecologists, and primary care physicians.

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

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

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

NEBIDO. Pursuant to the Schering Agreement, we are responsible for the commercialization and marketing of NEBIDO in the U.S., either independently or with marketing partners. Schering is exclusively responsible for the manufacture and supply of finished product to us. Schering currently manufactures NEBIDO for sale in Europe, however, the manufacturing facility expected to be used for the manufacture of commercial product for sale in the U.S. has not yet been inspected for compliance with U.S. current Good Manufacturing Practices ("cGMP").

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

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

IP 751. We are responsible for manufacturing and marketing of this compound. We are currently considering strategic partners for the commercialization of IP 751.

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
Pagoclone. We are responsible for manufacturing and marketing of pagoclone. We are currently evaluating commercialization options for pagoclone in parallel with our ongoing development program and preliminary market development activities.

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

COMPETITION

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

SANCTURA and SANCTURA XR. Current therapy for OAB includes anticholinergics, such as Detrol and Detrol LA (tolterodine) by Pfizer, Ditropan and Ditropan XL (oxybutynin) by Johnson & Johnson, Inc., Oxytrol (oxybutynin transdermal patch) by Watson Pharmaceuticals, Vesicare (solifenacin) by Astellas Pharma US, Inc. and Glaxo Smith Kline, Enablex (darifenacin) by Novartis A.G., generic oxybutynin, and generic oxybutynin extended release. Many of the products on the market for the treatment of OAB are available in once daily formulations, whereas SANCTURA is currently available as a twice daily formulation. We believe there are other products in various stages of development for the treatment of OAB, which may lead to further competition.

NEBIDO. Current preferred methods for treating male hypogonadism are topical and injectable treatments. Topical treatments include gels, such as AndroGel by Solvay and Testim by Auxilium, and transdermal patch systems, such as AndroDerm by Watson. There are several additional gel products in development. There are multiple injectable products currently marketed in the U.S., including DELATESTRYL, which require more frequent injections than NEBIDO. Testosterone supplements are also available in oral dose forms, however, they are not widely prescribed for use in the United States.

DELATESTRYL. Current preferred methods for treating male hypogonadism are topical and injectable treatments. Topical treatments include gels, such as AndroGel by Solvay and Testim by Auxilium, and transdermal patch systems, such as AndroDerm by Watson. There are several additional gel products in development. There are multiple injectable products currently marketed in the U.S., in addition to DELATESTRYL. The majority of the injectable treatments are generic. Testosterone supplements are also available in oral dose forms, however, they are not widely prescribed for use in the United States.

PRO 2000. Other than condoms, we are not aware of any product to prevent sexually−transmitted infections having been approved for use anywhere in the world. We believe there are approximately 60 new substances are being evaluated for this indication, but we believe only a few have reached the stage of development of PRO 2000. Advanced clinical stage topical microbicides include BufferGel by Reproprotect, Inc., Carraguard by The Population Council, and cellulose sulfate gel by Polydec Pharmaceuticals.

IP 751. Current treatments for interstitial cystitis are aimed at relieving symptoms and include Elmiron (pentosan polysulfate sodium), by Johnson & Johnson and Bayer Pharmaceuticals, and RIMSO 50 (dimethyl sulfoxide), by Edwards Life Sciences Research. As a first line of defense against mild discomfort, physicians may recommend aspirin and ibuprofen. Some patients have experienced improvement by taking antidepressants or antihistamines. In patients with severe pain, narcotic analgesics or longer acting narcotics may be necessary.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
A variety of treatments are currently prescribed for pain and inflammatory disorders, including opioids, NSAIDs, COX−2 inhibitors and combinations of these drugs. The most prevalent types of pain are related to the back, postoperative recovery, osteoarthritis, diabetic neuropathy, rheumatoid arthritis and cancer. NSAIDs, the global leaders in pain treatment, include Celebrex (celecoxib) and Bextra (valdecoxib) by Pfizer. The principal marketed opioids include oxycontin and morphine.

Pagoclone. According to the National Center for Stuttering, current treatment programs for this condition include speech therapies that are physical, psychological and nutritional, designed to reduce the tension on the vocal chords. In addition there are auditory feedback devices that are currently used by some people who stutter. We are not aware of any pharmaceutical products approved for the treatment of, or being developed, for stuttering at this time.

Aminocandin. There are several new echinocandins approved or under development for the treatment of esophageal candidiasis, invasive candidemia/candidiasis, or aspergillosis. Cancidas (caspofungin), by Merck & Co., is available in the U.S. for the treatment of esophageal candidiasis and is also approved for the treatment of aspergillosis in patients intolerant or refractory to other therapies. MYCAMINE (micafungin), by Astellas Pharma US, Inc, is available in the U.S. for the treatment of esophageal candidiasis. ERAXIS (anidulafungin), by Pfizer Inc., was approved by the FDA in June 2006 to treat candidemia and other forms of candidiasis, including esophageal candidiasis.

PATENTS AND PROPRIETARY RIGHTS

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

SANCTURA and SANCTURA XR. There are no existing U.S. composition of matter patents covering the use of orally administered SANCTURA to treat OAB. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Waxman−Hatch Act, provides for a period of market exclusivity in the U.S. for SANCTURA for five years following the date of FDA approval, May 28, 2004. This is the exclusivity period provided for drugs containing an active ingredient not previously approved by the FDA. We intend to seek more extensive market exclusivity protection for the SANCTURA brand through the development of SANCTURA XR, a once−daily formulation of the drug. Our licensor, Supernus, has filed three patent applications directed to various aspects of the once−a−day formulation, including but not limited to the use of bioavailability enhancers, elements of extended release matrices and drug release characteristics. These patent applications have been published but have not yet been examined by the United States Patent and Trademark Office. Once granted the corresponding patents would have identical patent terms extending into late 2024. Foreign counterparts are also being pursued in major markets outside the United States, such as Europe and Japan. We have also filed patent applications directed to additional uses of trospium chloride, the active ingredient in SANCTURA. These pending patent applications, which cover the use of trospium chloride for promoting uninterrupted sleep and treating interstitial cystitis, if granted, would enjoy patent terms ending in early 2024 and early 2026, respectively. Foreign counterparts of the former patent application are being pursued in Canada, Europe and Japan.

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

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
**DELATESTRYL.** We do not have any unexpired patent protection for DELATESTRYL.

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

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

**Pagoclone.** We licensed from Aventis rights under U.S. and foreign patents and patent applications covering compositions of matter, processes, and metabolites of pagoclone. A U.S. composition of matter patent was issued in October 1990 and four related U.S. patents were issued in February and March 1996 and February and October 1997. In addition, we own certain patent rights, which were assigned to us by Warner Lambert, which are directed to many uses of pagoclone, including the treatment of obsessive compulsive disorder and social anxiety disorder, and certain methods of manufacture of racemic pagoclone and an enantiomer of pagoclone. The patent rights assigned to us by Warner Lambert are set to expire as early as April 2022 to as late as March 2023. We have also filed a patent application that covers a transdermal patch including pagoclone, which, if granted, would enjoy a patent term extending into early 2025. The Company also owns U.S. Patent No. 6,855,721, which covers a method of alleviating stuttering by the administration of a therapeutically effective dose of pagoclone or a pharmaceutically acceptable salt thereof. This last patent is set to expire no earlier than July 2020.

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

**Citicoline.** U.S. patents were issued to us in September and October 1998 and in February 1999 relating to the use of citicoline in the protection of brain tissue from cerebral infarction following ischemic stroke. Except in the U.S. and Canada, we licensed worldwide rights to these patents to Ferrer in 1997. The rights in the U.S. and Canada were subsequently assigned to Ferrer by us in 2005. In May 2000, we were awarded a U.S. patent, including claims directed to a composition of matter, for a “hyperhydrated” form of citicoline. Patents and patent applications corresponding to this U.S. patent exist in various foreign jurisdictions, which are now being pursued by Ferrer.

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Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
GOVERNMENT REGULATION

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

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

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

Clinical trials are normally done in three phases, although the phases may overlap. Phase I trials are concerned primarily with the safety and pharmacokinetics of the product. Phase II trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase III trials are expanded clinical trials intended, among other things, to gather additional information on safety and effectiveness needed to clarify the product’s benefit−risk relationship, to discover less common side effects and adverse reactions, and to generate information for proper labeling of the drug. Reports on the progress of each phase of clinical testing are submitted to the FDA and may require the modification, suspension or termination of clinical trials if it is deemed that an unwarranted risk is presented to patients. When data is required from long−term use of a drug following its approval and initial marketing, the FDA can require Phase IV, or post−marketing, studies to be conducted.

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

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

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
for changes in product labeling, or to gain approval for the use of a product for clinical indications other than those for which the product was initially approved. In addition, the FDA or a foreign regulatory authority may require post–marketing reporting to monitor the side effects or ongoing safety of a drug. Results of such post–marketing programs may limit the further marketing of these products. Also, if there are modifications to an approved drug, including changes in manufacturing process or in manufacturing facility, an application seeking approval of such changes may be required to be submitted to and prior approved by the FDA or a foreign regulatory authority, and this review may affect production timelines or product availability.

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

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

SANCTURA, approved for marketing in the U.S. on May 28, 2004, has been granted five years of market exclusivity under the Waxman–Hatch Act.

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

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

**EMPLOYEES**

As of September 30, 2006, we had 158 full–time employees. None of our employees are represented by a labor union and we believe our employee relations are satisfactory. We are highly dependent upon certain key personnel and believe our future success will depend in large part on our ability to retain such individuals and attract other highly skilled management, marketing and scientific personnel.
ITEM 1A. Risk Factors

The following factors should be reviewed carefully, in conjunction with the other information contained in this Report and our consolidated financial statements. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this Form 10-K and presented elsewhere by our management from time to time. See “Part I—Note Regarding Forward Looking Statements.”

RISKS RELATED TO OUR BUSINESS

We are dependent on SANCTURA.

We currently derive a substantial portion of our revenue from Esprit under the SANCTURA Agreement. We believe that revenues derived under the SANCTURA Agreement will continue to account for a substantial portion of our revenue for the foreseeable future. We are highly dependent on Esprit for the commercialization and marketing of SANCTURA and for performance of its obligations under the SANCTURA Agreement. The failure of Esprit to perform its obligations under this agreement, or to market SANCTURA, could adversely affect our business, financial condition and results of operations. In particular, if sales of SANCTURA do not increase, we are unlikely to derive royalties in excess of the minimum royalties under the SANCTURA Agreement and, after the minimum royalty period expires in June 2008, our royalty revenue may decrease substantially. Esprit is not obligated to purchase any minimum amount of SANCTURA from us. SANCTURA may suffer from generic penetration after the expiration of the market exclusivity period in May 2009, and competes with many once-daily and other formulations of products to treat OAB. Our long-term success will be highly dependent on our ability to successfully develop, manufacture and commercialize SANCTURA XR. If SANCTURA does not continue to achieve market acceptance or if Esprit provides notice to us that it does not intend to pay us the development milestone related to FDA approval of SANCTURA XR causing the rights to SANCTURA XR to revert to us, then the marketing of SANCTURA XR may be adversely affected and if efforts to develop and market SANCTURA XR are unsuccessful, our business, financial condition and results of operations may be materially adversely affected. Further, our sales force subsidy for our co-promotion of SANCTURA and SANCTURA XR in the U.S. expires on December 31, 2008.

Because our marketing resources are limited, we may be unable to devote sufficient resources to SANCTURA to achieve increasing market acceptance of SANCTURA in the highly competitive marketplace for overactive bladder therapies. Our failure to expend the resources to adequately promote SANCTURA would have a material adverse effect on our business and results of operations.

Moreover, because we have fewer sales representatives than our competitors, our sales force may be unable to detail successfully to physicians who prescribe overactive bladder medications. We may not be able to retain all of our current sales representatives. Even if we hire additional representatives, they may not be effective in promoting the sale of SANCTURA. The failure of our sales representatives to be successful in selling SANCTURA would have a material adverse effect on operating results.

We may not compete successfully in the overactive bladder market.

Competition in the overactive bladder market is intense and has increased since the launch of SANCTURA in August 2004 and two other competitive products in early 2005. SANCTURA competes with drugs and other therapies for overactive bladder marketed by many large, multinational companies who have substantially greater marketing and financial resources and experience than us. In addition, antimuscarinics and antispasmodics for overactive bladder are the subject of testing or commercialization efforts by other companies, including certain treatments for which approval may be sought in the future. Launches of other competitive products may occur in the near future and we cannot predict with accuracy the timing or impact of the introduction of competitive products or their possible effect on our sales.

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
Our license for SANCTURA does not include any patents that we expect to use in commercializing the product for overactive bladder. Our ability to successfully commercialize SANCTURA in the U.S. will depend on the continued availability of market exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Waxman–Hatch Act, which provides protections for certain new products. The Waxman–Hatch Act provides for a period of market exclusivity in the U.S. for SANCTURA for five years from the date of FDA approval, May 28, 2004. The marketing of SANCTURA could be materially adversely affected if the period of market exclusivity is shortened. After this time, there may be generic versions of trospium chloride available to treat overactive bladder at significantly lower prices than SANCTURA, in which case sales of SANCTURA will likely decrease significantly. We cannot predict whether any patents will issue on the applications that have been filed for SANCTURA XR, an extended release, once–daily formulation of SANCTURA. If granted, there can be no assurance that these patents can or will preclude eventual market erosion from new technologies or competing products. If we were unable to obtain a patent on such formulation we will have to rely solely on market exclusivity for this formulation, which will be shorter than five years.

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

We currently have six compounds which are in various stages of development and have not been approved by the FDA, including SANCTURA XR and NEBIDO. These product candidates are subject to the risk that any or all of them are found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances. We are unable to predict whether any of these product candidates will receive regulatory clearances or will be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frames for commercialization of any products are long and uncertain. Even if these product candidates receive regulatory clearance, our products may not achieve or maintain market acceptance.

We rely on the favorable outcome of clinical trials of our product candidates including SANCTURA XR and NEBIDO.

Before obtaining regulatory approval for the commercial sale of any of the pharmaceutical products we are developing, we or our licensees must demonstrate that the product is safe and efficacious for use in each target indication. The process of obtaining FDA and other regulatory approvals is lengthy and expensive. If clinical trials do not demonstrate the safety and efficacy of certain products under development, we will be materially adversely affected. The results of pre–clinical studies and early clinical trials may not predict results that will be obtained in large–scale testing or use. Clinical trials of products we are developing may not demonstrate the safety and efficacy of such products. Regardless of clinical trial results, the FDA may not approve marketing of the product. The costs to obtain regulatory approvals are considerable and the failure to obtain, or delays in obtaining, regulatory approval could have a significant negative effect on our business performance and financial results. Even if pre–launch approval of a product is obtained, the FDA is authorized to impose post–marketing requirements. A number of companies in the pharmaceutical industry, including our company, have suffered significant setbacks in advanced clinical trials or have not received FDA approval, even after promising results in earlier trials. For example, while there have been three Phase II clinical trials of pagoclone that demonstrated statistically significant efficacy, two in panic disorder and one in GAD, other trials have failed to demonstrate statistically significant efficacy, prompting Pfizer (our previous licensee of this compound) to elect not to pursue further development of the compound and to return to us all rights to pagoclone.

We have regulatory and guideline risks.

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

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
If SANCTURA becomes subject to efficacy or safety concerns, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, unexpected side effects or regulatory proceedings, the impact on our revenues could be significant.

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

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

Acceptable levels of reimbursement for costs of developing and manufacturing of pharmaceutical products and treatments related to those pharmaceutical products by government authorities, private health insurers and other organizations, such as HMOs, will have an effect on the successful commercialization of, and attracting collaborative partners to invest in the development of, our products and product candidates. We cannot be sure that reimbursement in the United States or elsewhere will be available for any pharmaceutical products we may develop or, if already available, will not be decreased in the future. The U.S. Congress recently enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While the program established by this statute may increase demand for our products, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our drug products. Any reduction in demand would adversely affect our business. If reimbursement is not available or is available only at limited levels, we may not be able to obtain collaborative partners to manufacture and commercialize our products, and may not be able to obtain a satisfactory financial return on our own manufacture and commercialization of any future products.

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

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

We are currently dependent on Madaus to manufacture SANCTURA and will be dependent on a third party for the manufacture of SANCTURA XR. We are also dependent on third parties in the supply chain, for the manufacture of trospium chloride, the active pharmaceutical ingredient in SANCTURA and SANCTURA XR. If Madaus or any of the other third parties were unable to maintain compliance with FDA requirements for manufacturers of drugs sold in the U.S., we would need to seek alternative sources of supply, which could create disruptions in the supply of SANCTURA or SANCTURA XR.
We rely on third parties to commercialize and manufacture our products.

We have limited sales and marketing capabilities to market our products. Substantial additional funds will be required to complete development and commercialization of our products and, accordingly, we expect to seek corporate partnerships for the manufacture and commercialization of our products. We may not be successful in finding corporate partners and the terms of any such arrangements may not be favorable to us or our security holders. If we are unable to obtain any such corporate partners, development of our product candidates could be delayed or curtailed, which could materially adversely affect our operations and financial condition.

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

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

Any manufacturing facilities for any of our compounds are subject to FDA inspection both before and after NDA approval to determine compliance with current good manufacturing practices, or cGMP, requirements. There are a limited number of contract manufacturers that operate under cGMP that are capable of manufacturing our products. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our products or commercialize them. Facilities used to produce our compounds may not have complied, or may not be able to maintain compliance, with cGMP. The cGMP regulations are complex and failure to be in compliance could lead to non-approval or delayed approval of an NDA which would delay product launch or, if approval is obtained, may result in remedial action, penalties and delays in production of material acceptable to the FDA. Currently, Schering’s NEBIDO manufacturing facilities have not been approved by the FDA.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us.

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

We do not conduct our own research to discover new drug compounds. Instead, we depend on the acquisition of compounds from others for development through licensing, partnerships, corporate collaborations, strategic corporate transactions or company acquisitions. Therefore, in order to grow, we must continue to acquire and develop additional compounds. The success of this strategy depends upon our ability to identify, select and acquire compounds that meet the criteria we have established. Identifying suitable compounds is a lengthy, complex and uncertain process. In addition, we compete with other companies with substantially greater financial, marketing and sales resources, for the acquisition of compounds. We may not be able to acquire the rights to additional compounds through licensing or strategic acquisitions of selected assets or businesses, on terms we find acceptable or at all.
We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect our stock price, operating results and results of operations.

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

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

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

We need additional funds in the future.

Our existing cash resources will be insufficient to commercialize any of our current product candidates on our own. In addition, we continue to expend substantial funds for research and development, marketing, general and administrative expenses and manufacturing. We expect to continue to use substantial cash for operating activities in fiscal 2007 as we continue to fund our development activities, as well as marketing activities related to SANCTURA and DELATEGYSTRYL. We may seek additional funding through corporate collaborations, strategic combinations or public or private equity and debt financing options. Any such corporate collaboration, strategic combination or financial transactions could result in material changes to the capitalization, operations, management and prospects for our business and no assurance can be given that the terms of a strategic transaction would be favorable to us or our security holders. If we raise additional funds by issuing equity securities, existing stockholders will be diluted and future investors may be granted rights superior to those of existing stockholders. There can be no assurance that additional financing will be available on terms acceptable to us or at all. If we sell securities in a private offering, we may have to sell such shares at a discount from the market price of our stock which could have a depressive effect on our stock price. In addition, future resales of shares in the public market sold in a private offering could negatively affect our stock price.
Our cash requirements and cash resources will vary significantly depending upon the following principal factors:

- marketing success of SANCTURA;
- marketing success of DELATESTRYL, sales of which may be negatively impacted if NEBIDO is introduced to the market;
- the costs and progress of our research and development programs;
- the timing and cost of obtaining regulatory approvals; and
- whether we are successful in either in-licensing or out-licensing products.

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

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

We have incurred substantial net losses over the past five fiscal years including net losses of approximately $17,600,000, $31,800,000, $68,200,000, $53,200,000 and $50,600,000 for fiscal years 2002, 2003, 2004, 2005, and 2006, respectively. At September 30, 2006 we had an accumulated deficit of approximately $472,700,000.

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

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

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

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

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

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
On May 30, 2001, we entered into the Indemnity and Release Agreement with AHP, now Wyeth, which provides for indemnification of Redux-related claims brought by plaintiffs who initially elected not to stay in the AHP national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension, a serious disease involving the blood vessels in the lungs. This agreement also provides for funding of all defense costs related to all Redux-related claims and provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the AHP indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. We are unable to predict whether the existence of such litigation may adversely affect our business.

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

We rely on the protection provided by our intellectual property and have limited patent protection on some of our products.

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

• obtain and enforce patent protection on our products and technologies;

• maintain trade secrets; and

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

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

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

Our license for SANCTURA, a compound approved for use in the treatment of overactive bladder, does not include any patents that we expect to use in the commercialization of the product for overactive bladder. We do not otherwise currently own or have a license to issued patents that cover our SANCTURA product.

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

• to enforce any of our patents;
• to determine the scope and validity of the patent rights of others; or

• in response to legal action against us claiming damages for infringement of patent rights or other proprietary rights or seeking to enjoin commercial activities relating to the affected product or process.

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

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

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

We may depend on market exclusivity for certain of our products.

Assuming regulatory approvals are obtained, our ability to commercialize successfully certain drugs may depend on the availability of market exclusivity or patent extension under the Waxman−Hatch Act, which provides protections for certain new products. Under the Waxman−Hatch Act, a company may obtain five years of market exclusivity if the FDA determines such compound to be a chemical entity that has not been the subject of an approved NDA in the past. The period of market exclusivity under the Waxman−Hatch Act is considerably shorter than the exclusivity period afforded by patent protection, which, in the case of some patents, may last up to twenty years from the earliest priority date of the patent directed to the product, its use or method of manufacture. We are relying on market exclusivity under the Waxman−Hatch Act for SANCTURA.

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

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

Many of the other companies who market or are expected to market competitive drugs or other products are large, multinational companies who have substantially greater marketing and financial resources and experience.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
than us. We may not be able to develop products that are more effective or achieve greater market acceptance than competitive products. In addition, our competitors may develop products that are safer or more effective or less expensive than those we are developing or that would render our products less competitive or obsolete. As a result, our products may not be able to compete successfully. In addition, royalties payable to us under certain conditions may be reduced or eliminated if there is generic competition. In the event our products were unable to be sold at the rate we currently anticipate, we could potentially have excess inventory, resulting in an impairment charge that could have material effect on our financial statements.

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

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

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

We could be materially harmed if our agreements were terminated.

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

We depend upon key personnel and consultants.

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

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

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
We have product liability exposure and insurance uncertainties related to our products.

The use of products in clinical trials and the marketing of products may expose us to substantial product liability claims and adverse publicity. Certain of our agreements require us to obtain specified levels of insurance coverage, naming the other party as an additional insured. We currently maintain product liability and clinical trial insurance in the amount of $40,000,000. We may obtain additional coverage for products that may be marketed in the future, including SANCTURA XR and NEBIDO. We may not be able to maintain or obtain insurance coverage, or to obtain insurance in amounts sufficient to protect us or other named parties against liability, at a reasonable cost, or at all. In addition, any insurance obtained may not cover any particular liability claim. We have indemnified certain licensors, licensees and contractors and may be required to indemnify additional licensors, licensees or contractors against product liability claims incurred by them as a result of products we develop or market. If uninsured or insufficiently insured product liability claims arise, or if a successful indemnification claim was made against us, our business and financial condition could be materially adversely affected. In addition, any payments made by us in connection with product liability litigation could result in significant charges to operations and would materially adversely affect our results of operations and financial condition.

If third parties on which we rely for clinical trials services do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We depend on independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical trials of our product candidates and expect to continue to do so. We rely heavily on these parties for successful execution of our clinical trials, but we do not control many aspects of their activities. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the general investigational plan and protocol. Our reliance on these third parties that we do not control does not relieve us of our responsibility to comply with the regulations and standards of the FDA relating to good clinical practices. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trials plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

Risks Related to Our Common Stock and Other Securities

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

Our board of directors has the authority, without further approval of our stockholders, to fix the rights and preferences, and to issue up to 5,000,000 shares of preferred stock, 244,425 of which are currently issued and outstanding. In addition, vesting of shares of our common stock subject to awards under our 2004 Equity Incentive Plan accelerates and outstanding options under our stock option plans become immediately exercisable upon certain changes in control of the Company, except under certain conditions. In addition, Delaware corporate law imposes limitations on certain business combinations. These provisions could, under certain circumstances, delay or prevent a change in control of the Company and, accordingly, could adversely affect the price of our common stock.

We have never paid any dividends on our common stock.

We have not paid any cash dividends on our common stock since inception and do not expect to do so in the foreseeable future. Any dividends on our common stock will be subject to the preferential cumulative annual dividend of $0.1253 per share and $1.00 per share payable on our outstanding Series B preferred stock and Series C preferred stock, respectively, held by Wyeth and dividends payable on any other preferred stock we may issue.
If we pay cash dividends on our common stock, certain holders of our securities may be deemed to have received a taxable dividend without the receipt of any cash.

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

The price for our securities is volatile.

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

- market success of SANCTURA;
- results of clinical studies and regulatory reviews;
- the marketing approval of SANCTURA XR;
- results of our NEBIDO Phase III pharmacokinetic study;
- partnerships, corporate collaborations and company acquisitions;
- announcements by our corporate collaboration partners concerning our products, about which we generally have very limited control, if any, over the timing or content;
- changes in the levels we spend to develop, acquire or license new compounds;
- market conditions in the pharmaceutical and biotechnology industries;
- competitive products;
- sales, the possibility of sales, or buybacks of our common stock or other financings;
- our results of operations and financial condition including variability in quarterly operating results due to timing and recognition of revenue, receipt of licensing, milestone and royalty payments, regulatory progress and delays and timing and recognition of certain expenses;
- changes in proprietary rights of our, or our competitors, products;
- Redux−related litigation developments;
- public concern as to the safety or commercial value of our products; and
- general economic conditions.

The high and low sales prices of our common stock as reported by NASDAQ Stock Market were: $12.83 and $0.85 for fiscal 2002, $6.90 and $1.32 for fiscal 2003, $10.25 and $4.86 for fiscal 2004, $7.45 and $2.41 for fiscal 2005, and $6.62 and $2.52 for fiscal 2006. Our common stock is subject to delisting if our stock price drops below the bid price of $1.00 per share. If we were to fail to meet any of the continued listing requirements for the NASDAQ Stock Market, our common stock could be delisted from the NASDAQ Stock Market, the effects of which could include limited release of a market price of our common stock, limited liquidity for stockholders and limited news coverage and could result in an adverse effect on the market for our common stock.

The stock markets also experience significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of our common stock.
The price for our common stock could be negatively affected if we issue additional shares or if third parties exercise registration rights.

As of September 30, 2006, we had 56,040,456 shares of common stock issued and outstanding. Substantially all of these shares are eligible for sale without restriction. In addition, Wyeth has the right, under certain circumstances, to require us to register for public sale 622,222 shares of common stock issuable to it upon conversion of the Series B and C preferred stock it owns. We have outstanding registration statements on Form S−3 relating to the resale of our shares of common stock and on Form S−8 relating to shares issuable under our 1989 Stock Option Plan, 1994 Long−Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan, 2000 Stock Option Plan, and 2004 Equity Incentive Plan. The possibility of sales of such shares, private sales of securities or the possibility of resale of such shares in the public market may adversely affect the market price of our common stock.

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

As of September 30, 2006, we had reserved the following shares of our common stock for issuance:

- 10,817,308 shares issuable upon conversion of the $72,000,000 Convertible Senior Notes issued in July 2003, which are due in July 2008;
- 12,132,778 shares issuable upon exercise of outstanding options and Performance Stock Awards, certain of which may be subject to anti−dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if we issue additional securities below certain prices;
- 622,222 shares upon conversion of preferred stock owned by Wyeth, subject to anti−dilution provisions; and
- 2,414,618 shares reserved for grant and issuance under our stock option, stock purchase and equity incentive plans.

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

Increased leverage as a result of our convertible debt offering may harm our financial condition and results of operations.

At September 30, 2006, we had $72,000,000 of outstanding debt reflected in our balance sheet relating to our outstanding Convertible Notes. If the price of our common stock at the time of convertible debt is due does not exceed 150% of conversion price then in effect for a specified period, then the company may not be able to redeem the notes to cause a conversion, then the company may be obligated to repay the note holders in cash on the July 2008 due date. We may incur additional indebtedness in the future and the Convertible Notes do not restrict our future issuance of indebtedness. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

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

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

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

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

**ITEM 1B. Unresolved Staff Comments**

None.

**ITEM 2. Properties**

We lease our current corporate headquarters of approximately 45,100 square feet in Lexington, MA at an annual rent of approximately $1,100,000. The initial term of this lease expires in December 2010.
ITEM 3. Legal Proceedings

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

On May 30, 2001, we entered into an indemnity and release agreement with Wyeth pursuant to which Wyeth agreed to indemnify us against certain classes of product liability cases filed against us involving Redux. Our indemnification covers plaintiffs who initially opted out of Wyeth’s national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth agreed to fund all future legal costs related to our defense of Redux−related product liability cases. The agreement also provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. We believe this total insurance coverage is sufficient to address our potential remaining Redux product liability exposure.

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

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

General. Although we maintain certain product liability and director and officer liability insurance and intend to defend these and similar actions vigorously, we have been required and may continue to be required to devote significant management time and resources to these legal actions. In the event of successful uninsured or insufficiently insured claims, or in the event a successful indemnification claim were made against us and our officers and directors, our business, financial condition and results of operations could be materially adversely affected. The uncertainties and costs associated with these legal actions have had, and may continue to have an adverse effect on the market price of our common stock and on our ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, or to obtain product liability insurance for other products at costs acceptable to us, or at all, any or all of which may materially adversely affect our business, financial condition and results of operations.
**ITEM 4. Submission of Matters to a Vote of Security Holders**
Not applicable.

**EXECUTIVE OFFICERS**

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glenn L. Cooper, M.D</td>
<td>53</td>
<td>Chief Executive Officer and Chairman</td>
</tr>
<tr>
<td>Thomas F. Farb</td>
<td>50</td>
<td>President and Chief Operating Officer</td>
</tr>
<tr>
<td>Noah D. Beerman</td>
<td>44</td>
<td>Executive Vice President, Chief Business Officer</td>
</tr>
<tr>
<td>Mark S. Butler</td>
<td>60</td>
<td>Executive Vice President, Chief Administrative Officer and General Counsel</td>
</tr>
<tr>
<td>Michael W. Rogers</td>
<td>46</td>
<td>Executive Vice President, Chief Financial Officer and Treasurer</td>
</tr>
<tr>
<td>Bobby W. Sandage, Jr., Ph.D.</td>
<td>53</td>
<td>Executive Vice President, Research and Development and Chief Scientific Officer</td>
</tr>
<tr>
<td>John H. Tucker</td>
<td>43</td>
<td>Executive Vice President, Chief Sales and Marketing Officer</td>
</tr>
</tbody>
</table>

*Glenn L. Cooper, M.D.* is the Chairman and Chief Executive Officer of Indevus. Dr. Cooper has been Chairman since January 2000, Chief Executive Officer since May 1993, and was President until Thomas F. Farb’s election as President in 2006. Dr. Cooper joined the Company in May 1993 as President, Chief Executive Officer and a member of the Board of Directors. In January 2000, Dr. Cooper was appointed Chairman of the Board of Directors. From September 1992 to June 1994, Dr. Cooper was also President and Chief Executive Officer of Progenitor, Inc. Prior to joining Progenitor, Dr. Cooper was Executive Vice President and Chief Operating Officer of Sphinx Pharmaceuticals Corporation from August 1990. Prior to Sphinx, Dr. Cooper had been associated with Eli Lilly since 1985, from June 1987 to July 1990 as Director, Clinical Research, Europe, of Lilly Research Center Limited; from October 1986 to May 1987 as International Medical Advisor, International Research Coordination of Lilly Research Laboratories; and from June 1985 to September 1986 as Medical Advisor, Regulatory Affairs, Chemotherapy Division at Lilly Research Laboratories. Dr. Cooper received an M.D. from Tufts University School of Medicine, performed his postdoctoral training in Internal Medicine and Infectious Diseases at the New England Deaconess Hospital and Massachusetts General Hospital and received a B.A. from Harvard College.

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

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

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

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

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

John H. Tucker is the Executive Vice President, Chief Sales and Marketing Officer of Indevus, a position he has held since September 2004. Mr. Tucker
joined the Company in April 2002 as Vice President, Sales and Marketing and was appointed Senior Vice President in December 2003. Mr. Tucker was
previously at Ortho–McNeil Pharmaceuticals, a Johnson & Johnson company, from June 2001 to April 2002, where he developed and led a specialty sales,
account and marketing team focused on the promotion of products in key urology markets. Mr. Tucker also served as senior director of trade relations,
Mr. Tucker held a number of national sales and marketing management positions at Vivus from February 1997 to January 1998 and UCB Pharma from

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
ITEM 5.  Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Price Range of Securities

Our Common Stock trades on the NASDAQ National Market under the symbol “IDEV”. The table below sets forth the high and low sales prices of our Common Stock as reported by the NASDAQ National Market for the periods indicated. These prices are based on quotations between dealers, do not reflect retail mark-up, mark-down or commissions, and do not necessarily represent actual transactions.

<table>
<thead>
<tr>
<th>Fiscal Year Ended September 30, 2006:</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 1 through September 30, 2006</td>
<td>$6.39</td>
<td>$5.03</td>
</tr>
<tr>
<td>April 1 through June 30, 2006</td>
<td>6.22</td>
<td>4.40</td>
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<tr>
<td>January 1 through March 31, 2006</td>
<td>6.62</td>
<td>5.04</td>
</tr>
<tr>
<td>October 1 through December 31, 2005</td>
<td>5.41</td>
<td>2.52</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fiscal Year Ended September 30, 2005:</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 1 through September 30, 2005</td>
<td>$3.42</td>
<td>$2.55</td>
</tr>
<tr>
<td>April 1 through June 30, 2005</td>
<td>3.78</td>
<td>2.41</td>
</tr>
<tr>
<td>January 1 through March 31, 2005</td>
<td>6.08</td>
<td>2.73</td>
</tr>
<tr>
<td>October 1 through December 31, 2004</td>
<td>7.45</td>
<td>5.85</td>
</tr>
</tbody>
</table>

Approximate Number of Equity Security Holders

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

We have never paid a cash dividend on our Common Stock and anticipate that for the foreseeable future any earnings will be retained for use in our business, any dividends will be subject to the preferential dividend of $0.1253 per share payable on the outstanding Series B Preferred Stock ($30,000 per annum), $1.00 per share payable on the outstanding Series C Preferred Stock ($5,000 per annum) and dividends payable on any other preferred stock that we may issue.

Securities Authorized for Issuance under Equity Compensation Plans

Provided below is information required by Regulation S–K, Item 201(d) relative to our equity compensation plans and arrangements as of September 30, 2006:

<table>
<thead>
<tr>
<th>Plan category</th>
<th>Number of Securities to be issued upon exercise of outstanding options</th>
<th>Weighted—average exercise price of outstanding options</th>
<th>Number of securities remaining available for future issuance under equity compensation plans (Excluding securities reflected in column (a))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity compensation plans approved by security holders</td>
<td>11,781,378</td>
<td>$4.55</td>
<td>2,402,536</td>
</tr>
<tr>
<td>Equity compensation plans or arrangements not approved by security holders</td>
<td>—</td>
<td>—</td>
<td>12,082(1)</td>
</tr>
<tr>
<td>Total</td>
<td>11,781,378</td>
<td>$4.55</td>
<td>2,414,618</td>
</tr>
</tbody>
</table>

(1) Reflects the number of shares of Common Stock issuable pursuant to the remaining number of Restricted Stock Awards issuable under our 1997 Equity Incentive Plan which are available for future issuance other than upon the exercise of an option, warrant or right (see Note J of the Notes to Consolidated Financial Statements).
ITEM 6. Selected Financial Data

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Amounts in thousands except per share)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Statement of Operations Data:

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

### Balance Sheet Data:

| Working capital $54,876 | $79,233 | $131,288 | $73,866 | $34,876 |
| Total assets 92,307 | 112,531 | 173,838 | 90,071 | 43,931 |
| Convertible Notes, long−term — | — | — | — | — |
| Total liabilities including deferred revenue 216,511 | 227,667 | 236,868 | 83,817 | 6,700 |
| Accumulated deficit (472,675) | (422,121) | (368,903) | (300,691) | (268,879) |
| Total stockholders’ equity (deficit) (124,330) | (115,142) | (63,038) | 6,241 | 37,218 |

(1) The Company adopted SFAS 123R on a prospective basis beginning in fiscal 2006. See Note L of the Notes to Consolidated Financial Statements.
ITEM 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

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

Description of the Company

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

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

In addition to our core urology, gynecology and men’s health portfolio we are preparing to begin a Phase III development program for pagoclone which we are developing for the treatment of persistent developmental stuttering. Our product portfolio also contains aminocandin, an echinocandin for systemic fungal infections for which we recently licensed worldwide rights to Novexel. We also are receiving royalties under a patent we licensed to Eli Lilly & Company based on net sales of Sarafem in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre−menstrual dysphoric disorder.

Recent Product Developments

SANCTURA XR

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

Our development program for SANCTURA XR has included two randomized, double−blind, placebo−controlled Phase III trials conducted in the U.S. that were submitted in the NDA. We announced positive data from the first Phase III trial in June 2006 and positive data from the second Phase III trial in July 2006. The first trial included 601 patients who were studied at 55 sites. The second trial included 564 patients who were studied at 62 sites. Both trials were 12−week trials and measured the effects of 60mg of SANCTURA XR versus placebo, once daily, on symptoms of OAB. Patients treated with SANCTURA XR experienced statistically significantly fewer toilet voids per day at the end of the 12−week trial than did patients on placebo. SANCTURA XR treated patients also experienced statistically significantly fewer episodes of urge urinary incontinence per day at the end of the 12−week trial than did placebo patients. Treatment with SANCTURA XR also led to a statistically significant improvement (decrease) in average urgency severity, another key symptom of OAB. Additionally, SANCTURA XR had a rapid onset of action and achieved a statistically significant difference from placebo as early as Week 1 of therapy for key efficacy endpoints. The most common anticholinergic side effects were dry mouth (10.7% of the SANCTURA XR treated patients compared to 3.7% of the placebo treated patients) and constipation (8.5% of the SANCTURA XR treated patients compared to 1.5% of the placebo treated patients).

In November 2006, we entered into (i) a License and Supply Agreement and (ii) an amendment to an original licensing agreement with Madaus (the “Madaus Agreements”). Under the Madaus Agreements, we agreed to
In November 2006, we entered into the Helsinn Agreement whereby Helsinn agreed to supply trospium active pharmaceutical ingredient to us. Trospium active pharmaceutical ingredient is used in the production of SANCTURA XR. The term of the Helsinn Agreement is seven years and contains certain minimum purchase requirements.

NEBIDO

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

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

Pagoclone

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

In September 2006, we announced that following an End of Phase II meeting with the FDA, we had established a clinical plan towards regulatory approval of pagoclone for the treatment of persistent developmental stuttering and will initiate a Phase III trial in the first half of 2007. Specifically, the FDA advised us to: 1) pursue pediatric studies in parallel with adult studies so that if pagoclone is effective and safe in both populations, the NDA could be approvable for the broadest possible stuttering population; 2) conduct the next adult and pediatric placebo-controlled trials as fixed dose-response studies to determine the minimally-effective dose; and 3) pursue Phase III trials under special protocol assessments to allow the FDA to formally sign off on trial designs.
In June 2006, we initiated a Phase II proof of concept trial designed to evaluate the efficacy of various doses of pagoclone versus placebo in delaying the ejaculatory response in male patients with primary premature ejaculation. In September 2006, we elected to perform an interim analysis which revealed only a slight effect at the highest dose tested. Given the modest effect, it was unlikely that the completed trial would meet its clinical and statistical objectives. Accordingly, the study was discontinued and no further work on pagoclone for PE is currently planned.

Aminocandin

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

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements that have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reported periods. These items are regularly monitored and analyzed by management for changes in facts and circumstances and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

Expected Term of the SANCTURA Agreement and Deferred Revenue

We are recording the initial and milestone payments received from PLIVA and Esprit as deferred revenue and amortizing each component into revenue using the contingency−adjusted method over the estimated remaining duration of the SANCTURA Agreement commencing on the date such payments are earned. Through September 30, 2006, we have received $161,000,000 of such payments. Additionally, as a result of the October 2006 submission of the NDA, we received a $10,000,000 milestone payment from Esprit.

We believe the estimated term of the SANCTURA Agreement is a significant estimate which affects revenue recognized and the balance of deferred revenue on our balance sheet and we explain our estimate of the expected twelve year term of the SANCTURA Agreement below.

The SANCTURA Agreement expires on the later of (i) the twelfth (12th) anniversary of the launch date of SANCTURA or (ii) the expiration of the last to expire patent included in the Indevus Patent Rights covering SANCTURA XR. Securities and Exchange Commission Staff Accounting Bulletin No. 104 (“SAB 104”) specifies that unless evidence suggests otherwise, service revenues should be recognized over the contractual term of the arrangement or the expected period over which services are expected to be performed, if longer. We considered the following factors in evaluating the expected duration of the SANCTURA Agreement:

1. SANCTURA does not have marketing protection afforded by patents and is currently being marketed pursuant to five years of market exclusivity provided by the Waxman−Hatch Act;

2. the potential of success in developing SANCTURA XR including the ultimate approval by the FDA to market SANCTURA XR;

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
• the potential of success in obtaining approval of patents covering SANCTURA XR and the protection such patents may afford;

• if protection from patents was not obtained for SANCTURA XR, the potential benefit of any reliance on market exclusivity that may be provided by the Waxman–Hatch Act;

• the strong competition in the overactive bladder market including competition from large pharmaceutical companies.

After considering all of the above, we estimated the expected term of the SANCTURA Agreement to be twelve years, consistent with the negotiated minimum term of the arrangement of twelve years from launch of SANCTURA. In the event development of SANCTURA XR was terminated prior to approval for marketing by the FDA, the expected term of the arrangement would likely be less than twelve years. In the event SANCTURA XR is approved for marketing by the FDA, achieves an acceptable measure of market success, and we are able to obtain and benefit from patent protection for SANCTURA XR, the term of the arrangement may extend beyond the estimated twelve years.

We amortized $13,417,000, $13,875,000 and $6,250,000 of deferred revenue into contract and license fee revenue in fiscal 2006, 2005 and 2004, respectively, and the balance of deferred revenue related to the initial and the subsequent milestone payments at September 30, 2006 is $127,457,000. We will reevaluate our estimate of the expected term of the SANCTURA Agreement when new information is known that could affect our estimate. If we change our estimate of the duration of the SANCTURA Agreement in the future and extend our estimate of its duration we would decrease the amount of periodic revenue to be recognized from the amortization of remaining deferred revenue. If we decrease our estimate of the duration of the SANCTURA Agreement in the future we would increase the amount of periodic revenue to be recognized from the amortization of remaining deferred revenue.

Revenue Recognition Policy

Product revenue consists primarily of revenues from sales of products, commissions and royalties and reimbursements for royalties owed by the Company to Madaus GmbH (“Madaus”) pursuant to the SANCTURA Agreement (see Note O of Notes to Consolidated Financial Statements). Product revenue also includes revenue earned from shipments of DELATESTRYL, acquired in January 2006 from Savient Pharmaceuticals, Inc. (“Savient”). Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize the Company’s licensed technologies and are generally reported to the Company in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based. If the royalty report for such period is received subsequent to the time when the Company is required to report its results on Form 10–Q or Form 10–K and the amount of the royalties earned is not estimable, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received and when the amount of and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

The Company records sales of product as product revenue upon the later of shipment or as title passes to its customer. Sales of DELATESTRYL are reflected net of reserves for returns and allowances.

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

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
The Company’s business strategy includes entering into collaborative license, development or co-promotion agreements with strategic partners for the development and commercialization of the Company’s products or product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones and royalties on net product sales. Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. In multiple element arrangements where the Company has continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as the Company completes its performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement. The Company records such revenue as contract and license fee revenue.

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

Under the SANCTURA Agreement, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue using the contingency-adjusted performance model. Under this model, when a milestone is earned, revenue is immediately recognized on a pro-rata basis in the period the Company achieves the milestone based on the time elapsed from inception of the SANCTURA Agreement to the time the milestone is earned over the estimated duration of the SANCTURA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the SANCTURA Agreement.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force (“EITF”) Issue Number 00–21, “Accounting Revenue Arrangements with Multiple Deliverables” (“EITF 00–21”). Pursuant to EITF 00–21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as the Company completes its performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104 (“SAB 104”), unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements. In particular relating to the SANCTURA Agreement, the Company and PLIVA d.d. (“PLIVA”) were contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by the Company, reimbursements from PLIVA for PLIVA’s share are reflected in contract and license fee revenue. For promotion and advertising costs incurred by PLIVA, reimbursements to PLIVA for the Company’s share were reflected as a reduction of contract and license fee revenue.

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

As of September 30, 2006, we had an outstanding insurance claim of approximately $3,700,000, for services rendered through May 30, 2001 by the
group of law firms defending us in the Redux–related product liability litigation. The full amount of our current outstanding insurance claim is made pursuant to
our product liability policy issued to us by Reliance Insurance Company (“Reliance”), which is in liquidation proceedings. Based upon discussions with our
attorneys and other consultants regarding the amount and timing of potential collection of our claim on Reliance, we previously recorded a reserve against our
outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $1,258,000 reflecting our best estimate
given the available facts and circumstances. We believe our reserve of approximately $2,400,000 against the insurance claim on Reliance as of September 30,
2006 is a significant estimate reflecting management’s judgment. To the extent we do not collect the insurance claim receivable of $1,258,000, we would be
required to record additional charges. Alternatively, if we collect amounts in excess of the current receivable balance, we would record a credit for the additional
funds received in the statement of operations.

Redux–Related Liabilities

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

Accounting for Stock–Based Compensation

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

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

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

45
such persons who retire after meeting certain age and service requirements may have an extended period of time after retirement to exercise options that were
vested at the date of retirement. Pursuant to SFAS 123R, we are required to record the value of this modification to existing stock options. In the twelve month period ended September 30, 2006, we recorded $300,000 of noncash compensation expense related to this modification. Also, during the twelve months ended September 30, 2006, we amended certain provisions of outstanding stock options and recorded $472,000 of noncash compensation expense related to these modifications.

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

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

Presented below is the Company’s stock option activity:

<table>
<thead>
<tr>
<th>Stock Options</th>
<th>Warrants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Weighted Average</td>
</tr>
<tr>
<td>Shares</td>
<td>Exercise Price</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Outstanding at September 30, 2003</th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>Granted</td>
<td>10,263,170</td>
<td>$4.17</td>
<td>105,000</td>
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<tr>
<td>Exercised</td>
<td>1,661,500</td>
<td>$6.62</td>
<td>(20,000)</td>
</tr>
<tr>
<td>Cancelled</td>
<td>(331,795)</td>
<td>$3.01</td>
<td>(75,000)</td>
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<tr>
<td>Outstanding at September 30, 2004</td>
<td>10,931,792</td>
<td>$4.57</td>
<td>10,000</td>
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<tr>
<td>Granted</td>
<td>1,433,500</td>
<td>$3.84</td>
<td>—</td>
</tr>
<tr>
<td>Exercised</td>
<td>(245,791)</td>
<td>$2.37</td>
<td>—</td>
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<tr>
<td>Cancelled</td>
<td>(271,206)</td>
<td>$6.25</td>
<td>—</td>
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<tr>
<td>Outstanding at September 30, 2005</td>
<td>11,848,295</td>
<td>$4.49</td>
<td>10,000</td>
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<tr>
<td>Granted</td>
<td>606,250</td>
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<td>—</td>
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<tr>
<td>Exercised</td>
<td>(409,938)</td>
<td>$2.83</td>
<td>—</td>
</tr>
<tr>
<td>Cancelled</td>
<td>(263,229)</td>
<td>$4.99</td>
<td>(10,000)</td>
</tr>
<tr>
<td>Outstanding at September 30, 2006</td>
<td>11,781,378</td>
<td>$4.55</td>
<td>—</td>
</tr>
<tr>
<td>Options exercisable at end of period</td>
<td>9,579,206</td>
<td>$4.48</td>
<td>—</td>
</tr>
<tr>
<td>Weighted average fair value of options granted during fiscal 2006</td>
<td>$3.25</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
At September 30, 2006, stock options were outstanding and exercisable as follows:

<table>
<thead>
<tr>
<th>Range of Exercise Price</th>
<th>Number</th>
<th>Weighted Average Remaining Contractual Life</th>
<th>Weighted Average Exercise Price</th>
<th>Number</th>
<th>Weighted Average Exercise Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1.22−$ 2.71</td>
<td>3,021,002</td>
<td>3.9 years</td>
<td>$2.31</td>
<td>2,847,440</td>
<td>$2.29</td>
</tr>
<tr>
<td>$2.77−$ 4.16</td>
<td>3,407,251</td>
<td>5.3 years</td>
<td>$3.67</td>
<td>2,583,361</td>
<td>$3.81</td>
</tr>
<tr>
<td>$4.26−$ 6.19</td>
<td>3,671,750</td>
<td>4.1 years</td>
<td>$5.94</td>
<td>3,098,958</td>
<td>$6.01</td>
</tr>
<tr>
<td>$6.21−$20.13</td>
<td>1,681,375</td>
<td>7.0 years</td>
<td>$7.33</td>
<td>1,049,447</td>
<td>$7.60</td>
</tr>
<tr>
<td>$1.22−$20.13</td>
<td>11,781,378</td>
<td>4.8 years</td>
<td>$4.55</td>
<td>9,579,206</td>
<td>$4.48</td>
</tr>
</tbody>
</table>

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

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

Results of Operations

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

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

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

Contract and license fee revenue related almost entirely to the SANCTURA Agreement and increased $4,647,000, or 24%, to $23,714,000 in fiscal year 2006 from $19,067,000 in fiscal 2005. Sales force subsidy pursuant to the SANCTURA Agreement increased $2,122,000, or 32%, to $8,811,000 in fiscal 2006 from $6,689,000 in fiscal 2005. Fiscal 2006 reflected a slightly higher average subsidy rate than fiscal 2005 as well as a full year of subsidy compared to only ten months of subsidy in fiscal 2005. Sales force subsidies for the fiscal year ended September 30, 2007 are expected to approximate $8,750,000. Fiscal 2005 included a $1,490,000
reduction to contract and license fee revenue for net reimbursement due to PLIVA for SANCTURA promotion and advertising costs; the absence of a similar reimbursement in fiscal 2006 resulted in an increase in contract and license fee revenue. After the co-promotion period ended November 28, 2004, PLIVA became responsible for promotion and advertising costs. The fiscal year ended September 30, 2006 included $1,266,000 of contract and license fee revenue, $1,000,000 of which was received in cash, from the amended bucindolol license agreement. Also included in contract and license fee revenue was $13,417,000 and $13,875,000 from amortization of deferred revenue during fiscal 2006 and 2005, respectively.

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

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

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

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

General and administrative expense increased $1,768,000, or 13%, to $15,478,000 in fiscal 2006 from $13,710,000 in fiscal 2005. Included in the fiscal 2006 general and administrative expense were charges of approximately $2,800,000 for noncash stock–based compensation expense related to the adoption of SFAS 123R, increases in legal fees of approximately $400,000 and increased compensation expense of approximately $800,000 related primarily to higher staffing levels. Partially offsetting these increases was a decrease of $300,000 for Sarbanes–Oxley Section 404 compliance. In addition, in fiscal 2005 we incurred a charge of $1,300,000 related to the non–utilization of our former facilities. During the fiscal year ended September 30,
2006, we settled the remaining lease obligations relating to our former facility for a payment of $500,000 and reflected a credit of approximately $300,000 in marketing, general, and administrative expense related to the extinguishment of the remaining accrued liability.

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

Interest expense relates to our $72,000,000 Convertible Notes. Annual interest expense is approximately $5,200,000 and includes approximately $700,000 of amortization of debt issuance costs.

The provision for income taxes of $3,171,000 in fiscal 2005 relates to U.S. federal alternative minimum tax and state income tax. Tax recognition of the initial and milestone payments received pursuant to the SANCTURA Agreement in fiscal 2004 were deferred to fiscal 2005 when they were recognized in full. Utilization of tax loss carryforwards is limited for use against the U.S. federal alternative tax and by certain states resulting in federal and state tax obligations in fiscal 2005.

**Fiscal Year Ended September 30, 2005 Compared to Fiscal Year Ended September 30, 2004**

Our net loss decreased $14,994,000 to $(53,218,000), or $(1.13) per share, basic, in fiscal 2005 from $(68,212,000), or $(1.43) per share, basic, in fiscal 2004. This reduced loss is primarily the result of increased revenues from SANCTURA and decreased sales and marketing expenses, partially offset by increased research and development expenses.

Total revenues increased $14,610,000, or 78%, to $33,336,000 in fiscal 2005 from $18,726,000 in fiscal 2004 primarily due to SANCTURA. Fiscal 2005 reflected a full year of revenues related to the marketing of SANCTURA and amortization of deferred revenue. Fiscal 2004 reflected only a partial year of revenues from the marketing of SANCTURA and six months of amortization of deferred revenue. Fiscal 2005 was approved for marketing by the FDA on May 28, 2004 and launched in August 2004.

Product revenue, which includes royalties and sales of product, increased $4,529,000, or 46%, to $14,269,000 in fiscal 2005 from $9,740,000 in fiscal 2004. Royalties on SANCTURA were $6,742,000, including $1,789,000 of royalties due to Madaus, in fiscal 2005. This compares to $122,000 of royalties on SANCTURA, including $24,000 of royalties due to Madaus, in fiscal 2004. This increase is primarily due to a full year of marketing SANCTURA compared to only several months of marketing SANCTURA in fiscal 2004. Fiscal 2005 SANCTURA royalty revenue included $1,758,000 of minimum royalties, including $352,000 of royalties due to Madaus, from Esprit. Partially offsetting increased SANCTURA royalty revenue in fiscal 2005 was a $1,440,000, or 20%, decrease in sales of product, including bottles and samples, to $5,839,000 in fiscal 2005 from $7,279,000 in fiscal 2004. Fiscal 2004 sales of product were higher as PLIVA had purchased product to satisfy initial orders and to provide samples for the launch of SANCTURA. Additionally, royalties from Lilly on sales of Sarafem decreased $648,000, or 28%, to $1,687,000 in fiscal 2005 from $2,335,000 in fiscal 2004.

Contract and license fee revenue increased $10,081,000, or 112%, to $19,067,000 in fiscal 2005 from $8,986,000 in fiscal 2004, and relates almost entirely to the SANCTURA Agreement. Amortization of deferred revenue increased $7,625,000, or 122%, to $13,875,000 in fiscal 2005 from $6,250,000 in fiscal 2004. This increase is primarily due to a full year of amortization in fiscal 2005 compared to six months of amortization in fiscal 2004. Fiscal 2005 also included $6,689,000 of sales force subsidy. Partially offsetting these increases was a decrease of $4,052,000 in contract and license fee revenue to $1,490,000 of net SANCTURA promotion and advertising costs due to PLIVA from us in fiscal 2005 reflected as a reduction to revenue. This compares to $2,562,000 of net SANCTURA promotion and advertising costs due to us from PLIVA in fiscal 2004 reflected as revenue.
Cost of product revenue relates primarily to SANCTURA and includes cost of product sold and royalties we owe to Madaus. Cost of product revenue increased $643,000, or 8%, to $8,593,000 in fiscal 2005 from $7,950,000 in fiscal 2004. Cost of SANCTURA sold decreased $1,312,000 or 18%, to $5,967,000 in fiscal 2005 from $7,279,000 in fiscal 2004. We sell SANCTURA to our marketing partner at cost and this decrease is commensurate with the decreased sales of product as described above. Royalties to Madaus increased $1,765,000 to $1,789,000 in fiscal 2005 from $24,000 in fiscal 2004 commensurate with increased SANCTURA royalty revenue as described above. Pursuant to the SANCTURA Agreement, we are reimbursed the royalties we owe to Madaus on sales of SANCTURA. Royalties due to the Massachusetts Institute of Technology for their portion of the Sarafem royalties decreased to $337,000 in fiscal 2005 from $452,000 in fiscal 2004 commensurate with the decrease in royalties we received from Lilly.

Research and development expense increased $7,294,000, or 31%, to $30,597,000 in fiscal 2005 from $23,303,000 in fiscal 2004. Research and development expense related to milestones and up front payments pursuant to license arrangements increased $6,500,000, including the $7,500,000 up front payment made to Schering for the in-license of NEBIDO. Additionally contributing to increased research and development expense was approximately $1,300,000 of increased staffing and related support costs. Partially offsetting these increases was a noncash charge of approximately $1,000,000 incurred in fiscal 2004 relating to the extension of expiration dates of certain stock option grants to an officer. External costs related to the development of our product and product candidates was approximately $17,200,000 in fiscal 2005 compared to approximately $17,500,000 in fiscal 2004. Decreased external development costs related to SANCTURA, and due primarily to twice-a-day development in fiscal 2004, were offset primarily by increased development costs related to aminocandin. Total research and development expense for fiscal 2005 substantially relates to our major compounds being developed as follows: SANCTURA and SANCTURA XR $13,662,000, NEBIDO $7,576,000, PRO 2000 $1,157,000, pagoclone $2,575,000, IP 751 $525,000, and aminocandin $5,006,000. We also incurred research and development expenses for fiscal 2005 of $99,000 related to other compounds.

Marketing, general and administrative expense decreased $9,933,000, or 19%, to $41,983,000 in fiscal 2005 from $51,916,000 in fiscal 2004 primarily due to decreased marketing costs related to SANCTURA.

Marketing expenses decreased $9,975,000, or 26%, to $28,273,000 in fiscal 2005 from $38,248,000 in fiscal 2004. Promotion and advertising costs related to SANCTURA decreased approximately $15,500,000 as significant expenses were incurred in fiscal 2004 to launch SANCTURA. Subsequent to the Conversion, PLIVA was, and Esprit is now, responsible for such costs. Partially offsetting the decreased promotion and advertising costs are approximately $6,100,000 of increased sales force and sales operations-related costs. This increase reflects increased costs related to our approximately 85 person specialty sales force and related infrastructure which was in place for all of fiscal 2005 compared to approximately five months in fiscal 2004. Partially offsetting the increased costs related to our approximately 85 person specialty sales force and related infrastructure are decreased costs related to the approximately 200 person primary care sales force which was in place for only the first two months of fiscal 2005 compared to approximately five months in fiscal 2004.

General and administrative expense remained relatively constant at approximately $13,700,000 in fiscal 2005 and fiscal 2004. Certain nonrecurring expenses incurred in fiscal 2004 were offset by other increased costs incurred in fiscal 2005. In fiscal 2004, we extended the expiration dates of certain stock option grants to directors and officers and reflected a noncash charge of approximately $3,000,000 in general and administrative expense for these extensions. In fiscal 2004 we also incurred approximately $1,000,000 of expense for consulting services related to the SANCTURA Agreement. Fiscal 2005 included approximately $1,400,000 for consulting, accounting and other professional fees related to our implementation of Sarbanes-Oxley-required accounting and reporting control systems, tax compliance and other costs related to our expanded business activities. Also included in fiscal 2005 general and administrative expense is approximately $1,300,000 related to the non-utilization of our former facilities.

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
Investment income increased $1,746,000, or 125%, to $3,142,000 in fiscal 2005 from $1,396,000 in fiscal 2004. While weighted average invested balances in fiscal 2005 were somewhat lower than weighted average invested balances in fiscal 2004, the increase in investment income is primarily the result of higher interest rates.

Interest expense relates to our $72,000,000 of 6.25% Convertible Senior Notes due 2008 (the “Convertible Notes”). Annual interest expense is approximately $5,200,000 and includes approximately $700,000 of amortization of debt issuance costs.

The provision for income taxes of $3,171,000 in fiscal 2005 relates to U.S. federal alternative minimum tax and state income tax. Tax recognition of the initial and milestone payments received pursuant to the SANCTURA Agreement in fiscal 2004 were deferred to fiscal 2005 when they were recognized in full. Utilization of tax loss carryforwards is limited for use against the U.S. federal alternative tax and by certain states resulting in federal and state tax obligations in fiscal 2005.

**Liquidity and Capital Resources**

**Cash, Cash Equivalents and Marketable Securities**

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

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

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

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

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

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
common stock may be offered from time to time through one or more methods of distribution, subject to market conditions and our capital needs. The terms of any offerings would be established at the time of the offering. Currently, we do not have any commitments to sell such shares remaining under the registration statement.

Product Development

We expect to continue to expend substantial additional amounts for the development of our products. In particular, we are continuing to expend substantial funds for SANCTURA XR, NEBIDO and other development efforts. We are responsible for conducting and funding the development of SANCTURA XR. We could receive approximately $35,000,000 in a future payment contingent upon the approval of an NDA for SANCTURA XR. If Esprit provides notice to us no later than the approval date that it does not intend to proceed with the launch of SANCTURA XR, the U.S. rights to SANCTURA XR will revert to us and Esprit will not have an obligation to pay the development milestone of approximately $35,000,000 related to the FDA approval of the NDA for SANCTURA XR or the $20,000,000 long–term commercialization milestone.

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

Total research and development expenses incurred by us through September 30, 2006 on the major compounds currently being developed or marketed, including up–front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: $130,900,000 for SANCTURA and SANCTURA XR, $17,800,000 for NEBIDO, $17,600,000 for PRO 2000, $6,800,000 for IP 751, $32,900,000 for pagoclone, and $11,300,000 for aminocandin. In June 2002, we re–acquired rights to pagoclone from Pfizer Inc. During the period Pfizer had rights to pagoclone, Pfizer conducted and funded all development activities for pagoclone. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency–sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early–stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA.

Given the above uncertainties, and other risks, variables and considerations related to each compound and regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from September 30, 2006 through the preparation of an NDA for our major compounds currently being developed as follows: approximately $13,000,000 for NEBIDO, $13,000,000 for PRO 2000, approximately $46,000,000 for IP 751, and approximately $55,000,000 for pagoclone for stuttering. As a result of our recently announced agreement to outlicense aminocandin to Novexel, we do not expect to incur any expenses for future development. Actual costs to complete any of our products may differ significantly from the estimates. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development. We are currently considering strategic partners for future development and commercialization of IP 751 and PRO 2000 and evaluating commercialization options for pagoclone in parallel with our ongoing development program and preliminary market development activities.
Analysis of Cash Flows

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

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

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

Contractual Obligations and Off−Balance Sheet Arrangements

The following chart summarizes our contractual payment obligations as of September 30, 2006. The Convertible Notes and license fees are reflected as liabilities on our Balance Sheet as of September 30, 2006. Operating leases are accrued and paid pursuant to the lease arrangement. Purchase obligations relate to research and development agreements and arrangements; portions of these amounts are reflected as accrued expenses on our Balance Sheet as of September 30, 2006.

<table>
<thead>
<tr>
<th>Contractual Obligations</th>
<th>Less than 1 Year</th>
<th>1−3 Years</th>
<th>3−5 Years</th>
<th>Greater than 5 Years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convertible Notes (1)</td>
<td>$ —</td>
<td>$ 72,000,000</td>
<td>$ —</td>
<td>$ —</td>
<td>$ 72,000,000</td>
</tr>
<tr>
<td>Interest on Convertible Notes (1)</td>
<td>4,500,000</td>
<td>3,600,000</td>
<td>—</td>
<td>—</td>
<td>8,100,000</td>
</tr>
<tr>
<td>Purchase obligations (2)</td>
<td>15,434,000</td>
<td>7,343,000</td>
<td>1,789,000</td>
<td>1,000</td>
<td>24,567,000</td>
</tr>
<tr>
<td>Operating leases (3)</td>
<td>1,231,000</td>
<td>2,215,000</td>
<td>1,251,000</td>
<td>—</td>
<td>4,697,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$ 21,165,000</td>
<td>$ 85,158,000</td>
<td>$ 3,040,000</td>
<td>$ 1,000</td>
<td>$ 109,364,000</td>
</tr>
</tbody>
</table>

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

Pursuant to certain of our in−licensing arrangements, we will owe payments to our licensors upon achievement of certain development, regulatory and licensing milestones. We generally cannot predict if or when such events will occur. In fiscal 2006, we recorded a license payment obligation to Madaus and an intangible asset of $1,500,000 in recognition of expected achievement of a contingent cumulative net sales milestone related to SANCTURA. We commenced amortizing the intangible asset to cost of revenue over the remaining estimated term of the Madaus license agreement and we expect to pay the milestone when it is achieved.

Pursuant to the Madaus Agreement, we are committed to purchase from Madaus significant minimum quantities of bulk SANCTURA tablets during fiscal 2007 aggregating approximately $3,900,000. If we do not satisfy this minimum purchase requirement, we would be subject to a minimum supply fee of a portion of the value of the unpurchased minimum quantities. Pursuant to the SANCTURA Agreement, Esprit agreed to purchase the same quantities of SANCTURA and to be responsible for commercial product procurement costs, including costs to manufacture SANCTURA and the minimum supply fee.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
Pursuant to the DELATESTRYL Agreement, we assumed Savient’s previous obligation to purchase approximately $1,100,000 of additional DELATESTRYL inventory. We believe the supplier defaulted on its obligation to provide DELATESTRYL in the time required and we believe we are no longer obligated to purchase this inventory. In the event the supplier was able to demonstrate compliance with the agreement and we were obligated to purchase such inventory, we may be required to provide a reserve for at least a portion of the value of this inventory.

We lease approximately 95 automobiles for our field sales force. The lease requires a minimum term of 12 months per automobile. We expect monthly lease expense related to this operating lease to be approximately $50,000. We are responsible for certain disposal costs in case of termination.

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

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

Other

In May 2005, the FASB issued SFAS No. 154, “Accounting Changes and Error Corrections”. SFAS No. 154 is a replacement of Accounting Principles Board Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application as the required method for reporting a change in accounting principle. SFAS No. 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS No. 154. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We will adopt this pronouncement beginning October 1, 2006. We do not expect the adoption of SFAS No. 154 will have a material impact on our consolidated results of operations and financial condition.

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

In June 2006, the FASB ratified Emerging Issues Task Force (“EITF”) Issue No. 06−3, “How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation)”. This standard allows companies to present in their statements of income any taxes assessed by a governmental authority that are directly imposed on revenue−producing transactions between a seller and a customer, such as sales, use, value−added, and some excise taxes.
on either a gross (included in revenue and costs) or a net (excluded from revenue) basis. This standard is effective for interim and fiscal years beginning after December 15, 2006. The Company is currently evaluating the potential impact of this issue on the financial statements, but does not believe the impact of the adoption of this standard will be material.

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

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

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

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

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

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

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

Risk related to the Convertible Notes

The fair value of our Convertible Notes is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Convertible Notes are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, a decrease of 10% of the market value of our Common Stock could reduce the value of a $1,000 Note by approximately $59. An increase in market interest rates could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, an interest rate increase of 1% could reduce the value of a $1,000 Convertible Note by approximately $8. The two examples provided above are only hypothetical and actual changes in the value of the Convertible Notes due to fluctuations in market value of our Common Stock or interest rates could vary substantially from these examples.

ITEM 8. Financial Statements and Supplementary Data

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

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

Not applicable.
ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of September 30, 2006, of the design and operation of our disclosure controls and procedures, as defined in Rule 13a–15(e) of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2006 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

Management’s Report on Internal Control Over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a−15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principals in the United States. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). Based upon that evaluation, management has concluded that our internal control over financial reporting was effective as of September 30, 2006.

Our assessment of the effectiveness of our internal control over financial reporting as of September 30, 2006 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears on page F–2.

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

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a–15(f) and 15d–15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

None.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
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 14A within 120 days after the close of our fiscal year except the information required by Regulation S−K, Item 201(d) which is reflected in Part II, Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities.

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ITEM 15. Exhibits, Financial Statement Schedules

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

   (2) Financial Statement Schedule: All financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.
(3) Exhibits. The following exhibits are filed as part of the annual report:

3.4 – Restated Certificate of Incorporation of Registrant, as amended (63)
3.5 – By–Laws of Registrant (50)
4.1 – Indenture dated as of July 16, 2003 between the Registrant, Lehman Brothers Inc. and Wachovia Capital Markets, LLC (51)
4.2 – Registration Rights Agreement dated as of July 16, 2003 between the Registrant, Lehman Brothers Inc. and Wachovia Capital Markets, LLC (51)
4.8 – 1997 Equity Incentive Plan and Form of Restricted Stock Award Agreement thereunder (25)(65)
4.9 – Form of Notice of Grant of Stock Options issued under the Registrant’s 2004 Equity Incentive Plan (65)
4.10 – Form of Option Agreement relating to Incentive Stock Options issued under the Registrant’s 2004 Equity Incentive Plan (65)
4.11 – Form of Option Agreement relating to Non–Qualified Stock Options issued under the Registrant’s 2004 Equity Incentive Plan (65)
4.12 – Form of Restricted Stock Award issued under the Registrant’s 2004 Equity Incentive Plan (65)
10.6 – Assignment of Invention and Agreement between Richard Wurtman, M.D., Judith Wurtman and the Registrant (1)
10.9 – Restated and Amended 1989 Stock Option Plan (4)
10.11 – Restated Amendment to MIT Option Agreement (1)
10.12(b) – Amendment Agreement between Registrant and Servier, Orsem and Oril Produits Chimiques dated November 19, 1992 (2) (6)
10.12(c) – Amendment Agreement dated April 28, 1993 between Registrant and Servier (9)
10.12(d) – Consent and Amendment Agreement among Servier, American Home Products Corp. and Registrant (17)
10.13 – Trademark License Agreement between the Registrant and Orsem dated February 7, 1990 (1)
10.14 – Supply Agreement between the Registrant and Oril Produits Chimiques dated February 7, 1990 (1) (2)
10.16 – Assignment of Invention by Richard Wurtman, M.D. (1)
10.25 – License Agreement between the Registrant and the Massachusetts Institute of Technology (3)
10.37 – License Agreement dated as of February 15, 1992 between the Registrant and Massachusetts Institute of Technology (5)
10.41 – 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)

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
| 10.44  | Consent Agreement between Registrant and Servier dated November 19, 1992 (12) |
| 10.45  | Agreement between Registrant and PAREXEL International Corporation dated October 22, 1992 (as of July 21, 1992) (2) (7) |
| 10.46  | License Agreement dated February 9, 1993 between the Registrant and Massachusetts Institute of Technology (2) (8) |
| 10.52  | License Agreement dated February 18, 1994 between Registrant and Rhone–Poulenc Rorer, S.A. (11) |
| 10.55  | Patent License Agreement between Registrant and Massachusetts Institute of Technology dated March 1, 1994 (11) |
| 10.59  | Exhibit D to Agreement between Registrant and Parexel International Corporation dated as of March 15, 1994 (2) (12) |
| 10.60(a) | Acquisition Agreement dated as of May 13, 1994 among the Registrant, Intercardia, Inc., Cardiovascular Pharmacology Engineering Consultants, Inc. (CPEC), Myocor, Inc. and the sellers named therein (13) |
| 10.60(b) | Amendment dated June 15, 1994 to Acquisition Agreement referenced in Exhibit 10.60(a) (13) |
| 10.61  | License Agreement dated December 6, 1991 between Bristol–Myers Squibb and CPEC, as amended (2) (13) |
| 10.61(a) | Letter Agreement dated November 18, 1994 between CPEC and Bristol–Myers Squibb (4) |
| 10.65(a) | 1994 Long–Term Incentive Plan, as amended (23) |
| 10.68(a) | Interneuron Pharmaceuticals, Inc. 1995 Employee Stock Purchase Plan, as amended (19) (58) |
| 10.78  | Contract Manufacturing Agreement dated November 20, 1995 between Registrant and Boehringer Ingelheim Pharmaceuticals, Inc. (2) (17) |
| 10.83  | Co–promotion Agreement effective June 1, 1996 between Wyeth–Ayerst Laboratories and Interneuron Pharmaceuticals, Inc. (2) (18) |
| 10.87  | Lease dated February 5, 1997 between Registrant and Ledgemont Realty Trust (21) |
| 10.93  | Form of Indemnification Agreement between Registrant and each director, executive officer and certain officers of the Registrant entered into as of October 6, 1997 (26) |
| 10.94  | 1998 Employee Stock Option Plan (27) |
| 10.96  | Assignment and Assumption and Royalty Agreement between Intercardia and Registrant dated May 8, 1998 (29) |
| 10.102 | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Michael W. Rogers dated and effective as of February 23, 1999 (34) (71) |
| 10.103 | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Bobby W. Sandage, Jr. dated and effective as of March 15, 1999 (34) (71) |
| 10.104 | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Mark S. Butler dated and effective as of March 15, 1999 (34) (71) |
| 10.105 | Employment Agreement between Interneuron Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated and effective as of May 1, 1999 (34) (71) |
| 10.108 | Exchange Agreement dated July 15, 1999 between Intercardia, Inc. and Interneuron Pharmaceuticals, Inc. (35) |

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
10.109  – Amended and Restated Limited Liability Company Agreement of CPEC LLC dated July 15, 1999 among CPEC LLC, Interneuron Pharmaceuticals, Inc. and Intercardia, Inc. (35)
10.110  – Assignment, Assumption and License Agreement dated July 15, 1999 by and between CPEC LLC and Intercardia, Inc. (35)
10.113  – License Agreement effective as of November 26, 1999 between Madaus AG and Interneuron Pharmaceuticals, Inc. (37) (2)
10.116(a) – 2000 Stock Option Plan (39)
10.119  – License Agreement by and between Charles S. Lieber, M.D. and Interneuron Pharmaceuticals, Inc. dated December 26, 2000 (42) (2)
10.120  – Indemnity and Release Agreement between American Home Products Corporation and Interneuron Pharmaceuticals, Inc. dated as of May 30, 2001 (43) (2)
10.124  – Form of Stock Purchase Agreement dated December 20, 2001 between Indevus Pharmaceuticals, Inc. and the Investors named on Schedule A attached thereto (45)
10.127  – Employment Agreement dated and effective as of October 1, 2002 by and between Indevus Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. (47) (71)
10.128  – Amendment No. 1 to Licensing Agreement by and between Registrant and Eli Lilly and Company and Eli Lilly S.A. (48) (2)
10.129  – Supply Agreement between Registrant and Madaus AG dated December 16, 2003 (48) (2)
10.130  – Development and License Agreement between Registrant and Shire Laboratories Inc. dated March 11, 2003 (49) (2)
10.131  – Amendment to the License Agreement by and between Registrant and Paligent Inc. dated April 10, 2003 (49)
10.132  – License Agreement by and between Registrant and Aventis Pharma SA dated April 18, 2003 (51) (2)
10.133  – License Agreement by and between Registrant and Sumner Burstein dated August 22, 2003 (52) (2)
10.134  – Assignment and Termination Agreement by and between Registrant and Manhattan Pharmaceuticals, Inc. dated August 22, 2003 (52) (2)
10.136  – Agreement by and between the Registrant and Ferrer Internacional S.A. dated January 22, 2004 (53)(2)
10.138  – 2004 Equity Incentive Plan (54)
10.139  – License, Commercialization and Supply Agreement dated April 6, 2004 between the Registrant and Odyssey Pharmaceuticals Inc. (55)(2)
10.140  – Fiscal 2005 CEO Bonus Plan, as adopted by the Board of Directors on December 7, 2004 (56) (71)
10.141  – Fiscal 2005 Senior Executive Bonus Plan, as adopted by the Board of Directors on December 7, 2004 (56) (71)
10.143  – Amendment No. 1 to License, Commercialization and Supply Agreement dated April 30, 2005 between the Registrant and Odyssey Pharmaceuticals, Inc. (59)
10.144  – Amendment and Consent Agreement dated May 14, 2005 between the Registrant, Odyssey Pharmaceuticals, Inc., and Saturn Pharmaceuticals, Inc (60)
<table>
<thead>
<tr>
<th>Document Reference</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.145</td>
<td>License Agreement dated July 28, 2005 between the Registrant and Schering Aktiengesellschaft (61)</td>
</tr>
<tr>
<td>10.146</td>
<td>Fiscal 2006 CEO Bonus Plan, as adopted by the Board of Directors on September 20, 2005 (62) (71)</td>
</tr>
<tr>
<td>10.147</td>
<td>Fiscal 2006 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 20, 2005 (62) (71)</td>
</tr>
<tr>
<td>10.148</td>
<td>Collaborative Research and Licensing Agreement dated July 26, 2005 between the Registrant and Medical Research Counsel (63) (2)</td>
</tr>
<tr>
<td>10.149</td>
<td>Form of Indemnification Agreement between Registrant and certain directors, executive officers and officers of the Registrant (63) (71)</td>
</tr>
<tr>
<td>10.150</td>
<td>Asset Purchase Agreement dated December 12, 2005 by and between Saviant Pharmaceuticals, Inc. and the Registrant (2) (64)</td>
</tr>
<tr>
<td>10.151</td>
<td>Form of Employment Agreement by and between the Registrant and Noah D. Beerman, dated March 31, 2006 (66) (71)</td>
</tr>
<tr>
<td>10.152</td>
<td>Form of Employment Agreement by and between the Registrant and John H. Tucker, dated March 31, 2006 (66) (71)</td>
</tr>
<tr>
<td>10.153</td>
<td>Form of Underwriting Agreement, dated June 28, 2006; by and between the Registrant and UBS Securities LLC, as representative of the several underwriters named therein (67)</td>
</tr>
<tr>
<td>10.154</td>
<td>A copy of the Fiscal Year 2007 CEO Bonus Plan, as adopted by the Board of Directors on September 12, 2006 (68) (71)</td>
</tr>
<tr>
<td>10.155</td>
<td>A copy of the Fiscal Year 2007 Senior Executive Bonus Plan, as adopted by the Board of Directors on September 12, 2006 (68) (71)</td>
</tr>
<tr>
<td>10.156</td>
<td>Form of Employment Agreement by and between the Registrant and Thomas Farb dated on or about October 16, 2006 (69) (71)</td>
</tr>
<tr>
<td>10.157</td>
<td>Form of Indemnification Agreement with Thomas Farb dated on or about October 16, 2006 (63) (71)</td>
</tr>
<tr>
<td>10.158</td>
<td>Manufacturing and Supply Agreement by and between the Registrant and Schering AG, Germany dated on or about October 20, 2006 (2) (70)</td>
</tr>
<tr>
<td>10.159</td>
<td>License and Supply Agreement by and between the Registrant and Madaus GmbH dated on or about November 3, 2006 (2) (70)</td>
</tr>
<tr>
<td>10.160</td>
<td>Amendment and Agreement by and between the Registrant and Madaus GmbH dated on or about November 3, 2006 (2) (70)</td>
</tr>
<tr>
<td>10.161</td>
<td>Know−How License Agreement by and between the Registrant and Novexel SA dated December 4, 2006 (2) (70)</td>
</tr>
<tr>
<td>10.162</td>
<td>API Supply Agreement by and between the Registrant and Helsinn Chemicals SA and Helsinn Advanced Synthesis SA dated on or about November 22, 2006 (2) (70)</td>
</tr>
<tr>
<td>21</td>
<td>List of Subsidiaries (70)</td>
</tr>
<tr>
<td>23</td>
<td>Consent of PricewaterhouseCoopers LLP (70)</td>
</tr>
<tr>
<td>31.1</td>
<td>Certification of Principal Executive Officer required by Rule 13a–14(a) or Rule 15d–14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes–Oxley Act of 2002 (70)</td>
</tr>
<tr>
<td>31.2</td>
<td>Certification of Principal Financial Officer required by Rule 13a–14(a) or Rule 15d–14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes–Oxley Act of 2002 (70)</td>
</tr>
</tbody>
</table>

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer (70)

32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002, by Michael W. Rogers, Chief Financial Officer (70)

(1) Incorporated by reference to the Registrant’s Registration Statement on Form S–1 (File No. 33–32408) declared effective on March 8, 1990.
(2) Confidential Treatment requested for a portion of this Exhibit.
(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.
(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.
(11) Incorporated by reference to the Registrant’s Registration Statement on Form S–3 or Amendment No. 1 (File no. 33–75826).
(13) Incorporated by reference to the Registrant’s Form 8–K dated June 20, 1994.
(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.
(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.
SIGNATURES

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

Date: December 7, 2006

\[\text{INDEVUS PHARMACEUTICALS, INC.}\]

By: \(\text{/s/ GLENN L. COOPER}\)

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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ GLENN L. COOPER</td>
<td>Chief Executive Officer and Chairman (Principal Executive Officer)</td>
<td>December 7, 2006</td>
</tr>
<tr>
<td>Andrew Ferrara</td>
<td>Director</td>
<td>December 7, 2006</td>
</tr>
<tr>
<td>/s/ MICHAEL E. HANSON</td>
<td>Director</td>
<td>December 7, 2006</td>
</tr>
<tr>
<td>Stephen C. McCluski</td>
<td>Director</td>
<td>December 7, 2006</td>
</tr>
<tr>
<td>/s/ MALCOLM MORVILLE</td>
<td>Director</td>
<td>December 7, 2006</td>
</tr>
<tr>
<td>Cheryl P. Morley</td>
<td>Director</td>
<td>December 7, 2006</td>
</tr>
<tr>
<td>/s/ DAVID B. SHARROCK</td>
<td>Director</td>
<td>December 7, 2006</td>
</tr>
<tr>
<td>Michael W. Rogers</td>
<td>Executive Vice President, Chief Financial Officer, and Treasurer (Principal Financial Officer)</td>
<td>December 7, 2006</td>
</tr>
<tr>
<td>/s/ DALE RITTER</td>
<td>Senior Vice President, Finance, (Principal Accounting Officer)</td>
<td>December 7, 2006</td>
</tr>
</tbody>
</table>
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Financial Statements

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets—At September 30, 2006 and 2005
Consolidated Statements of Operations—For the years ended September 30, 2006, 2005 and 2004
Consolidated Statements of Stockholders’ Deficit—For the years ended September 30, 2006, 2005, and 2004
Consolidated Statements of Cash Flows—For the years ended September 30, 2006, 2005, and 2004
Notes to Consolidated Financial Statements

F−1
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have completed integrated audits of Indevus Pharmaceuticals, Inc.’s 2006 and 2005 consolidated financial statements and of its internal control over financial reporting as of September 30, 2006, and an audit of its 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)1, present fairly, in all material respects, the financial position of Indevus Pharmaceuticals, Inc. and its subsidiaries at September 30, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2006 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

Internal control over financial reporting

Also, in our opinion, management’s assessment, included in Management’s Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of September 30, 2006 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2006, based on criteria established in Internal Control—Integrated Framework issued by the COSO. The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management’s assessment and on the effectiveness of the Company’s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management’s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

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

/s/ P R I C E W A T E R H O U S E C O O P E R S  L L P

Boston, Massachusetts
December 7, 2006
### INDEVUS PHARMACEUTICALS, INC.
#### CONSOLIDATED BALANCE SHEETS
(Amounts in thousands except share data)

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2006</th>
<th>September 30, 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current assets:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$ 70,169</td>
<td>$ 85,098</td>
</tr>
<tr>
<td>Marketable securities</td>
<td>5,956</td>
<td>16,119</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>2,851</td>
<td>2,537</td>
</tr>
<tr>
<td>Inventories</td>
<td>1,628</td>
<td>971</td>
</tr>
<tr>
<td>Prepaid and other current assets</td>
<td>2,598</td>
<td>2,516</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>83,202</td>
<td>107,241</td>
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<tr>
<td>Property and equipment, net</td>
<td>880</td>
<td>1,103</td>
</tr>
<tr>
<td>Insurance claim receivable</td>
<td>1,258</td>
<td>1,258</td>
</tr>
<tr>
<td>Prepaid debt issuance costs</td>
<td>1,183</td>
<td>1,843</td>
</tr>
<tr>
<td>Inventories</td>
<td>3,293</td>
<td>—</td>
</tr>
<tr>
<td>Other assets</td>
<td>2,491</td>
<td>1,086</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>$ 92,307</td>
<td>$ 112,531</td>
</tr>
<tr>
<td><strong>LIABILITIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current liabilities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>$ 2,917</td>
<td>$ 2,297</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>11,026</td>
<td>9,910</td>
</tr>
<tr>
<td>Accrued interest</td>
<td>950</td>
<td>950</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>13,433</td>
<td>14,851</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>28,326</td>
<td>28,008</td>
</tr>
<tr>
<td>Convertible notes</td>
<td>72,000</td>
<td>72,000</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>114,041</td>
<td>127,457</td>
</tr>
<tr>
<td>Other</td>
<td>2,144</td>
<td>202</td>
</tr>
<tr>
<td>Minority interest</td>
<td>126</td>
<td>6</td>
</tr>
<tr>
<td>Commitments and contingencies (Notes G and I)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>STOCKHOLDERS’ DEFICIT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible preferred stock $.001 par value, 5,000,000 shares authorized:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Series B, 239,425 shares issued and outstanding (liquidation preference September 30, 2006 $3,026)</td>
<td>3,000</td>
<td>3,000</td>
</tr>
<tr>
<td>Series C, 5,000 shares issued and outstanding (liquidation preference September 30, 2006 $502)</td>
<td>500</td>
<td>500</td>
</tr>
<tr>
<td>Common stock, $.001 par value, 120,000,000 shares authorized; 56,040,456 shares issued and outstanding at September 30, 2006 and 47,825,896 shares issued at September 30, 2005</td>
<td>56</td>
<td>48</td>
</tr>
<tr>
<td>Additional paid-in-capital</td>
<td>344,789</td>
<td>307,435</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(472,675)</td>
<td>(422,121)</td>
</tr>
<tr>
<td>Accumulated other comprehensive loss</td>
<td>—</td>
<td>(4)</td>
</tr>
<tr>
<td>Treasury stock, at cost, 660,607 shares at September 30, 2005</td>
<td>—</td>
<td>(4,000)</td>
</tr>
<tr>
<td><strong>Total stockholders’ deficit</strong></td>
<td>(124,330)</td>
<td>(115,142)</td>
</tr>
<tr>
<td><strong>Total liabilities and stockholders’ deficit</strong></td>
<td>$ 92,307</td>
<td>$ 112,531</td>
</tr>
</tbody>
</table>

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

F−3

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
Indevus Pharmaceuticals, Inc.
Consolidated Statements of Operations
(Amounts in thousands except per share data)

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

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

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
INDEVUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS’ DEFICIT
(Dollar amounts in thousands)

<table>
<thead>
<tr>
<th>Common Stock</th>
<th>Preferred Stock</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Shares</td>
</tr>
<tr>
<td></td>
<td>Amount</td>
</tr>
<tr>
<td>Balance at September 30, 2003</td>
<td>47,175,661</td>
</tr>
<tr>
<td>Purchase of treasury stock</td>
<td></td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td>576,332</td>
</tr>
<tr>
<td>Proceeds from offering of Employee Stock Purchase Plan</td>
<td>68,120</td>
</tr>
<tr>
<td>Dividends on preferred stock</td>
<td></td>
</tr>
<tr>
<td>Stock–based compensation and other</td>
<td>5,783</td>
</tr>
<tr>
<td>Comprehensive loss:</td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td></td>
</tr>
<tr>
<td>Unrealized net loss on marketable and equity securities</td>
<td></td>
</tr>
<tr>
<td>Total comprehensive loss</td>
<td></td>
</tr>
<tr>
<td>Balance at September 30, 2004</td>
<td>47,825,896</td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td></td>
</tr>
<tr>
<td>Proceeds from offering of Employee Stock Purchase Plan</td>
<td></td>
</tr>
<tr>
<td>Dividends on preferred stock</td>
<td></td>
</tr>
<tr>
<td>Stock–based compensation and other</td>
<td></td>
</tr>
<tr>
<td>Comprehensive loss:</td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td></td>
</tr>
<tr>
<td>Unrealized net gain on marketable and equity securities</td>
<td></td>
</tr>
<tr>
<td>Total comprehensive loss</td>
<td></td>
</tr>
<tr>
<td>Balance at September 30, 2005</td>
<td>47,825,896</td>
</tr>
<tr>
<td>Public offering of common stock, net of issuance costs of $2,405</td>
<td>8,050,000</td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td>86,562</td>
</tr>
<tr>
<td>Proceeds from offering of Employee Stock Purchase Plan</td>
<td>68,067</td>
</tr>
<tr>
<td>Dividends on preferred stock</td>
<td></td>
</tr>
<tr>
<td>Stock–based compensation and other</td>
<td>9,931</td>
</tr>
<tr>
<td>Comprehensive loss:</td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td></td>
</tr>
<tr>
<td>Unrealized net gain on marketable and equity securities</td>
<td></td>
</tr>
<tr>
<td>Total comprehensive loss</td>
<td></td>
</tr>
<tr>
<td>Balance at September 30, 2006</td>
<td>56,040,456</td>
</tr>
</tbody>
</table>

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

F–5

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
<table>
<thead>
<tr>
<th></th>
<th>Accumulated Deficit</th>
<th>Accumulated Other Comprehensive Income (Loss)</th>
<th>Treasury Shares</th>
<th>Total Equity (Deficit)</th>
<th>Comprehensive Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balance at September 30, 2003</strong></td>
<td>(300,691)</td>
<td>(67)</td>
<td></td>
<td>6,241</td>
<td></td>
</tr>
<tr>
<td>Purchase of treasury stock</td>
<td></td>
<td>1,166,200</td>
<td>(7,319)</td>
<td>(7,319)</td>
<td></td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td>(84,751)</td>
<td>582</td>
<td>1,990</td>
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<tr>
<td>Proceeds from offering of Employee Stock Purchase Plan</td>
<td>(17,838)</td>
<td>92</td>
<td>237</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dividends on preferred stock</td>
<td></td>
<td></td>
<td>(35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock–based compensation and other</td>
<td>(6,486)</td>
<td>43</td>
<td>4,124</td>
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<td></td>
</tr>
<tr>
<td><strong>Comprehensive loss:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>(68,212)</td>
<td></td>
<td>(68,212)</td>
<td>(68,212)</td>
<td></td>
</tr>
<tr>
<td>Unrealized net loss on marketable and equity securities</td>
<td></td>
<td>(64)</td>
<td>(64)</td>
<td>(64)</td>
<td></td>
</tr>
<tr>
<td><strong>Total comprehensive loss</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(68,276)</td>
</tr>
<tr>
<td><strong>Balance at September 30, 2004</strong></td>
<td>(368,903)</td>
<td>(131)</td>
<td>1,057,125</td>
<td>(63,038)</td>
<td></td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td>(246,791)</td>
<td>1,620</td>
<td>584</td>
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<tr>
<td>Proceeds from offering of Employee Stock Purchase Plan</td>
<td>(138,364)</td>
<td>908</td>
<td>328</td>
<td></td>
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</tr>
<tr>
<td>Dividends on preferred stock</td>
<td></td>
<td></td>
<td>(35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock–based compensation and other</td>
<td>(11,363)</td>
<td>74</td>
<td>110</td>
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<tr>
<td><strong>Comprehensive loss:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>(53,218)</td>
<td></td>
<td>(53,218)</td>
<td>(53,218)</td>
<td></td>
</tr>
<tr>
<td>Unrealized net gain on marketable and equity securities</td>
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<td>127</td>
<td>127</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total comprehensive loss</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(53,091)</td>
</tr>
<tr>
<td><strong>Balance at September 30, 2005</strong></td>
<td>(422,121)</td>
<td>(4)</td>
<td>660,607</td>
<td>(115,142)</td>
<td></td>
</tr>
<tr>
<td>Public offering of common stock, net of issuance costs of $2,405</td>
<td></td>
<td></td>
<td></td>
<td>35,028</td>
<td></td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td>(323,376)</td>
<td>2,082</td>
<td>1,159</td>
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<tr>
<td>Proceeds from offering of Employee Stock Purchase Plan</td>
<td>(125,666)</td>
<td>754</td>
<td>640</td>
<td></td>
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</tr>
<tr>
<td>Dividends on preferred stock</td>
<td></td>
<td></td>
<td>(35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock–based compensation and other</td>
<td>(211,565)</td>
<td>1,164</td>
<td>4,570</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Comprehensive loss:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>(50,554)</td>
<td></td>
<td>(50,554)</td>
<td>(50,554)</td>
<td></td>
</tr>
<tr>
<td>Unrealized net gain on marketable and equity securities</td>
<td></td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total comprehensive loss</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(50,550)</td>
</tr>
<tr>
<td><strong>Balance at September 30, 2006</strong></td>
<td>(472,675)</td>
<td></td>
<td></td>
<td></td>
<td>(124,330)</td>
</tr>
</tbody>
</table>

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

F−6
<table>
<thead>
<tr>
<th>Description</th>
<th>2006</th>
<th>2005</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flows from operating activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(50,554)</td>
<td>$(53,218)</td>
<td>$(68,212)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash (used in) provided by</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>operating activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>447</td>
<td>403</td>
<td>122</td>
</tr>
<tr>
<td>Amortization of convertible note issuance costs</td>
<td>660</td>
<td>660</td>
<td>660</td>
</tr>
<tr>
<td>Minority interest in net income of consolidated subsidiary</td>
<td>435</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Noncash consideration</td>
<td>(266)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Impairment and loss on equity securities</td>
<td>—</td>
<td>185</td>
<td>—</td>
</tr>
<tr>
<td>Noncash stock-based compensation</td>
<td>4,535</td>
<td>75</td>
<td>4,089</td>
</tr>
<tr>
<td>Lease abandonment</td>
<td>—</td>
<td>1,310</td>
<td>—</td>
</tr>
<tr>
<td>Changes in assets and liabilities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>(314)</td>
<td>4,505</td>
<td>(6,887)</td>
</tr>
<tr>
<td>Inventories</td>
<td>(3,950)</td>
<td>189</td>
<td>(1,160)</td>
</tr>
<tr>
<td>Prepaid and other assets</td>
<td>(1,221)</td>
<td>652</td>
<td>(3,013)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>620</td>
<td>(4,064)</td>
<td>4,353</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>(14,834)</td>
<td>(1,442)</td>
<td>143,750</td>
</tr>
<tr>
<td>Accrued expenses and other liabilities</td>
<td>2,745</td>
<td>(5,012)</td>
<td>4,945</td>
</tr>
<tr>
<td>Net cash (used in) provided by operating activities</td>
<td>(61,699)</td>
<td>(55,757)</td>
<td>78,647</td>
</tr>
<tr>
<td>Cash flows from investing activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(224)</td>
<td>(957)</td>
<td>(636)</td>
</tr>
<tr>
<td>Purchases of marketable securities</td>
<td>(5,956)</td>
<td>—</td>
<td>(61,208)</td>
</tr>
<tr>
<td>Proceeds from maturities and sales of marketable securities</td>
<td>16,123</td>
<td>37,780</td>
<td>63,671</td>
</tr>
<tr>
<td>Other</td>
<td>—</td>
<td>22</td>
<td>—</td>
</tr>
<tr>
<td>Net cash provided by investing activities</td>
<td>9,943</td>
<td>36,845</td>
<td>1,827</td>
</tr>
<tr>
<td>Cash flows from financing activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from sale of common stock, net</td>
<td>35,028</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from exercise of stock options and stock issued under employee</td>
<td>1,799</td>
<td>911</td>
<td>2,227</td>
</tr>
<tr>
<td>stock purchase plan</td>
<td>—</td>
<td>—</td>
<td>(7,319)</td>
</tr>
<tr>
<td>Purchase of treasury stock</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Net cash provided by (used in) financing activities</td>
<td>36,827</td>
<td>911</td>
<td>(5,092)</td>
</tr>
<tr>
<td>Net change in cash and cash equivalents</td>
<td>(14,929)</td>
<td>(18,001)</td>
<td>75,382</td>
</tr>
<tr>
<td>Cash and cash equivalents at beginning of period</td>
<td>85,098</td>
<td>103,099</td>
<td>27,717</td>
</tr>
<tr>
<td>Cash and cash equivalents at end of period</td>
<td>$ 70,169</td>
<td>$ 85,098</td>
<td>$103,099</td>
</tr>
</tbody>
</table>

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

F–7
A. Nature of the Business

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

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

The Company is subject to numerous risks and uncertainties. Such risks include but are not limited to dependence on the success of SANCTURA, SANCTURA XR and NEBIDO; the early stage of product candidates under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR and NEBIDO; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO; dependence on third parties for manufacturing, marketing and clinical trials; competition; need for additional funds and corporate partners, including for the development of our products; failure to acquire and develop additional product candidates; history of operating losses and expectation of future losses; product liability and insurance uncertainties; risks relating to the Redux−related litigation; our reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity; valuation of our common stock; risks related to repayment of debts; risks related to increased leverage; and other risks.

B. Summary of Significant Accounting Policies

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

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

Cash, Cash Equivalents and Marketable Securities: The Company invests available cash primarily in short−term bank deposits, money market funds, repurchase agreements, domestic and foreign commercial paper and
government securities. Cash and cash equivalents includes investments with maturities of three months or less at date of purchase. Marketable securities consist of investments purchased with maturities greater than three months and are classified as noncurrent if they mature one year or more beyond the balance sheet date and not considered available to fund current operations. The Company classifies its investments in debt securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time the investments are purchased. At September 30, 2006 and 2005, all investments held were classified as "available-for-sale." Investments are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income or loss until realized. The fair value of these securities is based on quoted market prices.

Accounts Receivable: Trade accounts receivable are recorded at the invoiced amount and do not bear interest. At September 30, 2006 and 2005, the Company had not recorded an allowance for doubtful accounts as the Company believes all balances to be fully collectible.

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

To date, the Company’s revenues have been generated from a limited number of sources. In fiscal 2006, the Company’s revenue was primarily generated pursuant to the SANCTURA Agreement (see Note O). Total revenues generated in accordance with these agreements were $44,937,000, or 89%, of total revenue in fiscal 2006, $31,650,000, or 95%, of total revenue in fiscal 2005 and $16,214,000, or 87%, of total revenue in fiscal 2004. Esprit also represented approximately 88% of accounts receivable at September 30, 2006. The Company believes credit risk associated with Esprit is not significant.

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

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

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

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

Impairment of Long-Lived Assets: The Company evaluates the recoverability of its long-lived assets when the facts and circumstances suggest that these assets may be impaired. When the Company conducts an evaluation 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: Product revenue consists primarily of revenues from sales of products, commissions and royalties and reimbursements for royalties owed by the Company to Madaus GmbH ("Madaus") pursuant to
the SANCTURA Agreement (see Note O). Product revenue also includes revenue earned from shipments of DELATESTRYL, acquired in January 2006 from Savient Pharmaceuticals, Inc. (“Savient”). Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize the Company’s licensed technologies and are generally reported to the Company in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based. If the royalty report for such period is received subsequent to the time when the Company is required to report its results on Form 10–Q or Form 10–K and the amount of the royalties earned is not estimable, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received and when the amount of and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

The Company records sales of product as product revenue upon the later of shipment or as title passes to its customer. Sales of DELATESTRYL are reflected net of reserves for returns and allowances.

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

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

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

Under the SANCTURA Agreement, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue using the contingency-adjusted performance model. Under this

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
model, when a milestone is earned, revenue is immediately recognized on a pro-rata basis in the period the Company achieves the milestone based on the time elapsed from inception of the SANCTURA Agreement to the time the milestone is earned over the estimated duration of the SANCTURA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the SANCTURA Agreement.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force (“EITF”) Issue Number 00–21, “Accounting Revenue Arrangements with Multiple Deliverables” (“EITF 00–21”). Pursuant to EITF 00–21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as the Company completes its performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104 (“SAB 104”), unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements. In particular relating to the SANCTURA Agreement, the Company and PLIVA d.d. (“PLIVA”) were contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by the Company, reimbursements from PLIVA for PLIVA’s share are reflected in contract and license fee revenue. For promotion and advertising costs incurred by PLIVA, reimbursements to PLIVA for the Company’s share were reflected as a reduction of contract and license fee revenue.

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

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

Accounting for Stock-Based Compensation: On October 1, 2005, the Company adopted Statement of Financial Accounting Standards (“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. The Company’s Consolidated Statement of Operations for the fiscal year ended September 30, 2006 therefore includes charges for stock-based compensation. During the fiscal years ended September 30, 2005 and 2004, the Company applied Accounting Principles Board (“APB”) Opinion No. 25, “Accounting for Stock Issued to
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:

In May 2005, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 154, “Accounting Changes and Error Corrections.” SFAS No. 154 is a replacement of APB No. 20 and FASB Statement No. 3. SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application as the required method for reporting a change in accounting principle. SFAS No. 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS No. 154. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company does not believe the adoption of the pronouncement, beginning October 1, 2006, will have a material impact on its financial statements.

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

In June 2006, the FASB issued EITF Issue No. 06−3, “How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation)”. This standard allows companies to present in their statements of income any taxes assessed by a governmental authority that are directly imposed on revenue−producing transactions between a seller and a customer, such as sales, use, value−added, and some excise taxes, on either a gross (included in revenue and costs) or a net (excluded from revenue) basis. This standard is effective for interim and fiscal years beginning after December 15, 2006. The Company is currently evaluating the potential impact of this issue on the financial statements, but does not believe the impact of the adoption of this standard will be material.

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

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

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 or the Company’s 2009 fiscal year. This standard formalizes the measurement principles to be utilized in determining fair value for purposes such as derivative valuation and impairment analysis. The Company is still evaluating the implications of this standard, but does not currently expect it to have a significant impact.

C. Marketable Securities

Investments in marketable securities consisted of the following at September 30, 2006 and 2005:

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th></th>
<th>2005</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost</td>
<td>Market Value</td>
<td>Cost</td>
<td>Market Value</td>
</tr>
<tr>
<td>State government obligations</td>
<td>$ —</td>
<td>$ —</td>
<td>$15,000,000</td>
<td>$15,000,000</td>
</tr>
<tr>
<td>U.S. corporate notes</td>
<td>5,956,000</td>
<td>5,956,000</td>
<td>1,123,000</td>
<td>1,119,000</td>
</tr>
<tr>
<td></td>
<td>$5,956,000</td>
<td>$5,956,000</td>
<td>$16,123,000</td>
<td>$16,119,000</td>
</tr>
</tbody>
</table>

The Company reports unrealized gains and losses for its available-for-sale securities in accumulated other comprehensive income. Realized gains and losses of individual securities are reclassified into earnings when individual securities are sold using the specific identification method.

At September 30, 2006, there were no gross unrealized gains or losses on marketable securities. At September 30, 2005, there were no gross unrealized gains and gross unrealized losses on marketable securities was $4,000. At September 30, 2005, state government obligations consisted of auction rate securities having stated maturities between 27 and 40 years from the respective balance sheet dates. These securities are readily liquid, available to fund current operations and classified as available-for sale and are therefore classified as current marketable securities. At September 30, 2006, the Company had U.S. corporate notes of $5,956,000 maturing within one year of the balance sheet date. At September 30, 2005, the Company had U.S. corporate notes of $1,119,000 maturing within one year of the balance sheet date. At September 30, 2006 and 2005, respectively, the Company had no investments in an unrealized loss position for which other-than-temporary impairments have not been recognized.
D. Inventories

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

The components of inventory at September 30, 2006 and 2005 are as follows:

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>$ —</td>
<td>$ 971,000</td>
</tr>
<tr>
<td>Finished goods</td>
<td>4,921,000</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$ 4,921,000</strong></td>
<td><strong>$ 971,000</strong></td>
</tr>
</tbody>
</table>

Raw materials at September 30, 2005 consist solely of tablets of SANCTURA in bulk form purchased from the Company’s supplier. Finished goods at September 30, 2006 consisted of DELATESTRYL. The Company acquired the DELATESTRYL finished goods inventory pursuant to a product acquisition agreement (see Note O) and has classified $3,293,000 of the inventory as a noncurrent asset.

E. Property and Equipment

At September 30, 2006 and 2005, property and equipment consisted of the following:

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office and other equipment</td>
<td>$ 2,068,000</td>
<td>$ 1,911,000</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>384,000</td>
<td>317,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,452,000</strong></td>
<td><strong>2,228,000</strong></td>
</tr>
</tbody>
</table>

Less: accumulated depreciation and amortization

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1,572,000)</td>
<td>(1,125,000)</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$ 880,000</strong></td>
<td><strong>$ 1,103,000</strong></td>
</tr>
</tbody>
</table>

There were no assets under capital leases at September 30, 2006 and 2005.

Depreciation and amortization expenses for the three years ended September 30, 2006, 2005, and 2004 were $447,000, $403,000, and $122,000, respectively.

F. Accrued Expenses

At September 30, 2006 and 2005, accrued expenses consisted of the following:

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical and sponsored research</td>
<td>$ 3,889,000</td>
<td>$ 3,020,000</td>
</tr>
<tr>
<td>Compensation related</td>
<td>2,836,000</td>
<td>2,547,000</td>
</tr>
<tr>
<td>Lease abandonment</td>
<td>—</td>
<td>849,000</td>
</tr>
<tr>
<td>Professional fees</td>
<td>1,402,000</td>
<td>1,074,000</td>
</tr>
<tr>
<td>Income taxes</td>
<td>22,000</td>
<td>802,000</td>
</tr>
<tr>
<td>Redux related</td>
<td>559,000</td>
<td>578,000</td>
</tr>
<tr>
<td>Manufacturing and production costs</td>
<td>1,266,000</td>
<td>—</td>
</tr>
<tr>
<td>Other</td>
<td>1,052,000</td>
<td>1,040,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$ 11,026,000</strong></td>
<td><strong>$ 9,910,000</strong></td>
</tr>
</tbody>
</table>
G. Commitments

The Company leases its facilities, as well as certain office equipment and furniture under non-cancelable operating leases. Rent expense under these leases was approximately $1,188,000, $940,000, and $600,000 for the years ended September 30, 2006, 2005, and 2004, respectively.

At September 30, 2006, the Company’s future minimum payments under non-cancelable lease arrangements are as follows:

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>Operating Leases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>$ 1,231,000</td>
</tr>
<tr>
<td>2008</td>
<td>1,096,000</td>
</tr>
<tr>
<td>2009</td>
<td>1,119,000</td>
</tr>
<tr>
<td>2010</td>
<td>1,137,000</td>
</tr>
<tr>
<td>2011</td>
<td>114,000</td>
</tr>
<tr>
<td>Thereafter</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total lease payments</strong></td>
<td><strong>$ 4,697,000</strong></td>
</tr>
</tbody>
</table>

Pursuant to certain of our in-licensing arrangements, the Company will owe payments to our licensors upon achievement of certain development, regulatory and licensing milestones. The Company cannot predict if or when such events will occur.

Pursuant to the agreement with Madaus related to SANCTURA, the Company is committed to purchase from Madaus significant minimum quantities of bulk SANCTURA tablets during fiscal 2007 aggregating approximately $3,930,000. If this minimum purchase requirement is not satisfied, the Company would be subject to a minimum supply fee of a portion of the value of the unpurchased minimum quantities. Pursuant to the SANCTURA Agreement, Esprit agreed to purchase the same quantities of SANCTURA and to be responsible for commercial product procurement costs, including costs to manufacture SANCTURA and the minimum supply fee.

The Company leases approximately 95 automobiles for its field sales force. The lease requires a minimum term of 12 months per automobile. The Company expects monthly lease expense related to this operating lease to be approximately $50,000. The Company is responsible for certain disposal costs in case of termination.

In June 2005, the Company occupied new corporate headquarters and ceased using its former facilities prior to the April 2007 expiration of the lease period for such facilities. As a result, the Company recorded a charge of approximately $1,310,000 in fiscal 2005 related to the non-utilization of its former facilities. The charge represented the Company’s best estimate of fair value of its ongoing liability determined by comparing future lease payment obligations, net of potential sub-lease rental, and related costs in accordance with SFAS 146, “Accounting for Costs Associated with Exit or Disposal Activities” (“SFAS 146”). During its fiscal year ended September 30, 2006, the Company settled the remaining lease obligations relating to its former facility for a payment of $500,000 and reflected a credit of approximately $300,000 in marketing, general, and administrative expense related to the extinguishment of the remaining accrued liability.

The Company’s lease for its new corporate headquarters encompasses 45,100 square feet at an annual rent of approximately $1,100,000. The initial lease term will expire in December 2010 and the Company has a right to extend lease for an additional five-year period at current market rates.
Guarantees

Our charter provides for indemnification, to the fullest extent permitted under Delaware law, of any person who is made a party to any action or threatened with any action as a result of such person’s serving or having served as one of our officers or directors. We have separate indemnification agreements with certain of our officers, directors and employees. The indemnification obligation survives termination of the indemnified party’s involvement with us but only as to those claims arising from such person’s role as an officer or director. The maximum potential amount of future payments that we could be required to make under the charter provision and the corresponding indemnification agreements is unlimited; however, we have director and officer insurance policies that, in most cases, would limit our exposure and enable us to recover a portion of any future amounts paid.

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

H. Convertible Notes

In July 2003, the Company received net proceeds of approximately $68,700,000 from the sale of $72,000,000 aggregate principal amount of 6.25% Convertible Senior Notes due 2008 (the “Convertible Notes”) to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The Convertible Notes are convertible at anytime prior to the July 15, 2008 maturity date into the Company’s Common Stock at an initial conversion price of $6.656 per share, subject to adjustment for certain events; the Company has reserved approximately 10,800,000 shares of Common Stock for issuance pursuant to such a conversion and has registered with the SEC the Convertible Notes and Common Stock for resale. Additionally, all or a portion of the Convertible Notes are redeemable by the Company for cash at any time after July 20, 2006, provided the Company’s Common Stock equals or exceeds 150% of the conversion price then in effect for a specified period. All of the Convertible Notes are subject to repurchase by the Company at the option of the Convertible Note holders if a change in control occurs. As of September 30, 2006, all of the Convertible Notes were outstanding. Interest is payable semiannually in arrears on January 15 and July 15 through the maturity date. Prepaid debt issuance costs related to the Convertible Notes were $3,301,000 and are being amortized to interest expense on a straight-line basis over the five year term of the Convertible Notes. At September 30, 2006, the market value of a $1,000 Convertible Note was approximately $1,169.

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

In May 2001, the Company entered into the AHP Indemnity and Release Agreement pursuant to which Wyeth agreed to indemnify the Company against certain classes of product liability cases filed against the Company related to Redux (dexfenfluramine 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

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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, 2006, the Company has an accrued liability of approximately $559,000 for Redux–related expenses, including legal expenses. The amounts the Company ultimately pays could differ significantly from the amount currently accrued at September 30, 2006. To the extent the amounts paid differ from the amounts accrued, the Company will record a charge or credit to the statement of operations.

As of September 30, 2006, the Company had an outstanding insurance claim of approximately $3,700,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux–related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company’s current outstanding insurance claim is made pursuant to the Company’s product liability policy issued to the Company by Reliance Insurance Company (“Reliance”). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $1,258,000 reflecting the Company’s best estimate given the available facts and circumstances. The amount the Company collects could differ from the $1,258,000 reflected as a noncurrent insurance claim receivable at September 30, 2006.

J. Stockholders’ Equity

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 (see Note O).

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 56,040,456 shares of Common Stock outstanding at September 30, 2006, there were approximately 30,743,000 shares of Common Stock reserved for issuance (“Reserved Common Shares”). Included in the number of Reserved Common Shares are the following: (i) 10,817,000 shares reserved for issuance upon conversion of the Convertible Notes; (ii) 14,441,000 shares reserved for issuance under the Company’s various stock plans; (iii) 4,756,000 shares of Common Stock reserved for issuance upon conversion of the Company’s authorized but unissued Preferred Stock; (iv) 622,000 shares of Common Stock issuable upon conversion of issued and outstanding Preferred Stock; and (v) 106,000 shares reserved for issuance under the 1995 and 1997 Plans. (See Note L.)

K. Basic and Diluted Loss per Share

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. 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, 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.

During the year ended September 30, 2005, 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 5,200,925 shares of Common Stock at prices ranging from $4.26 to $20.13 with expiration dates ranging up to March 1, 2015 and a warrant to purchase 10,000 shares of Common Stock with an exercise price of $6.19 and with an expiration date of July 17, 2006. 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, 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, 2005, 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 6,114,889 shares of Common Stock at prices ranging from $1.22 to $4.16 with expiration dates ranging up to September 12, 2015 and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

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

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L. Stock Plans and Stock Compensation

The Company has several stock−based employee compensation plans, including (i) the 1989 Stock Option Plan (the “1989 Plan”) that expired in 1999; (ii) the 1994 Long−Term Incentive Plan (the “1994 Plan”) that expired in 2004; and (iii) 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 1989 and 1994 Plans which were outstanding as of the date the 1989 and 1994 Plans 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 6,000,000 shares may be granted. Under the 2000 Plan, the 2004 Plan, and under the 1989, 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 1989, 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 1997 Equity Incentive Plan (the “1997 Plan”) provides for the grant of restricted stock awards which entitle the plan participants to receive up to an aggregate of 1,750,000 shares of the Company’s Common Stock upon satisfaction of specified vesting periods. As of September 30, 2006, restricted stock awards to acquire an aggregate of 1,737,918 shares had been granted, net of forfeitures, to employees of the Company primarily in consideration of services rendered by the employee to the Company and payment of the par value of the shares. As of September 30, 2006, 1,737,918 shares have vested and been issued and there were 12,082 restricted stock awards available for grant by the Company under the 1997 Plan.

The Company’s 1995 Employee Stock Purchase Plan (the “1995 Plan”) covers an aggregate of 800,000 shares of Common Stock which is offered in one−year offerings (an “Offering”). Each Offering is divided into two six−month Purchase Periods (the “Purchase Periods”). Stock is purchased at the end of each Purchase Period with employee contributions at the lower of 85% of the 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. At September 30, 2006, there were 94,253 shares remaining to be purchased under the 1995 Plan.

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 $3,331,000, before tax, for the twelve months ended September 30, 2006. 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.

During its 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 twelve months ended September 30, 2006, the Company recorded $300,000 of noncash compensation expense related to this modification. During the twelve months 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. Pursuant to SFAS 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.

During its fiscal year ended September 30, 2006, the Company granted certain restricted and other unvested 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 year ended September 30, 2006, $432,000 of noncash compensation expense related to these stock awards was recognized.

Calculation of the fair value of these restricted and other unvested 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 was used to simulate future stock movements in order to determine the expected percentage of shares that will vest.

<table>
<thead>
<tr>
<th>Fiscal Year Ended September 30, 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected volatility</td>
</tr>
<tr>
<td>Risk–free interest rate</td>
</tr>
<tr>
<td>Dividend rate</td>
</tr>
</tbody>
</table>

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 twelve month period ended September 30, 2006 under SFAS 123R and did not capitalize any such costs on the consolidated balance sheets, as such costs that qualified for capitalization were not material. In the twelve month period ended September 30, 2006, the Company recorded $4,535,000 of these noncash expenses. Stock compensation expense recognized pursuant to the adoption of SFAS 123R increased the net loss for the twelve month period ended September 30, 2006, by $4,535,000, and increased loss per share, basic and diluted, by $0.09. There was no impact in the twelve month period ended September 30, 2006, on cash flows from operations, investing or financing activities in connection with the adoption of SFAS 123R. In the twelve month period ended September 30, 2006, the Company allocated $851,000 and $3,684,000 to research and development and marketing, general and administrative expense, respectively.

The Company had previously adopted the provisions of SFAS No. 123, “Accounting for Stock–Based Compensation,” as amended by SFAS No. 148, “Accounting for Stock–Based Compensation—Transition and Disclosure,” through disclosure only. The following table illustrates the effect on net loss and loss per share for the twelve month periods ended September 30, 2005 and 2004 as if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock–based employee awards.

<table>
<thead>
<tr>
<th>Fiscal year ended September 30, 2005</th>
<th>Fiscal year ended September 30, 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss as reported</td>
<td>$ (53,218,000)</td>
</tr>
<tr>
<td>Add: Employee compensation expense for share options included in reported net loss, net of income taxes</td>
<td>75,000</td>
</tr>
<tr>
<td>Less: Total employee compensation expense for share options determined under the fair value method, net of income taxes</td>
<td>(3,247,000)</td>
</tr>
<tr>
<td>Pro forma net loss</td>
<td>$ (56,390,000)</td>
</tr>
</tbody>
</table>

Loss per share:

| Basic and diluted—as reported       | $ (1.13)                            | $ (1.43)                            |
| Basic and diluted—pro forma         | $ (1.20)                            | $ (1.39)                            |

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The fair value of options at date of grant was estimated using the Black–Scholes option–pricing model.

The Company’s expected stock–price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources.

The Company determined the weighted–average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns.

The risk–free interest rate used for each grant is equal to the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

Below are the factors used to determine the value of options, including the value of stock offered under the 1995 Plan, granted pursuant to SFAS 123R:

<table>
<thead>
<tr>
<th>Twelve Months Ended September 30,</th>
<th>2006</th>
<th>2005</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Executives</td>
<td>Non–executives</td>
<td>All Grants</td>
</tr>
<tr>
<td>Option life</td>
<td>8 years</td>
<td>6.25 years</td>
<td>4 years</td>
</tr>
<tr>
<td>Risk–free interest rate</td>
<td>4.95%</td>
<td>4.61%</td>
<td>3.94%</td>
</tr>
<tr>
<td>Stock volatility</td>
<td>73.0%</td>
<td>65.0%</td>
<td>60.0%</td>
</tr>
<tr>
<td>Dividend rate</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

As of September 30, 2006, there remained approximately $5,738,000 of compensation costs related to non–vested stock options to be recognized as expense over a weighted average period of approximately 1.3 years.

Presented below is the Company’s stock option activity:

<table>
<thead>
<tr>
<th>Stock Options</th>
<th>Warrants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Weighted Average</td>
</tr>
<tr>
<td>Shares</td>
<td>Exercise Price</td>
</tr>
<tr>
<td>Outstanding at September 30, 2003</td>
<td>10,263,170</td>
</tr>
<tr>
<td>Granted</td>
<td>1,661,500</td>
</tr>
<tr>
<td>Exercised</td>
<td>(661,083)</td>
</tr>
<tr>
<td>Cancelled</td>
<td>(331,795)</td>
</tr>
<tr>
<td>Outstanding at September 30, 2004</td>
<td>10,931,792</td>
</tr>
<tr>
<td>Granted</td>
<td>1,433,500</td>
</tr>
<tr>
<td>Exercised</td>
<td>(245,791)</td>
</tr>
<tr>
<td>Cancelled</td>
<td>(271,206)</td>
</tr>
<tr>
<td>Outstanding at September 30, 2005</td>
<td>11,848,295</td>
</tr>
<tr>
<td>Granted</td>
<td>606,250</td>
</tr>
<tr>
<td>Exercised</td>
<td>(409,938)</td>
</tr>
<tr>
<td>Cancelled</td>
<td>(263,229)</td>
</tr>
<tr>
<td>Outstanding at September 30, 2006</td>
<td>11,781,378</td>
</tr>
<tr>
<td>Options exercisable at end of period</td>
<td>9,579,206</td>
</tr>
<tr>
<td>Weighted average fair value of options granted during fiscal 2006</td>
<td>$ 3.25</td>
</tr>
</tbody>
</table>

During its fiscal year ended September 30, 2006, the Company granted unvested restricted stock awards 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. Service–based stock awards
granted during the period have a weighted average grant date fair value of $6.36, the closing price of the common stock on the date of the grant. Service and market–based stock awards were valued using a lattice model. Service and market–based stock awards granted during the period have a weighted average grant date fair value of $4.13. None of the service or market–based restricted stock awards were vested as of September 30, 2006.

At September 30, 2006, there remained approximately $1,900,000 of compensation expense related to restricted and other performance–based stock awards to be recognized as expense over approximately 2.4 years.

At September 30, 2006, stock options were outstanding and exercisable as follows:

<table>
<thead>
<tr>
<th>Range of Exercise Price</th>
<th>Outstanding</th>
<th>Exercisable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td>Remaining Contractual Life</td>
<td>Exercise Price</td>
</tr>
<tr>
<td>$1.22−$ 2.71</td>
<td>3,021,002</td>
<td>2,847,440</td>
</tr>
<tr>
<td>$2.77−$ 4.16</td>
<td>3,407,251</td>
<td>2,583,361</td>
</tr>
<tr>
<td>$4.26−$ 6.19</td>
<td>3,671,750</td>
<td>3,098,958</td>
</tr>
<tr>
<td>$6.21−$20.13</td>
<td>1,681,375</td>
<td>1,049,447</td>
</tr>
</tbody>
</table>

The aggregate intrinsic value of outstanding options as of September 30, 2006 was $19,100,000, of which $16,100,000 was related to exercisable options. The intrinsic value of options exercised during the twelve months ended September 30, 2006, 2005 and 2004 was $1,431,000, $960,000 and $2,273,000, respectively. The intrinsic value of options vested during the twelve months ended September 30, 2006 was $1,327,000. The weighted average contractual life for total options exercisable at September 30, 2006 was approximately 3.9 years.

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

M. Income Taxes

The provision for income taxes for the fiscal years ended September 30, 2006, 2005 and 2004 consist of the following:

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2005</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current tax expense (benefit):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal</td>
<td>$ —</td>
<td>$ 1,665,000</td>
<td>$ —</td>
</tr>
<tr>
<td>State</td>
<td>—</td>
<td>1,506,000</td>
<td>—</td>
</tr>
<tr>
<td>Deferred tax expense:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal</td>
<td>14,841,000</td>
<td>17,564,000</td>
<td>24,227,000</td>
</tr>
<tr>
<td>State</td>
<td>682,000</td>
<td>(900,000)</td>
<td>2,670,000</td>
</tr>
<tr>
<td>Change in Valuation Allowance</td>
<td>(15,523,000)</td>
<td>(16,664,000)</td>
<td>(26,897,000)</td>
</tr>
<tr>
<td></td>
<td>$ —</td>
<td>$ 3,171,000</td>
<td>$ —</td>
</tr>
</tbody>
</table>

The Company’s effective tax rate varies from the statutory rate as follows:

<table>
<thead>
<tr>
<th>Fiscal Years Ended September 30,</th>
<th>2006</th>
<th>2005</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. statutory rate</td>
<td>(34.0)%</td>
<td>(34.0)%</td>
<td>(34.0)%</td>
</tr>
<tr>
<td>State taxes</td>
<td>(1.4)</td>
<td>4.8</td>
<td>(6.0)</td>
</tr>
<tr>
<td>Permanent differences</td>
<td>2.9</td>
<td>0.7</td>
<td>—</td>
</tr>
<tr>
<td>Credit generation</td>
<td>1.3</td>
<td>(1.2)</td>
<td>—</td>
</tr>
<tr>
<td>Expiration of credit</td>
<td>0.5</td>
<td>2.8</td>
<td>—</td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>30.7</td>
<td>33.2</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>— %</td>
<td>6.3%</td>
<td>— %</td>
</tr>
</tbody>
</table>

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Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
Significant components of the Company’s deferred tax assets as of September 30, 2006, 2005 and 2004 are shown below. As required by SFAS No. 109, the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss and research credit carryforwards and deferred income. The Company has determined that, at this time, it is more likely than not that the Company will not realize the benefits of federal and state deferred tax assets and as a result, a full valuation allowance has been established at September 30, 2006.

At September 30, 2006, 2005 and 2004, the significant components of the Company’s deferred tax asset consisted of the following:

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2005</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal and state net operating loss carryforwards</td>
<td>$82,856,000</td>
<td>$65,020,000</td>
<td>$101,085,000</td>
</tr>
<tr>
<td>Federal and state tax credit carryforwards</td>
<td>8,647,000</td>
<td>9,589,000</td>
<td>7,091,000</td>
</tr>
<tr>
<td>Capital loss carryforwards</td>
<td>2,074,000</td>
<td>2,133,000</td>
<td>1,733,000</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>9,526,000</td>
<td>8,691,000</td>
<td>8,700,000</td>
</tr>
<tr>
<td>Investment in CPEC LLC</td>
<td>5,657,000</td>
<td>6,287,000</td>
<td>6,918,000</td>
</tr>
<tr>
<td>Investment in unconsolidated subsidiaries</td>
<td>11,726,000</td>
<td>11,726,000</td>
<td>13,755,000</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>50,983,000</td>
<td>52,500,000</td>
<td></td>
</tr>
<tr>
<td><strong>Total deferred tax asset before valuation allowance</strong></td>
<td>171,469,000</td>
<td>155,946,000</td>
<td>139,282,000</td>
</tr>
<tr>
<td>Valuation allowance against total deferred tax asset</td>
<td>(171,469,000)</td>
<td>(155,946,000)</td>
<td>(139,282,000)</td>
</tr>
<tr>
<td><strong>Net deferred tax asset</strong></td>
<td>$—</td>
<td>$—</td>
<td>$—</td>
</tr>
</tbody>
</table>

As of September 30, 2006, the Company had net operating loss carryforwards for federal income tax purposes of approximately $237,000,000 which expire at various dates from 2006 through 2025. In addition, the Company had approximately $5,307,000 of tax credit carryforwards for federal income tax purposes expiring at various dates through 2025 and capital loss carryforwards of approximately $5,186,000 for federal income tax purposes expiring at various dates through 2010. Approximately $18,000,000 of the net operating loss carryforwards available for federal income tax purposes relate to exercises on 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 net operating loss and tax credit carryforwards may be subject to annual limitations due to a change in ownership of more than 50%.

N. Related Party Transactions

The Company has or had agreements with certain directors and an officer who is not an employee to provide technical and other consulting services. Total amounts due or paid pursuant to such agreements were approximately $357,000, $400,000 and $310,000 in fiscal 2006, 2005, and 2004, respectively.

O. Product Agreements

Madaus: In November 1999, the Company entered into an agreement with Madaus under which we licensed exclusive rights to develop and market SANCTURA in the United States. In exchange for these rights, we have agreed to pay Madaus potential regulatory and sales milestone payments and royalties on net sales or, if sublicensed by us, we would pay to Madaus a portion of royalties on net sales received from the sublicensee, in lieu of royalty payments. The Company is responsible for all clinical development and regulatory activities and costs related to the compound in the United States. In December 2002, we entered into a manufacturing agreement with Madaus whereby Madaus produces and sells to us commercial quantities in bulk form. (See Note R for recent agreements with Madaus.)
Esprit and PLIVA: In April 2004, the Company entered into a license, commercialization and supply agreement with PLIVA through its specialty-branded subsidiary, Odyssey Pharmaceuticals, Inc. for the U.S. commercialization of SANCTURA for overactive bladder (the “SANCTURA Agreement”). In May 2005, the Company, PLIVA and Esprit entered into an Amendment and Consent Agreement (the “Amendment and Consent”), 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. Upon the effectiveness of the Amendment and Consent Agreement, 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. Additionally, the annual sales force subsidy was increased to $8,750,000 through December 31, 2007 and extended for one additional year at an annual rate of $4,375,000. Further, Esprit is not subject to minimum detail and sales force requirements. Esprit granted Indevus the right to co-promote one of Esprit’s future products on terms to be negotiated. Except if the context indicates otherwise, all references to the SANCTURA Agreement shall mean the agreement as amended by the Amendment and Consent.

Under the SANCTURA Agreement, the Company received $30,000,000 upon the initial signing, $120,000,000 upon the approval of SANCTURA by the FDA in May 2004, $10,000,000 upon initiation of the SANCTURA XR Phase III clinical trial program in September 2005 and $10,000,000 upon submission of the SANCTURA XR NDA to the FDA in October 2006. In addition, the Company is eligible to receive approximately $35,000,000 in a future payment contingent upon FDA approval of an NDA for SANCTURA XR, as well as a payment of $20,000,000 related to the achievement of a long-term commercialization milestone in 2013. Esprit will not have an obligation to pay the development milestone of approximately $35,000,000 related to the FDA approval of the NDA for SANCTURA XR or the $20,000,000 long-term commercialization milestone and the rights to SANCTURA XR will revert to the Company if Esprit provides notice to the Company no later than the approval date that it does not intend to proceed with the launch of SANCTURA XR. The Company is amortizing the milestone payments earned over an estimated term of the SANCTURA Agreement of twelve years.

For the six months following the approval of SANCTURA, called the co-promotion period, the Company received a commission based on net sales of SANCTURA. The Company was co-promoting SANCTURA with PLIVA through a joint sales force of approximately 500 sales representatives. The Company established a sales force initially numbering approximately 280 representatives promoting SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians.

The Company exercised its right to convert the SANCTURA Agreement into a royalty-bearing structure effective November 29, 2004 (the “Conversion”). Upon the Conversion, approximately 200 of the Company’s primary care sales representatives became PLIVA employees and PLIVA became responsible for promotional, advertising and sales force-related costs. Effective upon the Conversion, the Company began receiving royalties on net sales of SANCTURA and a sales force subsidy at an annual rate of approximately $7,700,000, subject to increases for inflation commencing July 1, 2006.

Under the SANCTURA Agreement, we supply SANCTURA to our marketing partner, which is responsible for product distribution. We are responsible for funding the development of SANCTURA XR and we are eligible to receive additional payments upon achievement of regulatory milestones.

Savient: In January 2006, we acquired DELATESTRYL, an injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient for a total purchase price of $6,800,000 and accounted for the transaction as the purchase of inventory. Upon closing, we paid Savient $5,600,000 and we owe Savient an additional $1,300,000 which is payable in two installments of approximately $644,000 on the first and second anniversary of the closing. Additionally, we assumed Savient’s previous obligation to purchase approximately
$1,100,000 of additional DELATESTRYL inventory. However, we believe the supplier defaulted on its obligation to provide DELATESTRYL in the time required and we believe we are no longer obligated to purchase this inventory. However, in the event the supplier was able to demonstrate compliance with the agreement and we are obligated to purchase such inventory, we may be required to provide a reserve for at least a portion of the value of this inventory.

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

**Supernus:** In March 2003, the Company signed an exclusive development agreement with Supernus Pharmaceuticals, Inc. (formerly Shire Laboratories Inc.) (“Supernus”) under which Supernus is developing extended release formulations of SANCTURA. The agreement includes potential future development and commercialization milestone payments from Indevus to Supernus, as well as royalties based on potential future sales of SANCTURA XR. Indevus will be responsible for all development costs and the commercialization of extended release formulations of SANCTURA under this agreement.

**Schering:** In July 2005, the Company licensed exclusive U.S. rights from Schering AG, Germany (“Schering”) to market NEBIDO, a long−acting injectable testosterone preparation for the treatment of male hypogonadism (the “Schering Agreement”). Pursuant to the terms of the Schering Agreement, the Company will be responsible for the development and commercialization of NEBIDO in the U.S. and Schering will be responsible for manufacturing and supplying finished product to the Company. The Company agreed to pay to Schering up to $30,000,000 in up−front, regulatory milestone, and commercialization milestone payments. In fiscal 2005, the Company paid $7,500,000 of the $30,000,000 as an up−front milestone payment which was charged to research and development expense. Upon approval by the FDA to market the product, the Company will pay Schering a $5,000,000 regulatory milestone. When commercialization of the product commences, the Company will pay Schering 25% of net sales of NEBIDO to cover both the cost of finished product and royalties.

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

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

**Manhattan Pharmaceuticals, Inc. and Samner Burstein, Ph.D.:** In June 2002, the Company licensed exclusive, worldwide rights to IP 75I from Manhattan Pharmaceuticals, Inc. (“Manhattan”) in exchange for an up−front licensing payment, potential development milestones and royalty payments (the “Manhattan Agreement”). In August 2003, the Company simultaneously entered into a renegotiated agreement with
Manhattan and an agreement with Sumner Burstein, Ph.D. (the “Burstein Agreement”), the individual owner of intellectual property rights related to IP 751, whereby the Manhattan Agreement was terminated in exchange for a combination of cash and equity payments from the Company to Manhattan and the Company acquired an exclusive, worldwide license to certain IP 751 intellectual property rights from Dr. Burstein pursuant to the Burstein Agreement in exchange for an amount which was partially payable immediately and partially in the future and potential milestone and royalty payments. The Company reflected a charge of $1,060,000, including approximately $360,000 for approximately 60,000 shares of Common Stock issued to Manhattan, in research and development expense in the fiscal year ended September 30, 2003 related to these transactions. The Company remains responsible for the clinical development, regulatory review activities and commercialization of this compound.

Aventis:

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

B. Aminocandin. In April 2003, the Company licensed exclusive, worldwide rights from Aventis to aminocandin, an anti−fungal compound for the treatment of systemic, invasive fungal infections (the “Aminocandin Agreement”). In exchange for these rights and for Aventis’ inventory of aminocandin, Indevus made an up−front payment to Aventis, and is obligated to pay potential milestones and royalties on potential future sales. Under the Aminocandin Agreement, Indevus is responsible for all development and commercialization activities for both intravenous and oral formulations of aminocandin. Aventis has agreed to manufacture the key component of aminocandin, using its proprietary fermentation technology. The Company charged $1,500,000 to research and development expense in fiscal 2003 for the up−front payment. Upon commencement of the multi−dose phase I trial of aminocandin in fiscal 2005, the Company made a $750,000 milestone payment to Aventis which was charged to research and development expense in fiscal 2005. (See Note R.)

Lilly:

In June 1997, the Company licensed to Eli Lilly & Company (“Lilly”) worldwide, exclusive rights to Indevus’ patent covering the use of fluoxetine to treat certain conditions and symptoms associated with premenstrual syndrome (“PMS”). Lilly has received approval for fluoxetine to treat premenstrual dysphoric disorder, a severe form of PMS. The drug has been marketed under the trade name Sarafem® by Lilly and its sublicense, Galen Holdings, Inc., respectively. In December 2002, the Company entered into a renegotiated agreement with Lilly providing for Lilly to pay the Company up front and potential milestone payments, as well as royalties on net sales. The patent rights to the use of fluoxetine in treating PMS are licensed by the Company from the Massachusetts Institute of Technology, which is entitled to a portion of all payments, including royalties, made to Indevus by Lilly. The Company is entitled to receive royalties from Lilly through November 2007, unless additional patent extensions are applicable.

Ferrer:

In January 1993, the Company licensed from Ferrer International, S.A. (“Ferrer”) exclusive rights in the U.S., Puerto Rico and Canada to certain uses of citicoline, a drug under development for potential treatment for ischemic stroke. In January 2004, the Company entered into a new agreement with Ferrer covering the development, manufacture and marketing of citicoline in the U.S. and Canada. Under the terms of the new agreement, the Company granted Ferrer exclusive rights to its patents and know−how related to citicoline.

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In June 1998, the Company licensed to Ferrer, on a worldwide basis except for the U.S. and Canada, the use of Indevus’ patent rights relating to the use of citicoline in the protection of brain tissue from cerebral infarction following ischemic stroke. In exchange for the license to Ferrer, Indevus will be entitled to royalties from Ferrer on certain exports and sales of the solid form of citicoline in certain countries upon its approval in each relevant country.

Medical Research Council: In July 2005, the Company entered into the Collaborative Research and Licensing Agreement with the Medical Research Council, an agency of the United Kingdom (the “MRC”). The Company agreed to grant the MRC a non-exclusive license to PRO 2000 solely for its use in the Phase III trial and also supply, at no cost to the MRC, all PRO 2000 and placebo required for the Phase III trial, 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 STDs to be conducted primarily in Africa and India and the right to use the results of this trial. Under terms of this agreement the MRC will be responsible for all other trial costs. Additionally, the Company agreed to make PRO 2000 available in developing countries in high need under a license agreement to be negotiated in good faith, or to supply to the MRC PRO 2000 to be distributed in developing countries at the Company’s cost plus a mark up pursuant to a supply agreement to be negotiated. The Company will pay the MRC a minimal royalty on sales of PRO 2000 in non-developing countries.

Wyeth: In November 1992, the Company entered into an agreement with American Cyanamid Company (which subsequently was acquired by Wyeth) for the development and marketing in the U.S. of Redux™. In connection with this agreement, Wyeth purchased from the Company the Series B and C Preferred Stock which is outstanding at September 30, 2006 and 2005. Holders of Series B and C Preferred Stock are entitled to receive mandatory dividends of $0.13 and $1.00 per share, respectively, payable at the election of the Company in cash or Common Stock. Such dividends are payable annually on April 1 of each year, accrue on a daily basis and are cumulative. Holders of Series B and C Preferred Stock have participation rights and are entitled to a liquidation preference of $12.53 and $100.00 per share, respectively, plus accumulated and unpaid dividends. Holders of Series B and C Preferred Stock are entitled to convert such shares into an aggregate of 622,222 shares of Common Stock (a conversion price of $5.63 per share) subject to anti-dilution adjustments. Holders of the Series B and C Preferred Stock are entitled to vote on all matters submitted to a vote of stockholders other than the election of directors, equivalent to 568,850 shares of Common Stock.

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

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

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. Pursuant to the agreement under which bucindolol was acquired, the Company could have a maximum potential liability of approximately $1,700,000 if an NDA were filed and approved for bucindolol to treat congestive heart failure. In October 2003, CPEC LLC licensed its bucindolol development and marketing rights to ARCA Discovery, Inc. (“ARCA”) in exchange for potential future milestone and royalty payments. 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. The accounts of CPEC LLC are included in the Company’s consolidated financial statements.

Investment in Aeolus

In 2005, the Company liquidated its investment of 44,718 common shares of Aeolus and recorded a loss on equity securities of $185,000. Prior to this liquidation, the Company classified its investment in Aeolus as “available for sale” and as such stated its investment at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income.

Q. Quarterly Financial Data (Unaudited)

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>First Quarter</th>
<th>Second Quarter</th>
<th>Third Quarter</th>
<th>Fourth Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fiscal 2006</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total revenues</td>
<td>$ 8,974,000</td>
<td>$14,422,000</td>
<td>$11,879,000</td>
<td>$15,177,000</td>
</tr>
<tr>
<td>Net loss</td>
<td>(11,930,000)</td>
<td>(11,226,000)</td>
<td>(13,377,000)</td>
<td>(14,021,000)</td>
</tr>
<tr>
<td>Net loss per common share, basic and diluted</td>
<td>$ (0.25)</td>
<td>$ (0.24)</td>
<td>$ (0.28)</td>
<td>$ (0.25)</td>
</tr>
<tr>
<td><strong>Fiscal 2005</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total revenues</td>
<td>$ 5,763,000</td>
<td>$ 9,277,000</td>
<td>$ 8,193,000</td>
<td>$10,103,000</td>
</tr>
<tr>
<td>Net loss</td>
<td>(21,149,000)</td>
<td>(9,720,000)</td>
<td>(9,789,000)</td>
<td>(12,560,000)</td>
</tr>
<tr>
<td>Net loss per common share, basic and diluted</td>
<td>$ (0.44)</td>
<td>$(0.21)</td>
<td>$(0.21)</td>
<td>$(0.27)</td>
</tr>
</tbody>
</table>

The Company has numerous ongoing clinical programs to support multiple drug development efforts. The Company reflects the costs associated with third party contracts for these programs in the period in which they are best determined to have occurred. A reassessment of the timing in which certain contract costs occurred resulted in an adjustment of $1,100,000 to increase research and development costs related to the Company’s clinical programs in the three month period ended September 30, 2006. Approximately $400,000 of this adjustment related to fiscal 2005 and approximately $700,000 of this adjustment related to prior fiscal 2006 quarters.

R. Subsequent Events

Madaus SANCTURA XR Agreements

In November 2006, the Company entered into (i) a License and Supply Agreement and (ii) an amendment to its original license agreement with Madaus (the “Madaus Agreements”). Under the Madaus Agreements, we agreed to (a) purchase from Madaus all required trospium active pharmaceutical ingredient through November 2007 (b) license Madaus the rights to sell SANCTURA XR in all countries outside of the United States (the “Madaus Territory”) except Canada, Japan, Korea and China (the “Joint Territory”), (c) pay to Madaus a fee based on the number of capsules of SANCTURA XR sold by 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 by them 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 will 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. (See Note O.)

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. As the Company was unable to determine the stand alone value of the delivered items and obtain verifiable objective evidence to for the fair value of the undelivered elements, the Company concluded there was a single unit of accounting.

The Company is currently unable to determine the term of its performance obligation to provide future know−how under the Madaus Agreements. The Company will recognize revenue to the extent of direct costs, limited to the amount of cash received or receivable, as long as the overall arrangement is determined to be profitable. Profit under the Madaus Agreements and payments received in advance of revenue recorded will be recorded as deferred revenue until the earlier of (i) when the Company can meet the criteria for separate recognition of each element under EITF 00−21 or (ii) after the Company has fulfilled all of its contractual obligations under the arrangement.

In addition, we will evaluate payments made by us to Madaus 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)”, to determine whether future payments to Madaus will be recognized as a reduction of revenue or a cost of sales.

If either party decides to pursue development and commercialization of SANCTURA XR in any country in the Joint Territory, the other party has the option to share in such development and commercialization.

Novexel Agreement

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

Helsinn Agreement

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. The term of the Helsinn Agreement is seven years and contains certain minimum purchase requirements.

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Manufacturing and Supply Agreement

between Schering Aktiengesellschaft
13342 Berlin, Germany

(hereinafter referred to as “Schering”)

and Indevus Pharmaceuticals, Inc.
33 Hayden Avenue, Lexington, MA 02421, USA

(hereinafter referred to as “Indevus”)

Schering and Indevus are sometimes referred to herein individually as a “Party” and collectively as the “Parties”.

WHEREAS, Schering and Indevus have entered into the License Agreement (hereinafter defined) regarding the development and commercialization of Product (hereinafter defined) in the Field (hereinafter defined) in the US by Indevus; and

WHEREAS, upon request of Indevus and subject to the terms of the License Agreement (hereafter defined), Schering has initiated the development of a [*]; and

WHEREAS, it is set forth in the License Agreement that the Parties will enter into good faith negotiations about an agreement for the Manufacturing (hereinafter defined) and supply of Finished Product as soon as practicable after signing of the License Agreement consistent with the terms of Article 6 of the License Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

Article 1
Definitions

The following terms, when capitalized, shall have the following meanings (such meanings to be equally applicable to both the singular and plural forms of the terms defined), when used in this Agreement:

1.1 “[*]” shall mean a Product [*] as generally described in Schedule 1.1.
1.2 “[*]” shall mean a Product [*] as generally described in Schedule 1.2.
1.3 “Act” shall mean the United States Food, Drug, and Cosmetic Act of 1938, as amended, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.
1.4 “Affiliate” shall mean, with respect to a Party, any person, corporation, firm, joint venture or other entity which, directly or indirectly, through one or more intermediates, controls, is controlled by or is under common control with such Party. As used in this definition, “control” means possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise.
1.5 “Agreement” shall mean this Manufacturing and Supply Agreement, including any exhibits, schedules or attachments attached to this Agreement and any amendments to any of the foregoing.
1.6 “[*]” shall mean a Product [*] as generally described in Schedule 1.6.
1.7 “Audit Disagreement” shall have the meaning set forth in Section 9.3.
1.8 “Batch” shall mean a specific quantity of Clinical Supplies or Finished Product that is produced according to a single manufacturing order during the same cycle of Manufacture.
1.9 “Business Day” shall mean any day that is not a Saturday, a Sunday, a day on which the New York Stock Exchange is closed, or other day on which banks are required or authorized by law to be closed in Berlin, Germany.
1.10 “CBE” shall mean “Change Being Effected” as defined in the Act.
1.11 “CFR” shall mean the US Code of Federal Regulations.
1.12 “Change of Control” shall mean that (i) a majority of the outstanding voting securities of a Party becomes owned by one or more individuals or entities that did not own a majority of the voting securities of such Party as of the Effective Date; or (ii) the possession of the power to direct or cause the direction of the management and policies of a Party, whether through ownership of the outstanding voting securities or by contract or otherwise becomes vested in one or more individuals or entities that did not possess such power as of the Effective Date.
1.13 “Clinical Development” shall mean the conduct of studies of Product in humans to assess the dosing, safety and/or efficacy of Product.

[*] CONFIDENTIAL TREATMENT REQUESTED
1.14 “Clinical Supplies” shall mean supplies of Product and, if applicable, placebo, to be used for the conduct of Development in the Territory.

1.15 “Commercial Forecast” shall have the meaning set forth in Section 4.1.

1.16 “Commercialization” and “Commercialize” shall refer to all activities relating to the pre−marketing, marketing, distribution, import, sale and offer for sale of a Product, and the process of Commercialization, respectively.

1.17 “Commercially Reasonable Efforts” shall mean the level of endeavor which a company in the prescription pharmaceutical industry comparable in size to Indevus or Schering, as applicable, and active in development and commercialization of pharmaceutical compositions would ordinarily expend to accomplish an important objective.

1.18 “Confidential Information” shall have the meaning set forth in Section 15.1.

1.19 “Contract Quarter” shall mean any period of three (3) consecutive calendar months commencing with the first day of any January, April, July, or October.

1.20 “Contract Year” shall mean the period commencing on the Effective Date and ending on December 31, 2006, and each subsequent twelve (12) month period thereafter during the Agreement Term and any renewal term hereof.

1.21 “Current Good Manufacturing Practices” or the letters “GMP” or “cGMP” means current good manufacturing practice and standards as provided for (and as amended from time to time) in (i) the Current Good Manufacturing Practice Regulations of CFR Title 21, including those regulations set forth in 21 CFR Parts 210 and 211, (ii) European Community Directive 2003/94/EC (Principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use), and (iii) applicable ICH Harmonised Tripartite Guidelines, and subject to any arrangements, additions or clarifications agreed in writing from time to time between the Parties in the Quality Assurance Agreement.

1.22 “Development” or “Develop” shall mean all activities, or the performance thereof, relating to Pre−clinical Development and Clinical Development as are customary for a company in the pharmaceutical industry as part of the process of obtaining Regulatory Approval.

1.23 “Documentation” shall mean all required shipping documentation, including bills of lading, and such certificates of analysis and conformance and other appropriate and required documentation identifying the applicable Batch numbers, indicating conformance of the shipment with the Specifications, the Quality Assurance Agreement and all applicable Regulatory Standards.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
1.24 “DMF” shall mean a Drug Master File as defined in 21 CFR §314.420, including all supplements and amendments thereto.

1.25 “Effective Date” shall mean the date when this Agreement has been executed by authorized representatives of both Parties.

1.26 “FDA” shall mean the US Food and Drug Administration of the Department of Health and Human Services, or any successor agency with responsibility for regulating the development, manufacture and sale of human pharmaceutical products in the US.

1.27 “Field” shall mean any use of a pharmaceutical composition to restore testosterone concentrations to physiological levels (i) to treat hypogonadism in men or (ii) to treat any other urological or endocrinological indication in men; for the avoidance of doubt, [*] shall not be considered an “indication” within the meaning of this definition.

1.28 “Final Packaging” shall mean the labeling and packaging (as defined in the Act) of Finished Product, including product carton, package inserts, labels and associated components accompanying and necessary for use or sale of the Clinical Supplies or Finished Product in the Territory, as applicable.

1.29 “Finished Product” shall mean [*], provided that Regulatory Approval has been granted or marketing authorization is being sought for such Product by Indevus pursuant to a NDA, in either case, Packaged and labeled in a final form ready for commercial sale and distribution in the Territory.

1.30 “Firm Order” shall have the meaning set forth in Section 4.2.

1.31 “First Commercial Sale” shall mean the date Indevus or an Affiliate or Sublicensee of Indevus first sells, or otherwise disposes of, commercially, a Finished Product pursuant to a Regulatory Approval in the Territory.

1.32 “GAAP” shall mean US generally accepted accounting principles.

1.33 “Improvements” shall mean any and all developments, improvements or enhancements relating to Product including, without limitation, in the manufacture, formulation, preparation, presentation, means of delivery or administration, dosage, indication, use or methods of use or packaging.

1.34 “IND” shall mean an Investigational New Drug application filed with FDA pursuant to 21 CFR 312.1 et seq., as such regulations may be amended from time to time, the filing of which was or is necessary to commence clinical testing of Product in the Territory.

1.35 “Initial Payment” shall have the meaning set forth in Section 8.2.2.

1.36 “License Agreement” shall mean the License Agreement by and between the Parties dated as of July 28, 2005.

[∗] CONFIDENTIAL TREATMENT REQUESTED
1.37 "Launch Period" shall mean the period commencing on the First Commercial Sale and expiring on December 31 of the Year immediately following the Year in which the First Commercial Sale occurred.

1.38 “Long−acting Testosterone Product” shall mean any pharmaceutical composition formulated in [*], in each case other than Product introduced in the Territory by Indevus or any Affiliate or Sublicensee of Indevus.

1.39 “Manufacture” or “Manufacturing” shall mean all operations required to manufacture or have manufactured for supply to Indevus Clinical Supplies and Finished Product hereunder including, but not limited to the manufacture, preparation and processing of drug substance and drug product, filling and finishing of Finished Product, and Final Packaging, testing, releasing, handling, storage and Packing of Finished Product, or any step thereof, as the case may be.

1.40 “NDA” shall mean a New Drug Application as defined in the Act filed with the FDA, for marketing authorization of Products in the US, including any supplements or amendments thereto.

1.41 “Net Sales” shall mean with respect to any Product, the gross amount invoiced by Indevus or its Affiliates or Sublicensee from sales of Product in the Territory, commencing upon the date of First Commercial Sale, less deductions for: (a) transportation charges (freight, shipping and distribution), including insurance actually paid for distribution of Product; (b) sales, value−added and excise taxes, and other taxes, duties or surcharges paid or allowed by a selling party and any other governmental charges imposed upon the sale or use of Product; (c) any other fees paid to distributors, consignees or agents in connection with the sale of Product; (d) allowances or credits to customers, not in excess of the selling price of Product, on account of governmental requirements, rejection, outdated or return of Product; (e) rebates or premiums granted or allowed to customers in connection with the sale of Product; (f) trade, quantity, or cash discounts, chargebacks or retroactive price reductions granted in connection with the sale of Product; and (g) write offs for bad debts. Net Sales shall be determined at the time such Net Sales are recognized as revenue in accordance with GAAP by Indevus and all accounting terms used shall be interpreted in accordance with GAAP.

For the purpose of calculating Indevus’ Net Sales, the Parties recognize that (i) Indevus’ customers may include parties in the chain of commerce who enter into agreements with Indevus as to price even though legal title to Product does not pass directly from Indevus to such customers, and even though payment for such Product is not made by such customers to Indevus, and (ii) in such cases, chargebacks paid by Indevus to or through a Third Party (such as a wholesaler) can be deducted by Indevus from gross revenues in order to calculate Indevus’ Net Sales. Sales between Indevus and Affiliates or Sublicensees shall be excluded from the computation of Net Sales, except where such entities are end users in which case Net Sales shall include Net Sales to such entities; provided, however, if such entities are using such Products solely for research or clinical testing purposes, indigent or other public support programs, then such sales between Indevus and Affiliates shall be excluded from the computation of Net Sales.

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1.42 “Notional Net Sales Price” or “Notional NSP” shall mean, solely for the purposes of Section 8.2 and 8.3, an estimate of the Net Sales price of Product in the Territory at the time of determination, which shall be determined in accordance with Section 8.2.1.

1.43 “Outside US Change Request” shall have the meaning set forth in Section 11.1.

1.44 “Pack”, “Packed”, or “Packing” shall mean the operations which comprise the packing and packaging of Clinical Supplies and Finished Product, as the case may be, solely for the purpose of shipping such articles in accordance with the Act and pursuant to this Agreement.

1.45 “Pre-clinical Development” shall mean all activities relating to the planning and execution of non-human studies conducted in vitro or in relevant in vivo animal models directed towards obtaining Regulatory Approval of Product in the Territory. This includes pre-clinical testing, pharmacokinetics, toxicology, documentary and medical writing directly related to Pre-clinical Development activities, and related regulatory affairs.

1.46 “Product” shall mean the pharmaceutical composition containing the Substance in a [*].

1.47 “Product Competition” shall be present commencing as of the first calendar quarter (the “Triggering Quarter”) in which (a) [*] have a market share in the Territory of [*] or greater of the [*] in such calendar quarter of (i) [*]; and (ii) such [*], and (b) the [*] in the Territory has decreased by [*] or greater [*]; provided, however, that Product Competition shall not be deemed to be present for any calendar quarter after the Triggering Quarter if in such calendar quarter Long-acting Testosterone Products do not have a market share in the Territory of [*] or greater of the [*] of (i) [*] and (ii) [*].

1.48 “Quality Assurance Agreement” shall mean the quality assurance agreement between the Parties in which the responsibilities concerning quality control and quality assurance of Substance and Finished Product are set forth and which is attached as Exhibit 1.48, as same may be amended from time to time by mutual agreement of the Parties.

1.49 “Regulatory Authority” shall mean any court, tribunal, arbitrator, agency, commission, official or other instrumentality of any national, state, county, city or other political subdivision, that performs a function for such political subdivision similar to the function performed by the FDA for the US with regard to the approval, licensing, registration or authorization to test, manufacture, promote, market, distribute, use, store, import, transport or sell a product in the defined territory or political subdivisions, or with respect to the approval of pricing or reimbursement for such product.

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[*] CONFIDENTIAL TREATMENT REQUESTED
1.50 “Regulatory Approval” shall mean any approvals, product and/or establishment licenses, registrations or authorizations of any Regulatory Authority necessary for marketing Product in the Field in the Territory.

1.51 “Regulatory Standards” shall mean (i) obtaining and maintaining any and all permits, licenses, filings and certifications required by the FDA or other Regulatory Authorities, and compliance with the cGMPs of the FDA or other Regulatory Authorities, applicable to any Manufacturing or Schering Facilities, and (ii) any laws, rules, regulations and standards of any Regulatory Authority, whether within or outside the Territory, that apply to any Manufacturing or Schering Facilities.

1.52 “Schering Facilities” [*].

1.53 “SEC” shall mean the US Securities and Exchange Commission or any successor agency.

1.54 “SKU” (Stock Keeping Unit) means a stocking unit comprised of one (1) box containing one (1) unit of Finished Product or as otherwise agreed to by the Parties.

1.55 “Specifications” shall mean those specifications that are, as of the Effective Date, set forth in the IND and attached to the Quality Assurance Agreement, as such specifications may be amended and set forth in the NDA. The specifications shall be deemed amended effective upon the date such amended specifications are set forth in the NDA and the amended specifications shall be appended to the Quality Assurance Agreement; provided, however that a failure or delay in effecting any such amendment to this Section 1.55 shall not affect the revised meaning of this Section 1.55 as of the effective date of the amended specifications.

1.56 “Steering Committee” shall mean the committee established by the Parties pursuant to Section 5.1 of the License Agreement.

1.57 “Subcontractor” shall have the meaning set forth in Section 2.8.

1.58 “Sublicensor” shall mean a Third Party to whom Indevus has granted a license or sublicense to develop, import, use, sell, offer for sale or otherwise exploit Product in the Territory.

1.59 “Substance” shall mean testosterone undecanoate (TU).

1.60 “Superseded Finished Product” shall have the meaning set forth in Section 4.1.2.

1.61 “Supply Price” shall have the meaning set forth in Section 8.1.

1.62 “Supply Team” shall have the meaning set forth in Section 7.1.

1.63 “Territory” shall mean the US.

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1.64 “Third Party” shall mean any entity other than Schering or Indevus and their respective Affiliates.
1.65 “US” shall mean the United States of America, including the District of Columbia, and its territories, possessions, and commonwealths, including, without limitation, the Commonwealth of Puerto Rico.
1.66 “US Change Request” shall have the meaning set forth in Section 11.2.
1.67 “[*]” shall mean a calendar year.

Defined terms used herein that are not defined in this Article 1 but are defined in the License Agreement shall have the meanings ascribed to such terms in the License Agreement. Where words and phrases are used herein in the singular, such usage is intended to include the plural forms where appropriate to the context, and vice versa. The words “including”, “includes” and “such as” are used in their non-limiting sense and have the same meaning as “including without limitation” and “including but not limited to”. References to Articles, Sections, subsections, and clauses are to the same with all their subparts as they appear in this Agreement.

Article 2
Manufacture and Supply

2.1 General Scope. During the term of this Agreement, and subject to the terms and conditions set forth in this Agreement, Schering shall Manufacture and supply or cause to have Manufactured and supplied by an Affiliate or a Third Party (subject to Section 2.8) to Indevus or Indevus’ designee all of Indevus’ requirements of Clinical Supplies and Finished Product for Clinical Development and Commercialization, respectively, of Product in the Field in the Territory, and Indevus shall purchase from Schering, all of Indevus’ requirements of Clinical Supplies and Finished Product for Clinical Development and Commercialization, respectively, of Product in the Field in the Territory.

The following scenarios have to be distinguished:

(i) In case the FDA only grants Regulatory Approval for the [*] as Finished Product, Schering will only supply Finished Product in the form of the [*].

(ii) In case the FDA only grants Regulatory Approval for the [*] as Finished Product, Schering will only supply Finished Product in the form of the [*].

(iii) In case the FDA only grants Regulatory Approval for the [*] as Finished Product, Schering will only supply Finished Product in the form of the [*].

(iv) In case the FDA grants Regulatory Approval for the [*] as Finished Product, Schering will only supply Finished Product in the form of the [*].

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Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
In case the FDA grants Regulatory Approval for [*] as Finished Product and the FDA approved prescribing information specifies a distinction between [*], Schering will supply Finished Product in the form of the [*], as requested by Indevus from time to time in accordance with the terms of this Agreement.

In case the FDA grants Regulatory Approval for [*] as Finished Product but the FDA approved prescribing information does not specify a distinction between [*], then Schering will supply Finished Product in the form of the [*] and, subject to the following sentence, the [*] as requested by Indevus from time to time in accordance with the terms of this Agreement. In the event Indevus requests that Schering supply the [*] under the circumstances provided by this subsection (vi), such supply will be subject to a minimum purchase obligation of Indevus of the [*] corresponding to Finished Product from a [*] litre production campaign per Year and an agreement of the Parties on the payment mechanism with respect to the supply of such [*] following good faith negotiations.

2.2 Supply of Others. During the term of this Agreement, neither Schering nor any of its Affiliates shall supply or otherwise make available Product for use in the Field in the Territory for or on behalf of (or authorize or permit any Third Party to make Product for or on behalf of) any person or entity other than Indevus, Indevus’ Affiliates and Sublicensees, provided that this Section 2.2 shall not prohibit Schering from supplying Product for use in the Territory as set forth in Section 2.5(ii) of the License Agreement.

2.3 DMF. With respect to the DMFs for Substance and Product, Section 3.5 of the License Agreement is hereby incorporated by reference, as if stated in its entirety, herein. Schering shall keep current any such DMFs.

2.4 Analytical Technology Transfer. Schering shall, on one instance only, provide copies or grant access to all necessary documentation and support to enable successful transfer of analytical test methods to Indevus and/or its designees.

2.5 Effect of [*]. As contemplated by Section 6.5 of the License Agreement, in the event of [*], Schering shall have the right to terminate this Agreement on not less than [*] prior written notice to Indevus and provided that Schering has to enable the technology transfer of the manufacturing process (including any required license to intellectual property and know−how) to an alternate manufacturer of Finished Product designated by Indevus, in accordance with Section 2.6. In the event of such termination of this Agreement, commencing as of the effective date of such termination through the expiration of the [*] (as defined in the License Agreement), in consideration of such technology transfer and any such required license, Indevus shall pay Schering, at Indevus’ discretion, either (i) reimbursement of the reasonable costs incurred by Schering for the technology transfer plus a royalty equal to [*] of Net Sales or (ii) a royalty equal to [*] of Net Sales. In the event of any inconsistency between the terms of this Section 2.5 and Section 6.5 of the License Agreement, the terms of this Section 2.5 shall control.

[*] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
2.6 Technology Transfer Obligations. In addition to the obligations set forth in Section 2.4, Schering shall, on one instance only, pursuant to Schering’s obligations to enable the technology transfer as set forth in Sections 2.4, 2.5 or 4.5, as applicable:

2.6.1 provide copies or grant access to Indevus and/or its designees, including analytical laboratories and the alternate manufacturer (at Indevus’ request) with the then most current version of all materials, documents describing intellectual property and know−how, regulatory filings, reagents, expertise, equipment, data, and other information necessary to Manufacture the Product;

2.6.2 provide to Indevus and/or its designees, including analytical laboratories and the alternate manufacturer (at Indevus’ request) copies or grant access to the relevant documentation constituting the required material support, including specifications as to materials to be used and control methods;

2.6.3 assist Indevus and/or its designees, including analytical laboratories and the alternate manufacturer (at Indevus’ request) with the working up and use of the technology and with the training of the alternate manufacturer’s personnel to the extent reasonably necessary in the Manufacture of Product by the alternate manufacturer and/or analytical laboratory up to an effort equivalent of three (3) man months. In this regard, Schering will receive Indevus’ and/or the alternate manufacturer’s and/or analytical laboratory’s staff, as applicable, in its premises for certain periods, the term of which will be agreed by the Parties; and

2.6.4 comply with such other obligations and responsibilities as are necessary to fully enable Indevus or such alternate manufacturer to undertake the Manufacturing and Packaging of Finished Product in accordance with the Specifications.

2.7 Quality Assurance Agreement. The responsibilities of the Parties concerning the quality of Product shall be set forth in the Quality Assurance Agreement. In the event the Quality Assurance Agreement contains material provisions that substantially differ from applicable Regulatory Standards, the Regulatory Standards shall control. Indevus shall inform Schering about all material revisions to the applicable Regulatory Standards applicable to Product in the Territory.

2.8 Subcontractors. The identity and function of each person or entity to whom Schering subcontracts or otherwise delegates all or any portion of its obligations hereunder, whether Affiliates of Schering or Third Parties (collectively, “Subcontractors”) shall be provided to the Supply Team. Schering shall be entitled to appoint a Subcontractor for the full or partial Manufacturing and Packing of Clinical Supplies and Finished Product without
Indevus’ prior written consent only in those instances where Indevus would not be required to notify the FDA of the respective subcontracting. Any subcontracting which requires notification of the FDA shall be subject to Indevus’ prior written consent; such consent not to be withheld unreasonably. In any event, (i) Schering shall maintain an oversight program whereby Schering measures and evaluates each Subcontractor’s performance of any Manufacturing activities; (ii) Schering may subcontract Manufacturing only to a Subcontractor who, based on Schering’s good faith business judgment and observations, is not subject to any conditions that might reasonably be expected to impede approval of such Subcontractor’s site by the FDA, provided, however, that if such site is the subject of any unresolved Section 483 comments by the FDA that might reasonably affect Manufacture, then such determination shall be subject to review by the Supply Team, or such Subcontracting will be effective only after a successful pre–approval inspection of the Subcontractor’s site by the FDA; and (iii) any Subcontractor who fails a pre–approval inspection by the FDA with respect to Product shall be prohibited from performing any Manufacturing hereunder unless and until all problems and issues identified by the FDA have been corrected to the satisfaction of the Supply Team. Schering will inform the Supply Team about such inspections and corrections. Notwithstanding the Supply Team’s review or approval of any document or activity, Schering shall be and remain responsible for the performance of any Subcontractor.

Article 3
Product Supply for Clinical Development

3.1 Clinical Supplies. Indevus has received from Schering [*] units of Clinical Supplies. Indevus will provide to Schering its requirements for any additional units of Clinical Supplies at least six (6) months prior to anticipated delivery setting forth the quantity, amount of placebo (if any), the Final Packaging and the delivery time. The details of delivery will be discussed and agreed upon by the Parties separately.

3.2 Costs of Clinical Supplies. Schering shall bear the costs for Manufacture of Clinical Supplies delivered to Indevus up to an amount of [*] units. In the event Indevus requires Clinical Supplies in excess of [*] units in total such additional Clinical Supplies shall be supplied to Indevus at the Notional Net Sales Price, provided that if such additional Clinical Supplies are provided prior to the Launch Period, then the price for such Clinical Supplies shall be determined by the Supply Team.

Article 4
Forecasting and Ordering for Commercialization

4.1 Commercial Forecasts.

4.1.1 Forecasts. Within five (5) Business Days after the Effective Date and thereafter within the first five (5) Business Days of each Contract Quarter, Indevus will provide to Schering a rolling non–binding (except as set forth in Section 4.3) forecast for (a) prior to Regulatory Approval, six (6) consecutive Contract

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Quarters and (b) commencing with the first Commercial Forecast submitted after Regulatory Approval, eight (8) consecutive Calendar Quarters, (starting with the first complete Contract Quarter following the date of the forecast – Q1) of the estimated quantities of Finished Product in SKUs that Indevus intends to order (the “Commercial Forecast”) as follows:

- With respect to the [*] as Finished Product, until Indevus notifies Schering that it no longer requires the [*];
- with respect to the [*] as Finished Product, until Indevus notifies Schering that it no longer requires the [*];
- with respect to the [*] as Finished Product, until Indevus notifies Schering that it no longer requires the [*];
- with respect to [*] as Finished Product, specifying the number of [*], until Indevus notifies Schering that it no longer requires [*].

For the first two (2) Contract Quarters, the Commercial Forecast shall be made by month, and for the remaining Contract Quarters, the Commercial Forecast shall be made by Contract Quarter.

4.1.2 General. The Commercial Forecasts shall be sent by e-mail and facsimile to Schering’s supply manager. Except as otherwise specifically set forth herein, all Commercial Forecasts made hereunder shall be made to assist Schering in planning its production and shall not be Firm Orders or binding purchase orders, unless as set forth in Section 4.2. Each Commercial Forecast provided by Indevus shall supersede any previous Commercial Forecast. In the event Indevus notifies Schering, as provided under Sub-section 4.1.1, that Indevus no longer requires a particular Finished Product that had been specified in a previous Commercial Forecast (a “Superseded Finished Product”), any previous Commercial Forecasts with respect to such Superseded Finished Product shall be deemed void and of no further force and effect and shall be superseded by the first Commercial Forecast with respect to Finished Product provided after the date of such notification by Indevus, which thereafter shall constitute the Commercial Forecast; provided, however, that (a) in case a Commercial Forecast for the [*] constitutes a Firm Order, (b) Schering has already started activities to customize the [*] for Commercialization by Indevus in the Territory at the time of notification by Indevus, and (c) the respective [*] cannot be used by Schering outside the Territory, then such Firm Order with respect to the [*] shall remain in force.

4.2 Firm Orders. Subject to the provisions of Section 4.1.2 and to the extent consistent with the volume limitations set forth in Section 4.4, the [*] of each Commercial Forecast submitted after Regulatory Approval, as updated

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Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
each Contract Quarter, shall be a non-cancelable, legally binding commitment on the part of Schering to supply, and on the part of Indevus to purchase, the quantity of Finished Product as set forth in the Commercial Forecast, each such [*] commitment being “Firm Orders”. The Parties acknowledge and agree that Indevus may use validation batches of the [*], manufactured by Schering, to satisfy all or any portion of Indevus’ requirements for launch quantities of the [*] as Finished Product, subject to compliance with applicable laws and other provisions of this Agreement. The Supply Team will discuss the timing of the initiation of production of validation batches. Accordingly, with respect to Commercial Forecasts submitted by Indevus prior to Regulatory Approval, only the quantity, if any, of Finished Product forecasted for the first Contract Quarter of each Commercial Forecast that exceeds the quantity of validation batches supplied by Schering shall constitute a Firm Order. Subject to the foregoing sentence, the minimum size of a Firm Order (consisting of one delivery) shall be [*] of Finished Product or a Batch size, whichever is lower.

4.3 Purchase Orders. Indevus or its designee shall provide Schering with purchase orders containing the information as listed in Schedule 4.3 of its requirements for Finished Product, specifying the required delivery date in each purchase order. Schering shall acknowledge and provide Indevus with a written acceptance of each purchase order within five (5) Business Days following Schering’s receipt thereof. Schering will use Commercially Reasonable Efforts to comply with any demands for supply of Finished Product in excess of the amounts of Finished Product set forth in Firm Orders.

4.4 Variation of Commercial Forecast. With every quarterly update of a Commercial Forecast following Regulatory Approval, Indevus may increase or decrease:

4.4.1 the forecast of Finished Product for the third Contract Quarter (Q3) of the Commercial Forecast as that Contract Quarter rolls from Q3 to Q2 (becoming a Firm Order) by [*] during the Launch Period and [*] for the period thereafter, and

4.4.2 the forecast for the respective Contract Quarters [*] during the Launch Period and four through eight (8) for each Year thereafter [*] or ([*], as applicable) of the Commercial Forecast by [*] during the Launch Period and [*] for each Year thereafter of the forecast in the Commercial Forecast of the preceding Contract Quarter

4.4.3 Any variations beyond the limits set forth herein require the mutual agreement of the Parties. No variation limits set forth in this Section 4.3 shall apply to Commercial Forecasts submitted by Indevus prior to Regulatory Approval, provided that the forecast for launch quantities of Finished Product does not exceed the quantities of validation batches supplied by Schering.

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4.5 Inability to Supply.

4.5.1 Notice of Inability to Supply. Schering shall immediately notify Indevus in writing if and when Schering determines that it will be unable to supply Finished Product under the terms of this Agreement. For purposes of this Section 4.5, an “Inability to Supply” shall mean: Schering’s failure for any reason, including force majeure reasons or otherwise, to supply Indevus with quantities of Finished Product meeting the Specifications and applicable Regulatory Standards, at least equal to (i) [*] of Finished Product quantities specified in two (2) consecutive Firm Orders or (ii) [*] of Finished Product quantities specified in one (1) Firm Order, provided that in (i) and (ii) Schering has not cured the respective failure (if curable) within ninety (90) days and further provided that the right to cure (ii) shall not be applicable after such failure has occurred a second time in two (2) Contract Years;

4.5.2 Consequences of Inability to Supply. In the case of an Inability to Supply Schering shall remedy the Inability to Supply, fulfill purchase orders with such quantities of Finished Product as are available, and resume supplying acceptable Finished Product to Indevus as soon as is reasonably possible, and/or, upon Indevus’ request, establish and fully cooperate with Indevus to secure adequate supplies of Finished Product from alternative sources, including locating qualified third party manufacturers and sources of materials, assuming liability for any excess manufacturing cost incurred by Indevus, and complying with the technology transfer obligations set forth in Section 2.6. In the event of any Inability to Supply, Indevus shall be relieved from its obligations under this Agreement to purchase any minimum quantities of Finished Product identified in any outstanding portions of Commercial Forecasts, Firm Orders or purchase orders or subject to the minimum purchase obligation set forth in Section 8.3 (or any corresponding obligations set forth in the License Agreement) and shall be relieved of any further minimum purchase obligations or obligations to provide Firm Orders unless and until such Inability to Supply is remedied. Except as set forth in Section 17.5, nothing in this Section 4.5 shall limit any contractual or other rights or remedies that may be available to Indevus on account of any Inability to Supply under this Agreement.

Article 5
Packaging and Delivery,

5.1 Final Packaging; Packing for Shipment. Indevus shall provide Schering with specifications for the FDA approved labeling, artwork, drawings and any additional Final Packaging which shall accompany Finished Product (and which shall be used by Schering solely for the Manufacture and supply to Indevus or Indevus’ designee of Finished Product pursuant to this Agreement) sufficient time in advance to enable Schering to Manufacture Finished Product in due time prior to the scheduled delivery to Indevus. Schering will establish, update as necessary and implement processes and procedures designed to

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ensure that all Finished Product and Clinical Supplies are labeled and packaged in accordance with Indevus’ artwork and labeling Specifications and in accordance with Schering’s technical requirements and standards. Except with the prior written approval of Indevus, Schering shall not include any other packaging or inserts with, or affix any other labeling or artwork to, the Finished Product. Schering will provide shipment preparation and Packing of Clinical Supplies and Finished Product in accordance with Schering’s technical requirements, Schering’s standards and with the Quality Assurance Agreement, as applicable, with details to be discussed in the Supply Team. Indevus shall be responsible for ensuring that all packaging, labels and labeling including, but not limited to the package make-up, package inserts and other elements relating to packaging, labels and labeling as well as all promotional material complies with all laws and regulations applicable to such packaging, labels and labeling in the Territory. The Batch coding of Finished Product will be effected in accordance with the Batch labeling instructions defined by Schering.

5.2 Delivery to Indevus. Schering agrees to deliver Clinical Supplies and Finished Product [*] Schering Facility to a carrier designated by Indevus at the delivery dates set forth in the respective purchase order, provided that such delivery date is at least ninety (90) days and not greater than one hundred twenty (120) days from the date of such purchase order, subject to the provisions of this Section 5.2 and Section 5.6. In the event Indevus requests shipment or delivery that differs from this agreed upon schedule, Indevus will notify Schering in writing as soon as practicable, but in no event less than two (2) weeks in advance of the requested date of shipment by Schering and Schering will use Commercially Reasonable Efforts to comply with Indevus’ request. Schering will arrange for the delivery of Clinical Supplies or Finished Product in a manner consistent with good commercial practices, applicable Regulatory Standards, any agreed-upon shipping specifications and the Quality Assurance Agreement, as applicable.

Unless otherwise agreed to in advance, deliveries made against Firm Orders will not exceed the requested quantity of Finished Product by more than [*] nor be less than [*] of the requested quantity of Finished Product, provided that these percentages may be adjusted if required in order to cure cumulative over- or under- deliveries in the same Contract Year.

5.3 Delivery Times. Schering shall use Commercially Reasonable Efforts to meet the delivery dates pursuant to Section 5.2 above.

5.4 Title and Risk of Loss. Title and risk of loss with respect to Clinical Supplies and Finished Product furnished hereunder shall pass to Indevus upon delivery by Schering of such Clinical Supplies and Finished Product cleared according to Section 5.2.

5.5 Shelf Life. All Finished Product supplied to Indevus shall have the longest remaining shelf life reasonably possible.

5.6 Documentation; Release of Shipments. Schering will prepare and execute all reasonably necessary shipping documents, including a Packing
List, Certificate of Analysis, Certificate of Compliance and all other Documentation required by the Quality Assurance Agreement. Unless otherwise agreed in writing by the Parties, Schering shall not ship or invoice Indevus for Finished Product until at least ten (10) Business Days after Schering has provided Indevus with a Certificate of Analysis, a Certificate of Compliance and any other release Documentation required by the Quality Assurance Agreement.

Article 6
Regulatory Matters, Recalls and Pharmacovigilance

6.1 General Regulatory Matters. In addition to the specific requirements of this Article 6 and the Quality Assurance Agreement, Schering shall (i) be responsible for obtaining and maintaining in good order all site licenses and current registrations granted by the FDA and any other applicable Regulatory Authority for the Manufacture of the Clinical Supplies and Finished Product at the Schering Facility(ies) as contemplated hereunder and will make copies of such registrations and all related documents available to Indevus and its designee for inspection during audits upon Indevus’ reasonable request; and (ii) take all steps necessary to be obtain and maintain FDA approval as a manufacturer of Finished Product under Indevus’ NDA, and comply with regulations promulgated by the FDA and any other applicable Regulatory Authority in connection with Schering’s Manufacture of the Clinical Supplies and Finished Product hereunder. In addition, Sections 3.4 and 3.5 of the License Agreement are hereby incorporated by reference, as if stated in their entirety, herein.

6.2 Records. Schering will maintain complete and accurate records and Documentation of all validation data, stability testing data, batch records, quality control and testing relating to the Substance and the Finished Product and the Manufacture, Final Packaging, labeling, testing and shipment thereof. Records which include the information relating to the Manufacturing, Final Packaging and quality operation for each lot of Substance and Finished Product will be prepared by Schering at the time such operations occur. Schering will prepare, maintain and retain such records in compliance with cGMP’s and other applicable Regulatory Standards, the Specifications and the Quality Assurance Agreement, for annual report requirements, and for periods meeting all applicable regulations of the FDA and make such records and Documentation available to Indevus upon Indevus’ reasonable request and in accordance with the Quality Assurance Agreement. The records and Documentation shall be subject to audit and inspection under this Article 6 and the Quality Assurance Agreement.

6.3 Regulatory Communications and Inspections. Schering shall take all reasonable steps necessary for the Schering Facilities to obtain and maintain approval by the FDA as a manufacturer of Finished Product under Indevus’ NDA for Product. Schering will provide Indevus with reasonable advance notice of any related FDA inspections (or within five (5) Business Days after any unannounced contact, inspection or audit commences) and, at the conclusion of such inspections, provide Indevus in writing with the results and outcome of such inspection, an estimate of the timeline associated with
correcting any deficiencies identified by such inspection, and copies of any observations by the FDA (such as 483 comments) that would in any event become publicly available, including pursuant to The Freedom of Information Act, 5 U.S.C. § 552, as amended, and the HHS Freedom of Information Regulations (45 CFR Part 5). Indevus shall provide such assistance in connection with such inspection as may be reasonably requested by Schering. Schering shall discuss with the Supply Team any comments related to and affecting Schering’s performance of any Manufacturing activities and shall be responsible for and shall take appropriate actions to correct in a timely manner any deficiencies identified by such inspection. Schering shall retain copies in accordance with Regulatory Standards, and will also inform Indevus in writing as to any written communications or correspondence between Schering and the FDA relating to Schering’s activities under this Agreement within five (5) Business Days after receiving or providing such communication or correspondence.

6.4 Recalls and Other Corrective Actions. The Parties shall advise each other as soon as reasonably practicable but whenever possible no later than forty−eight (48) hours in advance of any planned recall, market withdrawals, or other corrective action related to Product intended to be conducted by either Party or any of its Affiliates that implicates Product supplied by Schering to Indevus and shall keep each other informed with respect to the status of any such actions. Unless regulated otherwise herein, Indevus shall have responsibility for and shall make all decisions relating to conducting any recall, market withdrawals, or other corrective action related to Product in the Territory. The Parties shall consult with each other with respect thereto and Indevus shall consider in good faith any comments or suggestions of Schering, provided, however, that nothing herein shall prohibit Indevus, from initiating or conducting any recall or other corrective action mandated by the FDA or applicable law. At Indevus’ request, Schering shall provide reasonable assistance in conducting such recall, market withdrawal or other corrective action, including, without limitation, providing all pertinent records that Indevus may reasonably request to assist in effecting such action. Indevus shall bear any and all costs of any such recall, market withdrawal or other corrective action with respect to Product in the Territory, except that Schering shall bear any and all such costs if such recall, market withdrawal or other corrective action is attributable predominantly to the fault of Schering or results from a negligent or reckless act or omission or intentional misconduct on the part of Schering or its Affiliates or the failure of Substance or Product to be manufactured or shipped by Schering or its Affiliates in compliance with all applicable laws, rules and regulations, and the Specifications or any breach by Schering of applicable laws, rules or regulations, or the provisions of this Agreement.

6.5 Adverse Drug Experiences and Safety Reporting. With respect to adverse drug experiences and safety reporting, the parties have entered into a Pharmacovigilance Agreement effective as of August 1, 2006.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
Article 7
Supply Team and Escalation Procedure

7.1 Supply Team. Within thirty (30) days after the Effective Date, Schering and Indevus will establish a team consisting of four (4) members, two (2) representatives nominated by Schering and two (2) representatives by Indevus, which team shall discuss and supervise all issues in the Manufacturing and supply of Product (“Supply Team”). Unless otherwise agreed between the Parties, the Supply Team will meet quarterly (in person, telephonically or via videoconference). Either Party may replace any or all of its representatives in and/or invite other representatives of such Party to attend meetings of the Supply Team at any time upon written notice to the other Party. Regardless of the number of individuals attending any Supply Team meeting, Schering and Indevus shall have a single vote each.

7.2 Escalation Procedure. If any issues or disputes cannot be resolved within the Supply Team, these issues shall be referred to the Steering Committee for resolution. The Steering Committee shall decide on these issues. If an issue escalated by the Supply Team cannot be resolved by the Steering Committee, it shall be referred to Indevus’ CEO and Schering’s Head of Industrial Operations and Environment for resolution. If the issue can nevertheless not be resolved it shall be referred to dispute resolution pursuant to Section 17.11.

7.3 Limitation of Power. Notwithstanding the tasks of the Supply Team and the Steering Committee herein (and whether or not issues or disputes are able to be resolved through such process), each Party to this Agreement shall retain the rights, remedies, powers and discretion granted to it hereunder and its obligations hereunder, and neither the Supply Team nor the Steering Committee shall have the power to amend or modify this Agreement, which may be amended or modified only as provided in Section 17.1.

Article 8
Supply Price, Notional NSP, Payment Terms

8.1 Supply Price.

8.1.1 Subject to the provisions of this Section 8.1, the supply price for Finished Product shall be [*] (the “Supply Price”, respectively) which shall incorporate all fully-burdened costs and expenses incurred by Schering or its designees associated with the Manufacture, procurement, testing, Final Packaging, Packing, supply and delivery of Finished Product [*] Schering Facility to a carrier designated by Indevus.

8.1.2 Except as set forth in the following sentence, in the event Schering develops an Improvement pursuant to Section 6.8.2 of the License Agreement and Indevus Commercializes such Improvement in the Field in the Territory, then the Supply Price for the Finished Product of such Improvement shall be proportionally adjusted to reflect such increased or decreased costs and expenses.

[*] CONFIDENTIAL TREATMENT REQUESTED
For the avoidance of doubt, the Supply Price shall remain unchanged in case Indevus Commercializes (i) an Improvement pursuant to Section 6.8.1 of the License Agreement and/or (ii) [*].

8.2 Payment Mechanism. With respect to the payment of the Supply Price the following mechanism shall apply:

8.2.1 Determination of Notional NSP. Indevus shall determine the Notional NSP (i) for the Launch Period, based on the estimated Net Sales price, at least four (4) weeks prior to the first delivery and (ii) subsequent to the Launch Period, by reference to the average Net Sales price of Finished Product in the Territory as evidenced by the last four reports provided under Section 9.1 (or such lesser number of reports as have actually been produced as of the date of any particular determination) and shall provide the Notional NSP to the Steering Committee.

8.2.2 Initial Payment. Within sixty (60) days after the later of Indevus’ receipt of Finished Product or the related Documentation, Indevus shall pay Schering an amount equal to the applicable percentage of the Supply Price set forth in Schedule 8.2.2 which amount shall be calculated, for purposes of this Section 8.2.2, based on the Notional NSP determined under Section 8.2.1 (the “Initial Payment”). During the Launch Period the Initial Payment shall be due ninety (90) days after the later of Indevus’ receipt of Finished Product or the related Documentation.

8.2.3 Adjustment. Within sixty (60) days after the end of each Contract Quarter (commencing with the first complete Contract Quarter ending after the date of First Commercial Sale), Indevus shall calculate and pay Schering the difference between the Supply Price payable for such Contract Quarter and the Initial Payment. Such calculation may be included in the report provided for under Section 9.1. In the event that for any Contract Quarter the Initial Payment exceeds the Supply Price payable for such Contract Quarter, Indevus will offset such excess amount from the next Initial Payment due from Indevus hereunder.

8.3 Minimum Purchase Obligation. As contemplated by Section 6.7 of the License Agreement, for the period commencing after the second Royalty Year (as defined in the License Agreement) and expiring on the earlier of the sixth anniversary of First Commercial Sale or the commencement of [*], Indevus shall either (a) for each Royalty Year during such period, purchase from Schering at the Supply Price, a minimum of [*] of the units of Finished Product that were purchased in the second Royalty Year; or (b) if the actual quantity of Finished Product purchased by Indevus for any such Royalty Year is less than such minimum quantity, pay Schering a supply fee for such Royalty Year equal to the difference, if any, between (i) the amount that would have been payable to Schering if the [*] and (ii) the sum of (x) the [*] under Section 7.3.1 of the License Agreement. In the event of any inconsistency between the provisions of this Section 8.3 and the provisions of Section 6.7 of the License Agreement, the provisions of this Section 8.3 shall control.

[*] CONFIDENTIAL TREATMENT REQUESTED
**Article 9**

**Accounting and Audit**

9.1 **Net Sales Reports.** Within sixty (60) days following the end of each Contract Quarter commencing with the first complete Contract Quarter ending after the date of First Commercial Sale, Indevus shall submit to Schering a report summarizing the Net Sales, the sales quantities of Product and the number of distributed commercial samples (if any) during the relevant Contract Quarter, the Supply Price payable for such Contract Quarter, and the difference between such Supply Price and the Initial Payment under Section 8.2.2.

9.2 **Records and Auditing.** Indevus shall maintain complete and accurate records which are relevant to payments under this Agreement and, upon the written request of Schering with at least ten (10) Business Days’ notice, Indevus shall permit an independent certified public accounting firm of internationally recognized standing selected by Schering and consented to by Indevus, to have access to such records during reasonable business hours for any Contract Year ending not more than three (3) full Years prior to the date of such request for examination at Schering’s expense and not more often than once each Year, for the sole purpose of verifying for Schering the correctness of calculations under this Agreement. Schering shall bear its own costs related to such audit; provided, that for any underpayments by Indevus in an amount greater than five percent (5%) of the amounts owed in the aggregate by Indevus under this Agreement and the License Agreement for the applicable period or periods being examined, Indevus shall pay Schering the amount of underpayment, interest on the amount of the underpayment as provided for in Section 10.2 from the time the payment was due and the reasonable out−of−pocket costs of such accounting firm. For any underpayments by Indevus in an amount less than five percent (5%) of the amounts owed in the aggregate by Indevus for the applicable period or periods being examined under this Section 9.2, Indevus shall pay Schering the amount of such underpayment. Any overpayments by Indevus will, at Indevus’ option, be refunded to Indevus or credited to future payments. The accounting firm shall disclose to Schering only whether the reports are correct or incorrect and the specific details concerning any discrepancies. Any records or accounting information received from Indevus shall be confidential information solely for the purpose of Section 9.2. Results of any such audit shall be provided to both Parties and shall be considered Confidential Information as defined in Section 13.1. Upon the expiration of twenty−four (24) months following the end of any Contract Year the calculation of amounts owed for such Contract Year shall be binding and conclusive upon Schering, and Indevus shall be released from any liability or accountability with respect to payments for such Contract Year.

9.3 **Audit Disagreement.** If there is a dispute between the Parties following any audit pursuant to Section 9.2, either Party may refer the issue (an “Audit Disagreement”) to an independent certified public accountant for
resolution. In the event an Audit Disagreement is submitted for resolution by either Party, the Parties shall comply with the following procedures:

(i) The Party submitting the Audit Disagreement for resolution shall provide written notice to the other that it is invoking the procedures of this Section 9.3.

(ii) Within thirty (30) Business Days of the giving of such notice, the Parties shall jointly select a recognized international accounting firm to act as an independent expert to resolve such Audit Disagreement.

(iii) The Audit Disagreement submitted for resolution shall be described by the Parties to the independent expert, which description may be in written or oral form, within ten (10) days of the selection of such independent expert.

(iv) The independent expert shall render a decision on the matter as soon as possible.

(v) The decision of the independent expert shall be final and binding unless such Audit Disagreement involves alleged fraud, breach of this Agreement or construction or interpretation of any of the terms and conditions hereof.

(vi) All reasonable fees and expenses of the independent expert, including any Third Party support staff, or other costs incurred with respect to carrying out the procedures specified at the direction of the independent expert in connection with such Audit Disagreement, shall be borne by each party in inverse proportion to the disputed amounts awarded to the Party by the independent expert through such decision. For example, Party A disputes US$ 100, the independent expert awards Party A US$ 60: Party A must pay forty percent (40%) and Party B sixty percent (60%) of the independent expert’s costs.

**Article 10**

**Payment Terms**

10.1 **Payments.** Payments due under this Agreement shall be due on such date as specified in this Agreement and, in the event such date is not a Business Day, then the next succeeding Business Day, and shall be made by wire transfer of immediately available funds to a bank account designated by Schering to Indevus in writing at least ten (10) Business Days before payment is due. Any payments by Indevus under this Agreement shall be made in US Dollars.

10.2 **Interest.** Any failure by Indevus to make a payment within ten (10) Business Days after the date when due, shall obligate Indevus to pay to Schering imputed interest, the interest period commencing on the due date and ending on the payment day, at a rate per annum equal to the Prime Rate as publicly announced by Bank of America on [REUTERS_screen <USPRIME1>] plus [*], or the highest rate allowed by law, whichever is lower.

[*] CONFIDENTIAL TREATMENT REQUESTED
The interest calculation shall be based on the [act/360 computation] method. The interest rate shall be adjusted whenever there is a change in the Prime Rate quotation on REUTERS screen <USPRIME1> mentioned above. Interest shall be compounded annually in arrears. Such interest shall be due and payable on the date of underlying payment is made.

10.3 Taxes. Schering shall pay any and all taxes levied on account of all payments it receives under this Agreement. If laws or regulations require that taxes be withheld, Indevus will (a) deduct those taxes from the remittable payment, (b) timely pay the taxes to the proper taxing authority and (c) send confirmation of payment to Schering within thirty (30) days of payment to the relevant taxing authority. Indevus agrees to make all lawful and reasonable efforts to minimize such taxes to Schering. If Indevus is so required then Schering and Indevus shall co−operate in all respects and take all reasonable steps to lawfully reduce to the extent possible payment of any such withholding taxes, Schering shall provide Indevus prior to any payments under this Agreement, with all necessary forms or documentation required to claim the exemption from such withholding taxes.

Article 11
Change Management

11.1 Changes Required by Schering. If, during the course of this Agreement, Schering wishes or is required by a Regulatory Authority outside the Territory to make a change to the Specifications, or the Manufacturing process, or the site of Manufacture of Finished Product; or any other aspects with respect to Finished Product, which may have an impact on the Regulatory Approval in the Territory (“Outside US Change Request”); then, prior to the implementation of any such Outside US Change Request, Schering shall validate the effect of the change on the Product as required by the Act, provide Indevus detailed information on the results of such validation, and:

11.1.1 if the change is an annual reportable change, i.e. does not require approval of or advance notice to the FDA as determined under the Act, Schering will provide to Indevus the necessary information in a mutually agreed upon format for Indevus’ annual report;

11.1.2 if the change is a CBE change, a CBE 30 change or a change which requires prior approval of the FDA (as determined under the Act), Schering shall submit to Indevus in writing details of the Outside US Change Request before implementation and the reasons therefore. Indevus shall review such Outside US Change Request without undue delay and shall respond in writing whether it consents to it or not. Indevus shall not unreasonably withhold or delay consent to such Outside US Change Request, provided that if the change is required by a Regulatory Authority outside the Territory Indevus shall give its consent. If approved by Indevus, any such changes that require prior approval of the FDA will not be implemented until such approval is granted by the FDA; and
11.1.3 the determination of the level of reporting required for the US (Annual Reportable, CBE 0, CBE 30, PAS) for (a) and (b) above shall be made by Schering in accordance with applicable Regulatory Standards following confirmation or consultation with the FDA, as appropriate.

11.2 Change Required by Indevus. If, during the course of this Agreement, Indevus requests, or is required by the FDA to demand, a change to the Specifications, or the Manufacturing process, or the site of Manufacture of the Finished Product; or any other aspects with respect to the Finished Product, ("US Change Request"); then Indevus shall submit to Schering in writing details of the requested change. Schering shall review such US Change Request without undue delay and provide Indevus with its likely effect on Schering’s production systems together with the investments and/or the costs necessary to implement such a change as well as any impact on the price. If the change is required by the FDA the Parties will discuss the regulatory basis of such US Change Request. If Schering believes that meetings should be held with the FDA regarding the basis of such US Change Request, Indevus will not unreasonably withhold its consent to do so and Schering will be included in all such meetings. Subject to approval by Schering which shall not be unreasonably withheld or delayed, Schering will use Commercially Reasonable Efforts to implement the US Change Request without undue delay. If the change is not required by the FDA and Indevus wishes to proceed, subject to approval by Schering, Schering will implement such US Change Request.

11.3 Packaging and Labeling Changes. If, during the course of this Agreement, Indevus wishes to change the secondary packaging, the labels or the labeling of Finished Product, then Indevus shall submit to Schering all information required therefore including, but not limited to art work and lay out, specifications for modified packaging, labels and labeling, pharmacological information, usage instructions and warnings to be applied which, for Finished Product, shall be consistent with the FDA approved labeling, reasonably in advance of the delivery date where the changes shall first be implemented. Schering shall review such proposal in due course (but no more than one (1) month) and, in the event of doubt, discuss with Indevus its possible effect(s) on Schering’s manufacturing system including, if such changes are beyond Schering’s capabilities taking into account the technical requirements, the impact on costs and timelines and the possible impact on the price of the Finished Product.

11.4 Regulatory Filings of Changes. If a change relates to the DMF(s) Schering will determine the requirements of the FDA for such a change following consultation with Indevus. Schering will submit such change to the DMF(s). Schering will provide to Indevus a revised authorization letter when a change is made to the DMF(s) and Indevus will submit it to the FDA along with any other necessary regulatory filings. Besides with respect to the DMF(s) Indevus shall be responsible for any other filings required by the FDA, and Schering will reasonably assist Indevus to meet the respective governmental and/or regulatory requirements which, in Indevus’ judgment, must be fulfilled before implementation of the respective change.

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
11.5 **Costs.** Schering shall bear all costs arising from (a) an Outside US Change Request; (b) a US Change Request that is required in order to Manufacture and supply Finished Product as contemplated herein in compliance with the Specifications or applicable Regulatory Standards or for any Schering Facility (including that of a Subcontractor) to be approved by the FDA as a manufacturer of Finished Product under Indevus’ NDA; and/or (c) changes that are primarily intended to benefit Schering or a Schering Facility, including, but not limited to process changes, site changes and supplier changes to improve operational efficiency, effectiveness and risk-management. The costs arising from a change request by Indevus pursuant to Section 11.3 shall be borne by Indevus. In case a Product developed under Section 6.8.1 of the License Agreement becomes available, the costs for implementation of changes pursuant to Section 11.3 to be borne by Indevus shall not exceed the costs attributable to the respective Firm Order amounts for the then current Finished Product plus [*] of any excess costs.

11.6 **Disputes on Changes.** If the Parties cannot agree upon a change request pursuant to Sections 11.1 to 11.3 above, the matter will be referred to the Steering Committee.

**Article 12**

**Non−Compliance**

12.1 **Inspection by Schering.** Schering will analyze each lot of Substance, Clinical Supplies and Finished Product for compliance with the Specifications. Schering will send to Indevus a certificate of analysis and a certificate of compliance (together with any other Documentation required under the Quality Assurance Agreement) prior to each shipment of Clinical Supplies and/or Finished Product and, unless otherwise agreed to by the Parties, will not ship Clinical Supplies or Finished Product until at least ten (10) Business Days after Indevus receives such Documentation.

12.2 **Notice of Failure to Meet Specifications.** In the event Schering discovers that any Batch or lot of Finished Product fails to conform to the Specifications or applicable Regulatory Standards, Schering will notify Indevus within two (2) Business Days, if such Batch or lot has been shipped to Indevus, of such failure to meet the Specifications or applicable Regulatory Standards, and of the nature thereof in detail, and will supply to Indevus such information related thereto as Indevus may reasonably request, including the results of all inside and outside laboratory testing and conclusions, if any. At its expense, Schering shall investigate all such failures promptly, and cooperate with Indevus in determining the cause for the failure and a corrective action to prevent future failures. In case a Batch or lot of Substance or Finished Product fails to conform to the Specifications or applicable Regulatory Standards which has not been included in Finished Product shipped to Indevus but where it reasonably could be expected to possibly have a negative impact on Indevus’ supply of Finished Product, the matter will be discussed in the Supply Team.

[*] **CONFIDENTIAL TREATMENT REQUESTED**
12.3 Non-Compliance. Within thirty (30) Business Days following the receipt by Indevus or Indevus’ designee at the final distribution point in the Territory of the later of (a) a shipment of Clinical Supplies or Finished Product; or (b) the related Documentation, Indevus and/or its designees shall have the opportunity to inspect (or to have inspected) such shipment for transport damages, shortage and, as far as reasonably practicable, any other defects and to perform quality control and acceptance testing, as required under the Quality Assurance Agreement, in order to determine whether such Clinical Supplies or Finished Product conforms to the Specifications. Indevus shall notify Schering of any such damages, shortage and other reasonably discernible defects discovered by Indevus promptly following Indevus’ discovery thereof, but in any event within such thirty (30) Business Day period.

12.4 Procedure as to Non-Compliant Goods.

12.4.1 Non-Compliant Clinical Supplies or Finished Product. Unless otherwise requested by Schering pursuant to the following sentence, Indevus shall return non-compliant Clinical Supplies or Finished Product to Schering. Schering may decide, however, to have an agent inspect such goods for non-compliance while in the possession of Indevus; Indevus shall then be responsible for storing the non-compliant Clinical Supplies or Finished Product appropriately for a reasonable period of time, not to exceed thirty (30) days. If returned to Schering, the inspection shall be made on return to Schering. If Schering accepts the Clinical Supplies or Finished Product as being non-compliant and the Clinical Supplies or Finished Product has not yet been returned to Schering, Schering shall decide whether such non-compliant Clinical Supplies or Finished Product shall be returned to Schering or destroyed, subject to applicable laws and regulations; the costs of such storage, return or destruction shall be borne by Schering. At Indevus’ option and request, Schering will (i) supply replacement Finished Product together with the relevant batch record and certificate of analysis to Indevus at no additional charge within two (2) months of notification of non-compliance pursuant to Section 12.3 above; (ii) refund the Initial Payment applicable to the non-compliant Finished Product to Indevus, or (iii) credit Indevus’ account in an amount equal to the Initial Payment for the non-compliant Finished Product.

12.4.2 Non-Compliant Documents. Schering shall immediately upon receipt of Indevus’ notification of non-compliance pursuant to Section 12.3, inspect the relevant Documentation for non-compliance. If Schering accepts such Documentation as being non-compliant, Schering shall attempt to remedy the defect by providing to Indevus compliant Documentation as soon as reasonably practical. If the defect can only be cured by sending new Clinical Supplies or Finished Product together with the relevant new batch record, certificate of analysis, and certificate of compliance, Schering will use Commercially Reasonable Efforts to supply such replacement products to Indevus at no additional charge within two (2) months of Indevus’ notification of non-compliance pursuant to Section 12.3.
12.4.3 Disputes. If there is a dispute as to whether any portion of any shipment of Clinical Supplies or Finished Product or a batch record or certificate of analysis is not in compliance, the Parties will attempt to reach a mutually acceptable resolution of the dispute. If they are unable to do so after a reasonable period of time (such period not to exceed thirty (30) days from the date of original notification), such dispute shall be resolved by having an independent, mutually acceptable, qualified third party examining the respective Clinical Supplies or Finished Product or batch record or certificate of analysis which shall be chosen by the Supply Team or the Steering Committee. If this third party finds the Clinical Supplies or Finished Product or batch record or certificate of analysis as being non-compliant, Section 12.4.1 Sentences 4 and 5 and Section 12.4.2 Sentences 2 and 3 shall apply. Any out-of-pocket costs relating to the third party examination shall be borne by the Party which claimed compliance or non-compliance incorrectly.

Article 13
Representations and Warranties

13.1 General Representations. Each Party hereby represents and warrants to the other Party as follows:

13.1.1 Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated;

13.1.2 Such Party has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and the execution, delivery and performance by such Party of this Agreement have been duly authorized by all necessary corporate action. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms except as enforceability may be limited by (A) any applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor’s rights generally, or (B) general principles of equity, whether considered in a proceeding in equity or at law;

13.1.3 All necessary consents, approvals and authorizations of all governmental authorities and other persons required to be obtained by such Party in connection with this Agreement have been obtained; and

13.1.4 The execution and delivery of this Agreement and the performance of such Party’s obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or
regulations or any judgment, injunction, decree, determination or award presently in effect having applicability to it, and (b) do not conflict with, or constitute a default under, any agreement of such Party with any Third Party.

13.2 Additional Schering Representations and Warranties. Schering hereby represents and warrants to Indevus that:

13.2.1 Clinical Supplies or Finished Product (as applicable) will have been Manufactured in compliance with all applicable laws and regulations, including, without limitation, the applicable provisions of the Act and regulations thereunder relating to Manufacture, supply and Product hereunder, including, without limitation, Current Good Manufacturing Practices, and in compliance with the specific U.S. regulatory approvals regarding Clinical Supplies or Finished Product and such quality assurance and quality control practices as are standard in the US pharmaceutical manufacturing industry;

13.2.2 Clinical Supplies or Finished Product (as applicable) shall conform to the then current Specifications at the time of delivery to carrier and shall continue to conform thereto for the shelf−life approved by FDA;

13.2.3 Clinical Supplies or Finished Product (as applicable) will conform to all covenants and obligations of Schering contained in this Agreement and the Quality Assurance Agreement (as applicable), each as may be amended from time to time by mutual agreement of the Parties;

13.2.4 neither Schering nor any of its Subcontractors or any of their respective employees engaged in performing Schering’s obligations under this Agreement, is, nor shall it or any of such individuals be at the time of performing any of the activities to be performed by Schering hereunder, disqualified or debarred by the FDA for any purpose pursuant to 21 U.S.C Section 355a; and

13.2.5 Clinical Supplies or Finished Product (as applicable) shall not be manufactured in violation of any applicable federal, state or local laws or regulations applicable to Product for use in the Territory, in either the Territory or in the country of Manufacture.

13.3 Effect of Representations and Warranties. It is understood that if the representations and warranties made by a Party under this Article 13 are not true and accurate, and the other Party incurs damages, liabilities, costs or other expenses as a result, the Party making such representations and warranties shall indemnify and hold the other Party harmless from and against any such damages, liabilities, costs or other expenses incurred as a result.
13.4 Disclaimer. EXCEPT AS SET FORTH ABOVE, SCHERING MAKES NO OTHER WARRANTY OR REPRESENTATION, EXPRESS OR IMPLIED, CONCERNING ITS PERFORMANCE HEREUNDER, INCLUDING ANY WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO CLINICAL SUPPLIES OR FINISHED PRODUCT.

Article 14
Indemnification

14.1 Schering. Schering shall indemnify, defend and hold harmless Indevus and its directors, officers, employees, agents, successors and assigns (each a “Indevus Indemnitee”) from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' and professional fees and other expenses of litigation and/or arbitration) (a “Liability”) resulting from a claim, suit or proceeding, including a product liability claim (“Claim”), made or brought by a Third Party against an Indevus Indemnitee arising out of, attributable to, or based on any claims alleging (i) any breach by Schering of the representations and warranties set forth in Section 13.1 or 13.2 except to the extent caused by the negligence or willful misconduct of Indevus; or (ii) the negligence or willful misconduct by Schering or any designee of Schering in exercising or performing any of Schering’s rights or obligations under this Agreement.

14.2 Indevus. Indevus shall indemnify, defend and hold harmless Schering and its directors, officers, employees, agents, successors and assigns (each a “Schering Indemnitee”) from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys’ and professional fees and, other expenses of litigation and/or arbitration) (a “Liability”) resulting from a claim, suit or proceeding including a product liability claim (a “Claim”), made or brought by a Third Party against a Schering Indemnitee, arising out of, attributable to, or based on any claims alleging (i) any breach by Indevus of the representations and warranties set forth in Section 13.1, or (ii) any development, testing, importation, use, marketing, promotion, offer for sale, sale or other distribution of any Product by Indevus or its Affiliates and Sublicensee; except in each case to the extent caused by the negligence or willful misconduct of Schering.

14.3 Procedure. In the event that any Indemnitee intends to claim indemnification under this Article 14 it shall promptly notify the other Party (the “Indemnitor”) in writing of such alleged Liability. Failure to provide prompt notice shall not relieve any Party of the duty to defend or indemnify unless such failure materially prejudices the defense of any matter. The Indemnitor shall have the sole right to control the defense and settlement thereof provided, however, that an Indemnitor shall not, without the written consent of the other Party, as part of any settlement or compromise (i) admit to liability on the part of the other Party; (ii) agree to an injunction against the other Party; or (iii) settle any matter in a manner that separately apportions fault to the other Party. The Parties further agree that as part of the settlement of any indemnified Claim, unless otherwise agreed by the Indemnitees, an Indemnifying Party shall use Commercially Reasonable Efforts to obtain a full,
complete and unconditional release from the claimant on behalf of the Indemnitees. The Indemnitee shall cooperate with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by this Article 14, the Indemnitee shall have a reasonable opportunity to participate in decision-making with respect to the strategy of such defense, and the Parties shall reasonably cooperate with each other in connection with the implementation thereof. The Indemnitee shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any Claim without the prior written consent of the Indemnitor, which the Indemnitor shall not be required to give. Actions taken by the Indemnitor hereunder shall be without prejudice to the Indemnitor’s right to contest the Indemnitee’s right to indemnification and subject to refund in the event the Indemnitor is ultimately held not to be obligated to indemnify the Indemnitee.

14.4 **Survival.** This Article 14 shall survive expiry or termination of this Agreement for any reason.

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**Article 15**

**Confidentiality**

15.1 **Confidential Information.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party shall keep confidential and shall not publish or otherwise disclose to any Third Party or use for any purpose other than as provided for in this Agreement any Know-how and other information and materials furnished to it by the other Party pursuant to this Agreement, or any provisions of this Agreement that are the subject of an effective order of the SEC granting confidential treatment (collectively “Confidential Information”), except to the extent that it can be established by the receiving Party that such Confidential Information:

1. is or becomes public or available to the general public otherwise than through the act or default of the receiving Party;

2. is obtained by the receiving Party from a Third Party who is lawfully in possession of such Confidential Information and is not subject to an obligation of confidentiality or non-use owed to the disclosing Party or others;

3. is previously known to the receiving Party prior to disclosure to the receiving Party by the disclosing Party under this Agreement, as shown by written evidence, and is not obtained or derived directly or indirectly from the disclosing Party;

4. is disclosed by the receiving Party pursuant to the requirement of law, provided that the receiving Party has complied with the provisions set forth in Section 15.3; or

5. is independently developed by the receiving Party without the use of or reliance on any Confidential Information provided by the disclosing Party hereunder, as shown by contemporaneous written evidence.
15.2 Public Domain. For the purposes of this Agreement, specific information disclosed as part of the Confidential Information shall not be deemed to be in the public domain or in the prior possession of the receiving Party merely because it is embraced by more general information in the public domain or by more general information in the prior possession of the receiving Party.

15.3 Legal Disclosure. If the receiving Party becomes legally required to disclose any Confidential Information provided by the disclosing Party, the receiving Party will give the disclosing Party prompt notice of such fact so that the disclosing Party may seek to obtain a protective order or other appropriate remedy concerning such disclosure and/or waive compliance with the non-disclosure provision of this Agreement. The receiving Party will reasonably cooperate with the disclosing Party in connection with the disclosing Party’s efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure or the disclosing Party waives such compliance, the receiving Party will make such disclosure only to the extent that such disclosure is legally required and will use its reasonable efforts to have confidential treatment accorded to the disclosed Confidential Information.

15.4 Permitted Use and Disclosures. Each Party hereto may use or disclose Confidential Information disclosed to it by the other Party to the extent such use or disclosure is reasonably necessary in complying with applicable governmental regulations or otherwise submitting information to Regulatory Authorities, tax or other governmental authorities, conducting Pre-clinical Development or Clinical Development, or otherwise exercising its rights hereunder. If a Party is required to make any such disclosure of another Party's Confidential Information, other than pursuant to a confidentiality agreement, it will give reasonable advance notice to the latter Party of such disclosure and, save to the extent inappropriate in the case of patent applications, will use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise).

15.5 Public Disclosure. Except as otherwise required by law or set forth herein, neither Party shall issue a press release or make any other public disclosure of the terms of this Agreement without the prior approval of such press release or public disclosure. Each Party shall submit any such press release or public disclosure to the other Party to review and approve any such press release or public disclosure, which approval shall not be unreasonably withheld or delayed. If the receiving Party does not respond within forty-eight (48) hours from submission, the press release or public disclosure shall be deemed approved. In addition, if a public disclosure is required by law, including without limitation in a filing with the SEC, the disclosing Party shall provide copies of the disclosure forty-eight (48) hours prior to such filing or other disclosure for the non-disclosing Party's prior review and comment, provided, however that such right of review and comment shall only apply for

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
the first time that specific information is to be disclosed, and shall not apply to the subsequent disclosure of substantially similar information that has
previously been disclosed unless there have been material developments relating to Product since the date of the previous disclosure.

15.6 Confidential Terms. Except as expressly provided herein, each Party agrees not to disclose any terms of this Agreement to any Third Party without
the consent of the other Party which consent shall not be unreasonably withheld or delayed; except that disclosures may be made as required by
securities or other applicable laws, or to actual or prospective investors or corporate partners, or to a Party's accountants, attorneys and other
professional advisors and that Indevus may file this Agreement as an exhibit to any filing with the SEC and may distribute any such filing in the
ordinary course of its business, provided, however, that to the maximum extent allowable by SEC rules and regulations, the Parties shall be obligated to
maintain the confidentiality obligations set forth herein.

15.7 Publications. Each Party acknowledges the other Party's interest in publishing its results related to Product to obtain recognition within the
scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent
protection and in protecting business interests and trade secret information. Accordingly, neither Party shall submit for written or oral publication any
manuscript, abstract or the like relating to Product without the prior approval of the other Party. Any Party proposing to submit such publication shall
deliver the proposed publication or an outline of the oral disclosure at least thirty (30) Business Days prior to planned submission or presentation (three
(3) Business Days review in the case of meeting abstracts or similar presentations which do not contain Confidential Information of Schering). At the
reasonable request of the other Party, the submission of such publication may be delayed such that any issues of patent protection may be addressed. In
the absence of any such request, upon expiration of the applicable period referred to in this Section 15.7 the publishing Party shall be free to proceed
with the publication or presentation. If the other Party requests modifications to the publication, the publishing Party shall edit such publication to
prevent disclosure of trade secret or proprietary business information prior to submission of the publication or presentation. The contribution of each
Party, if any, shall be noted in all publications or presentations by acknowledgment or co-authorship, whichever is appropriate.

15.8 Survival. This Article 15 will survive expiry or termination of this Agreement for any reason.

Article 16
Term and Termination

16.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided herein, shall continue in effect until the
expiry of the [*] as defined in the License Agreement.

[*] CONFIDENTIAL TREATMENT REQUESTED

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16.2 Termination for Cause. Failure of Indevus or Schering to comply with any of the respective material obligations and conditions contained in this Agreement shall entitle the other Party to give the Party in default notice requiring it to cure such default. If such default is not cured within ninety (90) days after receipt of such notice, the notifying Party shall be entitled (without prejudice to any of its other rights conferred on it by the Agreement) to terminate this Agreement by giving a notice to take effect immediately. Notwithstanding the foregoing, in the event of a non-monetary default, if the default is not reasonably capable of being cured within the ninety (90) day cure period by the defaulting Party and such defaulting Party is making a good faith effort to cure such default, the notifying Party may not terminate this Agreement, provided however, that the notifying Party may terminate this Agreement if such default is not cured within one hundred and eighty (180) days of such original notice of default. The right of either Party to terminate this Agreement as herein above provided shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default.

16.3 Termination for Change of Control. Schering shall be entitled to terminate the Agreement upon written notice to Indevus within ninety (90) days after a Change of Control of Indevus if a direct competitor with respect to Product in the Field in the Territory acquires control over Indevus.

16.4 Termination for Insolvency. If voluntary or involuntary proceedings by or against a Party are instituted in bankruptcy or under any insolvency law, or a receiver or custodian is appointed for such Party, or proceedings are instituted by or against such Party for corporate reorganization or the dissolution of such Party, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or if such Party makes an assignment for the benefit of creditors, or substantially all of the assets of such Party are seized or attached and not released within sixty (60) days thereafter, the other Party may immediately terminate this Agreement effective upon notice of such termination.

16.5 Indevus Rights Not Affected. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code licenses of rights to “intellectual property” as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that each Party shall retain and may fully exercise all of their respective rights, remedies and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy or reorganization case by or against a Party under the Bankruptcy Code, the other Party shall be entitled to all applicable rights under Section 365 (including 365(n)) of the Bankruptcy Code. Upon rejection of this Agreement by a Party or a trustee in bankruptcy for such Party, pursuant to Section 365(n), the other Party may elect (i) to treat this Agreement as terminated by such rejection or (ii) to retain its rights (including any right to enforce any exclusivity provision of this Agreement) to intellectual property (including any embodiment of such intellectual property) under this Agreement and under any agreement supplementary to this Agreement for the duration of this Agreement and any period for which this Agreement could have been
extended by such other Party. Upon written request to the trustee in bankruptcy or bankrupt Party, the trustee or Party, as applicable, shall (i) provide to the other Party any intellectual property (including such embodiment) held by the trustee or the bankrupt Party and shall provide to the other Party a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property and (ii) not interfere with the rights of the other Party to such intellectual property as provided in this Agreement or any agreement supplementary to this Agreement, including any right to obtain such intellectual property (or such embodiment or duplicates thereof) from a Third Party.

16.6 Effect of Termination and Expiration.

16.6.1 Accrued Rights and Obligations. Termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement. It is understood and agreed that monetary damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching Party may be entitled to injunctive relief as a remedy for any such breach.

16.6.2 Survival. The rights and obligations set forth in this Agreement shall extend beyond the term or termination of this Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge.

Article 17
Miscellaneous

17.1 Entire Agreement. This Agreement, together with its Schedules (including the portions of the License Agreement incorporated by reference herein) constitutes the entire agreement, both written and oral, between the Parties with respect to the subject matter hereof, and all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, are merged and canceled, and are null and void and of no effect. No amendment or change hereof or addition hereto shall be effective or binding on either of the Parties hereto unless reduced to writing and duly executed on behalf of both Parties.

17.2 Assignment. This Agreement and any rights and obligations hereunder shall not be assignable by either Party to any Third Party hereto without the written consent of the other Party which consent shall not be unreasonably withheld or delayed; except that either Party may assign this Agreement, without such consent, to an entity that acquires all or substantially all of its business or assets to which this Agreement pertains, whether by merger, reorganization, acquisition, sale, or otherwise. This Agreement shall
be binding upon and inure to the benefit of the Parties and their successors and assigns. Any successor or permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment not in accordance with this Section 17.2 shall be null and void and of no legal effect.

17.3 Independent Contractors. The relationship of the Parties hereto is that of independent contractors. The Parties hereto are not deemed to be agents, partners or joint ventures of the others for any purpose as a result of this Agreement or the transactions contemplated thereby.

17.4 Notices. All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by telecopy or other electronic facsimile transmission (and promptly confirmed by personal delivery, registered or certified mail or overnight courier) or by registered or certified mail, return receipt requested, postage prepaid, or sent by internationally−recognized overnight courier, in each case to the respective address specified below, or such other address as may be specified in writing to the other Party hereto:

If to Schering:
Schering Aktiengesellschaft
13342 Berlin
Germany
Attn. Legal Department
Fax−No. +49−30−46814086

If to Indevus:
Indevus Pharmaceuticals, Inc.
33 Hayden Avenue, Lexington,
MA 02421
USA
Attn. Glenn L. Cooper, M.D.
Fax−No. +1−781−862−3859

17.5 Force Majeure. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses (except for payment obligations) on account of failure of performance by the defaulting Party if the failure is occasioned by war, strike, fire, Act of God, terrorism, earthquake, flood, lockout, embargo, governmental acts or orders or restrictions or delays or failures to act, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence, intentional conduct or misconduct of the non−performing Party and the non−performing Party has exerted Commercially Reasonable Efforts to overcome such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance.

17.6 Severability. In the event that any provisions of this Agreement are determined to be invalid or unenforceable, the remainder of the Agreement shall remain in full force and effect without said provision unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. In such event the Parties shall, in good faith, negotiate a substitute valid provision for any provision declared invalid or unenforceable, which shall most nearly approximate the economic effect and intent of the invalid provision that it can be reasonably assumed that the Parties would have entered into this Agreement with the substituted provision. The same shall apply in case of an omission.
17.7 Waiver. It is agreed that no waiver by either Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default.

17.8 Compliance with Laws. Each Party shall furnish to the other Party any information requested or required by that Party during the term of this Agreement or any extensions hereof to enable that Party to comply with the requirements of any government agency.

17.9 Further Assurances. At any time or from time to time on and after the date of this Agreement, either Party shall at the request of the other Party hereto (i) deliver to the requesting Party any records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as the requesting Party may reasonably deem necessary in order for the requesting Party to obtain the full benefits of this Agreement and the transactions contemplated hereby.

17.10 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, US, without giving effect to the choice of laws provisions thereof.

17.11 Dispute Resolution.

17.11.1 The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a “Dispute”) by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within sixty (60) days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of Indevus and the Head of the Global Business Unit Gynecology & Andrology of Schering. Such persons shall negotiate in good faith to achieve a resolution of the Dispute referred to them within thirty (30) days after such notice is received by the Party to whom the notice was sent. If such persons are unable to settle the Dispute between them within thirty (30) days, they shall so report to the Parties in writing. The Dispute shall then be referred to mediation as set forth in the following subsection 17.11.2.

17.11.2 Upon the Parties receiving the report of the persons referred to in subsection 17.11.1 that the Dispute referred to them pursuant to subsection 17.11.1 (a) has not been resolved, the Dispute may be referred to mediation by written notice from either Party to the other. The mediation shall be conducted pursuant to the mediation rules of the American Arbitration Association (“AAA”). In the event Indevus is the claimant, the mediation shall be held in London, England; in the event Schering is the claimant, the mediation shall be held in New, York, New York, US. If the Parties have not reached a settlement within sixty (60) days of the date of the notice of mediation, the Dispute may be referred to arbitration pursuant to subsection 17.11.3.
17.11.3 If, after the procedures set forth in subsections 17.11.1 and 17.11.2, the Dispute has not been resolved, and if a Party decides to institute arbitration proceedings, it shall give written notice to that effect to the other Party. The Parties shall refrain from instituting the arbitration proceedings for a period of sixty (60) days following such notice. During such period, the Parties shall continue to make good faith efforts to amicably resolve the dispute without arbitration. If the Parties have not reached a settlement during that period the arbitration proceedings shall go forward and be conducted in accordance with the then applicable commercial arbitration rules of the AAA except where modified herein. Each such arbitration shall be conducted by a panel of three arbitrators with appropriate experience in the biotechnology or pharmaceutical industry: one arbitrator shall be appointed by each of Schering and Indevus and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two Party-appointed arbitrators. In the event Indevus is the claimant, the arbitration shall be held in London, England; in the event Schering is the claimant, the arbitration shall be held in New York, New York, US. The arbitrators shall have the authority to grant specific performance. Any award so rendered shall be final and binding and judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the costs of the mediation and arbitration levied by the AAA. Any mediation or arbitration proceeding entered into pursuant to this Section 17.11 shall be conducted in the English language.

17.12 **Headings.** The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

17.13 **Counterparts.** This Agreement may be executed in two counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

IN WITNESS WHEREOF Schering and Indevus have executed this Agreement by their respective duly authorized representatives.

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Schering Aktiengesellschaft

Date

By: /s/ Klaus Bril
Print Name: Klaus Bril
Title: Head of Portfolio Management
GBU Gynecology & Andrology

By: /s/ Dr. Hans−Joachim Riedel
Print Name: Dr. Hans−Joachim Riedel
Title: Head of Commercial Cooperations

Indevus Pharmaceuticals, Inc.

Date

By: /s/ Glenn L. Cooper, M.D.
Print Name: Glenn L. Cooper, M.D.
Title: Chairman and Chief Executive Officer

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
SCHEDULE 1.1

[*]

[*] CONFIDENTIAL TREATMENT REQUESTED

− 38 −
by and between

SCHERING AKTIENGESELLSCHAFT
Müllerstraße 178
13353 Berlin
Germany

(hereinafter referred to as “SCHERING”)

and

INDEVUS PHARMACEUTICALS, INC.
33 Hayden Avenue
Lexington, MA 02421
U.S.A.

(hereinafter referred to as “INDEVUS”)

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Preamble
This Quality Assurance Agreement (hereinafter “QAA”) effective as of _____, 2006 (the “Effective Date”) defines the conditions to be fulfilled by SCHERING and INDEVUS in order to ensure that all aspects of the Manufacture of Substance and Finished Product under the Manufacturing and Supply Agreement between the Parties dated as of the Effective Date (the “MSA”) are carried out in accordance with the Specifications and applicable DMF(s), Current Good Manufacturing Practices and applicable Regulatory Standards, and established Testing Standards and Manufacturing Description(s) (each as defined herein or in the MSA).

§ 1 Definitions

“Annual Product Review” shall mean an annual evaluation of the quality standards of the Substance and Finished Product in order for the Parties to jointly determine if changes in Specifications, manufacturing or testing procedures are necessary.

“Executed Batch Record” shall mean production and control records prepared for each batch of Finished Product produced and shall include complete information relating to the production and control of each batch.

“Master Batch Record” shall mean written procedures for production and process control designed to assure that Finished Product has the identity, strength, quality, and purity they purport or are represented to possess and is used to ensure uniformity from batch to batch.

“Manufacturing Descriptions” shall mean the written descriptions of Manufacturing set forth in Appendix 2.

“Packaging Components” shall mean any material employed in the packaging, including Final Packaging, of a medicinal product, excluding any outer packaging used for transportation or shipment. Packaging components are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

“Starting Material” shall mean the Substance and any other material used in the production of Finished Product, but excluding Packaging Components.

“Testing Standards” shall mean the written description of the testing methods as specified in Appendix 1.

All capitalized terms not defined herein but defined in the MSA shall have the same meanings as ascribed to them in the MSA.

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
§ 2 Subject Matter of the QAA

The subject−matter of this QAA is to ensure that all aspects of the Manufacture of Substance and Finished Product under the MSA are carried out in accordance with the Specifications and applicable DMF(s), cGMP regulations and applicable Regulatory Standards, and the established Testing Standards and Manufacturing Description(s).

This QAA governs the rights, duties and responsibilities of SCHERING and INDEVUS regarding the Manufacture of Substance and Finished Product.

The appendices mentioned in this QAA, and all documents to which reference is made in the appendices shall become an integral part of this QAA.

SCHERING may comply with any and all obligations under this QAA through a Subcontractor provided that SCHERING is entitled to subcontract the respective activity to a Subcontractor pursuant to Section 2.8 of the MSA.

§ 3 Quality System; Validation

SCHERING confirms that it is maintaining (and shall continue to maintain) an effective pharmaceutical quality system to ensure that the Substance and Finished Product are Manufactured according to the Specifications and applicable DMFs and with cGMP regulations and applicable Regulatory Standards.

SCHERING will validate all processes, methods, equipment, utilities, facilities and computers used in the Manufacture, formulation, Final Packaging, storage, testing, Packing and shipment of Finished Product in conformity with cGMP regulations, especially US federal regulation 21CFR211.194(a)(2), and as required by applicable Regulatory Standards so as to ensure that Manufacturing is able to commence in accordance with such regulations and standards and in conformity with the Specifications and applicable DMFs.

SCHERING declares that it is in possession of the Manufacturing authorization(s) necessary to carry out Manufacture at the time of entering into this QAA. SCHERING will ensure that this authorization is retained unconditionally during the term of this QAA and the MSA and will prove such authorization to INDEVUS when required by submitting relevant documentation to INDEVUS.

§ 4 Instructions for the Manufacture

SCHERING will Manufacture Substance and Finished Product in conformity with the Specifications and applicable DMFs, with cGMP regulations and applicable Regulatory Standards, and with the Manufacturing Description(s) and with the Testing Standards.

§ 5 Manufacture of Substance and Finished Product

Those employees of the Parties named as responsible persons for Manufacture, quality assurance, quality control and Finished Product release as well as employees
named as contact partners in the logistics function are specified in Appendix 4. Both Parties must be informed immediately in writing of any changes in the fields of responsibility of the responsible persons and/or contact partner, should these occur.

The pharmaceutical responsibilities of the Parties shall be as set out in Appendix 5.

§ 5.1. Quality Control and Sampling

During Manufacture of Substance and Finished Product(s), SCHERING will draw representative samples according to cGMP.

SCHERING will sample, store and maintain appropriate reserve samples (identified by Batch number) (the “Reserve Samples”) of (a) Finished Product, (b) all Substance used in the production of Finished Product, and (c) all key raw materials used to Manufacture Substance and Finished Product, in accordance with cGMPs and other US federal requirements including 21CFR211.170(b) and in each case with respect to quantities determined by accepted statistical procedures and stored under conditions and in the same immediate container–closure system as defined in the Specifications and applicable DMFs.

The Reserve Samples shall also be visually inspected at least once a year for evidence of deterioration, recording the results of such inspection, as required by cGMP regulations, especially US federal regulation 21CFR211.170(b). Release testing will be performed according to the Specifications and applicable DMFs and to Testing Standards.

Reserve Samples of Starting Materials will be stored until at least one year after the expiration date of the last Batch of the Finished Product produced from them. Reserve Samples of every Batch of Finished Product shall be kept for one year after the expiration date of the respective Batch and in sample quantities of at least twice the quantity necessary for testing to determine whether Substance in the Finished Product meets its established Specifications as defined in the NDA and applicable DMFs, and as required by cGMP regulations, especially US federal regulation 21CFR211.170(a).

SCHERING shall provide INDEVUS and any Regulatory Authority with reasonable access to and portions of the Reserve Samples for testing and other purposes upon reasonable request of INDEVUS.

§ 5.2. Batch Documentation

SCHERING will document the conduct of all the procedural steps stipulated in the Manufacturing Description as well as all in–process controls in Batch–specific records as customarily kept by SCHERING. SCHERING will provide INDEVUS with timely notification of all significant deviations, notes to file, and other deficiencies that may reasonably be expected to impact the quality of the Finished Product, as well as all FDA correspondence regarding testing, Manufacture, Final Packaging, or Packing of the Finished Product. SCHERING will provide INDEVUS with a complete copy of
the Executed Batch Records of the first [*] Batches of Finished Product. An English version of the Master Batch Record for Finished Product will be provided to INDEVUS. Such records will be provided to INDEVUS prior to shipment of such Batches in accordance with the provisions of Section 5.6 of the MSA.

The records must be accompanied by a Certificate of Compliance (COC) and a Certificate of Analysis (COA) for the Substance used in Finished Product and the Finished Product. Deviation and Out of Specification (OOS) reports will be included if applicable, which detail in writing any problems and deviations within the Manufacturing process and analytical testing. The accompanying COC, COA, and deviation and OOS reports will be provided in English.

All additional Batches will be accompanied by some pages of the Executed Batch Record mutually agreed between the Parties, the COA and the COC for Substance used in Finished Product and for Finished Product, and, if applicable, deviation and OOS reports.

SCHERING will retain the complete Batch documentation for at least [*] after the expiration date of the respective Batch as required by cGMP regulations, especially US federal regulation 21CFR211.180. SCHERING will provide these records to INDEVUS on reasonable request.

SCHERING will present Manufacturing and testing documentation to Regulatory Authorities upon request as appropriate and in the manner required by cGMP regulations, especially US federal regulation 21CFR211.180(c) and (d). To the extent not covered by this Section 5.2, the provisions of Section 6.2 of the MSA shall also govern any records and Documentation.

§ 5.3. Final Packaging; Packing for Shipment
Final Packaging and Packing for shipment shall be governed by Section 5.1 of the MSA which is hereby incorporated by reference herein, as if stated herein, in its entirety.

§ 5.4. Release ofFinished Product(s)
SCHERING will release the Finished Product for shipment to INDEVUS’ designee, in accordance with Section 5.6 of the MSA, under SCHERING’s procedures in accordance with the Specifications and applicable DMFs, cGMP regulations, especially US federal regulation 21CFR211.165, applicable Regulatory Standards, and established Testing Standards and Manufacturing Description(s).

INDEVUS shall have the right to inspect (or to have inspected) such shipment for transport damages, shortage and, as far as reasonably practicable, any other defects, and to perform quality control and acceptance testing as set forth in the MSA.

[*] CONFIDENTIAL TREATMENT REQUESTED
§ 6 Stability Testing
SCHERING shall be responsible for conducting the stability testing of the Substance and of the Finished Product in conformity with cGMP regulations, especially US federal regulation 21CFR211.166 and ICH guidance Q1A through F, and with applicable Regulatory Standards, the established Testing Standards and the stability study protocol as laid out in Appendix 3.

§ 7 Change Management
Change management shall be governed by Article 11 of the MSA, which is hereby incorporated by reference herein, as if stated herein, in its entirety.

§ 8 Annual Product Review
Following consultation with INDEVUS SCHERING will perform an Annual Product Review of the quality standards of the Finished Product and to determine the need for changes in product Specifications or Manufacturing or control procedures, in conformity with cGMP regulations, especially US federal regulation 21CFR211.180(e). The content of the Annual Product Review will be agreed to by both INDEVUS and SCHERING.

§ 9 Inspections and Quality Audits
INDEVUS is entitled to conduct inspections and audits of the SCHERING facilities in which Substance and Product are Manufactured, including all quality control procedures and documentation, at normal business hours upon [*] prior written announcement. Inspections shall not be more than [*], unless there are important and objective reasons for additional inspections. Requests for such additional inspections will be accommodated in a timely manner and with reasonable advance notice.

SCHERING will permit inspections by the FDA at any time upon request. SCHERING shall notify INDEVUS of the FDA inspections on a timely basis. SCHERING will provide written information regarding outcomes of the FDA inspections and copies of observations. Responses to observations of the FDA resulting from inspections specific to the Substance and Finished Product will be agreed between SCHERING and INDEVUS to the extent any DMF relating to the Manufacture of Finished Product to INDEVUS or the NDA is affected. To the extent not covered by this Section 9, the provisions of Section 6.3 of the MSA shall also govern any inspections by the FDA.

§ 10 Complaints from the Market
INDEVUS will forward to SCHERING Finished Product complaints about the quality of the Finished Product(s) after confirming by investigation the details and authenticity. All authenticated complaints shall be forwarded to SCHERING for internal investigation; all other complaints, and the results of investigation determining same, will be maintained by INDEVUS and forwarded to SCHERING upon request. For authenticated complaints SCHERING shall review without undue delay the respective Batch documentation, carry out tests to clarify the cause of such a complaint, its alleged technical defect and present INDEVUS with a response [*] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
summarizing the results of such investigation. The final response has to be sent to INDEVUS within [*] of receipt of the Finished Product complaint. For Finished Product complaints where the nature of the complaint is such that patient safety could be put at risk, preliminary investigation statements must be available within [*] of receipt, a final statement must be written without any undue delay, within [*] at the latest. The final response must also include details on the confirmed or assumed causes of technical defect(s). SCHERING shall be responsible for the appropriate measures to prevent the re-occurrence of any such defects and report such measures in the final response.

If for any reason items remain outstanding, SCHERING will provide periodic progress updates. SCHERING and INDEVUS shall agree on the frequency on a case by case basis.

§ 11 Recalls and Other Corrective Actions
Recalls and other corrective actions shall be governed by Section 6.4 of the MSA, which is hereby incorporated by reference herein, as if stated herein, in its entirety.

§ 12 Amendments
This QAA and the Appendices hereto may be revised from time to time, but only upon mutual written agreement of the Parties.

§ 13 Other Provisions
The terms of this QAA are intended to supplement (but not limit) the terms of the MSA, and with regard to all other issues not mentioned herein including, but not limited to confidentiality, term and termination, assignment and severability the respective provisions of the MSA shall apply. In case of ambiguities between this QAA and the MSA, the latter shall prevail.

Berlin,

INDEVUS
Fr. Dr. Lehne

SCHERING
Hr. Dr. Höfert

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List of Appendices

to the Quality Assurance Agreement
between INDEVUS and SCHERING

• Specification(s), Testing Standard(s) for Substance and Finished Products Appendix 1
• Manufacturing Description Appendix 2
• Stability Study Protocol for Finished Product Appendix 3
• List of responsible persons and named contact partner Appendix 4
• Pharmaceutical responsibilities Appendix 5
Appendix 1

to the Quality Assurance Agreement between SCHERING and INDEVUS

Specification(s), Testing Standard(s) for Substance and Finished Product(s)

[*]

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[*] CONFIDENTIAL TREATMENT REQUESTED
Appendix 2

to the Quality Assurance Agreement between SCHERING and INDEVUS

Manufacturing Description

[*] CONFIDENTIAL TREATMENT REQUESTED

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Appendix 3

to the Quality Assurance Agreement between SCHERING and INDEVUS

Stability Study Protocol for Finished Product(s)

[*]

[⁎] CONFIDENTIAL TREATMENT REQUESTED

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Appendix 4

to the Quality Assurance Agreement between SCHERING and INDEVUS

List of responsible persons and named contact partner:

[*]

[&] CONFIDENTIAL TREATMENT REQUESTED
Appendix 5

to the Quality Assurance Agreement between SCHERING and INDEVUS

Pharmaceutical responsibilities

[*]

[⁎] CONFIDENTIAL TREATMENT REQUESTED
SCHEDULE 4.3

[∗]

[∗] CONFIDENTIAL TREATMENT REQUESTED

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[*]

[*] CONFIDENTIAL TREATMENT REQUESTED

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Dear Dr. Cooper,

Reference is made to the License Agreement between Schering Aktiengesellschaft („Schering”) and Indevus Pharmaceuticals, Inc. („Indevus”) dated July 28, 2005 (as amended by the side letter dated February 20, 2006 – “License Agreement”) and the discussions regarding the manufacture and usage of the validation batches. This letter sets forth the terms and conditions for such activities.

1. **Indevus requests and Schering agrees to manufactures a set of [*] batches for the Product [*], containing a fill volume of [*] filled with a solution of the Substance as active pharmaceutical ingredient and excipients [*] for intramuscular injection whereby each ml solution contains [*] Substance corresponding to [*] testosterone and each [*] with [*] solution for injection contains [*] Substance [*] These [*] validation batches for [*] will be manufactured from [*] of solution containing the Substance each and shall completely be filled into [*]. It is currently estimated that the amount of [*] manufactured by the [*] validation batches will be between [*] in total. Timelines for manufacture of these validation batches will be agreed in the Supply Team. Following manufacture of such validation batches Schering will provide to Indevus copies of the respective Certificate of Analysis and the Certificate of Compliance. The [*] from such validation batches, after substraction of the [*] described in No. 4, are expected to be available for commercial use by Indevus under the License Agreement.

2. Subject to No. 4, the [*] resulting from the validation batches pursuant to No. 1 may be used as commercial supply under a Manufacturing and Supply Agreement between Indevus and Schering dated as of the date hereof ("Manufacturing and Supply Agreement"). The ordering and delivery with respect to such [*] (as Finished Product) shall be governed by the terms and conditions of the Manufacturing and Supply Agreement. It is further understood and agreed that the decision on the timing of the production of the validation batches will determine the extent of stability data available at the time of the intended NDA filing by Indevus.

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[*] CONFIDENTIAL TREATMENT REQUESTED
3. Indevus agrees to pay an amount of US Dollar [*] manufactured in the validation batches pursuant to No. 1, provided that Indevus shall not be obliged to pay more than [*] for the entire amount of [*] manufactured in such validation batches. Subject to receipt by Indevus of the copies of the respective Certificates of Analysis and Certificates of Compliance and a visual inspection by Indevus of the validation batches inventory at Schering, the lump sum payment for the entire amount of [*] manufactured in such validation batches shall be paid by Indevus to Schering not before [*] and not later than [*]. This amount is not refundable but will be off-set against the Initial Payment (as defined in the Manufacturing and Supply Agreement payable under the Manufacturing and Supply Agreement).

4. Out of the validation batches of [*] produced pursuant to No. 1 above, Schering will keep an appropriate number of [*] for (i) characterization and release testing in connection with the process validation and quality control, (ii) [*] stability testing, (iii) for use as retention samples, and (iv) other needs as applicable (reference standards etc.). No. 3 shall not apply with respect to these [*].

5. In case Indevus wishes Schering to manufacture validation batches for the [*] as well, the Parties will negotiate about such validation: Should Schering agree to manufacture such validation batches, similar terms than for the [*] shall apply.

6. Capitalized terms used in this letter shall have the meaning ascribed to them in the License Agreement, unless otherwise defined or stated.

7. All other terms of the License Agreement shall remain unchanged and in full force and effect.

To signify acceptance with the above we would kindly ask you to countersign and return the attached copy of this letter.

With kind regards
Schering Aktiengesellschaft

/s/ Dr. Riedel        /s/ Dr. Horn

Agreed and accepted for and on behalf of
Indevus Pharmaceuticals, Inc.:

/s/ Glenn L. Cooper, M.D.
Glenn L. Cooper, M.D.

[*] CONFIDENTIAL TREATMENT REQUESTED
LICENSE AND SUPPLY AGREEMENT

by and between

INDEVUS PHARMACEUTICALS, INC.

and

MADAUS GMBH
THIS LICENSE AND SUPPLY AGREEMENT is effective as of November 3, 2006 ("Effective Date"), by and between INDEVUS PHARMACEUTICALS, INC., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 33 Hayden Avenue, Lexington, Massachusetts 02421, United States ("Indevus"), and MADAUS GmbH, a company with limited liability organized and existing under the laws of Germany and having its principal office at Colonia–Allee 15, 51067 Cologne, Germany ("Madaus"). Indevus and Madaus are collectively referred to herein as the "Parties.

W I T N E S S E T H:

WHEREAS, Madaus is interested in developing and commercializing Product (as defined below) in the Madaus Territory (as defined below) and obtaining from Indevus an exclusive license under the SANCTURA XR Patents and the Indevus Know–How (each as defined below), and Indevus is willing to grant such right and license to Madaus, subject to and on the terms and conditions set forth herein;

WHEREAS, during the Supply Term (as defined below), Madaus desires to purchase from Indevus, and Indevus desires to supply to Madaus, Bulk Drug Product (as defined below) for the Madaus Territory, subject to and on the terms and conditions set forth herein; and

WHEREAS, the Parties desire to set forth a procedure to regulate the commercialization of the Product in the Joint Territory (as defined below);

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, where used in the singular or plural, shall have the respective meanings set forth below. To the extent any defined terms used herein are stated to have the meaning ascribed to them in any other agreement referred to herein, such definitions are incorporated by reference herein:

1.1. "Affiliate" shall mean (i) any corporation or business entity of which more than fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party; (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds more than fifty percent (50%) (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of a Party or (iii) any corporation or business entity of which a Party has the right to acquire, directly or indirectly, at least fifty percent (50%) of the securities or other ownership interests representing the equity, voting stock or general partnership interests.

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
1.2. “Amendment and Agreement” means the Amendment and Agreement entered into as of the Effective Date by and between Madaus and Indevus.

1.3. “[*]” means the Supply Agreement dated as of November 13, 2002 by and between Madaus and [*]

1.4. “Bulk Drug Product” means encapsulated Product as manufactured for the Indevus Territory, in the form prior to being in its finished and packaged form.

1.5. “Business Day(s)” means any day that is not a Saturday or a Sunday or a day on which the New York Stock Exchange is closed.

1.6. “Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.7. “Calendar Year” means each successive period of twelve (12) months commencing on January 1 and ending on December 31.


1.10. “Competing Product” means any once−a−day dosage formulation for the treatment of overactive bladder and/or urinary incontinence, including a Generic Drug, other than (i) Product, or (ii) the drugs marketed by Madaus or one of its Affiliates or sublicensees on the date hereof and listed on Schedule 1.10.

1.11. “Compound” means the chemical compound known as trospium chloride.

1.12. “Compound Supply Agreement” means the agreement between Madaus and Indevus dated as of the Effective Date relating to the supply by Madaus to Indevus or its designees of Compound obtained by Madaus under the [*].

1.13. “Current Good Manufacturing Practices” or “GMP” or “cGMP” means the current good manufacturing practice and standards as provided for (and as amended or updated from time to time) in applicable ICH Harmonised Tripartite Guidelines.

1.14. “Development Committee” shall have the meaning set forth in Section 4.3.

1.15. “DMF” means a Drug Master File as defined in CFR Title 21 part 314, section 420, including all supplements and amendments thereto.

1.16. “Effective Date” means the date first above written.

[*] CONFIDENTIAL TREATMENT REQUESTED

1.18. “EMEA Authority” shall mean EMEA or the applicable Regulatory Authority (as hereinafter defined) in a country which is an EMEA member at the time in question.

1.19. “FDA” means the United States Food and Drug Administration and any successor agency having substantially the same functions.

1.20. “First Commercial Sale” means the date of the first commercial sale of Product in the Madaus Territory by Madaus or its Affiliates, sublicensee(s) or Marketing Distributors.


1.22. “Generic Competition” in any particular country shall commence on the first date on which Generic Drugs achieve a market share in one Calendar Quarter of [*] or greater of the total prescriptions for Product in such country (as so shown by IMS (or IMS−equivalent) data for such prescriptions in that Calendar Quarter).

1.23. “Generic Drug(s)” means any product containing Compound that is either defined in a particular country in the Madaus Territory as a generic drug to Product by applicable legal texts or regulatory authorities in such country or is AB rated or substitutable by a pharmacist for Product, other than a product introduced in such country by Madaus, its Affiliates or sublicensees.

1.24. “IND” mean Indevus’ Investigational New Drug Application [*], including all supplements and amendments thereto.

1.25. “Indevus Know−How” means all unpatented information and data, materials, inventions, improvements and know how, (i) that are necessary or useful for the development and/or commercialization of Product or Compound, (ii) that are owned by Indevus at the Effective Date of this Agreement or that are generated, developed, discovered, invented or made by or on behalf of Indevus during the Term of this Agreement, (iii) that are in Indevus’ possession or control, and (iv) as to which Indevus has the right to license or sublicense in the Indevus Territory, the Madaus Territory and/or the Joint Territory, as applicable. Indevus Know−How shall not include data, materials, inventions, improvements and know how relating to the use of Compound in (i) a pulmonary inhalation product, or (ii) an oral liquid formulation intended for pediatric or elderly use in overactive bladder, incontinence or detrusor instability.

1.26. “Indevus’ Manufacturing Costs” means the costs incurred by Indevus (including all costs paid to Third Parties) in connection with or to enable the manufacturing and supply of Bulk Drug Product, as described on Schedule 1.26.

[*] CONFIDENTIAL TREATMENT REQUESTED
1.27. “Indevus Territory” means the United States of America, including the District of Columbia, and its territories and possessions.

1.28. “Initial Supply Term” shall have the meaning set forth in Section 12.1.

1.29. “Joint Territory” means Canada, Japan, Korea and China.

1.30. “Joint Territory Agreements” means those agreements in effect as of the Effective Date between Madaus and any Third Party covering the commercialization of Product in any country in the Joint Territory, as listed on Schedule 1.30.

1.31. “Launch” means the date of the First Commercial Sale in the applicable country(ies) in the Madaus Territory.

1.32. “Losses” means any and all damages, awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties (including penalties imposed by any governmental authority), costs, fees, liabilities, obligations, taxes, liens, losses, and expenses (including court costs, interest and reasonable fees of attorneys, accountants and other experts) awarded or otherwise paid or payable to Third Parties.

1.33. “MAA” or “Marketing Approval Application” means a marketing authorization application (including or comparable to an NDA), including all supporting documentation and data submitted for such application to be accepted for review or approval, filed with the requisite Regulatory Authority of any country in the Madaus Territory, and requesting approval for commercialization of Product in such country.

1.34. “Madaus Know−How” means all unpatented information and data, materials, inventions, improvements and know how, (i) that are necessary or useful for the development and/or commercialization of Product, (ii) that are owned by Madaus at the Effective Date of this Agreement or that are generated, developed, discovered, invented or made by or on behalf of Madaus during the Term of this Agreement, (iii) that are in Madaus possession or control, and (iv) as to which Madaus has the right to license or sublicense in the Indevus Territory, the Madaus Territory and/or the Joint Territory, as applicable.

1.35. “Madaus License” means the license agreement dated as of November 26, 1999 by and between Madaus and Indevus, as amended in Amendment No. 1 thereto dated as of January 19, 2004, and as further amended in the Amendment and Agreement.

1.36. “Manufacturing Payment” shall have the meaning set forth in Section 5.4.

1.37. “Manufacturing Payment Term” means the period commencing on the date of the First Commercial Sale and ending on the later of (a) [*] or (b) the last day of the Extension Period. For purposes of this calculation, the “Extension Period” shall be a period equal to the number of days from (i) the date of the First Commercial Sale of SANCTURA XR in the Territory (as each of such terms are defined in the Madaus License, as amended by the Amendment and Agreement), until (ii) the date of the First Commercial Sale (as defined in this Agreement) in either the Major European Countries or the Other Major Countries.

[⁎] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
1.38. “Madaus Territory” means worldwide, other than the Indevus Territory and the Joint Territory, and subject to adjustments pursuant to Section 12.4.2.

1.39. “Major European Countries” means United Kingdom, Sweden, Germany, Denmark and Spain.

1.40. “Manufacturing Facility” means any manufacturing facility that is identified in the NDA to manufacture Bulk Drug Product.

1.41. “Marketing Distributor” means a Third Party to whom Madaus or its Affiliate has granted a right to distribute, market, sell and/or promote Product in the Madaus Territory.

1.42. “Mutual Recognition Procedure” shall mean the mutual recognition procedure for marketing authorization in accordance with Directive No. 2003/83/EC of November 6, 2001 or any successor regulations and/or directives.

1.43. “NDA” means Indevus’ new drug application intended to be submitted to the FDA for marketing authorization of Product in the United States, and any amendments and supplements thereto.

1.44. “Net Sales” means the actual gross amount invoiced by Madaus, its Affiliates or its sublicensees for the commercial sale of Product in the Madaus Territory to a Third Party, commencing upon the date of First Commercial Sale, after deducting, in accordance with GAAP, the following:

   (a) trade, cash, quantity or ordinary discounts;
   (b) allowances for product returns, including allowances or credits for rejected Product, or spoilage or recalled Product;
   (c) rebates and charge backs;
   (d) sales or excise taxes, VAT or other taxes, and transportation and insurance charges and additional special transportation, custom duties, and other governmental charges;
   (e) rebates or similar payments paid in connection with sales of Product to any governmental or regulatory authority in respect of any state or federal programs similar to Medicare or Medicaid in the United States in any country of the Madaus Territory; and
   (f) retroactive price reductions and write−offs or allowances for bad debt, not to exceed two percent (2%) of Net Sales.
1.45. “Other Major Countries” means Australia, Austria, India and Portugal.

1.46. “Party” means Indevus or Madaus.

1.47. “Product” means a controlled or extended-release oral formulation of Compound for the treatment of overactive bladder and/or urinary incontinence that requires a prescription from a physician or other health care professional in the Madaus Territory, that is intended to be administered once a day, and which (i) but for the license granted herein, cannot be manufactured, used or sold without infringing a Valid Claim which is contained in a SANCTURA XR Patent or (ii) utilizes the SLI Intellectual Property.

1.48. “Proprietary Information” means any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned and under the protection of one Party and provided to the other Party in connection with this Agreement.

1.49. “Regulatory Approval” means (i) in the case of the Major European Countries, approval of the MAA by the EMEA in such Major European Countries (and/or the applicable Regulatory Authorities in any Major European Country not failing to provide or rejecting such approval), or (ii) in any other country(ies) of the Madaus Territory, such approvals of the MAA by Regulatory Authorities as are required to market Product in such country; in each case including any required pricing and reimbursement approvals.

1.50. “Regulatory Authority” means the FDA and/or any other governmental regulatory authority, court, arbitrator, agency, commission, official or other instrumentality of any federal, state, county, city or other political subdivision, domestic or foreign, that performs a function for such political subdivision similar to the function performed by the FDA for the United States with regard to the approval, licensing, registration or authorization to develop, test, manufacture, package, market, distribute, use, store, import, transport or sell Product in the Madaus Territory or with respect to the approval of pricing or reimbursement for such product.

1.51. “Renewal Supply Term” shall have the meaning set forth in Section 12.1.

1.52. “Royalty Year” means (i) for the year in which the First Commercial Sale occurs (the “First Royalty Year”), the period commencing with the first day (the “Commencement Date”) of the Calendar Quarter in which such First Commercial Sale occurs and expiring on the last day of the twelfth (12th) month following the Commencement Date; and (ii) for each subsequent year, each successive twelve (12) month period commencing on the date immediately following the last day of the First Royalty Year.

1.53. “Samples” means units of Product distributed or provided to health care professionals in the Madaus Territory for dispensing, in turn, to patients for “trial use” at no cost to the patient as well as units distributed or provided for development, testing, clinical trials or as donations (for example, to non-profit institutions or government agencies for non-commercial purposes).
1.54. “SANCTURA XR Patents” means all patents and patent applications in any country in the Madaus Territory that, as of the Effective Date or at any time during the Term of this Agreement (a) are owned by Indevus or to which Indevus through license has rights in the Madaus Territory from a Third Party, and (b) that are necessary for the use or commercialization of Product or would be infringed by the importing, marketing, offering for sale or sale of Product in any country in the Madaus Territory, including (x) all patents that are Development Patents or Licensed Patents (each as defined in the Supernus Agreement), and (y) all certificates of invention and applications for certificates of invention, substitutions, divisions, continuations, continuations-in-part, patents issuing thereon or reissues or reexaminations thereof and any and all supplementary protection certificates or the like of any such patents and current and future patent applications, including the patents and patent applications listed on Schedule 1.54.


1.56. “SLI Intellectual Property” shall have the meaning ascribed to such term in the Supernus Agreement.

1.57. “Specifications” means the procedures, requirements, standards, quality assurance and quality release specifications of the Bulk Drug Product as set forth on Schedule 1.57, along with any agreed amendments or modifications thereto. Schedule 1.57 sets forth the Specifications as of the Effective Date, which are the specifications set forth in the NDA. The Specifications shall mean the Specifications included in the NDA that is approved by the FDA. Regardless of the Specifications, Madaus shall have the option to purchase from Indevus during the Supply Term, subject to the provisions of Section 5.4.5 and 5.6, either (a) capsules of Bulk Drug Product marked with the designation “SANCTURA XR”; (b) unmarked capsules of Bulk Drug Product; or (c) capsules of Bulk Drug Product marked with another designation selected by Madaus, in each case in accordance with the terms of this Agreement.

1.58. “Supernus Agreement” means the Development and License Agreement by and between Indevus and Supernus Pharmaceuticals, Inc. (f/k/a Shire Laboratories Inc.) (“Supernus”) effective as of March 11, 2003, including any amendments thereto, a copy of which has previously been provided to Madaus.

1.59. “Supernus Side Agreement” means the Side Agreement dated as of the Effective Date by and among Indevus, Madaus and Supernus.

1.60. “Supernus Payments” means amounts payable by Indevus to Supernus pursuant to the Supernus Agreement with respect to the Madaus Territory or the Joint Territory, as applicable.

1.61. “Supply Price” shall have the meaning set forth in Section 5.4.

1.62. “Supply Term” means the Initial Supply Term and any Renewal Supply Term(s).
1.63. “Third Party(ies)” means a person or entity who or which is neither a Party nor an Affiliate of a Party.

1.64. “Trademark” means the trademark SANCTURA XR™ and any related trademark, symbol, logo trade dress and/or trade name that Indevus may adopt and register for use in the promotion of Product.

1.65. “Valid Claim” means a claim of (i) an issued and unexpired and not lapsed (unless reinstated) patent included within the SANCTURA XR Patents, which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise or (ii) any patent application which shall not have been abandoned, cancelled, withdrawn or pending for more than five (5) years from the earliest priority date claimed for such application.

Where words and phrases are used herein in the singular, such usage is intended to include the plural forms where appropriate to the context, and vice versa. The words “including”, “includes” and “such as” are used in their non-limiting sense and have the same meaning as “including without limitation” and “including but not limited to”. References to Articles, Sections, subsections, and clauses are to the same with all their subparts as they appear in this Agreement. “Herein” means anywhere in this Agreement. “Hereunder” and “hereto” means under or pursuant to any provision of this Agreement.

ARTICLE II
LICENSE; SUBLICENSES

2.1. License Grant. Indevus hereby grants to Madaus an exclusive license under the SANCTURA XR Patents and the Indevus Know−How to use, develop, import, offer for sale, sell, or have sold Product, into and throughout the Madaus Territory; provided, however, that Indevus shall retain such rights in the Madaus Territory as are reasonably necessary for Indevus to exercise its rights and perform its obligations as set forth in this Agreement. If Madaus has the right to use a second source of Bulk Drug Product pursuant to the terms of this Agreement, such license shall include also the right to make and have made Product in the Madaus Territory, pursuant to such SANCTURA XR Patents and Indevus Know−How.

2.2. Sublicense under Supernus Agreement. The license granted to Madaus under Section 2.1 includes a sublicense by Indevus of Indevus’ rights under the Supernus Agreement to the SLI Intellectual Property, solely to use, develop, import, offer for sale, sell, or have sold Product into and throughout the Madaus Territory. Madaus acknowledges that it is a sublicensee under the Supernus Agreement to the extent stated in the foregoing sentence and agrees that its rights are limited (and that any sublicensee of Madaus’ rights under this Agreement shall be limited) by the terms and conditions of the Supernus Agreement, to the same extent as Indevus is limited by such terms and conditions, as such terms apply to the sublicense granted to Madaus hereunder, subject to the terms and conditions of the Supernus Agreement.
to the terms of the Supernus Side Agreement. Notwithstanding anything to the contrary in this Agreement (except as set forth in the Supernus Side Agreement), the rights and licenses granted by Indevus to Madaus hereunder are subject to the terms, conditions and provisions of the Supernus Agreement such that Madaus shall be subject to any restrictions or limitations on the rights granted to Indevus under the Supernus Agreement expressly applicable to sublicensees or sub−sublicensees (other than the Supernus Payments). The Parties acknowledge and agree that amounts equal to the amounts of the Supernus Payments with respect to the Madaus Territory accruing after the date hereof with respect to such period are required to be paid by Madaus to Indevus hereunder.

2.3. Sublicenses. Subject to and consistent with the terms and conditions of this Agreement, Madaus shall have the right to grant sublicenses of any of the rights granted to Madaus under Section 2.1 above and Section 3.1.2 below to Affiliates or any Third Party to develop, use, import, offer for sale, market, and sell Product in the Madaus Territory provided, however, that any sublicensee is bound by all of the terms, conditions, obligations, restrictions and other covenants of this Agreement that protect or benefit Indevus’ rights and interests, including the obligations under the Supernus Agreement, and that Madaus shall remain responsible for the performance by the sublicensee of such obligations.

2.4. Limitation. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right to either Party, to or in respect of any product, patent, trademark, Proprietary Information of the other Party, except as expressly set forth herein.

ARTICLE III
TRADEMARKS

3.1. Ownership; License.

3.1.1 Indevus shall own and, in its discretion, shall file, register and maintain appropriate registrations of the Trademark in the Madaus Territory and the Joint Territory for use on and in connection with the marketing, sale, advertising and/or promotion of Product in the Madaus Territory.

3.1.2 Indevus hereby grants to Madaus an exclusive right and license to use the Trademark solely in connection with the marketing, sale, advertising and/or promotion of Product in the Madaus Territory. Madaus may, at its sole option, use the Trademark on and in connection with the commercialization of Product in the Madaus Territory provided, however, that Madaus agrees not to assign or transfer any of its rights in and to the Trademark and/or any associated registrations or applications to any Third Party, except in connection with a permitted assignment of this Agreement as a whole. The rights to use of the Trademark hereunder are subject to the laws of the countries in the Madaus Territory.
3.1.3 Madaus acknowledges that Indevus owns all rights, title and interests in and to the Trademark in the Madaus Territory and the Joint Territory and that nothing in this Agreement grants Madaus or any persons or entity any rights, title or interest therein, except as specifically set forth in Section 3.1.2. Except as specifically set forth in this Agreement, Madaus and its Affiliates shall not, either during the Term of this Agreement or at any time thereafter, use, attempt to register, or register, as a trade/service mark, corporate name, trade name or domain name, or challenge or contest the validity of, the Trademark or any other trade names/marks and/or logos of Indevus, or any trademarks confusingly similar to SANCTURA XR™, or assist any Third Party in doing any of the foregoing. Madaus acknowledges that any use of the Trademark, and any goodwill associated with such use, shall vest in and inure to the benefit of Indevus.

3.1.4 If Madaus uses a trademark other than the Trademark in connection with the commercialization of Product in the Madaus Territory, Indevus acknowledges that as between the Parties, Madaus shall own all rights, title and interests in and to the trademark (except to the extent it is a trademark already owned, registered, licensed, or used with a trademark (™) designation by Indevus) and that nothing in this Agreement grants Indevus or any persons or entity any rights, title or interest therein. Except as set forth in the Madaus License and in the Supply Agreement as of December 16th, 2002 between the Parties, Indevus and its Affiliates shall not, either during the Term of this Agreement or at any time thereafter, use, attempt to register, or register, as a trade/service mark, corporate name, trade name or domain name, or challenge or contest the validity of, any such trademark used by Madaus or any other trade names/marks and/or logos of Madaus, or any trademarks confusingly similar to any such trademark selected by Madaus, or assist any Third Party in doing any of the foregoing. Indevus acknowledges that any use of that trademark, and any goodwill associated with such use, shall vest in and inure to the benefit of Madaus.

3.1.5 If and to the extent Madaus uses the Trademark, (a) packaging materials, package inserts, labels and marketing, sales, advertising and promotional materials relating to Product distributed in the Madaus Territory or the Joint Territory and bearing the Trademark shall display the Trademark only in a form and style and with a placement determined solely by Indevus, and (b) the appearance of the Trademark and any other Indevus’ trademarks, trade dress, style of packaging and the like with respect to Product shall be determined by Indevus, subject to the terms of this Section 3. Regardless of whether Madaus uses the Trademark, Madaus will include on its packaging relating to Product a mutually agreed-upon reference to the SANCTURA XR Patents licensed by Indevus to Madaus hereunder.

3.2 Trademark Infringement.

3.2.1 Madaus shall promptly notify Indevus of any actual, alleged or threatened infringement of the Trademark or of any unfair trade practices, passing off of counterfeit goods, or similar offenses of which it becomes aware. Indevus reserves the right to determine, in its sole discretion, whether to and to what extent to institute, prosecute or defend any actions or proceedings involving or affecting any rights relating to the Trademark in the Madaus Territory. Upon Indevus’ reasonable request, Madaus shall
cooperate with and assist Indevus in any of Indevus’ enforcement efforts with respect to the Trademark. Money damages so recovered shall be allocated in the same manner set forth in Section 11.3.5.

3.2.2 Indevus shall promptly notify Madaus of any actual, alleged or threatened infringement of the trademark Madaus may use in lieu of the Trademark or of any unfair trade practices, passing off of counterfeit goods, or similar offenses of which it becomes aware in connection with the Product. Madaus reserves the right to determine, in its sole discretion, whether to and to what extent to institute, prosecute or defend any actions or proceedings involving or affecting any rights relating to its trademark.

3.3. Competing Marks. Madaus shall not market, promote, sell and/or distribute, or authorize or permit another to market, promote, sell and/or distribute, any product other than Product under the Trademark or any confusingly similar trade names/marks and/or logos. Except as provided by Section 4.7.6, and subject to the other terms and conditions of this Agreement, Madaus shall, however, be free to market, promote, sell and/or distribute, and authorize and permit another to market, promote, sell and/or distribute, any product including the Product in the Madaus Territory under a trademark other than the Trademark so long as it is not confusingly similar to the Trademark.

ARTICLE IV
DEVELOPMENT AND REGULATORY MATTERS; COMMERCIALIZATION

4.1. Exchange of Information. Within ten (10) Business Days after execution of this Agreement, Indevus shall disclose to Madaus in English and in writing all Indevus Know−How not previously available or made available to Madaus. Within ten (10) Business Days after submission with the FDA of Indevus’ NDA for Product, Indevus shall provide Madaus with a copy of such NDA. As Indevus develops further Indevus Know−How, it shall promptly disclose it to Madaus in English and in writing.

4.2. Development. To the extent Madaus determines to commercialize the Product in a country in the Madaus Territory, Madaus will be responsible for all preclinical development, toxicology and clinical development required for such commercialization. The progress and results of such development and regulatory submissions and review, as well as such other information reasonably requested by Indevus relating to the progress, goals or performance of such development, will be reported to Indevus at meetings of the Development Committee.

4.3. Development Committee. The Parties agree to establish a development committee (the “Development Committee”) to facilitate the development and Regulatory Approval of Product in the Madaus Territory and/or Joint Territory as follows:

4.3.1 Composition of the Committee. The Development Committee shall be comprised of two (2) named representatives of Indevus and two (2) named representatives of Madaus, all of whom shall be qualified to appropriately represent such party at the Development Committee level. The initial representatives for each Party

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hereto shall be set forth on Schedule 4.3. Each Party may substitute one or more of its representatives, in its sole discretion, effective upon written notice to the other Party of such change. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend Development Committee meetings, subject to compliance with Article VIII. The Development Committee shall use its reasonable efforts in good faith to resolve by consensus any issue relevant to the development of the Product in the Madaus Territory and/or Joint Territory.

4.3.2 Development Committee Resolution. If the Development Committee is unable to reach unanimous agreement on any issue relating to the development and/or Regulatory Approval of Product in the Madaus Territory or the Joint Territory, notwithstanding the exercise of its reasonable efforts as provided in Section 4.3.1, then no action shall be taken with respect to the particular development or Regulatory Approval issue.

4.3.3 Meetings and Costs. Either Party shall have the right to call meetings of the Development Committee upon reasonable advance notice to the other Party, with the location for such meetings alternating between Madaus and Indevus facilities (or such other locations as are determined by the Development Committee), until the expiration of the earlier of (a) the Initial Supply Term; (b) the last Launch of Product in the Major European Counties, the Other Major Countries or the Joint Territory or (c) the fifth anniversary of the Effective Date (or such other date as to which the Parties may mutually agree). Alternatively, the Development Committee may meet by means of conference call or other similar communications equipment. Any costs incurred by either Party in connection with meetings of the Development Committee shall be borne by the respective Party incurring such cost.

4.3.4 Development Committee Responsibilities. The Development Committee shall be responsible for overseeing the development and Regulatory Approval of Product in the Madaus Territory and/or Joint Territory, including review and approval of all clinical protocols, regulatory progress and regulatory strategy, drafts of submissions of Product prescribing information and other regulatory correspondence and proposed responses thereto.

4.4 Regulatory Matters. Subject to the terms of Section 4.3 and 12.4.2, Madaus shall own, control and retain primary legal and financial responsibility for the preparation, filing and prosecution and maintenance of all filings and regulatory applications required to obtain and maintain authorization to develop, sell and use Product in the Madaus Territory. Madaus shall notify Indevus within five (5) Business Days after the submission of any MAAs, the receipt of any Regulatory Approvals and of the dates of First Commercial Sale in each country in the Madaus Territory. Subject to the terms of Section 4.3, Madaus shall be solely responsible for filing all reports required to be filed in order to maintain any Regulatory Approvals granted for Product in the Madaus Territory, for all promotional materials for Product in the Madaus Territory, and for all interactions with Regulatory Authorities in the Madaus Territory regarding such Regulatory Approvals and approval of all such promotional materials. Madaus shall promptly notify Indevus with respect to any material changes or material problems that
4.5. **Adverse Drug Experiences and Safety Reporting.** Each Party shall maintain a safety database for Product. Indevus and Madaus agree to promptly exchange all relevant information that relates to the safety of Product, including all adverse reaction reports. With respect to adverse drug experiences reports relating to Product, the Parties will agree, within six (6) months after the Effective Date but in any event no later than the commencement of any clinical trials in the Madaus Territory, on operating procedures for the exchange of safety information between the Parties sufficient to enable each Party to comply with its legal obligations to report to the appropriate Regulatory Authorities in the countries in which Product is being developed or commercialized by such Party, in accordance with the appropriate laws and regulations of the relevant countries and authorities. These operating procedures will (a) include measures necessary for each Party to comply with such laws and regulations as apply to such Party; (b) define responsibilities for adverse experience handling for initial, follow-up and/or periodic submission to government agencies of significant information on Product from pre clinical laboratory, animal toxicology and pharmacology studies and Pre-clinical Development; (c) include arrangements for the exchange of serious and non-serious cases including formats and timelines, Periodic Safety Update Reports, Periodic Reports and answers to safety related queries by Regulatory Authorities; and (d) be promptly amended as changes in legal obligations require or as otherwise agreed by the Parties.

4.6. **Regulatory Cooperation.** Each Party shall inform the other Party, within two (2) Business Days, of its receipt of any information that: (a) raises any material concern regarding the safety or efficacy of Product; (b) concerns suspected or actual Product tampering or contamination or similar problems with respect to Compound or Product; (c) is reasonably likely to lead to a recall or market withdrawal of Product; or (d) concerns any ongoing or potential Regulatory Authority investigation, inspection, detention, seizure or injunction involving Compound or Product.

4.7. **Commercialization.**

   4.7.1 Madaus shall use reasonable commercial efforts consistent with normal business practices to develop and commercialize Product in the Madaus Territory. Where in this Section 4.7 Madaus is required to use reasonable commercial efforts consistent with normal business practices, such level of effort will be consistent with the level of effort used by Madaus in connection with other products of Madaus of similar importance which Madaus intends to launch and sell in the Madaus Territory, or in the absence of any such similar product then such effort shall be assessed by reference to good business practice in the light of all the circumstances then in effect.
4.7.2 In addition to and not in lieu of the obligations set forth in Section 4.7.1, Madaus shall:

(a) submit an MAA under the Centralized Procedure or Mutual Recognition Procedure with an EMEA Authority within nine (9) months after receipt by Madaus of the initial NDA submitted by Indevus with the FDA;

(b) Launch Product in the Major European Countries within six (6) months after Regulatory Approval has been obtained in the applicable jurisdiction;

(c) submit an MAA in the Other Major Countries within twelve (12) months after receipt by Madaus of the NDA submitted by Indevus with the FDA;

(d) Launch Product in the Other Major Countries within six (6) months after Regulatory Approval has been obtained in the applicable jurisdiction;

(e) expend, in connection with launch of Product, such amounts as are commercially reasonable in connection with the marketing and promotion of Product, with the objective of promoting the therapeutic profile and benefits of Product in the most commercially beneficial manner;

(f) provide Indevus with an annual written report and confer with Indevus at least quarterly to summarize and update the status of Madaus’ regulatory and commercialization efforts and activities with respect to Product; and

(g) within fifteen (15) days after the end of each month, provide Indevus with unaudited monthly sales reports of Net Sales in the Madaus Territory, including a report as to the number of Samples distributed during such month.

4.7.3 In the event that Madaus determines not to or fails to fulfill any of its obligations set forth in Section 4.7.2 with respect to any country in the Madaus Territory, Indevus shall have the right to terminate this Agreement with respect to such country by providing forty-five (45) days written notice of such election to Madaus. In such event, the provisions of Section 4.7.4 and 12.4.2 shall be applicable. Madaus shall inform Indevus promptly of any determination not to, or failure to, fulfill its obligations under Section 4.7.2 with respect to any country in the Madaus Territory. Such determination or failure by Madaus shall not constitute a breach of Section 4.7.2 with respect to any country and, subject to the provisions of Section 4.7.4, no damage claims or other claims for payment shall be based on such determination or failure, except to the extent such determination or failure is associated with or results in a breach of any other provision of
this Agreement, including Section 4.7.1 or any obligation under Article V or Article VI. The foregoing right to terminate with respect to a
country in the Madaus Territory shall not apply if Madaus’s determination or failure is due substantially to Indevus’ inability to obtain one or
multiple of one batch production, as may be requested by Madaus, pursuant to the last sentence of Section 5.6.2, unless a third party is willing
and able to fulfill (and does in fact fulfill) said obligations with respect to said country on the terms last offered to Madaus.

4.7.4 Notwithstanding (a) any determination by Madaus not to meet, or any failure of Madaus to meet, any of the obligations set forth in
Section 4.7.2 with respect to any country, and/or (b) any election by Indevus to terminate the Agreement with respect to such country, any
milestone payments otherwise due pursuant to Section 6.1 with respect to such country (or any jurisdiction that includes such country) shall
nevertheless be paid by Madaus, subject, however to the next sentence. As to any country as to which Madaus has made such milestone payment,
but determined not to meet, or failed to meet, any of the obligations set forth in Section 4.7.2 with respect to such country, Indevus shall
reimburse Madaus fifty percent (50%) of any milestone or similar payments Indevus receives during the Term from any Third Party with respect
to marketing Product in that country promptly upon receipt thereof.

4.7.5 If Madaus, its Affiliates or their respective Marketing Distributors sell Product to a customer who also purchases other products or
services from any such entity, Madaus agrees not to, and to require its Affiliates and their Marketing Distributors not to, discount or price
Product in a manner that is intended to disadvantage Product in order to benefit sales or prices of other products offered for sale by Madaus, its
Affiliates or their Marketing Distributors to such customer.

4.7.6 Subject to the terms of this Section 4.7.6, Madaus will not (and will ensure that its Affiliates do not) at any time during the Term of
this Agreement, directly or indirectly, in any country in the Madaus Territory or the Joint Territory, or in any country as to which this Agreement
has been terminated in accordance with Sections 4.7.3 and 12.4.2, develop, manufacture, use, market, import/export, offer for sale, sell or
distribute, any Competing Product, nor cause any Competing Product to be developed, manufactured, distributed, marketed or sold on its own
behalf or on behalf of any Third Party through any distributor or chain of distribution. Notwithstanding the foregoing, in the event that Madaus
purchases a Third Party or is purchased by, or takes control of or becomes controlled by a Third Party, which has developed or commercialized
(and is continuing to sell), a Competing Product (directly or indirectly) in a country in the Madaus Territory, then Madaus or such Third Party
shall, within six (6) months after such event either (i) cease marketing, or cause its applicable Affiliate to cease marketing, the Competing
Product in that country; (ii) divest, or cause its applicable Affiliate to divest, the Competing Product in that country; or (iii) give up Madaus’
rights with respect to Product in that country effective automatically at the end of such six (6) month period, in which case the provisions of
Section 12.4.2 shall be applicable.
ARTICLE V
MANUFACTURE AND SUPPLY

5.1. Manufacturing Responsibility. Subject to the terms and conditions of this Agreement, during the Supply Term Indevus or its designees shall have the exclusive right to, shall be responsible for, and shall use commercially reasonable efforts to, manufacture and supply all Bulk Drug Product required for development and commercialization of Product in the Madaus Territory and the Joint Territory. Subject to the terms and conditions of this Agreement, during the Supply Term, Madaus shall purchase all of its requirements of Bulk Drug Product for use in the Madaus Territory or the Joint Territory exclusively from Indevus.

5.2. Third Party Manufacturers. The obligation set forth in Section 5.1 shall be subject to the Manufacturing Facility’s being in compliance with cGMP and all other regulatory requirements including successful regulatory inspection by the FDA of any such facility. The Parties acknowledge and agree that Indevus intends to obtain Bulk Drug Product from Third Party manufacturers, but has not yet entered into agreements with any Third Party manufacturers with respect to such Bulk Drug Product.

5.3. Second Source. Madaus reserves the right to appoint a second source supplier of Bulk Drug Product (a) if Indevus fails after reasonable prior written notice (i) to meet FDA regulatory requirements with respect to production of Bulk Drug Product or (ii) is unable to deliver Bulk Drug Product in quantities which satisfy Madaus’ reasonable commercial requirements for Bulk Drug Product, or (b) pursuant to the provisions of Section 5.4.2. If Madaus appoints a second source supplier pursuant to the immediately preceding sentence, Indevus has the right to receive an adequate royalty, not to exceed 1% of Net Sales, for giving such a manufacturing license relying on Indevus Know−How, in addition to any royalties required under the Supernus Agreement.

5.4. Supply Price. The supply price for all Bulk Drug Product supplied during the Supply Term by Indevus under this Agreement (the “Supply Price”) shall equal the sum of (a) Indevus’ Manufacturing Costs, plus (b) [*] of Bulk Drug Product purchased and used for commercial sales of Product (the “Manufacturing Payment”), subject to the following:

5.4.1 During the Initial Supply Term, except as otherwise set forth herein, the portion of the Supply Price allocated to Indevus’ Manufacturing Costs shall not exceed [*] of Bulk Drug Product (the “Manufacturing Costs Cap”).

5.4.2 During any Renewal Supply Term, the Supply Price shall be calculated as follows:

(a) During any portion of any Renewal Supply Term that expires on or prior to the expiration of the Manufacturing Payment Term in which Indevus’ Manufacturing Costs exceed the Manufacturing Costs Cap, the Supply Price shall equal the sum of:
   (i) Indevus’ Manufacturing Costs (which shall in this case not be subject to the Manufacturing

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Costs Cap) plus (ii) the Manufacturing Payment, provided that the Manufacturing Payment shall be reduced by the amount by which Indevus’ Manufacturing Costs exceed the Manufacturing Costs Cap. If the Manufacturing Payment would be reduced to zero, Madaus shall have the right to appoint a second source supplier of Bulk Drug Product, provided, however, that in such event, Madaus shall continue to remain liable for any outstanding Binding Portion of a Forecast or Purchase Order.

If any portion of such Renewal Supply Term occurs prior to [*], the provisions of Section 3.7(b)(ii)(E) of the Madaus License, as amended by the Amendment and Agreement, shall also be applicable. For example, if during any portion of any Renewal Supply Term that expires on or prior to the expiration of the Manufacturing Payment Term, Indevus’ Manufacturing Costs equal [*] of Bulk Drug Product, the Manufacturing Payment will be reduced by [*] and, accordingly, the Supply Price will equal [*] (Indevus’ Manufacturing Costs of [*] plus the reduced Manufacturing Payment of [*] If such period is prior to [*], then the Additional Payment (as defined in the License Agreement, as amended by the Amendment and Agreement), shall also be reduced by [*].

(b) During any portion of any Renewal Supply Term that commences after the expiration of the Manufacturing Payment Term, the Supply Price for all Bulk Drug Product supplied by Indevus under this Agreement shall equal Indevus’ Manufacturing Costs, and the Manufacturing Costs Cap shall not be applicable. If Indevus’ Manufacturing Costs exceed [*] of Bulk Drug Product (subject to adjustment as set forth in the next paragraph), Madaus shall have the right to appoint a second source supplier of Bulk Drug Product, provided, however, that in such event, Madaus shall continue to remain liable for any outstanding Binding Portion of a Forecast or Purchase Order.

The adjustment applicable to this Section 5.4.2(b) shall be calculated based on:

(i) with respect to [*] the average of: (A) the number obtained by (i) dividing the consumer price index ("Verbraucherindex" 2000=100) as available on the German Federal Statistics Office (“Statistisches Bundesamt Deutschlands”) website at http://www.destatis.de/indicators/d/pre110ad.htm (the “Website”) with respect to the month most recently reported on the Website on the date of such inflation adjustment by (ii) the same index with respect to the most recent month reported on the Website for September 2011,
multiplied by (iii) [*] and (B) the increase in Indevus’ Manufacturing Costs from September 2011 until the date of any calculation required by this Section 5.4.2(b); and

(ii) with respect to [*] the average of (A) the number obtained by (i) dividing the consumer price index (“Verbraucherindex” 2000=100) as available on the German Federal Statistics Office (“Statistisches Bundesamt Deutschlands”) website at http://www.destatis.de/indicators/d/pre110ad.htm (the “Website”) with respect to the month most recently reported on the Website on the date of such inflation adjustment by (ii) the same index with respect to the most recent month reported on the Website for [*], multiplied by (iii) [*] and (B) the increase in Indevus’ Manufacturing Costs from [*] until the date of any calculation required by this Section 5.4.2(b).

(iii) The same adjustment shall be made annually and shall apply as to each new one-year period during any Renewal Supply Term commencing after the expiration of the Manufacturing Payment Term. An example of this adjustment, for illustrative purposes only, is set forth on Schedule 5.4.2(b).

5.4.3 Indevus will use commercially reasonable efforts, consistent with its agreements with Third Party manufacturers, to achieve production, volume and other efficiencies in the manufacturing of the Bulk Drug Product which, to the extent resulting in a reduction in Indevus’ Manufacturing Costs, shall result in a corresponding reduction in the portion of the Supply Price allocated to Indevus’ Manufacturing Costs.

5.4.4 With respect to Bulk Drug Product used in the Madaus Territory for Samples, such Bulk Drug Product (a) will not be subject to the Manufacturing Payment, and (b) will be provided to Madaus for a supply price equal to Indevus’ Manufacturing Costs; provided, however, that during each year of the Initial Supply Term, the Manufacturing Costs Cap shall be applicable to quantities of Bulk Drug Product used as Samples during that year that are less than ten percent (10%) of Madaus’ aggregate annual quantities of Bulk Drug Product purchased for such year hereunder. Any quantities of Bulk Drug Product used as Samples exceeding such amount shall not be subject to the Manufacturing Costs Cap.

5.4.5 With respect to Bulk Drug Product that are, in accordance with Madaus’ forecasts and Purchase Orders as provided herein, requested to be marked with a designation other than the SANCTURA XR designation (“Madaus Marked Capsules”), Madaus shall, in addition to the Supply Price (as adjusted in accordance with Section 5.4.2), be responsible for and shall pay Indevus within

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thirty (30) days after being invoiced, (a) the difference between (i) the amount of Indevus’ Manufacturing Costs that are associated with the production of Madaus Marked Capsules, and (ii) the amount of Indevus’ Manufacturing Costs that would have been associated with the production of Bulk Drug Product capsules marked with the SANCTURA XR designation, and (b) any additional costs incurred by Indevus that are not included in Indevus’ Manufacturing Costs but are associated with the production of Madaus Marked Capsules, including manufacturing, testing and storing such Madaus Marked Capsules, as well as any testing or regulatory filings required by any Regulatory Authority. For example, if at any time during the Initial Supply Term, Madaus is purchasing Madaus Marked Capsules under this Agreement, Indevus’ Manufacturing Costs associated with the production of Madaus Marked Capsules are [*] and Indevus’ Manufacturing Costs that would have been associated with the production of the same quantity of Bulk Drug Product capsules marked with the SANCTURA XR designation are [*] then, in addition to the Supply Price for such Madaus Marked Capsules, Madaus shall pay Indevus an additional [*] of Madaus Marked Capsules.

5.4.6 Sales of Bulk Drug Product between Madaus and its Affiliates or licensees or sublicensees, or among such Affiliates and licensees or sublicensees, shall not be considered sales of Bulk Drug Product for purposes of calculating the Manufacturing Payment, but in such cases the Manufacturing Payment shall be calculated on the number of capsules of Product sold by such Affiliates or licensees or sublicensees to Third Parties who are not a Madaus licensee or sublicensee.

5.5. Forecasts.

5.5.1 Forecasts Prior to Launch. Not later than thirteen (13) months prior to the estimated Launch of Product in the first country in the Madaus Territory, Madaus shall provide Indevus a written forecast of its estimated requirements for Bulk Drug Product for the six (6) consecutive Calendar Quarters commencing with the Calendar Quarter in which such Launch is estimated to occur, broken down on a quarterly basis. Not less than ten (10) months prior to the estimated Launch of Product in such country, Madaus shall provide Indevus with an updated forecast (the “Launch Forecast”) of its estimated requirements of Bulk Drug Product for each such six (6) Calendar Quarters, broken down on a quarterly basis. Not less than three (3) months prior to the estimated Launch of Product in such country, Madaus shall provide Indevus with a forecast of its estimated requirements of Bulk Drug Product for the six (6) consecutive Calendar Quarters commencing at the beginning of the Calendar Quarter that is at least nine (9) months after the date of such forecast, broken down on a quarterly basis.

5.5.2 Forecasts After Launch. Within thirty (30) days after the initial Launch of Product in the Madaus Territory and thereafter on a quarterly basis during the Supply Term, Madaus shall provide Indevus with an updated rolling forecast of its estimated requirements of Bulk Drug Product, broken down on a quarterly basis, for six (6) consecutive calendar quarters (commencing at the beginning of the first complete Calendar Quarter that commences after at least nine (9) months after the date of such forecast, broken down on a quarterly basis.

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5.5.3 Firm Commitment. To the extent any forecast required hereunder (commencing with the Launch Forecast) is required to be provided to Indevus for any period for which Indevus is required to provide a binding forecast to its Third Party manufacturers for Compound or Bulk Drug Product (i.e., that portion of the forecast is required to constitute a firm order and/or binding commitment to submit purchase orders for the aggregate quantities specified therein), the corresponding period of the forecast provided hereunder shall also be binding (the “Binding Portion”). For example, if the first two (2) Calendar Quarters of any forecast provided by Indevus to a Third Party manufacturer is deemed under Indevus’ agreement with such Third Party to be a binding forecast, then the first two (2) Calendar Quarters of the forecast required hereunder for the comparable period shall constitute the “Binding Portion” and the following four (4) Calendar Quarters of such forecast shall be non-binding, good faith estimates for planning purposes only and shall not constitute binding commitments by Madaus to purchase Bulk Drug Product. Subject to the foregoing, each forecast provided by Madaus shall supersede any previous forecast. Each forecast provided by Madaus shall designate the quantities of Bulk Drug Product that Madaus desires to be either (a) marked with the SANCTURA XR designation; (b) unmarked; and/or (c) marked with a designation other than the SANCTURA XR designation.

5.5.4 Coordination With Other Agreements. The provisions of Sections 5.5, 5.6, 5.9 and 5.10.3 are based on Indevus’ current negotiations with Third Party manufacturers. Indevus agrees to provide Madaus with copies of the provisions of those contracts relating to forecasts, purchase orders, minimum batch quantities, failure to place purchase orders and acceptance or rejection, promptly after their conclusion and signing by all parties thereto. If those provisions change in any material respect in terms of minimum batch quantities, timing and/or the binding nature of forecasts or purchase orders required to be provided by Indevus to such Third Party manufacturers, from those on which Sections 5.5, 5.6, 5.9 and 5.10.3 are based, the Parties will amend these Sections to comply and/or coordinate with such changes, with such amendment to be entered into promptly after such conclusion and signing. Notwithstanding the foregoing, a delay in executing such amendment shall not adversely affect the Parties’ rights or obligations hereunder.

5.6. Purchase Orders.

5.6.1 Subject to the terms and conditions of this Agreement, Madaus shall be bound to order one hundred percent (100%) of the forecasted quantities of Bulk Drug Product that are subject to a Binding Portion of the Launch Forecast or a rolling forecast. At least two hundred eighty (280) days prior to the desired delivery date, Madaus shall submit a firm, binding, non-cancelable purchase order of its requirements for Bulk Drug Product (“Purchase Order”) specifying (a) requested delivery dates for each batch and (b) the quantities of Bulk Drug Product that Madaus desires to be either (i) marked with the SANCTURA XR designation; (ii) unmarked; and/or (iii) Madaus Marked Capsules, provided that such breakdown corresponds to the breakdown set forth in Madaus’ forecasts for the corresponding periods and subject to the provisions of Section 5.4.5 and 5.6.2. Within ten (10) days of receipt of each Purchase Order, Indevus shall provide
confirmation in writing of the Purchase Order and delivery date(s) requested by Madaus. Other than terms respecting quantity, delivery date(s), shipment method and destination(s), no modification or amendment to this Agreement shall be effected by or result from the receipt, acceptance, signing or acknowledgement of Purchase Orders or other business forms containing terms or conditions in addition to or different from the terms and conditions set forth in this Agreement, and in the event of a conflict between the terms of any Purchase Order and this Agreement, this Agreement shall control. Indevus will use commercially reasonable efforts to supply Madaus on or prior to the designated delivery date the quantities of Bulk Drug Product designated in such Purchase Order, provided, however, that Indevus shall not be obligated to satisfy the aggregate portion of any Purchase Order that would exceed the aggregate Binding Portion for such Calendar Quarter if its Third Party manufacturers have no obligation to Indevus to satisfy any such excess portion.

5.6.2 Except as set forth in this Section 5.6.2, Madaus’ Purchase Orders for each category of Bulk Drug Product (i.e., either (i) marked with the SANCTURA XR designation, (ii) unmarked, or (iii) Madaus Marked Capsules), shall be in ordinary production batch quantities of at least three to four batches, with each batch currently expected to consist of 1.5 million capsules. Notwithstanding the foregoing, with respect to Bulk Drug Product ordered for sale during the twelve (12) month period commencing with the first Launch in the Madaus Territory or ordered during said period for delivery during said period or thereafter, Madaus shall have the right to submit (and Indevus shall accept) Purchase Orders for one batch of Bulk Drug Product or multiples thereof, provided that (a) 100% of such batch is (i) marked with the SANCTURA XR designation or (ii) is unmarked, as designated in such Purchase Order, and (b) such quantities and breakdown correspond to the quantities and breakdown set forth in Madaus’ forecast for such period. If after the expiration of the period referred to in the preceding sentence, Madaus advises Indevus in writing that it desires to purchase Madaus Marked Capsules, but in ordinary production batch quantities that do not satisfy the three or four batch minimum quantities for such category, Indevus will negotiate in good faith with its Third Party manufacturer to produce one batch of such Madaus Marked Capsules or multiples thereof, subject to the provisions of Section 5.4.5.

5.7. **Terms of Shipment and Delivery.** Subject to the last sentence of this Section 5.7, the terms of delivery of the Bulk Drug Product to Madaus shall be DDP (INCOTERMS 2000) point of delivery at one (1) facility in Germany designated in writing by Madaus at least six (6) months prior to the requested delivery date. All Bulk Drug Product shall be suitably packed for shipment to such facility. If Madaus or its designee fails to take delivery of Bulk Drug Product subject to any Purchase Order on the scheduled delivery date, Madaus shall assume all risk of loss and be responsible for any costs associated therewith. Both Parties shall use their commercially reasonable efforts to accommodate reasonable change requests from the other relating to shipment and delivery of Bulk Drug Product.
5.8. **Payment Terms.** Madaus shall settle invoices received from Indevus with respect to the portion of the Supply Price allocated to Indevus’ Manufacturing Costs within thirty (30) days from the date of receipt of the Bulk Drug Product by Madaus or Madaus’ designee (subject to the provisions of Schedule 1.26 with respect to year end adjustments) or, for amounts in dispute pursuant to Section 13.6, within ten (10) days from the date the dispute is resolved. The portion of the Supply Price allocated to the Manufacturing Payment shall be paid in accordance with Section 6.3.

5.9. **Failure to Satisfy Binding Portion.** In addition to any other amounts due to Indevus under this Agreement, if in any Calendar Quarter Madaus fails to place Purchase Orders sufficient to satisfy the Binding Portion for such Calendar Quarter, Madaus shall be responsible for and shall pay Indevus, within thirty (30) days of receipt of invoice, that portion of Indevus’ Manufacturing Costs that Indevus is nevertheless responsible for under its agreements with Third Parties (as well as any related additional costs incurred by Indevus) and/or that Indevus has incurred internally, in each case as a result of Madaus’ failure to satisfy such Binding Portion. Failure of Madaus to place Purchase Orders sufficient to satisfy the Binding Portion of a forecast shall not constitute a material breach of this Agreement so long as Madaus complies with the provisions of this Section 5.9, unless such breach would cause Indevus to breach any of its agreements with its Third Party manufacturers.

5.10. **Pharmaceutical Responsibilities.**

5.10.1 **Changes.** Any changes or modifications to the Specifications, test methods, manufacturing process, Manufacturing Facilities and validation thereof that result from any requirements of any Regulatory Authority in the Madaus Territory shall be subject to the approval by Indevus, which approval Indevus agrees not to unreasonably withhold (subject to its agreements with its Third Party manufacturers) and, if so approved, all costs thereof (including any testing, qualification, scale−up, and regulatory filings) will be borne by Madaus in addition to, and not as a part of, Indevus’ Manufacturing Costs.

5.10.2 **Quality Responsibilities.** Schedule 5.10 outlines responsibilities and key contacts for Bulk Drug Product quality and compliance related issues.

5.10.3 **Acceptance and Release.** Indevus or its designees will analyze and conduct quality control testing of each lot of Bulk Drug Product in accordance with the Specifications and such other quality control testing procedures as are summarized on Schedule 5.10. Indevus will send to Madaus a certificate of analysis and a certificate of compliance simultaneously with each shipment of Bulk Drug Product. Madaus shall inspect such shipment and accept or reject Bulk Drug Product based on such documentation and communicate the outcome to Indevus within twelve (12) Business Days of receipt. If Madaus has not notified Indevus of rejection (which notification shall include Madaus’ basis for rejection and proposal for resolution of the cause of such rejection) within such period, such Bulk Drug Product shall be deemed to have been accepted. Any disagreement as to whether the Bulk Drug Product conforms to the Specifications shall be determined in accordance with Section 5.10.5.
5.10.4 Non-Conforming Product. Except with respect to Bulk Drug Product that was manufactured using Compound provided by Madaus under the [*], which shall be subject to the provisions of Section 5.10.6, with respect to Bulk Drug Product that Indevus agrees is non-conforming or has been determined under the procedure set forth in Section 5.10.5 to be non-conforming, then at its option Madaus may require that Indevus (i) either (a) supply an equal quantity of replacement Bulk Drug Product together with the relevant batch records and documentation to Madaus at no cost to Madaus, or (b)refund to Madaus or credit Madaus’ account for the portion of the Supply Price allocated to Indevus’ Manufacturing Costs, and (ii) dispose of the Product at its cost, except that Madaus shall follow any reasonable instructions from Indevus to return to Indevus or otherwise dispose of such non-conforming Product in another manner at Indevus’ cost.

5.10.5 Independent Testing. In the event of a disagreement between the Parties regarding whether the Bulk Drug Product conforms to the Specifications, the Parties will attempt to reach a mutually acceptable resolution of the dispute. If they are unable to do so after a reasonable period of time (such period not to exceed twenty (20) days from the date of original notification), the Parties shall cause a mutually agreeable independent Third Party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged non-conforming Bulk Drug Product. The independent party’s results shall be final and binding. Unless otherwise agreed by the Parties in writing, the out-of-pocket costs associated with such Third Party testing and review shall be borne by the party that was incorrect about whether the Bulk Drug Product conforms to the Specifications.

5.10.6 Supply of Compound for Non-Conforming Product. In the event Indevus supplies replacement Bulk Drug Product pursuant to Section 5.10.4 with respect to Bulk Drug Product that was originally manufactured using Compound obtained from [*], and such Compound included in the original non-conforming Bulk Drug Product did not conform to the specifications for such Compound, Madaus shall be responsible for the paying the portion of the Supply Price allocated to Indevus’ Manufacturing Costs on the original non-conforming Bulk Drug Product and such replacement Bulk Drug Product. The foregoing shall not apply if the non-conformity of the Compound arose after it left Madaus’ control and Indevus did not inspect the Compound before use.

5.11. Qualification and Inspection of Manufacturing Facilities and Records.

5.11.1 Qualification; Madaus Inspection. Indevus shall use commercially reasonable efforts to see that the Manufacturing Facilities pass inspection by the FDA, any EMEA Authority or any other Regulatory Authority in the Other Major Countries; and any costs incurred by Indevus that are associated with such inspection, or responding to such inspection, by any EMEA Authority or any Regulatory Authority in the Other Major Countries once the Manufacturing Facility has passed inspection by the FDA shall likewise be the sole responsibility of Indevus. Madaus shall have the right once every year, through one or more representatives during normal business hours, and upon at least ninety (90) days’ written notice to Indevus on times to be mutually agreed with the Third Party manufacturers, to inspect and audit the Manufacturing Facilities in order to ensure Indevus’ compliance with its obligations under this Agreement.

[*] CONFIDENTIAL TREATMENT REQUESTED
5.11.2 Governmental Inspections, Requests and Communications. Indevus shall advise Madaus of any written inquiries, notifications relating to any inspection requests or activities by any Regulatory Authority in regard to Bulk Drug Product. Indevus shall furnish to Madaus within two (2) Business Days a copy of all written reports by such Regulatory Authority that may reasonably be expected to adversely affect manufacturing and supply to Madaus of Bulk Drug Product.

5.11.3 Records. Indevus or its designees will maintain complete and accurate records and documentation of all validation data, stability testing data, batch records, quality control and testing relating to Bulk Drug Product and the manufacture, testing and shipment thereof.

5.12. Audit – Indevus’ Manufacturing Costs. Upon the written request of Madaus and not more than once in each Calendar Year, Indevus shall permit an independent certified public accounting firm of nationally recognized standing selected by Madaus and reasonably acceptable to Indevus, to have access during normal business hours at times mutually convenient to the Parties and upon reasonable notice to Indevus to such of the records of Indevus as may be reasonably necessary to verify the accuracy of Indevus’ Manufacturing Costs hereunder for any year ending not more than twenty−four (24) months prior to the date of such request. The accounting firm shall disclose to Madaus only whether the calculations are correct or incorrect and the specific details concerning any discrepancies.

If such accounting firm concludes, and Indevus agrees, that the Indevus Manufacturing Costs were lower than charged during such period, Indevus shall pay the additional funds within sixty (60) days of the date Madaus delivers to Indevus such accounting firm’s written report so concluding; provided that, in the event that Indevus shall not be in agreement with the conclusion of such Report (a) Indevus shall not be required to pay such sum and (b) such matter shall be resolved pursuant to the provisions of Section 13.6. In the event such accounting firm concludes that Indevus’ Manufacturing Costs were higher than charged during such period, Madaus shall pay Indevus the excess amount of Indevus’ Manufacturing Costs (up to the amount of the Manufacturing Costs Cap, to the extent applicable during such period) within thirty (30) days of receipt of such accounting firm’s written report. The fees charged by such accounting firm shall be paid by Madaus; provided, however, that if an error in favor of Madaus in the calculation of Indevus’ Manufacturing Costs of more than ten percent (10%) of Indevus’ Manufacturing Costs for the period being reviewed is discovered, then the fees and expenses of the accounting firm shall be paid by Indevus.

Upon the expiration of twenty−four (24) months following the end of any Calendar Year, the calculation of Indevus’ Manufacturing Costs payable with respect to such year shall be binding and conclusive upon Madaus, and Indevus and its sublicensees shall be released from any liability or accountability with respect to possible overcharges of Indevus’ Manufacturing Costs for such year.

5.13. Recall. In the event either Party believes a recall, field alert, Product withdrawal or field correction (any of the foregoing, a “Recall”) may be necessary with respect to

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
any Product provided under this Agreement, such Party shall immediately notify the other Party in writing. Madaus shall not act to initiate a Recall, without the express prior written approval of Indevus, unless otherwise required by applicable laws. Unless otherwise set forth herein, Indevus shall have responsibility for and shall make all decisions relating to conducting any Recall related to Product. The cost of any Recall shall be borne by the Parties in proportion to their respective responsibility for the Recall. For purposes hereof, such cost shall be limited to the reasonable, actual and documented administrative costs incurred by the Parties for such Recall as well as replacement of the Non-Conforming Product subject to the Recall, subject to the provisions of Section 5.10.6.

ARTICLE VI
PAYMENTS AND REPORTS

6.1 Milestone Payments. Subject to the terms and conditions contained in this Agreement, and in further consideration of the rights granted by Indevus hereunder, Madaus shall pay Indevus the following milestone payments:

6.1.1 US$400,000 within ten (10) days of the first acceptance for filing under the Centralized Procedure or Mutual Recognition Procedure of an MAA by an EMEA Authority or in the Major European Countries;
6.1.2 US$200,000 within ten (10) days of the first acceptance for filing of an MAA for Product in Japan (the other US$200,000 to be paid by Indevus in accordance with Article VII);
6.1.3 US$500,000 within ten (10) days of the First Commercial Sale of Product in the Major European Countries or in Europe (as defined in the Supernus Agreement); and
6.1.4 US$250,000 within ten (10) days of the First Commercial Sale of Product in Japan (the other US$250,000 to be paid by Indevus in accordance with Article VII).
6.1.5 US$250,000 within fifteen (15) days of the date on which Indevus or any Indevus Affiliate first enters into a sublicense with a Third Party with respect to a Product in Japan (the other US$250,000 to be paid by Indevus in accordance with Article VII).

Within the time periods set forth in this Section 6.1, Madaus shall notify Indevus in writing of the achievement of each such milestone and such notice(s) shall be accompanied by the appropriate milestone payment. Notwithstanding the provisions of Section 6.6, Indevus shall receive the full amount of such milestone payments, without any deduction for taxes (including withholding taxes), duties and other amounts assessed thereon and such taxes, duties or other amounts payable shall be the sole responsibility of Madaus.
6.2. **Royalties.**

6.2.1 In further consideration of the rights granted by Indevus hereunder, Madaus shall pay to Indevus royalties equal to five percent (5%) of Net Sales in each Royalty Year by Madaus or its Affiliates or sublicensees in the Madaus Territory. Royalties payable under this Section 6.2.1 (the “Section 6.2.1 Royalties”) shall accrue as of the date of First Commercial Sale of Product in the applicable country and shall continue and accrue on Net Sales until the expiration of the last to expire SANCTURA XR Patent in such country.

6.2.2 In further consideration of the rights granted by Indevus hereunder, Madaus shall pay to Indevus royalties equal to four percent (4%) of Net Sales in each Royalty Year, in each case sold by Madaus or its Affiliates or sublicensees in the Madaus Territory.

(a) Royalties payable under this Section 6.2.2 (the “Section 6.2.2 Royalties”) shall accrue on Net Sales in each country in the Madaus Territory until the earlier of in any such country, (i) the last date on which the manufacture, use or sale of Product in such country would infringe a Valid Claim of a SANCTURA XR Patent in such country but for the license granted by this Agreement; or (ii) twelve (12) years from the date of First Commercial Sale of Product in such country; provided, however, that commencing on the first date in which Generic Competition exists in any country in the Madaus Territory, the Section 6.2.2 Royalties will decrease to two percent (2%) of Net Sales in any such country; and commencing on the first date in which Generic Competition exists in any country in the Madaus Territory and Generic Drugs achieve a market share in one Calendar Quarter of seventy−five percent (75%) or greater of the total prescriptions or unit consumption, as applicable, of Product sold in such country, the Section 6.2.2 Royalties in such country will decrease to one and one−half percent (1.5%) of Net Sales in such country; and

(b) Notwithstanding the provisions of Section 6.6, Indevus shall receive the full amount of the Section 6.2.2 Royalties without any deduction for taxes (including withholding taxes), duties and other amounts assessed on such Net Sales or royalties and such taxes, duties or other amounts payable shall be the sole responsibility of Madaus.

6.2.3 After the expiration of the applicable royalty term in any country, Madaus shall be relieved of any royalty payment under the applicable sub−section of Section 6.2 in that country and, after the expiration of the royalty terms set forth in Section 6.2.1 and 6.2.2 in any country, Madaus shall have a perpetual, fully paid license to the rights licensed hereunder in that country, subject to any other payment obligations hereunder, including any Manufacturing Payments or Supply Price payments.
6.2.4 No royalties shall accrue on the disposition of Product by Madaus, its Affiliates or sublicensees as Samples (promotion or otherwise), for development, testing, clinical trials or as donations (for example, to non-profit institutions or government agencies for non-commercial purposes).

6.2.5 In the event Madaus or a Madaus Affiliate sells Bulk Drug Product rather than Product in finished packaged form to a Third Party, other than a sublicensee, and is unable to determine Net Sales as defined in this Agreement, then the royalty obligations of Section 6.2 shall apply to the Bulk Drug Product sold.

6.3. Reports; Payment of Royalties and Manufacturing Payment. During the Term, Madaus shall furnish to Indevus a quarterly written report (a “Section 6.3 Report”) for each Calendar Quarter showing, as applicable: (a) (i) gross sales and Net Sales of Product in the Madaus Territory during such Calendar Quarter (including a detailing of all deductions taken in the calculation of Net Sales) in each country’s currency, (ii) the formulas used in the calculation of the Section 6.2.1 Royalties and the Section 6.2.2 Royalties owed thereon, (iii) the applicable exchange rate to convert from each country’s currency to United States Dollars, and (iv) the Section 6.2.1 Royalties and the Section 6.2.2 Royalties payable to Indevus; and (b) the number of capsules of Product sold during the Calendar Quarter in the Madaus Territory by Madaus, its Affiliates and its sublicensees subject to a Manufacturing Payment payable under this Agreement and a calculation of the Manufacturing Payment payable under this Agreement. Section 6.3 Reports shall be due on the twentieth (20th) day following the close of each Calendar Quarter, subject to an extension in accordance with the terms of a sublicensing agreement solely with respect to the country(ies) covered by the sublicensing agreement (but in no event longer than an additional five (5) days for a total of twenty-five (25) days following the close of each Calendar Quarter with respect to such country(ies)). Royalties and Manufacturing Payments shown to have accrued by each Section 6.3 Report, if any, shall be due and payable on the date such report is due. Madaus shall keep complete and accurate records in sufficient detail to enable the royalties and the Manufacturing Payment payable hereunder to be determined.

6.4. Audit – Royalties and/or Manufacturing Payments. Upon the written request of Indevus and not more than once in each Calendar Year, Madaus shall permit an independent certified public accounting firm of nationally recognized standing selected by Indevus and reasonably acceptable to Madaus, to have access during normal business hours at times mutually convenient to the Parties and upon reasonable notice to Madaus to such of the records of Madaus as may be reasonably necessary to verify the accuracy of the royalty reports and/or Manufacturing Payment reports hereunder for any year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Indevus only whether the reports are correct or incorrect and the specific details concerning any discrepancies.

6.4.1 If such accounting firm concludes, and Madaus agrees, that additional royalties and/or Manufacturing Payments were owed during such period, Madaus shall pay the additional royalties and/or Manufacturing Payments within sixty (60) days of the
date Indevus delivers to Madaus such accounting firm’s written report so concluding; provided that, in the event that Madaus shall not be in agreement with the conclusion of such report (a) Madaus shall not be required to pay such additional royalties and (b) such matter shall be resolved pursuant to the provisions of Section 13.6. In the event such accounting firm concludes that amounts were overpaid by Madaus during such period, Indevus shall reimburse Madaus the amount of such overpayment within thirty (30) days of receipt of such accounting firm’s written report. The fees charged by such accounting firm shall be paid by Indevus; provided, however, that if an error in favor of Indevus in the payment of royalties and/or Manufacturing Payments of more than the greater of (i) $100,000 or (ii) ten percent (10%) of the royalties and/or Manufacturing Payments due hereunder for the period being reviewed is discovered, then the fees and expenses of the accounting firm shall be paid by Madaus.

6.4.2 Upon the expiration of twenty-four (24) months following the end of any Royalty Year the calculation of royalties payable with respect to such year shall be binding and conclusive upon Indevus, and Madaus and its sublicensees shall be released from any liability or accountability with respect to royalties for such year.

6.4.3 Indevus shall treat all financial information subject to review under this Section 6.4 in accordance with the confidentiality provisions of this Agreement, subject to Supernus’ related rights under the Supernus Agreement with respect to any Supernus Payments.

6.4.4 Madaus recognizes that Indevus has an interest in Madaus’ audit rights under Madaus’ agreements with sublicensees of Product to the extent that reports provided to Madaus by such sublicensees cover financial information that is required to be contained in a Section 6.3 Report. Accordingly, if Madaus exercises any such audit rights with respect to a specified period, it shall (a) use an independent certified public accounting firm of recognized standing; (b) notify Indevus in writing not later than ten (10) Business Days prior to the anticipated exercise of such planned exercise and of the name of the accounting firm (and, as soon as known to Madaus, the name of the individual(s) at such firm conducting such audit); (c) request, on behalf of Indevus, that such firm also review the information necessary to verify any financial information that is required to be contained in Section 6.3 Reports for the corresponding period; and (d) provide Indevus a copy of the portions of the results of any such audit that cover financial information contained in a Section 6.3 Report, subject to Indevus’ agreement to the confidentiality obligations contained in Madaus’ agreement with such sublicensee with respect to such audit.

Madaus shall not enter into a sublicense with respect to Product that is inconsistent with the foregoing sentence and, promptly after entering into any sublicense with respect to Product after the Effective Date, Madaus shall inform Indevus of Madaus’ audit rights under such sublicense agreement.

In the event that Madaus has not exercised such audit rights with respect to a specified period within thirty (30) days prior to the expiration thereof, Indevus shall have the right to request (by providing written notice of such request that is received by
Madaus not later than five (5) Business Days prior to the expiration thereof), that Madaus exercise such audit rights on Indevus’ behalf and at Indevus’ cost, in order to request relevant information necessary to verify any financial information contained in Section 6.3 Reports for the corresponding period. If so requested by Indevus, Madaus shall (a) exercise such audit right, (b) use good faith efforts to provide Indevus with direct access to the accounting firm conducting such audit, and (c) provide Indevus with a copy of the portions of the results of any such audit that cover financial information that should be contained in a Section 6.3 Report, subject to Indevus’ agreement to the confidentiality obligations contained in Madaus’ agreement with such sublicensee with respect to such audit. If as a result of any audit requested by Indevus under this paragraph, an error in favor of Indevus in the payment of Manufacturing Payments of more than the greater of (i) US$100,000 or (ii) ten percent (10%) of the Manufacturing Payments due hereunder for the period being reviewed is discovered, then the fees and expenses of the accounting firm shall be reimbursed by Madaus.

6.5. **Currency Conversion.** All payments to Indevus under this Agreement shall be made in United States dollars unless Indevus notifies Madaus at least five (5) Business Days before such payment is due that payments should be made in Euros. In the event a currency conversion is required, then (a) Section 6.2.1 Royalties and Section 6.2.2 Royalties shall be based on Net Sales first calculated in the currency in which sales took place and each of such amounts shall then be converted to United States Dollars on a monthly basis using the arithmetic averages of the closing conversion rates on the first and last Business Day of such month in the Calendar Quarter, as published by The Wall Street Journal, Eastern edition (if available), or any other publication as agreed to by the Parties, but in any event in accordance with GAAP; and (b) the Manufacturing Costs Cap and the Manufacturing Payment shall be converted from Euros to US Dollars based on the conversion rate on the last Business Day immediately preceding the due date for payment of Indevus Manufacturing Costs and the Manufacturing Payment, respectively, as offered by Deutsche Bank.

6.6. **Tax Withholding.** If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in Article V or Article VI, Indevus shall provide Madaus, prior to any such payment, annually or more frequently if required, with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary and, except as set forth in Section 6.1 and 6.2.2(b), Madaus shall make such withholding payments as required and subtract such withholding payments from the payments to Indevus required under this Agreement. Madaus shall submit appropriate proof to Indevus of payment of the withholding taxes within a reasonable period of time. Madaus will use efforts consistent with its usual business practices to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future taxation treaties or agreements between foreign countries, and Indevus shall cooperate with such efforts.

6.7. **Restrictions on Payment.** If by law, regulations or fiscal policy of a particular country, remittance of royalties in United States Dollars is restricted or forbidden, notice thereof will be promptly given to Indevus, and payment of the royalties shall be made by the

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
deposit thereof in local currency to the credit of Indevus in a recognized banking institution designated by Indevus. When in any country the law or regulations prohibit both the transmittal and deposit of royalties on sales in such a country, royalty payments shall be suspended for as long as such prohibition is in effect and as soon as such prohibition ceases to be in effect, all royalties that Madaus would have been under obligation to transmit or deposit but for the prohibition, shall forthwith be deposited or transmitted promptly to the extent allowable. Madaus will first obtain written agreement from Indevus before selling, directly or indirectly, Product in a country which restricts or forbids remittance of royalties to the United States.

ARTICLE VII
JOINT TERRITORY

7.1. Commercialization of Product in the Joint Territory. From time to time during the Term, the Parties shall meet and discuss a strategy for commercialization of the Product in countries in the Joint Territory.

7.1.1 Third Party Partner. If the Parties mutually determine that they wish to seek a Third Party partner for the commercialization of the Product in any country in the Joint Territory, then the Parties shall jointly engage in good faith discussions and negotiations relating to an agreement by and among the Parties and any mutually agreed potential Third Party partner. The Parties shall work together in good faith to negotiate and execute a commercialization agreement for the Product in the country(ies) in the Joint Territory with such Third Party partner on terms and conditions acceptable to both Parties, consistent with the terms set forth in Sections 7.2 and 7.4.1.

7.1.2 Unilateral Action. If within a reasonable period, only one Party determines to commercialize Product or to seek a Third Party partner or for the commercialization of the Product in any country in the Joint Territory and the other Party determines not to do so, then that first Party shall have the right to commercialize the Product or seek such a Third Party partner in such country. The other Party shall provide reasonable cooperation and support to the first Party in good faith in connection with such discussions and negotiations with the potential Third Party partner relating to any agreement with such Third Party, consistent with the terms set forth in Section 7.4.1. The Party determining not to commercialize the Product in a country may waive its rights to the benefits of the commercialization in that country and thereby avoid any obligation and duty to perform or be responsible for fifty percent (50%) of the commercialization obligations (including the Supernus Payments).

7.1.3 Joint Commercialization. If both Parties determine that they wish to jointly commercialize the Product in any country in the Joint Territory, then the Parties shall negotiate in good faith a collaboration agreement for the joint marketing and sale of the Product in the Joint Territory, including ownership of any import license (a “Collaboration Agreement”), consistent with the terms set forth in Sections 7.2, 7.4.1 and 7.4.2.
7.2. Supply of Product in the Joint Territory. In connection with any commercialization of Product in any country in the Joint Territory during the
Supply Term, Indevus shall have the exclusive right and responsibility for supplying Bulk Drug Product to Madaus and/or to any Third Party
commercialization partner under terms and conditions substantially identical to those set forth in Article V (including the second source
exception set forth in Section 5.3), except that (a) for purposes of any arrangement for supply of Bulk Drug Product for the Joint Territory, all
references in Article V to the “Madaus Territory” shall be deemed changed to and construed as the “Joint Territory”, mutatis mutandis, and
(b) assuming that in such country, each Party has the rights set forth in Section 7.4.1.

7.3. Joint Territory Agreements. Madaus represents and Indevus acknowledges that as of the Effective Date, Madaus is a party to the Joint Territory
Agreements and, to the extent any Joint Territory Agreement covers the commercialization of Product in any particular country in the Joint
Territory, the procedures set forth in Section 7.1 with respect to the commercialization of Product in such country shall be subject to Madaus’
obligations under such agreement. Notwithstanding the foregoing, as between the Parties, in any country in the Joint Territory subject to a Joint
Territory Agreement, the terms set forth in Section 7.4.1 shall apply.

7.4. Agreement Terms.

7.4.1 Except as otherwise set forth in this Article VII, in connection with any commercialization of Product in any country in the Joint
Territory, (i) each Party shall have the right to receive fifty percent (50%) of the marketing/licensing consideration (including license
fees, milestone payments, transfer price and/or supply price payments (excluding an amount equal to Indevus’ Manufacturing Costs),
royalties and/or other consideration payable by any such Third Party in connection with the grant of license or marketing rights
(including rights to use the Trademark or any trademark used by Madaus in the Madaus Territory, as applicable) to such Third Party, and
the duty to perform or be responsible for fifty percent (50%) of the commercialization obligations (including the Supernus Payments),
under any such agreement; and (ii) Indevus shall have the right to supply Bulk Drug Product required for commercialization of Product
in such country at a price equal to Indevus’ Manufacturing Costs at the time of such supply, which price and costs shall be based and
calculated in United States dollars.

7.4.2 Any Collaboration Agreement shall provide for (i) a means of determining which Party shall book the sales and distribute the
Product; (ii) the Parties’ respective development and commercialization activities with respect to the Product in such country in the
Joint Territory; and (iii) if required, each Party to grant the other Party and its Affiliates an exclusive (except as to such Party and its
Affiliates), license or sublicense in such country in the Joint Territory under, (A) if the granting Party is Madaus, the Madaus
Know−How or a Madaus trademark, or (B) if the granting Party is Indevus, the SANCTURA XR Patents, the Indevus Know−How, and
the Trademark, in each case, to use, sell, offer for sale and import
the Product in such country in the Joint Territory. The Collaboration Agreement shall also contain such further commercially reasonable and customary representations, warranties, covenants and agreements, satisfactory in form and substance to the Parties and their legal advisors, as are necessary or appropriate for transactions of this type.

ARTICLE VIII
CONFIDENTIALITY AND PUBLICITY

8.1. **Non-Disclosure and Non-Use Obligations.** All Proprietary Information disclosed by one Party to the other Party hereunder shall be maintained in confidence and shall not be disclosed to any Third Party or used for any purpose except as expressly permitted herein without the prior written consent of the Party that disclosed the Proprietary Information to the other Party during the Term of this Agreement and for a period of five (5) years thereafter. The foregoing non-disclosure and non-use obligations shall not apply to the extent that such Proprietary Information:

8.1.1 is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by business records;

8.1.2 is or becomes properly in the public domain or knowledge;

8.1.3 is subsequently disclosed to a receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or

8.1.4 is developed by the receiving Party independently of Proprietary Information received from the other Party, as documented by research and development records.

8.2. **Permitted Disclosure of Proprietary Information.** Notwithstanding Section 8.1, a Party receiving Proprietary Information of another Party may disclose such Proprietary Information:

8.2.1 to governmental or other regulatory agencies in order to obtain patents pursuant to this Agreement, or to gain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain such patents or authorizations;

8.2.2 by each of Madaus or Indevus to its respective agents, consultants, Affiliates, sublicensees and/or other Third Parties for the development and/or marketing of Product (or for such parties to determine their interests in performing such activities) on the condition that such Third Parties agree to be bound by the confidentiality obligations consistent with this Agreement; or

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
8.2.3 if required to be disclosed by law or court order, provided that notice is promptly delivered to the non-disclosing Party in order to provide an opportunity to challenge or limit the disclosure obligations.

8.3. Return of Proprietary Information. Subject to Indevus’ rights pursuant to Section 12.4.2, upon termination of this Agreement, the Party to which Proprietary Information has been disclosed pursuant to this Agreement shall, upon request, promptly return within thirty (30) days all such information, including any copies thereof, and cease its use or, at the request of the party transmitting such Proprietary Information, shall promptly destroy the same and certify such destruction to the transmitting party; except for a single copy thereof which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement.

8.4. Public Disclosure. Notwithstanding the provisions of this Article VIII, it is understood that the Parties may make disclosure of this Agreement and the terms hereof in any filings required by the SEC, other governmental authority or securities exchange, may file this Agreement as an exhibit to any filing with the SEC, other governmental authority or securities exchange, and may distribute any such filing in the ordinary course of its business. Except as set forth in this Agreement or as required by law, neither Party shall make any press release or other public announcement or other disclosure to a Third Party concerning the existence of or terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Each Party agrees to provide to the other Party a copy of any public announcement as soon as reasonably practicable under the circumstances prior to its scheduled release. Each party shall have the right to expeditiously (but in any event within twenty-four (24) hours of receipt) review any press release or announcement regarding this Agreement or the subject matter of this Agreement; provided, however, that such right of review shall only apply for the first time that specific information is to be disclosed, and shall not apply to the subsequent disclosure of substantially similar information that has previously been disclosed unless there have been material changes in the disclosure since the date of the previous disclosure.

8.5. Publications by Madaus. Madaus shall not submit for written or oral publication any manuscript, abstract or the like relating to Product without the prior approval of Indevus. If Madaus proposes to submit any such publication, it shall deliver the proposed publication or an outline of the oral disclosure at least fifteen (15) Business Days prior to planned submission or presentation. At the request of Indevus, the submission of such publication may be delayed, including so that any issues of patent protection may be addressed. In the absence of any such request, upon expiration of the applicable period referred to in this Section 8.5 Madaus shall be free to proceed with the publication or presentation. If Indevus requests modifications to the publication, Madaus shall so edit such publication, including to prevent disclosure of Proprietary Information, prior to submission of the publication or presentation. The contribution of each Party, if any, shall be noted in all publications or presentations by acknowledgment or co-authorship, whichever is appropriate.
ARTICLE IX
REPRESENTATIONS AND WARRANTIES

9.1. **General Representations.** Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

9.1.1 Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated;

9.1.2 Such Party has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and the execution, delivery and performance by such party of this Agreement have been duly authorized by all necessary corporate action;

9.1.3 This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms except as enforceability may be limited by (a) any applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor’s rights generally, or (b) general principles of equity, whether considered in a proceeding in equity or at law;

9.1.4 All necessary consents, approvals and authorizations of all governmental authorities and other persons required to be obtained by such Party in connection with this Agreement have been obtained; and

9.1.5 The execution and delivery of this Agreement and the performance of such Party’s obligations hereunder do not conflict with or violate any requirement of applicable laws or regulations or any judgment, injunction, decree, determination or award presently in effect having applicability to it.

9.2. **Indevus Representations and Warranties.** Indevus represents and warrants to Madaus that as of the Effective Date:

9.2.1 **Schedule 1.54** contains a complete and accurate list of the SANCTURA XR Patents; Indevus has not received any claims or notice of any challenges from Third Parties disputing the validity or enforceability of the SANCTURA XR Patents in the Madaus Territory; Indevus is not aware of any information relating to the institution or threatened institution of any interference, opposition, re-examination, reissue, revocation, nullification, or any litigation or official proceeding involving the SANCTURA XR Patents in the Madaus Territory;

9.2.2 Indevus has not received any notice alleging that the practice of the subject matter of the SANCTURA XR Patents in the Madaus Territory would infringe any Third Party patents;
9.2.3 Indevus has not granted to any Third Party any license or other rights to use the SANCTURA XR Patents in the Madaus Territory;

9.2.4 Indevus is not obligated under any agreement other than the Supernus Agreement to pay any Third Party any royalties in connection with or as a result of the use of the SANCTURA XR Patents with respect to Product in the Madaus Territory;

9.2.5 all Bulk Drug Product supplied by Indevus hereunder shall (i) meet the Specifications at the time of shipment to Madaus; and (ii) have been manufactured in conformance with cGMPs; and

9.2.6 the Supernus Agreement is in full force and effect and Indevus is not in default or breach in any material respect of the Supernus Agreement, nor has Indevus or any of its Affiliates received any notice of any defaults, breaches or violation thereunder.

9.3. THE LIMITED WARRANTIES SET FORTH IN THIS SECTION 9 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. INCLUDING ANY WARRANTY OF MERCHANTABILITY, WARRANTY OF NON-INFRINGEMENT AND ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. EXCEPT FOR THE WARRANTIES EXPRESSED IN THIS SECTION 9, NEITHER PARTY MAKES ANY OTHER WARRANTY, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE COMPOUND OR THE BULK DRUG PRODUCT.

ARTICLE X
INDEMNIFICATION AND INSURANCE

10.1. Indemnification by Indevus. Indevus will indemnify, defend and hold harmless Madaus, its Affiliates, directors, officers, employees, agents, successors, and assigns (each, a “Madaus Indemnitee”) from and against any and all Losses arising out of, attributable to or resulting from any claim, suit, action or proceedings (collectively, “Claims”) that are brought by a Third Party against a Madaus Indemnitee that are attributable to (i) any failure of Bulk Drug Product to conform to the Specifications; (ii) Indevus' negligence, recklessness or willful misconduct in exercising or performing any of its rights or obligations under this Agreement; or (iii) a breach by Indevus of any of its representations, warranties or covenants under this Agreement; provided, however, that Indevus shall not be obligated under this Section 10.1 to the extent any Claim arose out of (A) any failure of the quality of the Compound supplied by Madaus to Indevus, including any failure of such Compound to conform to the specifications thereof, (B) any Bulk Drug Product quantities which have been adulterated or otherwise mistreated by Madaus, (C) the processing of said Bulk Drug Product into finished product and/or the distribution and sale of said finished product in the Madaus Territory, (D) the negligence or wrongdoing on the part of Madaus, or (E) any breach by Madaus of any of its representations, warranties and/or covenants hereunder.
10.2. **Indemnification by Madaus.** Madaus shall indemnify, defend and hold harmless Indevus and its Affiliates, directors, officers, employees, agents, successors and assigns (each an "Indevus Indemnitee") from and against any and all Losses arising out of, attributable to or resulting from any Claims that are brought by a Third Party against an Indevus Indemnitee that are attributable to (i) any failure of Compound provided by Madaus under the [*] to conform to the Compound specifications; (ii) the development, use, marketing or sale of Product in the Madaus Territory; (iii) Madaus’ negligence, recklessness or willful misconduct in exercising or performing any of its rights or obligations under this Agreement; or (iv) a breach by Madaus of any of its representations, warranties or covenants under this Agreement; provided, however, that Madaus shall not be obligated under this Section 10.2 to the extent any Claim arose out of any (A) any failure of Bulk Drug Product to conform to the Specifications (except if the provisions of subsection (i) of this Section 10.2 are applicable), (B) the negligence or wrongdoing on the part of Indevus, or (C) any breach by Indevus of any of its representations, warranties and/or covenants hereunder.

10.3. **Indemnification by each Party.** In the event that negligence, recklessness or willful misconduct of both Indevus and Madaus is determined to have contributed to any such Losses, Indevus and Madaus will each indemnify and hold harmless the other with respect to that portion of the Losses attributable to its respective negligence, recklessness or willful misconduct.

10.4. **Procedure.** In the event that any Indemnitee intends to claim indemnification under this Article X, it shall promptly notify the other Party (the "Indemnitor") in writing of such Claim. Failure to provide prompt notice shall not relieve any Party of the duty to defend or indemnify unless such failure materially prejudices the defense of any matter. The Indemnitor shall have the sole right to control the defense and settlement thereof provided, however, that an Indemnitor shall not, without the written consent of the other Party, which shall not be unreasonably withheld, as part of any settlement or compromise (i) admit to liability on the part of the other Party; (ii) agree to an injunction against the other Party; or (iii) settle any matter in a manner that separately apportions fault to the other Party. The Parties shall have a reasonable opportunity to participate in decision-making with respect to the strategy of such defense, and shall reasonably cooperate with each other in connection with the implementation thereof. An Indemnitee shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any Claim without the prior written consent of the Indemnitor, which the Indemnitor shall not be required to give. Actions taken by the Indemnitor hereunder shall be without prejudice to the Indemnitor’s right to contest the Indemnitee’s right to indemnification and subject to refund in the event the Indemnitor is ultimately held not to be obligated to indemnify the Indemnitee.

10.5. **Insurance.** Each Party shall maintain, during the Term of this Agreement and for a period of five (5) years after any expiration or termination of this Agreement, a Commercial General Liability Insurance policy or policies (including coverage for Product Liability, Contractual Liability, Bodily Injury, Property Damage and Personal Injury), with minimum limits of [*] per occurrence and in the aggregate. Such insurance shall insure against all liability arising out of the manufacture, use, sale, or

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[*] CONFIDENTIAL TREATMENT REQUESTED
marketing of Product in the Madaus Territory. During the Term, each Party shall not permit such insurance to be reduced (other than by payment of Claims), expired or canceled without reasonable prior written notice to the other Party, unless outside of the control of the Party. In all cases prompt notification to the other Party of any redaction, cancellation or expiration of such insurance is required. Upon request each Party shall provide Certificates of Insurance to the other Party evidencing the coverage specified herein.

ARTICLE XI
PATENT MATTERS

11.1. Filing, Prosecution and Maintenance of Patents. As between the Parties, (a) Indevus shall retain sole ownership of the SANCTURA XR Patents and the Indevus Know−How and (b) Indevus shall have the sole right to file, prosecute and maintain the SANCTURA XR Patents. Indevus shall keep Madaus reasonably informed of all material matters relating to the filing, prosecution and maintenance of the SANCTURA XR Patents in the Madaus Territory and shall timely inform Madaus of any SANCTURA XR Patent issuing or granting from a patent application filed hereunder.

11.2. Patent Office Proceedings. Each Party shall inform the other Party of any request for, filing, or declaration of any proceeding before a patent office seeking to protest, oppose, cancel, reexamine, declare an interference proceeding, initiate a conflicts proceeding, or analogous process involving a patent application or patent included in the SANCTURA XR Patents of which it becomes aware in the Madaus Territory and the Joint Territory. Each Party thereafter shall cooperate with the other with respect to any such patent office proceeding by providing the other with reasonable information or assistance.

11.3. Third Party Infringement of SANCTURA XR Patents.

11.3.1 Each Party shall promptly give the other Party notice of any infringement or suspected infringement of any SANCTURA XR Patent by a Third Party in the Madaus Territory that comes to such Party’s attention. The Parties will thereafter consult and cooperate fully to determine a course of action, including, without limitation, the commencement of legal action by any Party.

11.3.2 Absent a mutual agreement, and subject to Supernus’ rights under the Supernus Agreement, Madaus shall have the first right, but not the obligation, to commence any form of action or take any such preliminary steps, as are necessary to terminate or prevent such infringement, to initiate and prosecute such legal action at its own expense and in the name of Indevus and Madaus, and/or to control the defense of any declaratory judgment action relating to SANCTURA XR Patents in the Madaus Territory. Madaus shall provide Indevus with notice of any such action it commences and apprise Indevus of any significant developments in the proceedings. Indevus shall reasonably cooperate with Madaus, including the joining of suit if necessary or desirable and executing all documents reasonably necessary for Madaus to prosecute, defend and maintain such action.

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Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
11.3.3 Madaus shall promptly inform Indevus if Madaus elects not to exercise such first right, and Indevus thereafter shall have the right either to initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of Indevus and, if necessary, Madaus. If Indevus elects to do so, the cost of any course of action, including the costs of any legal action commenced or any declaratory judgment action defended, shall be borne solely by Indevus, subject to the right to recover such costs pursuant to Section 11.3.5 hereof.

11.3.4 For any such legal action or defense, in the event that any Party is unable to initiate, prosecute, or defend such action solely in its own name, the other Party will join such action voluntarily and will execute all documents necessary for the Party to prosecute, defend and maintain such action. The Parties will cooperate with each other in the planning and execution of any such action and will provide each other with any information or assistance that either reasonably may request.

11.3.5 Any recovery obtained by Madaus or Indevus (whether by settlement or otherwise) shall be shared as follows:

(a) the Party that initiated and prosecuted, or maintained the defense of, the action shall recoup all of its costs and expenses (including attorneys’ fees) incurred in connection with the action;

(b) the other Party then shall, to the extent possible, recover its costs and expenses (including attorneys’ fees) incurred in connection with the action;

(c) if Indevus initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining shall be retained by Indevus; and

(d) if Madaus initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining shall be retained by Madaus, except that Indevus shall receive a portion equivalent to the royalties it would have received under Section 6.2 if such amount were deemed Net Sales.

11.4. **Conflict with Supernus Agreement.** To the extent that Indevus is not authorized under the Supernus Agreement to grant Madaus any of the rights set forth in this Article XI with respect to the filing, prosecution, maintenance and/or enforcement of any of the SANCTURA XR Patents, Madaus’ rights under this Article XI shall be limited to those which are permitted under such agreement in a manner to effectuate, to the greatest extent permitted, the intent and purposes of this Article XI, provided however, the foregoing limitation shall not apply as to loss of authorization under the Supernus Agreement resulting from a termination of the Supernus Agreement due to a breach of that agreement by Indevus (unless Madaus has breached this Agreement).
11.5. **Patent Marking.** Madaus shall mark, and to require its Affiliates and their Marketing Distributors to mark, all Product sold or distributed pursuant to this Agreement in accordance with the applicable patent statutes or regulations in the country or countries of manufacture and/or sale thereof.

11.6. **Ownership of New Inventions.** During the Term, except as otherwise provided in and subject to the terms of this Agreement,

11.6.1 As between the Parties, Indevus shall own and retain all rights, title and interest in all inventions, improvements, discoveries and know-how covering Product, including any Indevus Know-How, which are made, conceived, reduced to practice or generated during the Term solely by Indevus’ employees, agents, or other persons acting under its authority, subject to the license granted to Madaus under this Agreement with respect to the Madaus Territory, and shall have the sole right, at its option and expense, to file, prosecute and maintain any patent application or patent claiming such invention; and

11.6.2 As between the Parties, Madaus shall own and retain all rights, title and interest in all inventions, improvements, discoveries and know-how covering Product, including any Madaus Know-How, which are made, conceived, reduced to practice or generated during the Term solely by Madaus’ employees, agents, or other persons acting under its authority, subject to the license granted to Indevus under the Madaus License, and shall have the sole right, at its option and expense, to file, prosecute and maintain any patent application or patent claiming such invention.

11.6.3 As between the Parties, they shall each, as to their respective territories (the Madaus Territory or the Indevus Territory, as the case may be) have full rights, title and interest in all inventions, improvements, discoveries and know-how covering Product, including Know-How, which are jointly made, conceived, reduced to practice or generated during the Term by employees or agents of both of them, or other persons acting under the authority of both Madaus and Indevus. Madaus shall have the sole right, at its option and expense, to file, prosecute and maintain any patent application or patent claiming such invention in the Madaus Territory and Indevus shall have such right in the Indevus Territory. As to Joint Territory, rights shall be determined pursuant to Article VII.

**ARTICLE XII**

**TERM AND TERMINATION**

12.1. **Term and Expiration.** This Agreement shall be effective as of the Effective Date and, except as set forth in the next sentence or unless terminated earlier under Section 12.2,
the term of this Agreement shall extend for a period (the “Term”) which shall expire and terminate, on a country–by country basis, on the expiration of all royalty obligations with respect to such country under Section 6.2. Upon expiration of the royalty obligations with respect to a Product in a country hereunder, Madaus’ license to such Product pursuant to Section 2.1 and Trademark pursuant to Section 3.1.2 shall become a fully paid-up, perpetual license with respect to that country, subject to any other payment obligations hereunder, including any Manufacturing Payments or Supply Price payments. Notwithstanding the foregoing, the rights and obligations relating to manufacture and supply of Bulk Drug Product set forth herein, and the provisions of Article V, shall expire and terminate effective upon termination of Indevus’ first agreement with a Third Party manufacturer for the production of Bulk Drug Product entered into after the Effective Date (unless earlier terminated under Section 12.2, in which case it shall terminate then) (the “Initial Supply Term”), provided, however, that Indevus may elect to extend the Initial Supply Term for additional one (1)–year periods (each, a “Renewal Supply Term”) by providing written election thereof to Madaus not later than one (1) year prior to the expiration of the Initial Supply Term or any Renewal Supply Term. Unless mutually agreed to by the Parties, any then current Renewal Supply Term shall terminate on the expiration of the Manufacturing Payment Term. Furthermore, no Renewal Supply Term shall commence after a second source has been named pursuant to Section 5.4.2(a).

12.2. Termination.

12.2.1 Termination of Agreement for Cause. Either Party may terminate this Agreement by notice to the other Party at any time during the Term as follows:

(a) if the other Party is in breach of any material obligation hereunder, by causes and reasons within its control, and has not cured such breach within sixty (60) days after notice requesting cure of the breach, provided, however, that if the breach is not capable of being cured within sixty (60) days of such written notice, the Agreement may not be terminated so long as the breaching Party commences and is taking commercially reasonable actions to cure such breach as promptly as practicable; or

(b) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if the Party consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof.

12.2.2 Termination of Supply Term. Indevus shall have the right to terminate the Supply Term at any time by giving thirty (30) days’ written notice to Madaus, if the FDA or any other Regulatory Authority takes any action which would prohibit or materially restrict the manufacture, sale or use of Product or if the Product is otherwise withdrawn from the market in the United States. Under such circumstances, Madaus has the rights under Section 5.3.
12.3. **Discontinuation of Sales.** If Madaus or any sublicensee after having launched a Product in any country in the Madaus Territory discontinues sale of the Product in such country for a period of six (6) months or more for reasons unrelated to Force Majeure, regulatory or safety issues, Madaus shall immediately notify Indevus in writing and if Madaus subsequently fails to resume sales of any Product in such country within forty-five (45) days of having been notified in writing of such failure by Indevus, then Indevus may terminate the license granted to Madaus under Section 2.1 of this Agreement solely with respect to such country forthwith by giving notice in writing to Madaus. For the purpose of this Section 12.3, sales of minimal, commercially insignificant quantities of Product in a country shall be deemed to constitute a discontinuation of sales in such country.

12.4. **Effect of Expiration or Termination.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination.

12.4.1 **Outstanding Payment.** Payments of amounts owing to Indevus under this Agreement as of its expiration or termination shall be due and payable within the later of (i) to the extent such amounts can be calculated and a fixed sum determined at the time of expiration or termination of this Agreement, thirty (30) after the date of such expiration or termination, or (ii) ten (10) days after the date in which such amounts can be calculated and a fixed sum determined.

12.4.2 **Termination in Particular Countries.** In the event (a) Indevus exercises its right to terminate this Agreement with respect to any country(ies) in the Madaus Territory as provided by Section 4.7.3 or 12.3, or (b) Madaus gives up its rights with respect to Product in any country(ies) as provided by Section 4.7.6 then, effective immediately upon either such event, (i) all of Madaus’ rights, licenses and sublicenses hereunder shall automatically terminate with respect to such country(ies); (ii) such country(ies) shall no longer be included in the “Madaus Territory”; and (iii) Indevus shall have the exclusive right and license to use any and all Madaus Know–How, including the right to use and reference all MAAs, regulatory submissions and Regulatory Approvals in such country(ies), and, if required, Madaus shall transfer to Indevus ownership of any of such MAAs, regulatory submissions or Regulatory Approvals in such country.

12.4.3 **Sale of Remaining Inventory.** Upon termination of this Agreement (but not its expiration), Madaus shall notify Indevus of the amount of Product Madaus, its Affiliates and their Marketing Distributors then have on hand or have committed to purchase or sell. For a period ending upon the earlier of: (i) Madaus’, its Affiliates’ and their Marketing Distributors’ sale of all Product in their possession on the date of termination of this Agreement, or (ii) within the six (6) month period following such termination (the “Trailing Period”), Madaus, its Affiliates and their Marketing Distributors shall be permitted to sell all such Product and Indevus hereby grants a non–exclusive license reasonably necessary to sell such Product, subject to the payment of

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
Manufacturing Payments and royalties, at the same rates and on the same terms and conditions as the royalties set forth in Section 6.2.2, on any Net Sales of such Product; provided, however, that, in the event Madaus has Bulk Drug Product in inventory not committed to filling existing orders, Indevus shall have the right to purchase such Bulk Drug Product from Madaus at a price equal to Indevus’ Manufacturing Cost applicable to such Bulk Drug Product. Any remaining quantities of Product not sold during the Trailing Period shall be destroyed by Madaus at Madaus’ cost.

12.4.4 Survival. In addition to any other provisions of this Agreement which by their terms continue after the expiration of this Agreement, the provisions of Article VIII shall survive the expiration or termination of this Agreement and shall continue in effect for five (5) years from the date of expiration or termination. In addition, any other provision required to interpret and enforce the Parties’ rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement.

12.4.5 Non−Exclusive Right. Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity, or otherwise.

ARTICLE XIII
MISCELLANEOUS

13.1. Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement during the period of time when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, fire, flood, embargo, war, acts of war (whether war be declared or not), terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, factory shutdowns, failure of public utilities or common carriers, act of God or act, omission or delay in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practicable.

13.2. Assignment. Neither this Agreement nor any interest hereunder may be assigned or otherwise transferred without the prior written consent of the other Party; provided, however, that (a) Indevus may assign this Agreement to an Affiliate or in connection with the transfer or sale of its business or all or substantially all of its assets related to Product or in the event of a merger, consolidation, change in control or similar corporate transaction; and (b) Madaus may assign this Agreement to an Affiliate or in connection with the transfer or sale of its business or all or substantially all of its assets or in the event of a merger, consolidation, change in control or similar corporate transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement provided that in the case of an assignment to an Affiliate, the assigning Party shall remain fully liable thereon.

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
13.3. **Severability.** In the event that any of the provisions contained in this Agreement are held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affect the substantive rights of the Parties. In such event, the Parties shall replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

13.4. **Notices.** All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

   if to Madaus to:
   
   MADAUS GmbH
   Colonia–Allee 15
   51067 Cologne, Germany
   Attention: Geschaeftsfuehrung
   Fax No.: 011 49 221 8998 759

   if to Indevus to:
   
   Indevus Pharmaceuticals, Inc.
   33 Hayden Avenue
   Lexington, MA 02421
   Attention: Chief Executive Officer
   Fax No.: 781–862–3859

   or to such other address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered or sent by facsimile on a Business Day, upon confirmed delivery by nationally−recognized overnight courier if so delivered and on the third Business Day following the date of mailing if sent by registered or certified mail.

13.5. **Applicable Law.** The Agreement shall be governed by and construed in accordance with the laws of the United States of America and State of Delaware without reference to any rules of conflict of laws.

13.6. **Dispute Resolution**

   13.6.1 The parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement, including any
dispute relating to breach, termination or validity of this Agreement (a “Dispute”) by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within twenty (20) Business Days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of each Party. Such Chief Executive Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within twenty (20) Business Days after such notice is received by the Party to whom the notice was sent. If the Chief Executive Officers are unable to settle the Dispute between themselves within twenty (20) Business Days, they shall so report to the parties in writing. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

13.6.2 Any Dispute which has not been resolved by negotiation as provided in sub-section 13.6.1 within twenty (20) Business Days, shall be finally resolved by arbitration in accordance with the rules of arbitration of the International Chamber of Commerce (“ICC”). Each such arbitration shall be conducted by a panel of three arbitrators with experience in the pharmaceutical industry: one arbitrator shall be appointed by each of Indevus and Madaus and the third shall be appointed by the ICC. Any such arbitration shall be held in London, England. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be.

13.6.3 In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the mediation and arbitration levied by the ICC.

13.6.4 Any arbitration proceeding entered into pursuant to this Section 13.6 shall be conducted in the English language. Subject to the foregoing, for purposes of this Agreement, each Party consents, for itself and its Affiliates, to the jurisdiction of the courts of the State of New York, county of New York and the U.S. District Court for the Southern District of New York.

13.7. Entire Agreement. This Agreement, together with the Schedules and Exhibits hereto, the Amendment and Agreement, and the Supernus Side Agreement contain the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly merged in and made a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by all Parties hereto.

13.8. Independent Contractors. It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of such other Party.

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
13.9. **Waiver.** The waiver by a Party hereto of any right hereunder or the failure to perform or of a breach by another Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

13.10. **Headings.** The captions to the several Articles and Sections hereof are not a part of the Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

13.11. **Counterparts.** The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.12. **Use of Names.** Except as otherwise provided in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the consent of such other Party, which consent shall not be unreasonably withheld or delayed; provided, however, that either Party may use the name of the other Party in any document required to comply with applicable laws, rules or regulations.

13.13. **LIMITATION OF LIABILITY.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Glenn L. Cooper, M.D.
Name: Glenn L. Cooper, M.D.
Title: Chairman and Chief Executive Officer

MADAUS GmbH

By: /s/ Dr. Kurt N. Gebhart
Name: Dr. Kurt N. Gebhart
Title: Geschäftsführer

By: /s/ Dr. Ing. Freddy Santermans
Name: Dr. Ing. Freddy Santermans
Title: Geschäftsführer
SCHEDULE 1.10
CURRENT MADAUS PRODUCTS

**Dosage Forms**
- 5 mg. tablets
- 10 mg. tablets
- 20 mg. tablets
- 30 mg. tablets

**Sold under different brands including:**
- Spasmo-lyt
- Spasmo-Urgenin
- Spasmo-Urgenin Neo
- Spasmo-lyt Plus
- Spasmoplex
- Trosec
- Urplex
- Ceris
- Uricon
- Urplex

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
1. Costs payable to Third Parties for the procurement, supply and manufacturing of Compound and Bulk Drug Product, including (a) costs associated with the purchase of Compound and/or the purchase of Bulk Drug Product from any Third Party manufacturer during the Supply Term; (b) costs associated with the procurement of other raw materials and packaging components; (c) any other costs associated with Compound or Bulk Drug Product, or processing thereof, including analytical and stability testing, inspection, releasing, handling, warehousing, storage, packing, and transportation of Compound or Bulk Drug Product at all stages; and (d) FDA establishment fees charged by Third Party manufacturers.

2. Costs payable to Third Parties for the transport, delivery, customs clearance, and storage of Compound and Bulk Drug Product (including shipping/freight, export/import fees, taxes and duties) in accordance with Section 5.7.

3. Costs payable to the FDA as annual FDA fees (e.g., establishment fees and product fees).

4. Personnel costs, including salaries and benefits, consulting and outside contractor fees and expenses, and travel expenses, relating to managing the supply chain, regulatory audits and ensuring quality and regulatory compliance of Bulk Drug Product, and insurance (for loss or destruction of product), storage and warehousing.

5. Product liability insurance costs.

Indevus’ Manufacturing Costs will be determined using cost accounting methods in accordance with GAAP. Costs referred to in 3. and 4. above that are expected to be incurred during a production year will – except as otherwise hereinafter provided—be allocated on a per capsule basis, subject to a year-end true-up based on the actual production of capsules during a production year. Indevus will provide Madaus with a report of any such year-end adjustment within sixty (60) Business Days after the end of each production year. Product liability insurance costs will be allocated based on actual costs, giving effect to premium adjustments during the production year, associated with coverage relating to the Madaus Territory. Any payment due or from Madaus as a result of any such adjustments shall be credited against or added to the next payment required to be made by Madaus hereunder or, if such adjustment is made after termination or expiration of this Agreement, shall be paid by the applicable Party within thirty (30) days after receipt by Madaus of such report.

An example, for illustrative purposes only, is set forth on the following Schedule 1.26 (A):

[*]  CONFIDENTIAL TREATMENT REQUESTED
SCHEDULE 1.30
JOINT TERRITORY AGREEMENTS

Bukwang Pharmaceutical Inc. Co., Ltd. (Korea)
Nippon Chemiphar Co., Ltd. (Japan)
Oryx Pharmaceuticals, Inc. (Canada)

Wuhan Weiao Pharmaceutical Company Limited and Beshabar (Macao Commercial Offshore) Ltd (China)
INDEVUS:
Bobby W. Sandage, Jr., Ph.D.
Executive Vice President− Research and Development

Andreas Woppmann, Ph.D.
Vice President, Chemistry, Manufacturing and Quality

MADAUS:
Dr. Ing. Freddy Santermans
Geschäftsführer (General Manager)
MADAUS GmbH

Dr. med. Ralf T. Pohl
Geschäftsführer (General Manager)
MADAUS Research GmbH
[*]  CONFIDENTIAL TREATMENT REQUESTED
QUALITY MATTERS

[*] CONFIDENTIAL TREATMENT REQUESTED
THIS AMENDMENT AND AGREEMENT (“Amendment”) is made as of November 3, 2006 (“Amendment Effective Date”) by and between Indevus Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 33 Hayden Avenue, Lexington, MA 02421, United States (“Indevus”), and Madaus GmbH, a successor to Madaus AG, a company with limited liability organized and existing under the laws of Germany and having its principal office at Colonia–Allee 15, 51067 Cologne, Germany (“Madaus”). Indevus and Madaus are collectively referred to herein as the “Parties”.

W I T N E S S E T H:

WHEREAS, on November 26, 1999, Madaus and Indevus entered into a license agreement granting Indevus an exclusive license under the Madaus Know−How in the Territory, on the terms and conditions set forth therein, as amended in Amendment No. 1 thereto mutually executed by the Parties on January 19, 2004 (the “Agreement”);

WHEREAS, the Parties agree that certain provisions of the Agreement should be amended to reflect the current intentions of the Parties with respect to such license, and that it is in their mutual best interests to resolve and compromise amicably any actual or potential disputes and to avoid future disputes arising under the Agreement, and to provide for certain additional agreements between the Parties; and

WHEREAS, contemporaneously with this Amendment, the Parties are entering into the License and Supply Agreement (as defined herein).

NOW, THEREFORE, in consideration of the premises contained herein, and for other good and valuable consideration, the adequacy and receipt of which are hereby acknowledged, the Parties hereto intending to be legally bound agree as follows:

1. Definitions and References.

Except as set forth herein, capitalized terms not otherwise defined or amended in this Amendment shall have the meaning ascribed to them in the Agreement. Where words and phrases are used herein in the singular, such usage is intended to include the plural forms where appropriate to the context, and vice versa. The words “including”, “includes” and “such as” are used in their non-limiting sense and have the same meaning as “including without limitation” and “including but not limited to”. Except as otherwise indicated, references to Articles or
2. Amendments to the Agreement. The Agreement is hereby amended as of the Amendment Effective Date as set forth in this Paragraph 2 of this Amendment:

(a) The following new Sections are hereby added to Article 1 of the Agreement:

1.27 “Additional Payment” shall have the meaning set forth in Section 3.7.
1.28 “Amendment” shall mean the Amendment and Agreement by and between Madaus and Indevus dated November 3, 2006.
1.29 “Compound Supply Agreement” shall mean the Compound Supply Agreement by and between Madaus and Indevus dated November 3, 2006.
1.30 “Excluded Licensed Product” shall have the meaning set forth in Paragraph 2(f) of the Amendment.
1.31 “Joint Territory” shall mean Canada, Japan, Korea and China.
1.32 “License and Supply Agreement” shall mean that certain License and Supply Agreement between Madaus and Indevus effective as of November 3, 2006.
1.33 “Madaus Territory” shall mean worldwide, excluding the Territory and the Joint Territory.
1.34 “SANCTURA®” shall mean the 20 mg. dosage oral formulation of Compound marketed on the Amendment Effective Date in the Territory under the tradename SANCTURA® for twice−daily administration for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and/or urinary frequency.
1.35 “SANCTURA XR™” shall mean a controlled or extended−release oral formulation of Compound which is intended to be administered once a day, for the treatment of overactive bladder and/or urinary incontinence.
1.36 “Supply Agreement” shall mean the Supply Agreement by and between Madaus and Indevus dated as of December 16, 2002.

(b) The following sentence is added to the end of Section 1.17 of the Agreement: “Any product (other than an Excluded Licensed Product) which contains Compound as at least one active ingredient shall also be a “Licensed Product.” The following sentence is added to the end of Section 1.20 of the Agreement: “The First Commercial Sale of SANCTURA® occurred on August 23, 2004.”

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
(c) The last two sentences of Section 2.2 of the Agreement are hereby amended and restated to read in their entirety as follows:

“Indevus hereby grants to Madaus the right to use Indevus’ clinical and preclinical data relating to Compound or Licensed Product (other than a Licensed Product that (i) is a pulmonary inhalation product, or (ii) is an oral liquid formulation intended for pediatric or elderly use in overactive bladder, incontinence or detrusor instability) for Madaus’ own regulatory filings relating to the development and marketing of Compound or such Licensed Product or both outside the Territory. In addition, it is agreed and understood that after the applicable Distribution Period, Madaus shall have the right to make, have made, use, and sell Compound and/or Licensed Product (other than a Licensed Product that (i) is a pulmonary inhalation product, or (ii) is an oral liquid formulation intended for pediatric or elderly use in overactive bladder, incontinence or detrusor instability) in the Territory, by itself or through an Affiliate, using Indevus’ clinical and preclinical data relating to Compound or such Licensed Product in regard to Indevus’ regulatory filing.”

(d) Madaus hereby waives and terminates any and all rights to consent to any sublicense of Licensed Product. In accordance with the foregoing, Section 2.3(a) of the Agreement is hereby amended and restated in its entirety to read as follows:

“(a) Indevus shall have the right to issue sublicenses to Third Parties to make, have made, use, develop, import, offer for sale, sell or have sold the Licensed Product in the Territory as long as Indevus has rights thereto under this Agreement provided, however, that Indevus shall remain responsible for the performance by the sublicensee of any of Indevus’ obligations to Madaus under this Agreement.”

(e) The Parties acknowledge that (i) SANCTURA® is, and assuming First Commercial Sale of SANCTURA XR™, SANCTURA XR™ will be, a Licensed Product; (ii) it is possible that there may be additional Licensed Products during the term of the Agreement; and (iii) each Licensed Product has its own First Commercial Sale date and Distribution Period.

(f) Madaus hereby waives and terminates any and all rights to manufacture and/or supply (i) SANCTURA XR™; (ii) any Licensed Product that (A) is a pulmonary inhalation product or (B) is in an oral liquid formulation intended for pediatric or elderly use in overactive bladder, incontinence or detrusor instability; and/or (iii) with respect to any Licensed Product sold after November 12, 2007, Compound (each of the Licensed Products set forth in (i), (ii) and (iii), an “Excluded Licensed Product”). In consideration thereof, Indevus agrees to make the payments to Madaus set forth in Section 3.7(b)(ii) of the Agreement (as amended by this Amendment). Section 3.7 of the Agreement is hereby amended and restated in its entirety to read as follows:
3.7 Manufacturing.

(a) Licensed Products other than Excluded Licensed Products.

(i) Subject to the terms and conditions of this Section 3.7, Indevus accepts Madaus as exclusive manufacturer during the respective Distribution Periods of (A) SANCTURA® (also subject to the terms and conditions of the Supply Agreement), and (B) any other Licensed Product that is not an Excluded Licensed Product; provided that Madaus’ manufacturing facility is in compliance with cGMP and all other regulatory requirements in the Territory including successful regulatory inspection of any such facility.

(ii) Indevus reserves the right to appoint a second source supplier of a Licensed Product subject to Section 3.7 (a) if Madaus fails after reasonable prior written notice (a) to meet the regulatory requirements with respect to production of such Licensed Product or (b) is unable to deliver such Licensed Product in quantities which satisfy Indevus’ reasonable commercial requirements for that Licensed Product. If Indevus appoints a second source supplier pursuant to the immediately preceding sentence, Madaus has the right to receive an adequate royalty, not to exceed [*] of net sales, for giving such a manufacturing license relying on Madaus Know−How. With respect to any such Licensed Product manufactured by any such second source supplier and sold by Indevus or its designees prior to November 12, 2007, such Licensed Product will be manufactured using Compound supplied by Madaus and purchased by Indevus pursuant to the Compound Supply Agreement, provided that the Parties acknowledge and agree that the price for such Compound is not expected to exceed [*] 

(b) SANCTURA XR™.

(i) Subject to Section 3.7(c), Indevus or its designees shall have the exclusive right to manufacture and supply SANCTURA XR™ for use in the Territory, the Madaus Territory and the Joint Territory, whether as bulk drug product or as finished product.

(ii) Indevus shall pay Madaus an amount equal to [*] capsules of SANCTURA XR™ sold in the Territory through [*] (the “Additional Payment”). The payment of the Additional Payment shall be subject to the following:

(A) No Additional Payment shall accrue on the disposition of SANCTURA XR™ by Indevus, its Affiliates or sublicensees as samples (promotion or otherwise), for development, testing, clinical trials or as donations (for example, to non−profit institutions or government agencies for non−commercial purposes);

(B) The Additional Payment shall be reduced by the amount, if any, by which the cost to Indevus of obtaining Compound from Madaus pursuant to Section 3.7(c) and the Compound Supply Agreement exceeds the cost at which a Third Party supplier has agreed to supply Indevus with Compound;

(C) The Additional Payment shall be payable in accordance with the provisions of Section 5.3;

(D) No Additional Payment shall be payable with respect to any period after the first Calendar Quarter in which generic formulations of SANCTURA XR™ achieve a market share of [*] or greater of the total prescriptions for SANCTURA XR™ in the Territory (as so shown by IMS (or IMS equivalent) data for such prescriptions in that Calendar Quarter);

[*/] CONFIDENTIAL TREATMENT REQUESTED
(E) If, during any portion of any Renewal Supply Term that expires prior to the expiration of the Manufacturing Payment Term, Indevus’ Manufacturing Costs exceed the Manufacturing Costs Cap, then the Additional Payment shall be reduced by the amount by which Indevus’ Manufacturing Costs exceed the Manufacturing Costs Cap. With the exception of the term “Additional Payment”, all capitalized terms used in this subsection (E) shall have the respective meanings ascribed to them in the License and Supply Agreement (which definitions are incorporated by reference herein); and

(F) Sales of SANCTURA XR™ capsules between Indevus and its Affiliates or licensees or sublicensees, or among such Affiliates and licensees or sublicensees, shall not be considered sales of SANCTURA XR™ capsules for purposes of calculating the Additional Payment, but in such cases the Additional Payment shall be calculated based on the number of SANCTURA XR™ capsules sold by such Affiliates or licensees or sublicensees to Third Parties who are not an Indevus licensee or sublicensee.

(c) Compound. Subject to the terms and conditions of the Compound Supply Agreement, Indevus or its designees will use Compound supplied by Madaus and obtained by Madaus from [*] or its Affiliates or successors in connection with the manufacture of SANCTURA XR™ that is sold by Indevus or its designees prior to November 12, 2007.

(g) Section 5.3 of the Agreement is hereby amended and restated in its entirety to read as follows:

“5.3 Reports; Payment of Royalties and Additional Payment. Following the First Commercial Sale of a Licensed Product and during the term of the Agreement for so long as royalty payments or Additional Payments are due, Indevus shall furnish to Madaus a quarterly written report for the Calendar Quarter (a “Section 5.3 Report”) showing, as applicable, (a) the sales of all Licensed Products subject to royalty payments (i.e. not SANCTURA XR™, which is covered in (b)) sold by Indevus, its Affiliates and its sublicensees in the Territory during the Calendar Quarter (and a reconciliation of gross sales to Net Sales) and the royalties payable under this Agreement; and (b) the number of capsules of SANCTURA XR™ sold in the Territory during the Calendar Quarter by Indevus, its Affiliates and its licensees or sublicensees subject to an Additional Payment payable under this Agreement and a calculation of the Additional Payment payable under this Agreement. Section 5.3 Reports shall be due on the [*] following the close of each Calendar Quarter. Royalties and Additional Payments shown to have accrued by each Section 5.3 Report, if any, shall be due and payable on the date such report is due. Indevus shall keep complete and accurate records in sufficient detail to enable the royalties and the Additional Payment payable hereunder to be determined.

[*] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
Indevus recognizes that Madaus has an interest in Indevus’ audit rights under Indevus’ agreements with sublicensees of Licensed Product to the extent that reports provided to Indevus by such sublicensees cover financial information that is required to be contained in a Section 5.3 Report. Accordingly, if Indevus exercises any such audit rights with respect to a specified period, it shall (a) use an independent certified public accounting firm of recognized standing; (b) notify Madaus in writing not later than [*] Business Days prior to the anticipated exercise of such planned exercise and of the name of the accounting firm (and, as soon as known to Indevus, the name of the individual(s) at such firm conducting such audit); (c) request, on behalf of Madaus, that such firm also review, to the extent consistent with contractual rights and restrictions existing on the Amendment Effective Date, the information necessary to verify any financial information that is required to be contained in Section 5.3 Reports for the corresponding period; and (d) provide Madaus a copy of the portions of the results of any such audit that cover financial information contained in a Section 5.3 Report, subject to Madaus’ agreement to the confidentiality obligations contained in Indevus’ agreement with such sublicensee with respect to such audit.

Indevus shall not enter into a sublicense with respect to a Licensed Product that is inconsistent with the foregoing sentence and, promptly after entering into any sublicense with respect to Licensed Product after the Amendment Effective Date, Indevus shall inform Madaus of Indevus’ audit rights under such sublicense agreement.

Subject to contractual rights and restrictions existing on the Amendment Effective Date, in the event that Indevus has not exercised such audit rights with respect to a specified period within thirty (30) days prior to the expiration thereof, Madaus shall have the right to request (by providing written notice of such request that is received by Indevus not later than five (5) Business Days prior to the expiration thereof), that Indevus exercise such audit rights on Madaus’ behalf and at Madaus’ cost, in order to request relevant information necessary to verify any financial information contained in Section 5.3 Reports for the corresponding period. If so requested by Madaus, Indevus shall to the extent consistent with contractual rights and restrictions existing on the Amendment Effective Date, (a) exercise such audit right, (b) use good faith efforts to provide Madaus with direct contact to the accounting firm conducting such audit and (c) provide Madaus with a copy of the portions of the results of any such audit that cover financial information that should be contained in a Section 5.3 Report, subject to Madaus’ agreement to the confidentiality obligations contained in Indevus’ agreement with such sublicensee with respect to such audit. If as a result of any audit requested by Madaus under this paragraph, an error in favor of Madaus in the payment of Additional Payments of [*] of the Additional Payments due hereunder for the period being reviewed is discovered, then the fees and expenses of the accounting firm shall be reimbursed by Indevus.”


(a) Release by Indevus. Indevus, on its own behalf and on behalf of its Affiliates, predecessors, successors, and assigns and all others claiming by or through any of the foregoing (collectively, the “Indevus Parties”), hereby releases and forever discharges Madaus,
its Affiliates and their respective assigns, attorneys, agents, legal representatives, officers, directors, employees, predecessors, successors, distributors, manufacturers and Affiliates (collectively, the “Madaus Releases”) from any and all claims, causes of action, actions, duties, rights, damages, liabilities, losses, and obligations of every kind and manner whatsoever, in law or in equity, judicial or administrative, civil or criminal, whether or not now known, claimed or asserted, which any Indevus Party now has, had at any time or may in the future claim to have, against any of the Madaus Releasees based on, arising out of or related to the Agreement or the Supply Agreement and arising from or relating to any actions, omissions, or events prior to the Amendment Effective Date. provided, however, that the foregoing release shall not include, and Indevus shall retain, all claims, causes of action, actions, duties, rights, damages, liabilities, losses, or obligations (a) arising out of or under this Amendment, or (b) that are outstanding payment and/or supply or delivery obligations that have accrued under the Agreement or the Supply Agreement in the ordinary course of business (i) during the Calendar Quarter ended September 30, 2006 or (ii) commencing October 1, 2006 through the Amendment Effective Date.

(b) Release by Madaus. Madaus, on its own behalf and on behalf of its Affiliates, predecessors, successors, and assigns and all others claiming by or through any of the foregoing (collectively, the “Madaus Parties”) hereby releases and forever discharges the Indevus Parties and their respective assigns, attorneys, agents, legal representatives, officers, directors, employees, predecessors, successors, distributors, manufacturers and Affiliates (collectively, the “Indevus Releasees”) from any and all claims, causes of action, actions, duties, rights, damages, liabilities, losses, and obligations of every kind and manner whatsoever, in law or in equity, judicial or administrative, civil or criminal, whether or not now known, claimed or asserted, which any Madaus Party now has, had at any time or may in the future claim to have, against any of the Indevus Releasees based on, arising out of or related to the Agreement or the Supply Agreement and arising from any actions, omissions, or events prior to the Amendment Effective Date, provided, however, that the foregoing release shall not include, and Madaus shall retain, all claims, causes of action, actions, duties, rights, damages, liabilities, losses, or obligations (a) arising out of or under this Amendment, or (b) that are outstanding payment and/or supply or delivery obligations that have accrued in the ordinary course of business under the Agreement or the Supply Agreement (i) during the Calendar Quarter ended September 30, 2006 or (ii) commencing October 1, 2006 through the Amendment Effective Date.

4. Representations and Warranties. Each Party hereby represents and warrants to the other Party that:

(a) Such Party has the requisite corporate power and authority to execute and deliver this Amendment and to grant the releases and perform its other obligations hereunder; the execution, delivery and performance of this Amendment have been duly and validly authorized and no other corporate proceedings are necessary to authorize this Amendment or the performance hereof or thereof by such Party; and

(b) This Amendment has been duly and validly executed and delivered by such Party and, assuming due execution and delivery by the other Party, constitute the valid and binding obligations of such Party, enforceable against such Party in accordance with its terms.
5. Other.

(a) From and after the Amendment Effective Date all references to the Agreement shall mean the Agreement as amended by this Amendment. Except as expressly amended by this Amendment, all of the provisions of the Agreement shall remain in full force and effect.

(b) This Amendment may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

(c) This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware without reference to any rules of conflict of laws.

(d) All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by facsimile transmission (and promptly confirmed by personal delivery, registered or certified mail or overnight courier) or by registered or certified mail, return receipt requested, postage prepaid, or sent by internationally-recognized overnight courier, in each case to the respective address specified below, or such other address as may be specified in writing to the other party hereto:

if to Indevus to:

INDEVUS PHARMACEUTICALS, INC.
33 Hayden Avenue
Lexington, MA 02421

Attention: Chief Executive Officer
Fax No.: 781–862–3859

if to Madaus to:

MADAUS GmbH
Colonia-Allee 15
51067 Cologne, Germany

Attention: Geschäftsführung
Fax No.: 011 49 221 8998 759

[remainder of page intentionally left blank]
IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date first set forth above.

**Indevus Pharmaceuticals, Inc.**

By: /s/ Glenn L. Cooper, M.D.
Name: Glenn L. Cooper, M.D.
Title: Chairman and Chief Executive Officer

**Madaus GmbH**

By: /s/ Dr. Kurt N. Gebhart
Name: Dr. Kurt N. Gebhart
Title: Geschäftsführer

By: /s/ Dr. Ing. Freddy Santermans
Name: Dr. Ing. Freddy Santermans
Title: Geschäftsführer
KNOW−HOW LICENSE AGREEMENT

by and between

INDEVUS PHARMACEUTICALS, INC.

and

NOVEXEL SA
THIS KNOW−HOW LICENSE AGREEMENT ("Agreement") is effective as of December 4th, 2006 ("Effective Date"), by and between INDEVUS PHARMACEUTICALS, INC., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 33 Hayden Avenue, Lexington, Massachusetts 02421, United States ("Indevus"), and NOVEXEL SA, a corporation organized and existing under the laws of France and having its principal office at Parc Biocitech, 102, route de Noisy, F−93230 Romainville France ("Novexel"). Indevus and Novexel are collectively referred to herein as the “Parties”, and individually, as a “Party.”

WITNESSETH:

WHEREAS, effective April 18, 2003, Indevus entered into that certain License Agreement with Aventis Pharma SA ("Aventis") (as amended, the “2003 License”) under which, among other things, Indevus was granted an exclusive license under AVENTIS Intellectual Property (as defined in the 2003 License) to develop and commercialize Compound and Product (each as defined below);

WHEREAS, pursuant to the Assignment Agreement (as defined below) effective as of December 1, 2004, Aventis assigned to Novexel all of Aventis’s right, title and interest in and to all intellectual property rights relating to Compound and Product;

WHEREAS, pursuant to the Assignment Agreement, effective as of December 1, 2004, Aventis also assigned to Novexel the 2003 License and Aventis’s rights and obligations thereunder (except for the right to manufacture and supply Nucleus (as defined below) that was retained by Aventis) and Novexel assumed all such rights and obligations thereunder;

WHEREAS, under the 2003 License, Indevus, through its efforts to develop Product, has generated the Indevus Know−how (as defined below);

WHEREAS, Indevus has made a strategic corporate decision to search for a partner to pursue development and commercialization of Compound and Product and Novexel wishes to have an exclusive right to pursue such activities, Indevus and Novexel have agreed, and mutually desire, to simultaneously execute three agreements which will, together, allow Novexel to exclusively pursue development and commercialization of Compound and Product; and

WHEREAS the three agreements Indevus and Novexel have agreed to simultaneously execute include (i) a Termination Agreement terminating the 2003 License, (ii) this Know−How License Agreement under which Indevus will grant Novexel an exclusive license to Indevus Know−How (the “Know−How License”), and (iii) a letter agreement assigning Indevus’ rights and obligations relative to Aventis in the manufacture and supply of Nucleus to Novexel, to which Aventis is also a party (the “Side Agreement”).

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

Page 1
ARTICLE I
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, where used in the singular or plural, shall have the respective meanings set forth below:

1.1 "Affiliate" means (i) any corporation or business entity of which more than fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party or (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds more than fifty percent (50%) (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of a Party.

1.2 "Assignment Agreement" means the Subscription Agreement in relation to Novexel SA dated as of 25 October 2004 by and among Aventis, Novexel and the other parties listed on the signature page thereto, a redacted form of which has been previously provided to Indevus.

1.3 "Aventis" means Sanofi-aventis, the successor to Aventis Pharma SA.

1.4 "Business Day(s)" means any day that is not a Saturday or a Sunday or a day on which the New York Stock Exchange is closed or a day that is a bank holiday in France (which days are set forth on Schedule 1.4).

1.5 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.6 "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.7 "Centralized Procedure" means the European Union Centralized Procedure for marketing authorization in accordance with Council Regulation n° 2309/93 of July 22, 1993 or any successor regulations.

1.8 "Compound" means the chemical compound known under the International Non-proprietary name aminocandin and the code name HMR–3270 and diagrammed on Schedule 1.8, and any other compounds disclosed or covered or included in the Novexel Patent Assets or any compound that is part of the aminocandin family of compounds or any derivative, homolog, or analog of any of the foregoing, and any isomer, salt, hydrate, solvate, amide, ester, metabolite, or prodrug of any of the foregoing.

1.9 "Dominating Patent" shall mean an unexpired patent which has not been invalidated by a court or other governmental agency of competent jurisdiction which is owned by a Third Party and which Novexel or its sublicensees reasonably believe they have no
alternative to obtaining a royalty−bearing license under such patent in order to commercialize a Product under this Agreement without infringing such patent. Any Third Party patent that (i) [*] and (ii) becomes subject to the preceding sentence after the Effective Date, shall be deemed a Dominating Patent.


1.11 “FDA” means the United States Food and Drug Administration and any successor agency having substantially the same functions.

1.12 “First Commercial Sale” means the date of the first commercial sale of Product in the Territory by Novexel or its Affiliates, or their sublicensee(s) after all required Regulatory Approvals in the country of sale have been obtained.

1.13 “Indevus Know−How” means any and all information and materials, including but not limited to, discoveries, Inventory, information, processes, formulae, data, inventions (whether patentable or not), invention disclosures, know−how and trade secrets, patentable or otherwise, that relate to Compound or Product, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, and biological, technical and non technical data, and information relating to the results of tests, assays, methods, and processes, and specifications and/or other documents containing information and related data, and any preclinical, clinical, assay control, manufacturing, regulatory, and any other data or information used or useful for the development, manufacturing, regulatory filing or application and/or regulatory approval of Compound or Product that are immediately prior to the Effective Date, owned or controlled by Indevus. A list of the principal components of the Indevus Know−How is attached as Schedule 1.13.

1.14 “Inventory” means the materials set forth on Schedule 1.14 attached hereto and incorporated by reference herein that as of the Effective Date are stored and held by or on behalf of Indevus.

1.15 “Losses” means any and all damages, awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties (including penalties imposed by any governmental authority), costs, fees, liabilities, obligations, taxes, liens, losses, and expenses (including court costs, interest and reasonable fees of attorneys, accountants and other experts) awarded or otherwise paid or payable to Third Parties.

1.16 “Material Adverse Change” means a serious adverse condition or event relating to the clinical safety, efficacy, toxicity or side effects of Compound or Product that (i) was not included in the Indevus Know−How; (ii) was in the Indevus Know−How or was known to Novexel, but after the Effective date and reasonably diligent efforts by Novexel is determined by Novexel to be a condition or event that cannot be reasonably overcome; (iii) was not, as of the Effective Date, known to Novexel, including any action by any Regulatory Authority significantly limiting the development or commercialization of Compound or Product.

[*) CONFIDENTIAL TREATMENT REQUESTED
1.17 “NDA” means a new drug application or other submission filed with the applicable Regulatory Authority in any regulatory jurisdiction in the Territory to obtain Regulatory Approval of a Product in such regulatory jurisdiction, and any amendments and supplements thereto.

1.18 “Net Sales” means the actual gross amount invoiced by Novexel, its Affiliates or its sublicensees for the commercial sale of all Products in the Territory to a Third Party, commencing upon the date of First Commercial Sale, after deducting the following:

(a) trade, cash, quantity or ordinary discounts;
(b) allowances for product returns, including allowances or credits for rejected Product, or spoilage or recalled Product;
(c) rebates, credits, reimbursements and charge backs;
(d) sales or excise taxes, VAT or other taxes, and transportation and insurance charges and additional special transportation, custom duties, and other governmental charges;
(e) rebates or similar payments paid in connection with sales of Product to any governmental or regulatory authority in respect of any state or federal programs similar to Medicare or Medicaid in the United States in any country of the Territory;
(f) retroactive price reductions; and
(g) write−offs or allowances for bad debt, not to exceed two percent (2%) of Net Sales.

If Novexel or its Affiliates or sublicensees sells Product together with other products to Third Parties in a particular country and the price attributable to the Product is less than the average price of “arms length” sales of the Product alone in the particular country for the reporting period in which sales occur (such sales to be excluded from the calculation of the average price of “arms length” sales), Net Sales for any such sales shall be the average price of “arms length” sales by Novexel or its Affiliates or sublicensees of the Product alone and in the country during the reporting period in which such sales occur. If the average price of “arms length” sale of the Product cannot be determined in any given country, Net Sales will be determined by the value of the Product sold to similar customers in countries with similar pricing and reimbursement structures and for similar quantities. Any dispute as to the determination of value shall be resolved under the dispute procedure in accordance with the provisions of Section 10.6.

If a Product contains one or more therapeutically active ingredients in addition to Compound (“Combination Product”), the Net Sales from the Combination Product, for
the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product during the applicable royalty reporting period, by the fraction, A/A+B, where A is the weighted average per unit sale price of Product when sold in finished form with the Compound as the only active ingredient in the country in which the Combination Product is sold, and B is the weighted average per unit sale price of an active ingredient other than Compound (it being understood that if there are multiple other active ingredients they shall be designated as B−1, B−2, etc.) contained in the Combination Product when sold separately in finished form in the country in which the Combination Product is sold multiplied by the number of units of such active ingredient(s) in the Combination Product, in each case during the applicable royalty reporting period or, if sales of the Product alone did not occur in such period, then in the most recent royalty reporting period in which arm’s length fair market sales of such Product occurred. In the event that such weighted average sale price cannot be determined for either the Product or all other product(s) included in the Combination Product, Net Sales for the purpose of determining royalty payments due on a Combination Product shall be mutually agreed upon by the Parties based on the relative value contributed by each component, such agreement not to be unreasonably withheld, conditioned or delayed.

Use of Products for promotional or sampling purposes or for use in clinical trials contemplated under this Agreement shall not be considered in determining Net Sales. In the case of any sale of a Product between Novexel and its Affiliates or sublicensees for resale, Net Sales shall be calculated as above only on the first arm’s length sale thereafter to a Third Party.

1.19 “Novexel Know−How” means any and all information and materials, including but not limited to, discoveries, improvements, information, processes, formulae, data, inventions (whether patentable or not), invention disclosures, know−how and trade secrets, patentable or otherwise, that relate to Compound or Product, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, and biological, technical and non technical data, and information relating to the results of tests, assays, methods, and processes, and specifications and/or other documents containing information and related data, and any preclinical, clinical, assay control, manufacturing, regulatory, and any other data or information used or useful for the development, manufacturing, regulatory filing or application and/or regulatory approval of Compound or Product that are as of the Effective Date or at any time during the Term of this Agreement become, owned or controlled by Novexel (other than pursuant to the license granted by Indevus under this Agreement) and as to which Novexel has the right to license or sublicense.

1.20 “Novexel Patent Assets” means the United States patents and patent applications and any foreign counterparts thereof listed on Schedule 1.20 or which as of the Effective Date are, or at any time during the Term of this Agreement become, owned or controlled by Novexel, and relate to Compound or Product or any improvement, including all certificates of invention and applications for certificates of invention and substitutions, divisions, continuations, continuations−in−part, patents issuing thereon or reissues or reexaminations thereof, supplementary protection certificates or the like of any such patents and patent applications.
1.21 “Nucleus” means deacylmulundocandin, the starting material for the manufacture of the Compound, obtained by biochemistry through a biosynthesis from an Aspergillus strain, the first step of which leads to deoxymulundocandin and the second step of which leads to deacylmulundocandin.

1.22 “Product” means any product in final form (or where the context so indicates, the product being tested) which contains Compound as at least one of the therapeutically active ingredients.

1.23 “Proprietary Information” means any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned and under the protection of one Party and is being provided by that Party to the other Party in connection with this Agreement. For purposes of the confidentiality and non-use provisions of this Agreement, Novexel Know-How and Reports are deemed Novexel Proprietary Information and Indevus Know-How is deemed Indevus Proprietary Information.

1.24 “Regulatory Approval” means all authorizations and approvals (including pricing and reimbursement approvals where required for marketing), of all regional, federal, state or local agencies, departments, bureaus or other governmental entities, necessary for the manufacture, use, storage, import, export, transport and sale of Product in a jurisdiction.

1.25 “Regulatory Authority” means the FDA in the United States and any body in the European Union and any health regulatory authority(ies) in any country(ies) in the Territory that is equivalent to the FDA and holds responsibility for granting Regulatory Approval for a Product in such country(ies), and any successor(s) thereto having substantially the same functions.

1.26 “Royalty Year” means, (i) for the year in which the First Commercial Sale occurs, the period commencing with the first day of the Calendar Quarter in which the First Commercial Sale occurs and expiring on the last day of the Calendar Year in which the First Commercial Sale occurs and (ii) for each subsequent year, each successive Calendar Year.

1.27 “SEC” means the US Securities and Exchange Commission or any successor agency.

1.28 “Side Agreement” means the agreement entered into by and among Novexel, Indevus and Aventis on even date herewith and attached as Exhibit A which provides, inter alia, for Indevus’ rights and obligations under Sections 3.1.2 and 3.8 of the 2003 License to be assigned to Novexel, and that in the event of a termination of this agreement where Indevus will reacquire the rights consistent with the 2003 License, the rights and obligations under Sections 3.1.2 and 3.8 shall be reassigned back to Indevus.
“Termination Agreement” means the agreement entered into between the Parties on even date herewith, and attached as Exhibit B, which provides, inter alia, for the termination of the 2003 License in consideration of the Parties entering into this Agreement and Novexel, Indevus and Aventis entering into the Side Agreement.

“Territory” means all of the countries in the world.

“Third Party(ies)” means a person or entity who or which is neither a Party nor an Affiliate of a Party.

**ARTICLE II**

**LICENSE; SUBLICENSES**

2.1 **License Grant.** Indevus hereby grants to Novexel an exclusive license, with the right to sublicense in accordance with the terms of this Agreement (with the right of sublicensees to further sublicense), to use and practice the Indevus Know−How for any purpose in connection with Compound and/or Product, including to develop, make, have made, use, import, offer for sale, sell, market, promote, commercialize, distribute, or otherwise dispose of Compound and Product for any and all uses in the Territory.

2.2 **Delivery of Indevus Know−How.** Within thirty (30) days after the Effective Date, Indevus shall deliver to Novexel, at Indevus’s expense, all tangible items (except Inventory) within the Indevus Know−How in a form(s) to be agreed upon and to a place designated in writing by Novexel. The Parties shall agree on a mutual place and time within thirty (30) days after the Effective Date, to arrange for a delivery to Novexel’s personnel, at Indevus’s expense, all of the Indevus Know−How not available in tangible form. Such transfer shall be made by qualified Indevus personnel who understand, have used and are familiar with such Indevus Know−How.

2.3 **Sublicenses.** Subject to the terms and conditions of this Agreement, Novexel shall have the right to grant sublicenses of any of the rights granted to Novexel under Section 2.1 to Affiliates or any Third Party, provided, however, that any sublicense shall be consistent with Novexel’s obligations under this Agreement, including under Section 9.4. Novexel shall remain responsible for the performance by the sublicensee of such obligations. Novexel shall notify Indevus of any sublicense granted in the US, Japan and/or Europe.

2.4 **Inventory.** Effective as of the Effective Date, Indevus hereby assigns and transfers to Novexel all of Indevus’s right, title and interest in the Inventory. The Inventory shall be delivered for the account of Novexel, at Novexel’s expense, in accordance with and as soon as reasonably practicable after receipt by Indevus of written instructions from Novexel, provided, however, that prior to any such delivery, the Inventory shall be held from and after the Effective Date, for the account of Novexel and, from and after the Effective Date, Novexel shall bear all risk of partial or total deterioration or loss of any Inventory through no fault of Indevus, without any recourse against Indevus in relation thereto. To the best of Indevus’ knowledge, the Inventory at all times while held for the account of Indevus has been stored in accordance with cGMPs and all other applicable laws and regulations.
2.5 **Non−Use/Non−Disclosure.** From and after the Effective Date, Indevus agrees and covenants to Novexel that Indevus shall not disclose any Indevus Know−How to any Third Party without the prior written consent of Novexel. From and after the Effective Date (except if the provisions of Section 9.4.3 or 9.4.4 become applicable), Indevus agrees and covenants to Novexel that Indevus shall not use any Indevus Know−How for any purpose whatsoever. To implement the provision of this Section 2.5, Indevus shall make reasonable efforts to notify all of its employees who have used or have access to Indevus Know−How of the provisions of this Section 2.5, and in accordance with Indevus’ standard procedures, collect all documents and things containing Indevus Know−How and maintain them in a locked file.

2.6 **Technical Assistance.**

2.6.1 **Access to Indevus’s Records.** Upon Novexel’s request, within the six (6) month period after the Effective Date, Novexel personnel shall be permitted access to Indevus’s facility where the original documents and things within Indevus Know−How are maintained to inspect and copy, if desired, such original documents and things. Any such access shall be during normal business hours and upon at least five (5) Business Days advance notice.

2.6.2 **Assistance.** Within the one (1) year period after the Effective Date, Indevus shall make available to Novexel at Novexel’s designated facility, Indevus’ qualified personnel familiar with the Indevus Know−How to provide reasonable training and assistance to Novexel with its use of the Indevus Know−How, upon Novexel’s reasonable written request and at such times and for such periods as may be mutually agreed to in good faith, subject to the terms of this Section 2.6.2. Novexel shall bear all out of pocket expenses associated with such assistance. Such assistance shall be limited to [*]. Thereafter, if Novexel requests additional training or assistance, and Indevus agrees to provide such assistance, Novexel shall pay Indevus at the rate of [*] and bear all out of pocket expenses in the manner set forth above. Any such additional assistance shall be limited to [*].

2.7 **Regulatory Filings.** Within thirty (30) days after the Effective Date, Indevus, at its expense, shall transfer ownership to Novexel of any and all regulatory applications, filings and submissions with respect to Compound and Product so that Novexel can continue clinical development of Compound and Product in its own name, and in accordance with Section 3.2.

**ARTICLE III**

**DEVELOPMENT AND COMMERCIALIZATION**

3.1 **Development and Commercialization.** Novexel shall control and shall be solely responsible for development, manufacture and commercialization of Compound and

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Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
the Products conducted or performed after the Effective Date. Novexel shall comply with all applicable laws and regulations in the development and commercialization of Product. A summary of Novexel’s progress and results of such development and commercialization will be reported to Indevus at least on an annual basis. Such progress reports and the information, data and results contained therein (“Reports”) shall be deemed Proprietary Information of Novexel and shall remain the property of Novexel. Only those employees of Indevus who administer this Agreement shall have access to such Reports.

3.2 **Regulatory Matters.** Novexel shall own, control and retain primary legal and financial responsibility for the preparation, filing, prosecution and maintenance of all filings and regulatory applications required to obtain and maintain authorization to develop, manufacture, sell and use Product in the Territory. Novexel shall notify Indevus of the dates of First Commercial Sale in each country in the Territory. Novexel shall be solely responsible for filing all reports required to be filed in order to maintain Regulatory Approvals for Product in the Territory, and for all interactions with Regulatory Authorities in the Territory regarding such Regulatory Approvals. Novexel shall have sole responsibility for, bear all costs and expenses associated with and make all decisions with respect to any recall, withdrawal or seizure of the Product. Novexel shall notify Indevus with respect to any material changes or material problems that may arise in connection with its Regulatory Approvals in any country in the Territory.

3.3 **Diligence; Development and Commercialization.** Novexel shall use commercially reasonable efforts to develop and commercialize Product. As used herein, “commercially reasonable efforts” shall mean efforts and resources normally used by Novexel for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and reimbursement structure involved, the profitability of the concerned products, and other relevant factors if any.

3.4 **Trademark.** Novexel shall have the right to select, own and maintain trademarks for Product in the Territory.

3.5 **Agreements.** Schedule 3.5 sets forth a list of all contracts, agreements and other arrangements in effect as of the Effective Date between Indevus and any Third Parties relating to the research, development or storage of the Compound and Product. Indevus shall use commercially reasonable efforts to assign to Novexel, and Novexel shall assume all of Indevus’s obligations under, the contracts and agreements listed on Schedule 3.5 which Novexel shall specifically request, and Indevus shall terminate any such other contracts, agreements or other arrangements. From and after the Effective Date, Indevus shall have no obligations under any of the contracts or agreements assigned to Novexel except for payment obligations that accrued prior to the Effective Date.
3.6 Manufacturing and Supply. During the Term of this Agreement, and subject to the following sentence, Novexel shall have all rights and responsibility relating to chemistry, manufacturing and control for clinical and commercial use of Compound or Product. The Parties hereby acknowledge that pursuant to the 2003 License, Aventis retained the right to manufacture and supply or have manufactured or have supplied, the Nucleus under the terms and conditions set forth therein and that as of the Effective Date, Indevus and Aventis have not entered into the manufacturing and supply agreement referred to therein, but have extended the time period for entering into such an agreement through July 1, 2007, as established by the correspondence between Indevus and Aventis included in Exhibit C, which shall also include any amendments to the 2003 License.

ARTICLE IV
PAYMENTS AND REPORTS

4.1 License and Transfer Fees. In partial consideration of the rights granted by Indevus hereunder, Novexel shall pay Indevus the following non-refundable and non-creditable license fees by wire transfer of immediately available funds to a bank account or bank accounts designated by Indevus:

4.1.1 one million five hundred thousand dollars (US$1,500,000) payable within five (5) Business days after the Effective Date; and

4.1.2 two hundred fifty thousand dollars (US$250,000) on a quarterly basis, commencing twenty-four (24) months from the Effective Date, provided that such obligation shall expire on the commencement of the first Phase 2 clinical trial (first dosing of first patient) and payment of the milestone referred to in Section 4.2.1. Such payments may be temporarily suspended in the event of, and for the duration of, a Material Adverse Change, provided, that Novexel shall have provided Indevus with written notice and evidence of such Material Adverse Change prior to the date any quarterly payment required by this Section 4.1.2 would otherwise have been payable.

4.2 Milestone Payments. In further consideration of the rights granted by Indevus hereunder, Novexel shall pay Indevus the following non-refundable and non-creditable milestone payments, contingent upon occurrence of the specified event, with each milestone payment to be made no more than once with respect to the achievement of such milestone and no amounts payable for any subsequent or repeated achievement of such milestones, regardless of the number of Products for which such milestone may be achieved (but payable the first time such milestone is achieved):

4.2.1 For the first IV formulation of the first Product:

(a) US $2,000,000 upon commencement (first dosing of the first patient) of first Phase 2 clinical trial;

(b) US $750,000 upon the commencement (first dosing of the first patient) of the first Phase 3 clinical trial;
(c) US $1,500,000 upon the FDA’s acceptance for filing of the first NDA;

(d) US $750,000 upon the first acceptance for filing of an NDA with the EMEA;

(e) US $750,000 upon the first acceptance for filing of an NDA in Japan;

(f) US $3,500,000 upon receipt of first written Regulatory Approval in the United States by the FDA;

(g) US $2,000,000 upon receipt of written Regulatory Approval by the EMEA;

(h) US $2,000,000 upon receipt of written Regulatory Approval by the Regulatory Authority in Japan;

(i) US $750,000 upon the achievement of cumulative Net Sales of US $100,000,000;

(j) US $750,000 upon the achievement of cumulative Net Sales of US $200,000,000;

(k) US $750,000 upon the achievement of cumulative Net Sales of US $300,000,000; and

(l) US $750,000 upon the achievement of cumulative Net Sales of US $400,000,000.

4.2.2 For the first oral formulation of the first Product:

(a) US $2,250,000 upon the commencement (first dosing of the first patient) of the first Phase 3 Clinical Trial;

(b) US $2,625,000 upon the FDA’s acceptance for filing of the first NDA;

(c) US $1,875,000 upon the first acceptance for filing of an NDA by the EMEA;

(d) US $1,500,000 upon the first acceptance for filing of an NDA in Japan;

(e) US $5,000,000 upon receipt of first written Regulatory Approval in the United States by the FDA;

(f) US $4,000,000 upon receipt of written Regulatory Approval by the EMEA;

(g) US $2,000,000 upon receipt of written Regulatory Approval by the Regulatory Authority in Japan;
(h) US $1,500,000 upon the achievement of cumulative Net Sales of US $200,000,000;

(i) US $1,500,000 upon the achievement of cumulative Net Sales of US $400,000,000;

(j) US $1,500,000 upon the achievement of cumulative Net Sales of US $600,000,000;

(k) US $1,500,000 upon the achievement of cumulative Net Sales of US $800,000,000; and

(l) US $1,500,000 upon the achievement of cumulative Net Sales of US $1,000,000,000.

Novexel shall notify Indevus in writing within fifteen (15) Business Days after the achievement of each milestone (thirty (30) days for the milestones set forth in Section 4.2.1 (i), (j), (k) and (l), and Section 4.2 (b), (i), (j), (k) and (l)), and payment shall be made concurrent with such notice by wire transfer of immediately available funds to a bank account or bank accounts designated by Indevus.

4.3 Royalties.

4.3.1 In further consideration of the rights granted by Indevus hereunder, Novexel shall pay to Indevus in each Royalty Year royalties on Net Sales in the Territory at the following rates:

<table>
<thead>
<tr>
<th>Annual Net Sales in all countries in the Territory:</th>
<th>Royalty Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than US$500,000,000</td>
<td>5%</td>
</tr>
<tr>
<td>Greater than or equal to US$500,000,000 and less than US$1,000,000,000</td>
<td>6%</td>
</tr>
<tr>
<td>Greater than or equal to US$1,000,000,000</td>
<td>7.5%</td>
</tr>
</tbody>
</table>

4.3.2 Royalties shall accrue as of the date of First Commercial Sale of Product in the Territory and shall continue and accrue on Net Sales in each country in the Territory until the later of (a) the expiration of the last to expire Novexel Patent Asset that exists as of the Effective Date in such country and is listed on Schedule 1.20, or (b) [*] from the date of First Commercial Sale of Product in such country. After the expiration of the applicable royalty term in any country, Novexel shall be relieved of any royalty payment in that country.

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4.3.3 The payment of royalties hereunder shall be subject to the following:

(a) No royalties shall accrue on the disposition of Product by Novexel, Affiliates or sublicensees as samples or as donations (for example, to non-profit institutions or government agencies);

(b) In the event Novexel, a Novexel Affiliate or sublicensee sells Compound or bulk drug product rather than Product in finished packaged form to a Third Party, other than a sublicensee, and is unable to determine Net Sales as defined in this Agreement, then the royalty obligations shall apply to the Compound or bulk drug product sold; and

(c) Novexel shall be responsible for any royalties or other amounts payable to Third Parties in order to make, have made, use, sell or import Compound or Product in any country in the Territory, including pursuant to any license agreement with any Third Party. Notwithstanding the foregoing, except with respect to any payments required to be made in connection with the Nucleus, including the manufacture or rights to manufacture the Nucleus, if Novexel, its Affiliates, sublicensees or their co-promotion partners would be prevented from developing, making, having made, using, selling or importing Product in any country of the Territory on the grounds that by doing so they would infringe a Dominating Patent or other patent rights held by a Third Party in said country, and any of them enter into an agreement with a Third Party pursuant to which an actual royalty on Compound or Product is paid to such Third Party, then Novexel shall be entitled to a credit against future royalties otherwise payable to Indevus hereunder in an amount equal to [*] of the amount of such royalty payments paid to such Third Parties; provided that the credit for any given year will not exceed [*] of the royalties payable to Indevus for such year; and provided further that in such event Indevus has been informed of the Dominating Patent or other patent rights and has had an opportunity to provide input on any related discussion.

4.3.4 In the event that Novexel or any Novexel Affiliate or sublicensee determines to commercialize Product as an Over-the-Counter Product, the Parties shall negotiate in good faith a royalty payable to Indevus on Net Sales of Over-the-Counter Products in countries where the manufacture, use or sale of such Over-the-Counter Product would infringe any of the Novexel Patent Assets in such country.

4.3.5 Upon the expiration of the obligation of Novexel to make the royalty payments required by Section 4.3.1 in any country in the Territory, Novexel shall have a fully paid-up, royalty free, transferable license in such country to use the Indevus Know-How for any purpose whatsoever.

4.4 Reports; Payment of Royalties. Novexel shall furnish to Indevus by not later than twenty (20) days following the end of each Calendar Quarter a written report for such Calendar quarter showing: (i) gross sales and Net Sales of Product or Compound.

[*] CONFIDENTIAL TREATMENT REQUESTED
during such Calendar Quarter (including a detailing of all deductions taken in the calculation of Net Sales and, where available, the number of units sold) in each country’s currency, (ii) the formulas used in the calculation of the royalties owed thereon, (iii) the applicable exchange rate to convert from each country’s currency to United States Dollars, and (iv) the royalties payable to Indevus. Royalty payments shall first be calculated in the currency in which sales took place and then converted to United States Dollars using the arithmetic averages of the closing conversion rates on the first and last Business Day of such Calendar Quarter, as published by The Wall Street Journal, Eastern edition (if available), or any other publication as agreed to by the Parties. The royalties shown to have accrued by each report, if any, shall be due and payable on the date such report is due. Novexel shall keep, and shall require its Affiliates and sublicensees to keep, complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.

4.5 In order for Indevus to receive compensation on a quarterly basis, Novexel shall pay to Indevus, on a quarterly basis, royalties based on the cumulative Net Sales for the applicable Royalty Year to date, less royalties previously paid to Indevus on account of Net Sales for the previous Calendar Quarters in such Royalty Year. Any change in the amount that would have been payable from Novexel to Indevus under this Agreement which results from any restatements to a prior period’s financial results due to errors, omissions, or any other misstatements, shall be added to or deducted from, as applicable, the amount of the next payment due under this Agreement.

4.6 Financial Audits. Upon the written request of Indevus and not more than once in each Calendar Year, Novexel shall permit an independent certified public accounting firm selected by Indevus and reasonably acceptable to Novexel to have access during normal business hours, upon ten−days notice to Novexel, to such of the records of Novexel, its Affiliates and sublicensees, as applicable, as may be reasonably necessary to verify the accuracy of the reports under Section 4.4 for any Royalty Year ending not more than [*] prior to the date of such request. The accounting firm shall disclose to Indevus only whether the reports are correct or incorrect and the specific details concerning any discrepancies.

4.6.1 If such accounting firm concludes that additional amounts were owed by Novexel for such Royalty Year, Novexel shall pay the additional amounts within thirty (30) days of the date Indevus delivers to Novexel such accounting firm’s written report so concluding. In the event such accounting firm concludes that amounts were overpaid by Novexel during such period, Indevus shall repay Novexel the amount of such overpayment within thirty (30) days of the date Indevus delivers to Novexel such accounting firm’s written report so concluding. The fees charged by such accounting firm shall be paid by Indevus; provided, however, that if an error in favor of Indevus of more than the greater of (i) [*] or (ii) [*] of the amounts due hereunder for the period being reviewed is discovered, then the fees and expenses of the accounting firm shall be paid by Novexel.

4.6.2 Upon the expiration of thirty−six (36) months following the end of any Royalty Year the calculation of royalties or other payments payable with respect to such

[∗] CONFIDENTIAL TREATMENT REQUESTED

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Royalty Year shall be binding and conclusive upon Indevus, and Novexel shall be released from any liability or accountability with respect to royalties for such Royalty Year.

4.6.3 Indevus shall treat all financial information subject to review under this Section 4.6 in accordance with the confidentiality provisions of this Agreement and shall cause its accounting firm to enter into a reasonable and mutually satisfactory confidentiality agreement with Novexel obligating it to retain all such financial information in confidence pursuant to such confidentiality agreement.

4.7 Payments. All payments to Indevus under this Agreement shall be made in United States dollars.

4.8 Late Payment. In case of any late payment due hereunder by Novexel, Novexel shall pay to Indevus interest on the unpaid amount until such payment is paid in full, at the LIBOR Rate (as defined below), [*] but in no event in excess of the maximum rate permitted by applicable law.

“LIBOR Rate” means an interest rate per annum equal to the rate of interest per annum at which deposits in United States dollars are offered by the principal office of Citibank, N.A. in London, England, to prime banks in the London interbank market at 11:00 a.m. (London time) on the Business Day immediately preceding the commencement of such interest period.

4.9 Tax Withholding. If withholding taxes are payable with respect to any payments to Indevus hereunder, Novexel shall pay such withholding taxes and deduct the amount thereof from the amounts otherwise due to Indevus hereunder. Novexel shall provide Indevus with a certificate evidencing payment of any withholding taxes hereunder, together with a written statement of any such taxes paid with respect to Indevus’s tax liability. Novexel shall provide Indevus with both a written statement of any such withholding taxes and a certificate evidencing payment of such taxes. Novexel will use commercially reasonable efforts consistent with its usual business practices and reasonably cooperate with Indevus to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future taxation treaties or agreements between foreign countries. In the event that Novexel is legally required to file such forms for the benefit of Indevus, Indevus shall provide fully completed forms for verification and subsequent filing by Novexel.

4.10 Restrictions on Payment. If by law, regulations or fiscal policy of a particular country, remittance of royalties in United States Dollars is restricted or forbidden, notice thereof will be promptly given to Indevus, and payment of the royalties shall be made by the deposit thereof in local currency to the credit of Indevus in a recognized banking institution designated by Indevus. When in any country the law or regulations prohibit both the transmittal and deposit of royalties on sales in such a country, royalty payments shall be suspended for as long as such prohibition is in effect and as soon as such prohibition ceases to be in effect, all royalties that Novexel would have been under obligation to transmit or deposit but for the prohibition, shall forthwith be deposited or transmitted promptly to the extent allowable.

[*] CONFIDENTIAL TREATMENT REQUESTED
ARTICLE V
CONFIDENTIALITY AND PUBLICITY

5.1 Non−Disclosure and Non−Use Obligations. All Proprietary Information disclosed by one Party to the other Party hereunder shall be maintained in confidence and shall not be disclosed to any Third Party or used for any purpose except as expressly permitted herein without the prior written consent of the Party that disclosed the Proprietary Information to the other Party during the Term of this Agreement and for a period of five years thereafter, except that with respect to the Indevus Know−How, Indevus’s obligation hereunder shall continue throughout the Term of this Agreement. The foregoing non−disclosure and non−use obligations shall not apply to the extent that such Proprietary Information:

5.1.1 is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by business records;

5.1.2 is or becomes properly in the public domain or knowledge, but not by any action of the receiving Party;

5.1.3 is subsequently disclosed to a receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or

5.1.4 is developed by the receiving Party independently of Proprietary Information received from the other Party, as documented by research and development records.

5.2 Permitted Disclosure of Proprietary Information. Notwithstanding Section 5.1,

5.2.1 Novexel may disclose Indevus Proprietary Information:

(a) to governmental or other regulatory agencies in order to obtain patents, or to gain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain such patents or authorizations;

(b) to its respective agents, consultants, Affiliates, sublicensees and/or other Third Parties for the development and/or marketing of Product (or for such parties to determine their interests in performing such activities) on the condition that such Third Parties agree to be bound by the confidentiality obligations consistent with this Agreement; or

(c) if required to be disclosed by law or court order, provided that notice is promptly delivered to the non−disclosing Party in order to provide an opportunity to challenge or limit the disclosure obligations; and

5.2.2 Indevus may disclose Novexel Proprietary Information if required to be disclosed by law or court order, provided that notice is promptly delivered to the non−disclosing Party in order to provide an opportunity to challenge or limit the disclosure obligations.
5.3 **Return of Proprietary Information.** Upon termination of this Agreement, the Party to which Proprietary Information has been disclosed pursuant to this Agreement shall, upon request, promptly return within thirty (30) days all such information, including any copies thereof, and cease its use or, at the request of the Party transmitting such Proprietary Information, shall promptly destroy the same and certify such destruction to the transmitting party; except for a single copy thereof which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement. Upon termination of this Agreement, Novexel shall return to Indevus or destroy, as provided in Section 9.4, the Indevus Know−How, including any unused Inventory.

5.4 **Public Disclosure.** Notwithstanding the provisions of this Article V, it is understood that the Parties may make disclosure of this Agreement and the terms hereof in any filings required by the SEC, other governmental authority or securities exchange, may file this Agreement as an exhibit to any filing with the SEC, other governmental authority or securities exchange, and may distribute any such filing in the ordinary course of its business. Except as set forth in this Agreement or as required by law, neither Party shall make any press release or other public announcement or other disclosure to a Third Party concerning the existence of or terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Each Party agrees to provide to the other Party a copy of any public announcement as soon as reasonably practicable under the circumstances prior to its scheduled release. Each party shall have the right to expeditiously (but in any event within one Business Day of receipt) review any press release or announcement regarding this Agreement or the subject matter of this Agreement; provided, however, that such right of review shall only apply for the first time that specific information is to be disclosed, and shall not apply to the subsequent disclosure of substantially similar information that has previously been disclosed unless there have been material changes in the disclosure since the date of the previous disclosure.

**ARTICLE VI**

**REPRESENTATIONS AND WARRANTIES**

6.1 **General Representations.** Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

6.1.1 Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated;

6.1.2 Such Party has the corporate power and authority and the legal right to enter into this Agreement, the Termination and the Side Agreement and to perform its obligations hereunder and thereunder and the execution, delivery and performance by such party of this Agreement, the Termination and the Side Agreement has been duly authorized by all necessary corporate action;
6.1.3 Each of this Agreement, the Termination and the Side Agreement has been duly executed and delivered on behalf of such party, and each constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms except as enforceability may be limited by (a) any applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor’s rights generally, or (b) general principles of equity, whether considered in a proceeding in equity or at law;

6.1.4 All necessary consents, approvals and authorizations of all governmental authorities and other persons required to be obtained by such Party in connection with this Agreement, the Termination and the Side Agreement have been obtained; and

6.1.5 The execution and delivery of this Agreement, the Termination and the Side Agreement and the performance of such Party’s obligations hereunder and thereunder does not conflict with or violate any requirement of applicable laws or regulations or any judgment, injunction, decree, determination or award presently in effect having applicability to it.

6.2 Indevus Representations and Warranties. Indevus represents and warrants to Novexel that as of the Effective Date:

6.2.1 Indevus has not received any written notice alleging that the practice of the subject matter of the Indevus Know−How or the making, using or selling of Compound or Product in the Territory would infringe any Third Party patents and Indevus is not aware of any facts or circumstances that would support a claim of infringement;

6.2.2 there are no claims, judgments or settlements against or owed by Indevus relating to the Indevus Know−How;

6.2.3 Indevus has not previously assigned, transferred, conveyed or otherwise encumbered any right, title and interest in the Indevus Know−How, or entered into any agreement with any Third Party which is in conflict with the rights granted to Novexel pursuant to this Agreement;

6.2.4 No Third Party has claimed or threatened to claim ownership, control or the right to use Indevus Know−How and Indevus is not aware of any facts or circumstances that would support such a claim;

6.2.5 Indevus has not filed, and shall not file during the Term of this Agreement, any application for patent, copyright, trademark or other form of intellectual property right disclosing or claiming any Indevus Know−How;

6.2.6 Indevus does not own, control or otherwise possess any information or technology related to Compound or Product that is not included in Indevus Know−How; and
6.2.7 All of the information concerning Inventory set forth in Schedule 1.14, including the amount of each material listed, is true and accurate in all material respects; Indevus does not own or control any additional such materials; from and after the time such Inventory has been held for the account of Indevus, to the best of Indevus’ knowledge, the Inventory has been held and stored in accordance with cGMPs and all applicable laws and regulations.

6.3 Novexel Representations and Warranties. Novexel represents and warrants to Indevus that:

6.3.1 in accordance with the Assignment Agreement, effective as of December 1, 2004, the 2003 License, and all of Aventis’ rights thereunder, other than with respect to the Nucleus, have been assigned by Aventis to Novexel, and Novexel has assumed all of Aventis’ obligations thereunder; the Assignment Agreement is in full force and effect and no party thereto is in breach or default thereof; and

6.3.2 as of the Effective Date, Novexel owns all right, title and interest in and to the Novexel Patent Assets, all of which are listed on Schedule 1.20, and has not assigned, transferred, conveyed or otherwise encumbered its right, title or interest in the Novexel Patent Assets;

6.4 THE LIMITED WARRANTIES SET FORTH IN THIS SECTION 6 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, WARRANTY OF NON-INFRINGEMENT AND ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. EXCEPT FOR THE WARRANTIES EXPRESSED IN THIS SECTION 6, NEITHER PARTY MAKES ANY OTHER WARRANTY, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE COMPOUND OR THE PRODUCT.

ARTICLE VII
INDEMNIFICATION AND INSURANCE

7.1 Indemnification by Indevus. Indevus will indemnify, defend and hold harmless Novexel, its Affiliates, directors, officers, employees, agents, successors, and assigns (each, a “Novexel Indemnitee”) from and against any and all Losses arising out of, attributable to or resulting from any claim, suit, action or proceedings (collectively, “Claims”), that are brought by a Third Party against a Novexel Indemnitee that are attributable to a breach by Indevus of any of its representations, warranties or covenants under this Agreement; provided, however, that Indevus shall not be obligated under this Section 7.1 to the extent any Losses (A) arose out of the negligence or wrongdoing on the part of Novexel; (B) arose out of any breach by Novexel of any of its representations, warranties and/or covenants hereunder; or (C) are Losses subject to indemnification by Novexel under Section 7.2.

7.2 Indemnification by Novexel. Novexel shall indemnify, defend and hold harmless Indevus and its Affiliates, directors, officers, employees, agents, successors and
assigns (each a “Indevus Indemnitee”) from and against any and all Losses arising out of, attributable to or resulting from any Claims that are brought by a Third Party against an Indevus Indemnitee that are attributable to (i) the development, manufacture, use, marketing, promotion or sale of Compound or Product; (ii) Novexel’s negligence, recklessness or willful misconduct in exercising or performing any of its rights or obligations under this Agreement; or (iii) a breach by Novexel of any of its representations, warranties or covenants under this Agreement; provided, however, that Novexel shall not be obligated under this Section 7.2 to the extent any Losses (A) arose out of any breach by Indevus of any of its representations, warranties and/or covenants hereunder; or (B) are Losses subject to indemnification by Indevus under Section 7.1.

7.3 Procedure. In the event that any Indemnitee intends to claim indemnification under this Article VII it shall promptly notify the other Party (the “Indemnitor”) in writing of such Claim. Failure to provide prompt notice shall not relieve any Party of the duty to defend or indemnify unless such failure materially prejudices the defense of any matter. The Indemnitor shall have the sole right to control the defense and settlement thereof provided, however, that an Indemnitor shall not, without the written consent of the other Party, as part of any settlement or compromise (i) admit to liability on the part of the other Party; (ii) agree to an injunction against the other Party; or (iii) settle any matter in a manner that separately apportions fault to the other Party. The Parties shall have a reasonable opportunity to participate in decision-making with respect to the strategy of such defense, and shall reasonably cooperate with each other in connection with the implementation thereof. An Indemnitee shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any Claim without the prior written consent of the Indemnitor, which the Indemnitor shall not be required to give.

7.4 Insurance. Novexel shall maintain, during the Term of this Agreement and for a period of three (3) years after any expiration of termination of this Agreement, a Commercial General Liability Insurance policy or policies (including coverage for Product Liability, Contractual Liability, Bodily Injury, Property Damage and Personal Injury), with minimum limits per occurrence and in the aggregate customary for the stage of development and commercial activity of the aminocandin program, but in any event shall not be less than [*] total per year. Such insurance shall insure against liability arising out of the manufacture, use, sale, or marketing of Product in the Territory as appropriate for the stage and extent of development and commercial activity of the aminocandin program. During the Term, Novexel shall not permit such insurance to be reduced, expired or canceled without reasonable prior written notice to Indevus. Upon request Novexel shall provide Certificates of Insurance to Indevus evidencing the coverage specified herein.

[*] CONFIDENTIAL TREATMENT REQUESTED
ARTICLE VIII
PATENT MATTERS

8.1 Novexel shall be responsible in its sole discretion for all filing, prosecution, maintenance, enforcement and defense (including interference and opposition proceedings) of the Novexel Patent Assets. Notwithstanding the foregoing, Novexel shall prosecute, maintain, enforce and defend the Novexel Patent Assets in the US, Europe and Japan covering Compound.

ARTICLE IX
TERM AND TERMINATION

9.1 Term and Expiration. This Agreement shall be effective as of the Effective Date and unless terminated earlier under Section 9.2, the term of this Agreement shall extend for a period (the “Term”) which shall expire and terminate, on a country−by−country basis, on the expiration of all royalty obligations with respect to such country under Section 4.3.

9.2 Termination.

9.2.1 By Notice. Novexel shall have the right to terminate this Agreement (a) at any time upon [*] advance written notice to Indevus upon the occurrence of a Material Adverse Change, or (b) after the earlier of (i) the commencement of the first Phase 2 clinical trial, or (ii) [*] after the Effective Date, for any or no reason, upon [*] advance written notice to Indevus.

In the event of any termination under this Section 9.2.1, the provisions of Section 9.4.3 shall be applicable, provided, that any amounts payable pursuant to Section 4.1.2 that become due during the period commencing from the date of the termination notice until the effective date of termination shall not be payable.

9.2.2 Termination of Agreement for Cause. Either Party may terminate this Agreement by notice to the other Party at any time during the Term as follows:

(a) if the other Party is in breach of any material obligation hereunder by causes and reasons within its control, or has breached, in any material respect, any representations or warranties set forth herein, and has not cured such breach within (i) [*] Business Days in case the breach is a non payment of any amount due under this Agreement, and (ii) [*] for other cases of breach, after notice requesting cure of the breach. provided, however, that if a breach other than a non payment is not capable of being cured within [*] of such written notice, the Agreement may not be terminated sooner than [*] of such written notice so long as the breaching Party commences and is taking commercially reasonable actions to cure such breach as promptly as practicable; or
(b) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if the Party consents to the involuntary proceeding or such proceeding is not dismissed within [*] after the filing thereof.

9.3 Rights not Affected. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code licenses of rights to “intellectual property” as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that Novexel and Indevus shall retain and may fully exercise all of their respective rights, remedies and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy or reorganization case by or against a Party under the Bankruptcy Code, the other Party shall be entitled to all applicable rights under Section 365 (including 365(n)) of the Bankruptcy Code. Upon rejection of this Agreement by a Party or a trustee in bankruptcy for such Party, pursuant to Section 365(n), the other Party may elect (i) to treat this Agreement as terminated by such rejection or (ii) to retain its rights (including any right to enforce any exclusivity provision of this Agreement) to intellectual property (including any embodiment of such intellectual property) under this Agreement and under any agreement supplementary to this Agreement for the duration of this Agreement and any period for which this Agreement could have been extended by such other Party, subject, however, to the continued payment of all amounts owing under this Agreement, all of which amounts shall be deemed to be royalties for purposes of Section 365(n) of the Bankruptcy Code. Upon written request to the trustee in bankruptcy or bankrupt Party, the trustee or Party, as applicable, shall (i) provide to the other Party any intellectual property (including such embodiment) held by the trustee or the bankrupt Party and shall provide to the other Party a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property and (ii) not interfere with the rights of the other Party to such intellectual property as provided in this Agreement or any agreement supplementary to this Agreement, including any right to obtain such intellectual property (or such embodiment or duplicates thereof) from a Third Party.

9.4 Effect of Expiration or Termination. Upon termination of this Agreement, all rights and licenses granted to Novexel hereunder shall terminate upon the effective date of such termination and the Parties shall arrange for an orderly return to Indevus (or, at Indevus’ request, destruction by Novexel) of any Indevus Know−How in Novexel’s possession including any remaining Inventory. In the event of the commencement of a bankruptcy or reorganization case by or against a Party under the Bankruptcy Code, the other Party shall be entitled to all applicable rights under Section 365 (including 365(n)) of the Bankruptcy Code. Upon rejection of this Agreement by a Party or a trustee in bankruptcy for such Party, pursuant to Section 365(n), the other Party may elect (i) to treat this Agreement as terminated by such rejection or (ii) to retain its rights (including any right to enforce any exclusivity provision of this Agreement) to intellectual property (including any embodiment of such intellectual property) under this Agreement and under any agreement supplementary to this Agreement for the duration of this Agreement and any period for which this Agreement could have been extended by such other Party, subject, however, to the continued payment of all amounts owing under this Agreement, all of which amounts shall be deemed to be royalties for purposes of Section 365(n) of the Bankruptcy Code. Upon written request to the trustee in bankruptcy or bankrupt Party, the trustee or Party, as applicable, shall (i) provide to the other Party any intellectual property (including such embodiment) held by the trustee or the bankrupt Party and shall provide to the other Party a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property and (ii) not interfere with the rights of the other Party to such intellectual property as provided in this Agreement or any agreement supplementary to this Agreement, including any right to obtain such intellectual property (or such embodiment or duplicates thereof) from a Third Party.

[*] CONFIDENTIAL TREATMENT REQUESTED

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Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
expiration or termination of this Agreement, thirty (30) after the date of such expiration or termination, or (ii) ten (10) days after the date in which such amounts can be calculated and a fixed sum determined.

9.4.2 Sale of Remaining Product. Upon termination of this Agreement (but not its expiration), Novexel shall notify Indevus of the amount of Product Novexel, its Affiliates and their sublicensees then have on hand or have committed to purchase or sell. For a period ending upon the earlier of: (i) Novexel, its Affiliates and their sublicensees sale of all Product in their possession on the date of termination of this Agreement, or (ii) the end of the six (6) month period following such termination (the “Trailing Period”), Novexel, its Affiliates and their sublicensees shall be permitted to sell such Product and Indevus hereby grants Novexel a non−exclusive license reasonably necessary to sell such Product, subject to the payment of royalties at the same rates and on the same terms and conditions as the royalties set forth in Section 4.3, on any Net Sales of such Product during the Trailing Period.

9.4.3 Termination by Novexel by Notice. If Novexel terminates this Agreement pursuant to Section 9.2.1, the following shall be applicable:

(a) Indevus shall have a [*] period to determine whether it wishes to obtain a license under the Novexel Patent Assets and Novexel Know−How. Upon Indevus’ written request and expense, Novexel shall reasonably cooperate to facilitate Indevus decision−making, including providing Indevus with reasonable access to the Novexel Patent Assets and Novexel Know−How. If Indevus decides to license the Novexel Patent Assets and the Novexel Know−How, it shall so notify Novexel in writing and the Parties shall then immediately execute a license (the “Automatic License”) identical, except for the following changes, to the 2003 License: (i) Aventis shall be replaced by Novexel as the licensor and in all other aspects (except with respect to those provisions specifically not assigned to Novexel by Aventis, in particular the commitment to supply Nucleus or Nucleus intellectual property, which is addressed in subsection (iv) below; (ii) any milestone events set forth in the 2003 License already achieved as of the effective date of the termination of this Agreement shall be deleted; (iii) the License Fee in Section 5.1 of the 2003 Agreement shall be replaced by a payment equal to the amount of all patent costs on the Novexel Patent Assets paid by Novexel during the period commencing on the Effective Date and expiring on the effective date of the termination of this Agreement, as evidenced by appropriate back−up documentation, up to a maximum [*] per year during such period; (iv) Novexel’s rights under the Side Agreement shall be assigned to Indevus on and subject to the same terms and conditions as set forth in the Side Agreement or any supply agreement between Aventis and Novexel with respect to the Nucleus then in effect; and (v) in the event Indevus advises that it desires to include in the Automatic License any Novexel Patent Asset that was acquired by Novexel from a Third Party after the Effective Date (other than in connection with a royalty−bearing license) (a “New Novexel Patent Asset”).

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Asset”), the Parties shall negotiate in good faith any additional consideration to be payable by Indevus to Novexel for the rights to such New Novexel Patent Asset. If Indevus advises Novexel in writing that it does not wish to obtain the Automatic License under the Novexel Patent Assets and Novexel Know−How, then Indevus shall have no further rights with respect to the Novexel Patent Assets and Novexel Know−How, and Novexel shall have no further obligation to Indevus with respect to the Novexel Patent Assets and Novexel Know−How; and

(b) In the event Indevus elects to license the Novexel Patent Assets and Novexel Know−How in accordance with Section 9.4.3(a), (i) Novexel will, if requested by Indevus, cooperate with Indevus or Indevus’ designee to transfer to Indevus or Indevus’ designee the supervision of any ongoing clinical trial in such a way that no delay incurs in such clinical trial, if the termination of such trial would materially adversely affect the development of Product and Indevus has advised Novexel that it intends to continue development of Product; (ii) Novexel will promptly upon having sent such notice transfer to Indevus or Indevus’ designee all data, files, INDs, Regulatory Approvals, if any, and information, data, Novexel Know−how, etc in the possession of Novexel and related to Compound or Product; (iii) Indevus will be entitled to start negotiations with Third Parties in relation to Compound or Product immediately upon receipt of such notice; and (iv) Novexel will provide Indevus with reasonable assistance that Indevus may request in responding to due diligence requests by Third Parties that Indevus is negotiating with as potential licensees for Compound or Product, provided that Novexel shall not be required to disclose to such Third Parties Novexel Proprietary Information that does not relate to Compound or Product.

9.4.4 Termination by Indevus for Cause. If Indevus terminates this Agreement pursuant to Section 9.2.2(a), the provisions of Section 9.4.3 shall be applicable except that in the event that Indevus advises that it desires to include in the Automatic License any Novexel Know−How that was developed by Novexel after the Effective Date (other than Novexel Know−How included in a New Novexel Patent Asset), the Parties shall negotiate in good faith any additional consideration to be payable by Indevus to Novexel for the rights to such new Novexel Know−How, provided, however, that the nature of the breach by Novexel shall be a principal component in determining the amount of any such additional consideration.

9.4.5 Termination by Novexel for Cause. If Novexel terminates this Agreement pursuant to Section 9.2.2, effective as of the effective date of such termination, if requested by Novexel, the Parties shall immediately enter into a new, mutually agreeable agreement granting Novexel the same rights and obligations that were granted by Indevus to and assumed by Novexel under this Agreement, and providing for compensation to Indevus which will be negotiated in good faith between the Parties.

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9.4.6 **Survival.** In addition to any other provisions of this Agreement which by their terms continue after the expiration of this Agreement, the provisions of Article VII shall survive the expiration or termination of this Agreement and shall continue in effect for five (5) years from the date of expiration or termination (subject to the changes thereto as set forth in the Automatic License). In addition, any other provision required to interpret and enforce the Parties’ rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement.

9.4.7 **Non-Exclusive Right.** Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity, or otherwise.

**ARTICLE X**

**MISCELLANEOUS**

10.1 **Force Majeure.** Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement during the period of time when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, fire, flood, embargo, war, acts of war (whether war be declared or not), terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, factory shutdowns, failure of public utilities or common carriers, act of God or act, omission or delay in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practicable.

10.2 **Assignment.** The Agreement may not be assigned or otherwise transferred without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement to an Affiliate or in connection with the transfer or sale of its business or all or substantially all of its assets to which this Agreement relates or in the event of a merger, consolidation, change in control or similar corporate transaction. Any permitted assignee shall assume in writing all obligations of its assignor under this Agreement.

10.3 **Severability.** In the event that any of the provisions contained in this Agreement are held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the invalid provisions are of such essential importance for this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions. In such event, the Parties shall substitute such invalid provisions by valid ones, which in their economic effect come so close to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement also with those substituted provisions.
10.4 Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Novexel to:
Novexel SA
Parc Biocitech
102, route de Noisy
F–93230 Romainville France
Attention: Chief Executive Officer
Fax No: +33 1 48 46 39 26

if to Indevus to:
Indevus Pharmaceuticals, Inc.
33 Hayden Avenue
Lexington, MA 02421
Attention: Chief Executive Officer
Fax No.: 781–862–3859

or to such other address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered or sent by facsimile on a Business Day, upon confirmed delivery by nationally-recognized overnight courier if so delivered and on the third Business Day following the date of mailing if sent by registered or certified mail.

10.5 Applicable Law. The Agreement shall be governed by and construed in accordance with the laws of the United States of America and State of New York without reference to any rules of conflict of laws, except matters of intellectual property law, which shall be determined in accordance with the national intellectual property laws relevant to the intellectual property in question.

10.6 Dispute Resolution.

10.6.1 Except if a Party reasonably determines that it must seek a preliminary injunction, temporary restraining order or other provisional relief, the Parties shall resolve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a “Dispute”) in accordance with the following procedure. The Parties agree to attempt initially to solve Disputes by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within [*] Business Days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of each Party. Such Chief Executive Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within [*] Business Days after such notice is received by the Party to whom the notice was sent. If the Chief Executive

[**] CONFIDENTIAL TREATMENT REQUESTED
Officers are unable to settle the Dispute between them within [*] Business Days, they shall so report to the Parties in writing. The Dispute shall then be referred to mediation as set forth in the following subsection 10.6.2.

10.6.2 Upon the Parties receiving the Chief Executive Officers’ report that the Dispute referred to them pursuant to subsection 10.6.1 has not been resolved, the Dispute shall be referred to mediation by written notice from either Party to the other. The mediation shall be conducted pursuant to the LCIA Mediation Procedure. In the event Indevus is the claimant, the mediation shall be held in London, England; in the event Novexel is the claimant, the mediation shall be held in Geneva, Switzerland. If the Parties have not reached a settlement within twenty (20) Business Days of the date of the notice of mediation, the Dispute shall be referred to arbitration pursuant to subsection 10.6.3.

10.6.3 If after the procedures set forth in subsections 10.6.1 and 10.6.2, the Dispute has not been resolved, a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. The Parties shall refrain from instituting the arbitration proceedings for a period of sixty (60) days following such notice. During such period, the Parties shall continue to make good faith efforts to amicably resolve the dispute without arbitration. If the Parties have not reached a settlement during that period the arbitration proceedings shall go forward and be governed by the LCIA Arbitration Rules then in force. Each such arbitration shall be conducted by a panel of three arbitrators with appropriate experience in the biotechnology or pharmaceutical industry: one arbitrator shall be appointed by each of Novexel and Indevus and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two Party–appointed arbitrators. In the event Indevus is the claimant, the arbitration shall be held in London, England; in the event Novexel is the claimant, the arbitration shall be held in Geneva, Switzerland. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the mediation and arbitration levied by the LCIA. Any mediation or arbitration proceeding entered into pursuant to this Section 10.6 shall be conducted in the English language.

10.7 Entire Agreement. This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly merged in and made a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by all Parties hereto.

[*] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
10.8 **Independent Contractors.** It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of such other Party.

10.9 **Waiver.** The waiver by a Party hereto of any right hereunder or the failure to perform or of a breach by another Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

10.10 **Headings.** The captions to the several Articles and Sections hereof are not a part of the Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

10.11 **Counterparts.** The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

10.12 **Use of Names.** Except as otherwise provided in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the consent of such other Party, which consent shall not be unreasonably withheld or delayed; provided, however, that either Party may use the name of the other Party in any document required to comply with applicable laws, rules or regulations.

10.13 **Interpretation.**

10.13.1 Whenever any provision of this Agreement uses the term “including” (or “includes”), such term shall be deemed to mean “including without limitation” and “including but not limited to” (or “includes without limitations” and “includes but is not limited to”) regardless of whether the words “without limitation” or “but not limited to” actually follow the term “including” (or “includes”);

10.13.2 “Herein”, “hereby”, “hereunder”, “hereof” and other equivalent words shall refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used;

10.13.3 All definitions set forth herein shall be deemed applicable whether the words defined are used herein in the singular or the plural;

10.13.4 Wherever used herein, any pronoun or pronouns shall be deemed to include both the singular and plural and to cover all genders;

10.13.5 The recitals set forth at the start of this Agreement, along with the Exhibits and Schedules to this Agreement, and the terms and conditions incorporated in such recitals, Exhibits and Schedules shall be deemed integral parts of this Agreement and all
references in this Agreement to this Agreement shall encompass such recitals, Exhibits and Schedules and the terms and conditions incorporated in such recitals, Exhibits and Schedules, provided, that in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the Exhibits and Schedules, the terms of this Agreement shall control;

10.13.6 In the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement or otherwise, the terms and conditions of this Agreement shall govern;

10.13.7 The Agreement shall be construed as if both Parties drafted it jointly, and shall not be construed against either Party as principal drafter;

10.13.8 Unless otherwise provided, all references to Sections, Schedules and Exhibits in this Agreement are to Sections, Schedules and Exhibits of and to this Agreement;

10.13.9 All references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters or calendar years unless otherwise expressly provided;

10.13.10 Any reference to any federal, national, state, local or foreign statute or law shall be deemed to also refer to all rules and regulations promulgated thereunder, unless the context requires otherwise;

10.13.11 Any requirements of notice or notification by one Party to another shall be construed to mean written notice in accordance with Section 10.4; and

10.13.12 Wherever used, the word “shall” and the word “will” are each understood to be imperative or mandatory in nature and are interchangeable with one another.

[remainder of page intentionally left blank]
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Glenn L. Cooper, M.D.
Name: Glenn L. Cooper, M.D.
Title: Chairman and Chief Executive Officer

NOVEXEL SA

By: /s/ Iain Buchanan
Name: Iain Buchanan
Title: Chief Executive Officer

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<table>
<thead>
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(*) Every year on same date
(**) Dates are for 2007, but for following years, since they are catholic religious feasts, they are worldwide identical dates.
SCHEDULE 1.8
COMPOUND

[*]

[*] CONFIDENTIAL TREATMENT REQUESTED
1. Complete reports of all clinical trials undertaken including all adverse events identified by clinical investigators
   a. Phase I single dose study
   b. Phase I multi-dose study (terminated due to injection site irritation issues)
   c. Phase I multi-dose study with modified administration (terminated due to injection site irritation issues)
2. Complete reports and data from all formulation work including animal studies
3. All records (including batch records and GMP certifications) relating to synthesis, storage and transport of Inventory listed in Schedule 1.14
4. All correspondence with regulatory agencies relating to Compound
5. All correspondence with ethics committees and clinical investigators relating to Compound
6. Copies of all publications relating to Compound
SCHEDULE 1.14
INVENTORY
[*]

[*] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
SCHEDULE 1.20
NOVESEL PATENT ASSETS
[*]

[*]  CONFIDENTIAL TREATMENT REQUESTED
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<td><strong>CONFIDENTIAL TREATMENT REQUESTED</strong></td>
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Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
This letter is to inform you that Novexel is finalizing an agreement with Indevus whereby the rights to aminocandins licensed to Indevus by Aventis Pharma SA ("Aventis") under the 18 April 2003 License Agreement will be transferred to Novexel. As you are aware, the rights and obligations of Aventis under this License Agreement were transferred to Novexel as of December 1, 2004. However, the part of the License Agreement that dealt with supply of Nucleus remained with Aventis.

Novexel requests that the rights and obligations of Indevus under the License Agreement in Sections 3.1.2 and 3.8 now be assigned to Novexel. In the event the aforesaid agreement between Indevus and Novexel is terminated and Indevus reacquires the rights consistent with the License Agreement, these rights and obligations under Sections 3.1.2 and 3.8 shall be reassigned back to Indevus, upon joint notification by Novexel and Indevus to Aventis, thereto. The text of these Sections is reproduced below.

3.1.2 As long as AVENTIS manufactures and supplies or, in accordance with the provisions of Section 3.8 (a) hereof, AVENTIS’ permitted assignee manufactures and supplies, INDEVUS with Nucleus, in each case in accordance with the supply agreement contemplated by Section 3.8 (a) hereof, AVENTIS shall not be required to disclose or transfer to INDEVUS that portion of the AVENTIS Intellectual Property specifically covering the manufacturing process for the Nucleus, provided, however, that such information and AVENTIS Intellectual Property shall at all times be included in the Drug Master File relating to Compound and/or Product and AVENTIS hereby grants INDEVUS all rights of reference thereto. In the event that (i) AVENTIS and INDEVUS have not entered into such supply agreement relating to the manufacture and supply of the Nucleus by AVENTIS in the time period set forth in Section 3.8 hereto, or (ii) the Parties have entered into such supply agreement but for any reason AVENTIS or AVENTIS’ permitted assignee of such manufacturing right decides not to, or for any other reason, does not manufacture and supply INDEVUS with the Nucleus, AVENTIS shall promptly transfer to INDEVUS all AVENTIS Intellectual Property relating to the manufacturing process for the Nucleus and shall provide to INDEVUS in establishing a Third Party manufacturer of the Nucleus such reasonable assistance as can be expected to be needed by a manufacturer having a reasonably high level of knowledge and experience in the manufacturing of comparable products. Such assistance will be provided free of charge to the extent
that information has to be supplied, and on the basis of cost reimbursement if any employee of AVENTIS has to come on the concerned manufacturing premise, which in any case should be for a limited period of time, to be specified in the aforesaid supply agreement.

3.8 Manufacturing and Supply. INDEVUS shall have all rights and responsibility relating to chemistry, manufacturing and control for clinical and commercial use of Compound or Product such as but not limited to process development, scale up and manufacturing of Compound and Product, subject to the following:

(a) Manufacture of Nucleus. AVENTIS shall retain the right to manufacture and supply or, subject to the provisions of this Section 3.8 (a), have manufactured or have supplied the Nucleus for additional clinical trials and for commercial use by INDEVUS, provided that (i) AVENTIS can manufacture and supply, or any Third Party manufacturer that is a permitted assignee of AVENTIS’ rights under this Section 3.8 (a) can manufacture and supply, the Nucleus in accordance with cGMP and other regulatory requirements; and (ii) AVENTIS shall not have the right to assign its rights under this Section 3.8 (a) to a Third Party manufacturer or supplier of the Nucleus, without INDEVUS’ prior written consent, except with a sale or other divesture of the manufacturing site where the Nucleus is manufactured; and (iii) any such manufacture and supply is in accordance with the terms of the agreement referred to in the next sentence. INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within ninety (90) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.

(b) Other Manufacturing. In connection with any other manufacturing and supply of Compound and/or Product, INDEVUS will consider AVENTIS in priority to any Third Party, as such manufacturer and supplier.

If you are in agreement with these changes, please acknowledge by having this letter signed by an authorized member of your company.
Best regards,

For Novexel S.A.

/s/ Iain Buchanan
Name: Iain Buchanan
Title: CEO
Date:

for Aventis Pharma SA

/s/ Jean–Luc Renard
Name: Jean–Luc Renard
Title: President & CEO
Date:

For Indevus Pharmaceuticals Inc.

/s/ Glenn L. Cooper, M.D.
Name: Glenn L. Cooper, M.D.
Title: Chairman and Chief Executive Officer
Date:

for Aventis Pharma SA

/s/ Jose Ferrer
Name: Jose Ferrer
Title: VP, Legal Operations
Date:

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
EXHIBIT B
TERMINATION AGREEMENT

This Termination Agreement ("Termination Agreement") is executed, delivered, and effective on this 4th day of December 2006 (the "Effective Date") by and between Indevus Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 33 Hayden Avenue, Lexington, Massachusetts 02421, United States ("Indevus"), and Novexel SA, a corporation organized and existing under the laws of France and having its principal office at Parc Biocitech, 102, route de Noisy, F–93230 Romainville, France ("Novexel"). Indevus and Novexel may be referred to herein individually as a "Party" or collectively as the "Parties."

RECITALS

WHEREAS, effective April 18, 2003, Indevus entered into that certain License Agreement with Aventis Pharma SA ("Aventis") (as amended, the "2003 License") under which, among other things, Indevus was granted an exclusive license under AVENTIS Intellectual Property (as defined in the 2003 License) to develop and commercialize Compound and Product;

WHEREAS, pursuant to the Subscription Agreement in relation to Novexel SA dated as of 25 October 2004 by and among Aventis, Novexel and the other parties listed on the signature page thereto (the "Assignment Agreement"), effective as of December 1, 2004, Aventis assigned to Novexel all of Aventis’s right, title and interest in and to all intellectual property rights relating to Compound and Product, including the 2003 License and Aventis’s rights and obligations thereunder (except for the right to manufacture and supply Nucleus that was retained by Aventis) and Novexel assumed all such rights and obligations thereunder;

WHEREAS, under the 2003 License, Indevus, through its efforts to develop Product, has generated certain Indevus Know−How (as defined in the Know−How License, as defined below);

WHEREAS, Indevus has made a strategic corporate decision to search for a partner to pursue development and commercialization of Compound and Product and Novexel wishes to have an exclusive right to pursue such activities, Indevus and Novexel have agreed, and mutually desire, to simultaneously execute three agreements which will, together, allow Novexel to exclusively pursue development and commercialization of Compound and Product; and

WHEREAS the three agreements Indevus and Novexel have agreed to simultaneously execute include (i) this Termination Agreement terminating the 2003 License, (ii) a Know−How License Agreement under which Indevus will grant Novexel an exclusive license to Indevus Know−How (the "Know−How License"), and (iii) a letter agreement assigning Indevus’ rights and obligations relative to Aventis in the manufacture and supply of Nucleus to Novexel, to which Aventis is also a party (the "Side Agreement").

AGREEMENT

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Indevus and Novexel agree as follows:

− 7 −
1. Defined Terms. All capitalized terms in this Termination Agreement (except Effective Date), unless otherwise set forth herein, shall have their respective meanings as set forth in the 2003 License, a copy of which is attached hereto as Exhibit A.

2. Termination. The 2003 License is hereby terminated as of the Effective Date and simultaneously with the effectiveness of the Know−How License. Except as expressly set forth in Section 3 below, all of the rights and obligations of each Party shall terminate (including, without limitation, (a) Indevus’s diligence obligations under Article III and payment obligations under Article V of the 2003 License) and (b) all rights and licenses in, to and under AVENTIS Intellectual Property, AVENTIS Information and Inventions and Novexel’s rights in and to Joint Information and Inventions (collectively, the “Licensed Intellectual Property”) granted to Indevus under the 2003 License. For the avoidance of doubt, Indevus shall have no right to practice any of the Licensed Intellectual Property under the 2003 License.

3. Effect of Termination. Notwithstanding termination of the 2003 License, the following terms and conditions will apply:

   (a) Notwithstanding Section 8.4(a) of the 2003 License, (i) Indevus shall not have the right to sell or otherwise dispose of the stock of any Product, and Indevus shall transfer all such stock, if any, to Novexel pursuant to the provisions of the Know−How License, and (ii) Article IV of the 2003 License shall not survive termination of the 2003 License, provided, however, that Sections 4.1 and 4.2(c) of the 2003 License shall survive such termination for a period of seven (7) years after the Effective Date.

   (b) Within thirty (30) days after the Effective Date, Indevus shall deliver to Novexel, at Indevus’s expense, all tangible items (except Inventory) within the Aventis Know−How within its possession and control in a form(s) to be agreed upon and to a place designated in writing by Novexel. The Parties shall agree on a mutual place and time within thirty (30) days after the Effective Date, to arrange for a delivery to Novexel’s personnel, at Indevus’s expense, all of the Aventis Know−How within its possession and control not available in tangible form. Such transfer shall be made by qualified Indevus personnel who understand, have used and are familiar with such Aventis Know−How.

   (c) Indevus covenants (i) to inform, as soon as practicable after the Effective Date, its employees with access to any of the Licensed Intellectual Property that the 2003 License has been terminated and that Indevus no longer has the right to practice any of the Licensed Intellectual Property and (ii) to use its best efforts to ensure that no such employee practices any of the Licensed Intellectual Property after the Effective Date except pursuant to the terms of the Know−How License.

   (d) Notwithstanding the provisions of Section 2 above, the Parties hereby acknowledge that pursuant to the 2003 License, Aventis retained the right to manufacture and supply or have manufactured or have supplied, the Nucleus under the terms and conditions set forth therein and that as of the Effective Date, Aventis and Novexel have entered into a Side Agreement (as defined in the Know−How License) providing, inter alia, that Indevus’ rights and obligations under Sections 3.1.2 and 3.8 of the 2003 License be assigned to Novexel.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
4. **Representations and Warranties.**

(a) **General Representations and Warranties.** Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

(i) Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated;

(ii) Such Party has the corporate power and authority and the legal right to enter into this Termination Agreement, the Know−How License and the Side Agreement and to perform its obligations hereunder and thereunder and the execution, delivery and performance by such Party of this Termination Agreement, the Know−How License and the Side Agreement has been duly authorized by all necessary corporate action;

(iii) Each of this Termination Agreement, the Know−How License and the Side Agreement has been duly executed and delivered on behalf of such Party, and each constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms except as enforceability may be limited by (a) any applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor’s rights generally, or (b) general principles of equity, whether considered in a proceeding in equity or at law;

(iv) All necessary consents, approvals and authorizations of all governmental authorities and other persons required to be obtained by such Party in connection with this Termination Agreement, the Know−How License and the Side Agreement have been obtained; and

(v) The execution and delivery of this Termination Agreement, the Know−How License and the Side Agreement and the performance of such Party’s obligations hereunder and thereunder does not conflict with or violate any requirement of applicable laws or regulations or any judgment, injunction, decree, determination or award presently in effect having applicability to it.

(b) **Indevus Representations and Warranties.** Indevus represents and warrants to Novexel that as of the Effective Date:

(i) Indevus has not previously assigned, transferred, conveyed, sublicensed or otherwise encumbered any of the rights or licenses granted to it under the 2003 License, or entered into any agreement with any Third Party which is in conflict with this Termination Agreement;

(ii) Indevus has not filed, and shall not file, any application for patent, copyright, trademark or other form of intellectual property right
disclosing or claiming any Licensed Intellectual Property, Indevus Information and Inventions or Indevus’ rights in and to Joint Information and Inventions;

(iii) To Indevus’ knowledge, no contract research organization, corporation, business entity or individual which have been involved in any studies conducted for the purpose of obtaining regulatory approvals for any Product have been debarred entities or individuals within the meaning of 21 U.S.C. section 335(a) or (b);

(iv) In connection with the development of Compound and Product conducted by or on behalf of Indevus, Indevus and to Indevus’ knowledge, its contractors have complied and are complying in all material respects with applicable United States and European laws and regulations, including United States good laboratory practices, in its conduct of toxicology studies on Compound and United States good clinical practices in its conduct of clinical studies on Compound;

(v) Indevus has not received any notice of breach of the 2003 License from Aventis; and entering into this Termination Agreement and the accompanying Know−How License will not result in any breach of the 2003 License or any other Indevus agreement or arrangement with, or obligation to, any Third Party.

5. Release of Claims

(a) By Indevus. Except for the obligations set forth in this Termination Agreement, and in consideration of the release of claims by Novexel in Section 5(b) below, Indevus, on behalf of itself and its agents, attorneys, representatives, directors, officers, employees, subsidiaries, affiliates, heirs, successors, and assigns, including its parent company (if any), hereby waives any claim against Novexel resulting from or in any way arising out of the 2003 License and hereby releases and discharges Novexel and each of its parents, subsidiaries, affiliates, and each of its and their respective officers, directors, stockholders, employees, attorneys, agents, representatives, successors, and assigns from and for any and all claims, damages, actions, causes of action, liabilities, costs, losses, expenses, or claims for relief, known or unknown, fixed or contingent, at law or in equity, of any kind or nature that Indevus now has or has ever had or may hereinafter claim to have had against them arising out of, based upon, or related, directly or indirectly, to the 2003 License or the termination thereof.

(b) By Novexel. Except for the obligations set out in this Termination Agreement, in consideration of the release of claims by Indevus in Section 5(a) above, Novexel, on behalf of itself and its agents, attorneys, representatives, directors, officers, employees, subsidiaries, affiliates, heirs, successors, and assigns, including its parent company (if any), hereby waives any claim against Indevus resulting from or in any way arising out of the 2003 License and hereby releases and discharges Indevus and each of its parents, subsidiaries, affiliates, and each of its and their respective officers, directors, stockholders, employees,
attorneys, agents, representatives, successors, and assigns from and for any and all claims, demands, actions, causes of actions, suits, judgments, liabilities, costs, attorneys’ fees, losses, expenses, or claims for relief, known or unknown, fixed or contingent, at law or in equity, of any kind or nature that Novexel now has or has ever had or may hereinafter claim to have had against them arising out of, based upon, or related, directly or indirectly, to the 2003 License or the termination thereof.

(c) **Representations.** Indevus and Novexel each represents and warrants to the other that the representing Party has full legal right and authority to release the claims released hereby and that the representing Party has taken or obtained all legal action or approval necessary for the execution, delivery, and performance of the obligations hereunder. The Parties each represents and warrants to the other that the representing Party is, as of the Effective Date, the sole and lawful owner of all right, title, and interest in its claims released hereby and that the representing Party has not assigned or otherwise transferred any right, title, or interest in such claims.

6. **Negotiated Agreement.** The Parties agree that this Termination Agreement is a fully negotiated document that shall be deemed to have been jointly drafted by the Parties and, therefore, shall not be more strictly construed against any Party as the draftsman.

7. **Miscellaneous.**

(a) This Termination Agreement, together with any Exhibits hereto the Know−How License, and the Side Agreement are intended to embody the final, complete and exclusive agreements between the Parties with respect to the matters addressed herein and therein; are intended to supersede all prior agreements, understandings and representations written or oral, with respect thereto; and may not be contradicted by evidence of any such prior or contemporaneous agreement, understanding or representation, whether written or oral.

(b) **Amendment.** This Termination Agreement shall not be modified, amended, canceled or altered in any way, and may not be modified by custom, usage of trade or course of dealing, except by an instrument in writing signed by both Parties. All amendments or modifications of this Termination Agreement shall be binding upon the Parties despite any lack of consideration so long as the same shall be in writing and executed by the Parties.

(c) **Governing Law and Dispute Resolution.** This Termination Agreement shall be governed by and construed in accordance with the laws of the United States of America and State of New York without reference to any rules of conflict of laws, except matters of intellectual property law, which shall be determined in accordance with the national intellectual property laws relevant to the intellectual property in question. Any disputes incapable of being resolved by mutual agreement of the Parties shall be handled in accordance with Section 9.6 of the Know−How License.

(d) **Severability.** In the event that any term, condition or provision of this Termination Agreement is held to be or become invalid or be a violation of any applicable law, statute or regulation, the same shall be deemed to be deleted from this Termination Agreement and shall be of no force and effect and this Termination Agreement shall remain in full force and
effect as if such term, condition or provision had not originally been contained in this Agreement. The validity and enforceability of the other provisions shall not be affected thereby. In such case or in the event that this Termination Agreement should have a gap, the Parties hereto shall agree on a valid and enforceable provision completing this Termination Agreement, coming as close as possible to the economic intentions of the Parties. In the event of a partial invalidity the Parties agree that this Termination Agreement shall remain in force without the invalid part. This shall also apply if parts of this Termination Agreement are partially invalid.

(c) Assignment. This Termination Agreement may not be assigned or otherwise transferred by either Party, in whole or in part, whether voluntary, or by operation of law, without the consent of other Party, except in connection with a simultaneous permitted assignment of the Know−How License. Subject to the foregoing, this Termination Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

(f) Waiver. The performance of any obligation required of a Party hereunder may be waived only by a written waiver signed by the other Party, and such waiver shall be effective only with respect to the specific obligation described. The waiver by either Party of a breach of any provision of this Termination Agreement by the other Party shall not operate or be construed as a waiver of any subsequent breach of the same provision or another provision of this Termination Agreement.

(g) Captions. The section headings and captions contained herein are for purposes of reference and convenience only and shall not in any way affect the meaning or interpretation of this Termination Agreement.

(h) Word Meanings. Words such as herein, hereinafter, hereof and hereunder refer to this Termination Agreement as a whole and not merely to a section or paragraph in which such words appear, unless the context otherwise requires. The singular shall include the plural, and each masculine, feminine and neuter references shall include and refer also to the others, unless the context otherwise requires.

(i) English Language. The official language of this Termination Agreement is English. All contract interpretations, notices and dispute resolutions shall be in English. Any attachments or amendments to this Termination Agreement shall be in English. Translations of any of these documents shall not be construed as official or original versions of such documents.

(j) Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally−recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
if to Novexel to:
Novexel SA
Parc Biocitech
102, route de Noisy
F−93230 Romainville France
Attention: Chief Executive Officer Fax No: +33 1 48 46 39 26

if to Indevus to:
Indevus Pharmaceuticals, Inc.
33 Hayden Avenue
Lexington, MA 02421, USA
Attention: Chief Executive Officer
Fax No.: 781−862−3859

or to such other address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered or sent by facsimile on a Business Day, upon confirmed delivery by nationally−recognized overnight courier if so delivered and on the third Business Day following the date of mailing if sent by registered or certified mail.

(k) Counterparts. This Termination Agreement may be executed in two counterparts, each of which shall be deemed an original, but which taken together shall constitute one and the same instrument.

{Signature page follows.}
IN WITNESS WHEREOF, the Parties hereto have caused this Termination Agreement to be executed and delivered by the authorized representatives of each Party on the date first set forth above.

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Glenn L. Cooper, M.D.
Name: Glenn L. Cooper, M.D.
Title: Chairman and Chief Executive Officer

NOVESEL SA

By: /s/ Iain Buchanan
Name: Iain Buchanan
Title: Chief Executive Officer
THIS LICENSE AGREEMENT effective as of April 18, 2003 (“Effective Date”), by and between AVENTIS PHARMA SA (“AVENTIS”), a corporation organized and existing under the laws of France and having its principal office at 20 avenue Raymond Aron, 92165 Antony, France (“AVENTIS”) and INDEVUS PHARMACEUTICALS INC., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 99 Hayden Avenue, Suite 200, Lexington, Massachusetts 02421, United States (“INDEVUS”).

W I T N E S S E T H:

WHEREAS, AVENTIS is the owner of AVENTIS Intellectual Property, as defined herein and;

WHEREAS, INDEVUS desires to obtain exclusive license rights, with a right to grant sublicenses, under the AVENTIS Intellectual Property, and AVENTIS desires to grant such license to INDEVUS, upon the terms and conditions set forth herein; and

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, where used with an initial capital letter, and where used in the singular or plural, shall have the respective meanings set forth below:

1.1 “Act” shall mean the Federal Food Drug and Cosmetic Act of 1934, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.
1.2 “Affiliate” shall mean (i) any corporation or business entity of which more than fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party; (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds more than fifty percent (50%) (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, voting stock or general partnership interest of a Party or (iii) any corporation or business entity of which a Party has the right to acquire, directly or indirectly, at least fifty percent (50%) of the securities or other ownership interests representing the equity, voting stock or general partnership interest thereof.

1.3 “AVENTIS Intellectual Property” shall mean the AVENTIS Patent Assets and AVENTIS Know−How.

1.4 “AVENTIS Know−How” shall mean any and all information and materials, including but not limited to, discoveries, Improvements, information, processes, formulae, data, inventions (whether patentable or not), invention disclosures, know−how and trade secrets, patentable or otherwise, that relate to Compound or Product, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, and biological, technical and non technical data, and information relating to the results of tests, assays, methods, and processes, and specifications and/or other documents containing information and related data, and any preclinical, clinical, assay control, manufacturing, regulatory, and any other data or information, submitted, or required to be submitted, to any Regulatory Authority in connection with any regulatory filing or application relating to Compound or Product, Chemistry, Manufacturing and Control (CMC) data, or similar data used or useful for the development, manufacturing and/or regulatory approval of Compound or Product that are or become at any time during the Term of this Agreement owned or controlled by AVENTIS and as to which AVENTIS has the right to license or sublicense to another party including such rights which AVENTIS may have to information developed by Third Parties.

1.5 “AVENTIS Patent Assets” shall mean the United States patents and patent applications and any foreign counterparts thereof listed in Schedule 1.5 hereto which as of the Effective Date are owned by AVENTIS or which AVENTIS has or acquires rights from a Third Party, and relate to Compound, Product or any Improvement, including but not limited to methods of their development, manufacture, or use, or otherwise relate to AVENTIS Know−How, including all certificates of invention and applications for certificates of invention and substitutions, divisions, continuations, continuations−in−part, patents issuing thereon or reissues or reexaminations thereof, supplementary protection certificates or the like of any such patents and patent applications.

1.6 “Business Day(s)” shall mean any day that is not a Saturday or a Sunday or a day on which the New York Stock Exchange is closed or a day that is a Bank Holiday in France (which days are set forth on Schedule 1.6 hereto).
1.7 “Calendar Quarter” shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.8 “Calendar Year” shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.9 “Centralized Procedure” shall mean the European Union Centralized Procedure for marketing authorization in accordance with Council Regulation n° 2309/93 of July 22, 1993 or any successor regulations.


1.11 “cGMP” shall mean current applicable good manufacturing practices as defined in regulations promulgated by the FDA under the Act relating to the formulation, manufacture, testing prior to delivery, storage and delivery of Compound or Product.

1.12 “Committee” shall mean the steering committee described in Section 3.3.

1.13 “Compulsory License” shall mean any agreement under which any governmental body in any country in the Territory grants or compels INDEVUS to grant, license or marketing rights for Product to any Third Party.

1.14 “Compound” shall mean the chemical compound known under the International Non−proprietary name aminocandin and the code name HMR−3270 and diagrammed on Schedule 1.14 hereto, and any other compounds disclosed or covered or included in the AVENTIS Patent Assets or any compound that is part of the aminocandin family of compounds or any derivative, homolog, or analog of any of the foregoing, and any isomer, salt, hydrate, solvate, amide, ester, metabolite, or prodrug of any of the foregoing that exists and is owned or controlled by AVENTIS as of the Effective Date.

1.15 “Development Plan” shall mean the plan related to the conduct of the Development Program, as described in Section 3.3.5.

1.16 “Development Program” shall mean those activities to be undertaken by INDEVUS or its designee (or, to the extent specifically set forth in this Agreement, AVENTIS) with respect to Compound or Product which are devoted to the evaluation of a potential pharmaceutical product in clinical trials, and/or the conduct of any other activities or studies directed toward obtaining Regulatory Approval of Product.

1.17 “Dominating Patent” shall mean an unexpired patent which has not been invalidated by a court or other governmental agency of competent jurisdiction which is owned by a Third Party and which INDEVUS or its sublicensees reasonably believe they have no alternative to obtaining a royalty−bearing license under such patent in order to commercialize a Product under this Agreement without infringing such patent.
1.18 “Effective Date” shall mean the date first above written.


1.20 “End of Phase 2 Meeting” shall mean the first end of Phase 2 meeting with the FDA, as defined in 21 CFR Section 312.47, intended to determine the safety of proceeding to Phase 3, evaluate the Phase 3 plan and protocols and identify any additional information necessary to support an NDA for Product.

1.21 “FDA” shall mean the United States Food and Drug Administration.

1.22 “First Commercial Sale” shall mean the first sale of Product in any country by INDEVUS, its Affiliate or its sublicensee(s), for end use or consumption, after all required Regulatory Approvals have been granted by the governing health authority of such country.

1.23 “GAAP” shall mean generally accepted accounting principles in the United States.

1.24 “Generic Competition” in any particular country shall exist or commence on the earlier of (i) where IMS or IMS-equivalent data is available, the first date on which Generic Drugs achieve a market share in one Calendar Quarter of twenty percent (20%) or greater of the total prescriptions for Product in such country (as so shown by the average of the monthly IMS (or IMS-equivalent) data for such prescriptions) or (ii) the first date on which there are two Generic Drugs available in one Calendar Quarter in such country.

1.25 “Generic Drug(s)” shall mean any product containing compound that (i) is defined in a particular country in the Territory as a generic drug to the Compound by applicable legal texts or governing health authorities in such country, or (ii) can be substituted for the Compound by a pharmacy, other than a product introduced in such country by INDEVUS, its Affiliates or INDEVUS Sublicensees.

1.26 “Improvement” shall mean any and all improvements and enhancements, patentable or otherwise, related to the Compound or Product including, without limitation, in the manufacture, formulation, ingredients, preparation, presentation, means of delivery or administration, dosage, indication, use or packaging of Compound or Product.

1.27 “IND” shall mean an investigational new drug application and any amendments thereto relating to the use of Compound or Product in the United States or the equivalent application in any other regulatory jurisdiction in the Territory, the filing of which is necessary to commence clinical testing of pharmaceutical products in humans.

1.28 “INDEVUS Know−How” shall mean any and all information and materials, including but not limited to, discoveries, Improvements, information, processes, formulae, data, inventions (whether patentable or not), invention disclosures, know−how and trade secrets, patentable or otherwise, that relate to Compound or Product, including without limitation, all chemical,
pharmaceutical, toxicological, biochemical, and biological, technical and non technical data, and information relating to the results of tests, assays, methods, and processes, and specifications and/or other documents containing information and related data, and any preclinical, clinical, assay control, manufacturing, regulatory, and any other data or information (including without limitation any Drug Master Files (DMFs) if any, Chemistry, Manufacturing and Control (CMC) data or similar data) used or useful for the development, manufacturing, regulatory filing or application and/or regulatory approval of Compound or Product that as a result of the Development Program become owned or controlled by INDEVUS and as to which INDEVUS has the right to license or sublicense to another party including such rights which INDEVUS may have to information developed by Third Parties.

1.29 “INDEVUS Patent Assets” shall mean the United States patents and patent applications and any counterparts thereof which may be filed in other countries which at any time during the term of this Agreement are owned by INDEVUS or which INDEVUS has or acquires rights from a Third Party, and relate to Compound, Product or any Improvement, including but not limited to methods of their development, manufacture, or use, or otherwise relate to INDEVUS Know−How, including all certificates of invention and applications for certificates of invention, substitutions, divisions, continuations, continuations−in−part, patents issuing thereon or reissues or reexaminations thereof and any and all foreign patents and patent applications corresponding thereto, supplementary protection certificates or the like of any such patents and patent applications, including Program Information and Inventions and patents and patent applications resulting from the Development Program.

1.30 “NDA” shall mean a new drug application or other submission filed with the applicable Regulatory Authority in any regulatory jurisdiction in the Territory to obtain Regulatory Approval of a Product in such regulatory jurisdiction, and any amendments and supplements thereto.

1.31 “Net Sales” shall mean the gross amount invoiced by INDEVUS or its Affiliates or its sublicensees for sales of Product in the Territory commencing respectively on the date of First Commercial Sale in each country in the Territory, after deducting the following:

(i) trade, cash and quantity discounts not already reflected in the amount invoiced;

(ii) amounts repaid or credited for Product returns, including for rejections, or spoilage or recalls

(iii) rebates and chargebacks;

(iv) retroactive price reductions;

(v) sales or excise taxes, VAT or other taxes, custom duties, and other governmental charges and transportation and insurance charges to the extent included in the invoiced price; and if assessed directly against the seller, to the extent actually paid;

(vi) compulsory payments and rebates directly related to sales of Product to any governmental or regulatory authority in respect of any state or federal Medicare, Medicaid or similar programs in any country of the Territory; and
(vii) write offs for bad debts to the extent resulting exclusively from unpaid invoices of Products.

Sales or other transfers between INDEVUS and its Affiliates and/or its sublicensees shall be excluded from the computation of Net Sales and no payments will be payable on such sales or transfers except where such Affiliates or sublicensees are end users, but Net Sales shall include the subsequent sales to Third Parties by such Affiliates or sublicensees.

1.32 "Nucleus" shall mean deacetylmulundocandin, the starting material for the manufacture of the Compound, obtained by biochemistry through a biosynthesis from an Aspergillus strain, the first step of which leads to deoxymulundocandin and the second step of which leads to deacetylmulundocandin.

1.33 "Over−the Counter Product" shall mean a Product that is not a Prescription Product.

1.34 "Party" shall mean AVENTIS or INDEVUS, and “Parties” shall mean AVENTIS and INDEVUS.

1.35 “Phase 1 Multiple Dose Clinical Trial” shall mean the first clinical trial in which multiple dosage ranges of Product are initially introduced into humans.

1.36 “Phase 2 Clinical Trial” shall mean the first clinical trial of Product in patients with an indicated fungal infection that is designed to show safety and efficacy of Product for its intended use.

1.37 “Phase 3 Clinical Trial” shall mean the first clinical trial conducted after an End of Phase 2 Meeting and conducted on a sufficient number of patients that is designed to establish that Product is safe and efficacious for its intended use.

1.38 “Prescription Product” shall mean a Product subject to the provisions of Section 503 (b) 1 (B) of the Act.

1.39 “Product” shall mean any product in final form (or where the context so indicates, the product being tested in clinical trials) which contains Compound as at least one of the therapeutically active ingredients.

1.40 “Proprietary Information” shall mean any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned and under the protection of one Party and is being provided by that Party to the other Party in connection with this Agreement.

1.41 “Regulatory Approval” shall mean all authorizations and approvals (including pricing and reimbursement approvals where required for marketing), of all regional, federal, state or local agencies, departments, bureaus or other governmental entities, necessary for the manufacture, use, storage, import, export, transport and sale of Product in a jurisdiction.
1.42 “Regulatory Authority” shall mean the FDA in the U.S., and any body in the European Union and any health regulatory authority(ies) in any country(ies) in the Territory that is equivalent to the FDA and holds responsibility for granting Regulatory Approval for a Product in such country(ies), and any successor(s) thereto having substantially the same functions.

1.43 “Right of First Negotiation” shall have the meaning set forth in Section 2.4 of this Agreement.

1.44 “Royalty Year” shall mean, (i) for the year in which the First Commercial Sale occurs (the “First Royalty Year”), the period commencing with the first day of the Calendar Quarter in which the First Commercial Sale occurs and expiring on the last day of the Calendar Year in which the First Commercial Sale occurs and (ii) for each subsequent year, each successive Calendar Year.

1.45 “Sublicense Royalty Payments” shall mean royalty or other payments based on Net Sales of Product that are received by INDEVUS from a sublicensee of any of the rights granted by AVENTIS to INDEVUS under Section 2.1 of this Agreement, as consideration for the grant of such sublicense.

1.46 “Specifications” shall mean the written methods, formulae, procedures, specifications, tests (and testing protocols) and standards pertaining to the Nucleus as attached hereto as Schedule 1.46 and as they may be modified from time to time by mutual written agreement of the Parties and consistent with the Regulatory Approval.

1.47 “Territory” shall mean all of the countries in the world.

1.48 “Third Party(ies)” shall mean a person or entity who or which is neither a Party nor an Affiliate of a Party.

1.49 “Valid Claim” shall mean a claim of an issued and unexpired patent included within the AVENTIS Patent Assets, which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer.

ARTICLE II
LICENSES; SUBLICENSES

2.1 License Grant. In consideration of and subject to the terms and conditions of this Agreement, AVENTIS hereby grants to INDEVUS an exclusive (even as to AVENTIS) license under AVENTIS Intellectual Property, including the right to grant sublicenses (subject to Section 2.3 below), to develop, make, have made, use, import, offer for sale, market, commercialize, distribute, sell or otherwise dispose of Compound and Product for all uses in the Territory. Notwithstanding the foregoing, it is understood and acknowledged that (i) provided that
AVENTIS is manufacturing the Nucleus in accordance with Section 3.8 (a) and the supply agreement referred to therein, the rights hereby granted shall not extend to the right to manufacture the Nucleus; and (ii) to the extent any part of the AVENTIS Intellectual Property falls outside the scope of the license granted to INDEVUS hereunder, AVENTIS shall retain such right and shall be free to operate under such right.

2.2 Improvement by INDEVUS. All rights and title to and interest in any Improvement conceived, developed, discovered and/or reduced to practice solely by INDEVUS in connection with the license granted under Section 2.1 above or INDEVUS’ activities hereunder shall be vested solely in INDEVUS.

2.3 Sublicenses. INDEVUS shall have the right to grant sublicenses to Affiliates or, subject to the Right of First Negotiation set forth in Section 2.4 below, any Third Party to develop, make, have made, use, import, offer for sale, market, commercialize, distribute and sell and otherwise dispose of Compound or Product in the Territory; provided, however, that (i) INDEVUS shall not have the right to grant any such sublicenses to a Third Party prior to the completion of Phase 1 studies necessary to commence the first Phase 2 Clinical Trial and (ii) INDEVUS shall advise AVENTIS of any proposed sublicense with a Third Party and give due consideration to AVENTIS’ reasonable comments thereto. In the event of a sublicense by INDEVUS to a Third Party, the provisions of Section 5.3.2 of this Agreement shall be applicable. Any such sublicense shall be subject to the terms and conditions of this Agreement, and INDEVUS shall be responsible to AVENTIS for any non-performance by the sublicensee of INDEVUS’ obligations under this Agreement that are assumed by the sublicensee.

2.4 Right of First Negotiation. INDEVUS shall grant AVENTIS a right of first negotiation (the “Right of First Negotiation”) to obtain from INDEVUS a Sublicense Opportunity (as defined below), on and subject to the following terms and conditions:

2.4.1. In the event INDEVUS intends to begin negotiations relating to a sublicense of Compound or Product (a “Sublicense Opportunity”), INDEVUS shall give written notice of such intention to AVENTIS (the “Commencement Notice”). The Commencement Notice shall include a summary of any INDEVUS Know-How generated pursuant to the Development Program that has not been previously presented at a Committee meeting.

2.4.2. AVENTIS shall have the right to exercise the Right of First Negotiation by delivery to INDEVUS of a written notice (the “AVENTIS Notice”) within [*] days after the date of receipt of the Commencement Notice stating that it has a bona fide interest in entering into such Sublicense Opportunity and including a proposal by AVENTIS of the terms thereof.

2.4.3. If AVENTIS exercises the Right of First Negotiation pursuant to Section 2.4.2, INDEVUS and AVENTIS shall engage in exclusive, good faith negotiations to enter into an agreement relating to the Sublicense Opportunity on mutually acceptable terms and conditions within [*] days of the date of receipt by INDEVUS of the AVENTIS Notice stating that it has a bona fide interest in entering into such Sublicense Opportunity and including a proposal by AVENTIS of the terms thereof.

2.4.4. If AVENTIS exercises the Right of First Negotiation pursuant to Section 2.4.2, INDEVUS and AVENTIS shall engage in exclusive, good faith negotiations to enter into an agreement relating to the Sublicense Opportunity on mutually acceptable terms and conditions within [*] days of the date of receipt by INDEVUS of the AVENTIS Notice (the “Negotiation Period”). Such agreement would include the grant by INDEVUS to AVENTIS of an exclusive or non-exclusive sublicense under (i) the AVENTIS Intellectual Property and (ii) the INDEVUS

* CONFIDENTIAL TREATMENT REQUESTED
Patent Assets and INDEVUS Know−How, to develop, make, have made, use, import, offer for sale, market, commercialize, distribute and sell and otherwise dispose of Compound and Product for such uses and in such countries in the Territory, and on such terms and conditions, as may be negotiated in good faith and mutually agreed to by the Parties.

2.4.4. In the event that (i) INDEVUS has not received the AVENTIS Notice in accordance with Section 2.4.2 within [*] days after the date of receipt of the Commencement Notice by AVENTIS, or (ii) the AVENTIS Notice states that AVENTIS does not intend to exercise its Right of First Negotiation, or (iii) AVENTIS exercises the Right of First Negotiation but the Parties are unable to reach agreement prior to expiration of the Negotiation Period, the Right of First Negotiation shall expire and INDEVUS shall be free to enter into a transaction relating to such Sublicense Opportunity with any Third Party; provided, however, that INDEVUS shall not enter into a Sublicense Opportunity with a Third Party for a period of [*] days after expiration of the Negotiation Period if the terms of the sublicense with such Third Party are, in the aggregate, less favorable to INDEVUS than the terms agreed to by AVENTIS in the negotiations pursuant to Section 2.4.3.

ARTICLE III
DEVELOPMENT AND COMMERCIALIZATION

3.1 Exchange of Information.

3.1.1. Subject to subsection 3.1.2, AVENTIS shall disclose to INDEVUS in the language in which they are available (except that all information required to be submitted to any Regulatory Authority in connection with any Regulatory Approval shall be disclosed by AVENTIS to INDEVUS in English) and in writing, in electronic format, where available, and hard copies (or, upon INDEVUS' request, originals), (a) within ten (10) Business Days after execution of this Agreement, all AVENTIS Intellectual Property not previously available or made available to INDEVUS and (b) on an ongoing basis throughout the term of this Agreement, and in addition to the other communications required under this Agreement, all AVENTIS Intellectual Property, and any and all additions or revisions thereto, provided, however, that AVENTIS shall not be required to write any CMC documentation that does not exist as of the date of this Agreement. INDEVUS PHARMACEUTIC, 10−K, December 07, 2006

3.1.2. As long as AVENTIS manufactures and supplies or, in accordance with the provisions of Section 3.8 (a) hereof, AVENTIS’ permitted assignee manufactures and supplies, INDEVUS with Nucleus, in each case in accordance with the supply agreement contemplated by Section 3.8 (a) hereof, AVENTIS shall not be required to disclose or transfer to INDEVUS that portion of the AVENTIS Intellectual Property specifically covering the manufacturing process for the Nucleus, provided, however, that such information and AVENTIS Intellectual Property shall at all times be included in the Drug Master File relating to Compound and/or Product and AVENTIS hereby grants INDEVUS all rights of reference thereto. In the event that (i) (CONFIDENTIAL TREATMENT REQUESTED)

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
AVENTIS and INDEVUS have not entered into such supply agreement relating to the manufacture and supply of the Nucleus by AVENTIS in the time period set forth in Section 3.8 hereof, or (ii) the Parties have entered into such supply agreement but for any reason AVENTIS or AVENTIS’ permitted assignee of such manufacturing right decides not to, or for any other reason, does not manufacture and supply INDEVUS with the Nucleus, AVENTIS shall promptly transfer to INDEVUS all AVENTIS Intellectual Property relating to the manufacturing process for the Nucleus and shall provide to INDEVUS in establishing a Third Party manufacturer of the Nucleus such reasonable assistance as can be expected to be needed by a manufacturer having a reasonably high level of knowledge and experience in the manufacturing of comparable products. Such assistance will be provided free of charge to the extent that information has to be supplied, and on the basis of cost reimbursement if any employee of AVENTIS has to come on the concerned manufacturing premise, which in any case should be for a limited period of time, to be specified in the aforesaid supply agreement.

3.2 Diligence; Development and Commercialization.

3.2.1. INDEVUS Responsibility. INDEVUS shall use commercially reasonable efforts to develop and commercialize Product. As used herein, “commercially reasonable efforts” shall mean efforts and resources normally used by INDEVUS for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and reimbursement structure involved, the profitability of the concerned products, and other relevant factors if any. In furtherance of the objectives of the Development Program, INDEVUS shall provide general management and project management services, sufficient to support its obligations hereunder. The obligations set forth in this Section 3.2.1 are expressly conditioned upon the absence of any serious adverse conditions or event relating to the safety or efficacy of Compound or Product, including the absence of any action by any regulatory authority significantly limiting the development or commercialization of Compound or Product.

3.2.2. Potential AVENTIS Contribution. AVENTIS shall have the right but not the obligation to participate in the Development Program by conducting preclinical studies on the Compound or Product as determined by the Committee, provided, however, that (i) any such studies are approved in advance by the Committee and are specifically included in a Development Plan; (ii) all internal costs of any such studies shall be borne by AVENTIS, but AVENTIS shall be entitled to reimbursement by INDEVUS of costs incurred and paid by AVENTIS to Third Parties in conducting such studies if such costs are approved in advance in writing by INDEVUS, upon submission of appropriate supporting documentation therefore; and (iii) AVENTIS shall promptly report to INDEVUS the results of any such studies conducted by or on behalf of AVENTIS.

3.3 Steering Committee. The Parties hereby establish a steering committee (the “Committee”) to facilitate the Development Program as follows:

3.3.1. Composition of the Committee. The Development Program shall be conducted by INDEVUS under the supervision of the Committee, to the extent set forth herein. The Committee

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
shall be comprised of [*] named representatives of INDEVUS and [*] named representatives of AVENTIS. The initial representatives for each Party hereto are set forth on Schedule 3.3.1 hereto. Each Party may substitute one or more of its representatives, in its sole discretion, effective upon notice to the other Party of such change. After Regulatory Approval has been obtained, the Parties will discuss whether the Committee should be dissolved. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend Committee meetings, subject to compliance with Section 4.1. The Committee shall use its good faith efforts to resolve by consensus any issue relating to the Development Program. If the Committee shall arrive at a consensus on any issue relating to the Development Program, such consensus shall be binding upon the Parties hereto. All issues relating to costs of the Development Program shall be determined by and, except as otherwise contemplated by this Agreement, the responsibility of, INDEVUS.

3.3.2. Committee Resolution. If the Committee is unable to reach a consensus on any issue within thirty (30) days after such issue being presented to the Committee by a Party, notwithstanding the exercise of its best efforts, then such issue shall be referred to the chief executive officers of INDEVUS and AVENTIS (the “CEOs”). Any final decision of the CEOs shall be conclusive and binding on the Parties hereto, and must be reached, if practicable under the circumstances, within thirty (30) days after being referred to the CEOs. In the event that the Committee and/or the CEOs are unable to reach a consensus, issues shall be determined finally and conclusively by INDEVUS.

3.3.3. Meetings. During the Development Program, the Committee shall meet at least once each Calendar Quarter, starting in the Calendar Quarter in which this Agreement is executed, with the location for such meetings to be determined by the Committee, unless no later than thirty (30) days in advance of any meeting there is a determination by INDEVUS that no new business or other activity has transpired since the previous meeting, and that there is no need for a meeting. In such instance, the next quarterly meeting will be scheduled. The Committee may meet by means of conference call or other similar communications equipment. Each Party shall bear its own costs in connection with meetings of the Committee.

3.3.4. Committee Responsibilities. Except as specifically set forth in this Agreement, the Committee shall be responsible for overseeing the Development Program, including (i) reviewing and approving the Development Plan prepared by INDEVUS; (ii) facilitating the transfer of know−how as contemplated by this Agreement; (iii) coordinating scientific interactions; (iv) managing and assessing the progress of the development of Product and, to the extent contemplated by this Agreement, evaluating and, if determined by the Committee, approving AVENTIS to perform tasks required in connection with development of Product; and (v) resolving any disputes between the Parties relating to the Development Program. At each meeting, INDEVUS shall summarize the status of INDEVUS’ clinical development and regulatory activities with respect to Product, including any significant INDEVUS Know−How generated by INDEVUS in the course of conducting the Development Program. Any disclosures of such progress, results or know−how in any meeting shall be deemed Proprietary Information of INDEVUS.

* CONFIDENTIAL TREATMENT REQUESTED
3.3.5. **Development Plan.** Subject to the other provisions of this Section 3.3, the Development Program shall be governed by a plan which shall be provided by INDEVUS to the Committee (the “Development Plan), except that (i) the Development Plan for Year 1 of the Development Program is attached hereto as Exhibit 3.3.5, and (ii) all budget decisions relating to any Development Plan or the Development Program shall be determined solely by INDEVUS. Periodically, INDEVUS shall update the Development Plan, which update shall be reviewed and approved by the Committee, as per Section 3.3.4. (i).

3.3.6. **Primary Contacts.** INDEVUS and AVENTIS each shall appoint a person (a “Primary Contact”) to be the primary contact between the Parties with respect to the Development Program and to coordinate correspondence between the Parties. Each Party shall notify the other in writing within thirty (30) days after the Effective Date of the appointment of its Primary Contact and shall notify the other Party as soon as practicable upon changing this appointment in accordance with Section 3.3.4. (i). The Primary Contact of each Party will be one of its three representatives in the Committee.

3.4 **Reports.** INDEVUS shall provide to the AVENTIS Primary Contact a copy of the annual reports to the INDs submitted by INDEVUS. Any disclosures of such clinical trial progress and results in any of the foregoing reports shall be deemed Proprietary Information of INDEVUS.

3.5 **Regulatory Matters.**

3.5.1. INDEVUS shall own, control and retain primary legal responsibility for the preparation, filing and prosecution of all filings, regulatory applications and Regulatory Approvals. INDEVUS shall promptly notify AVENTIS upon the receipt of Regulatory Approvals and of the date of First Commercial Sale.

3.5.2. AVENTIS shall transfer to INDEVUS as soon as practicable after the Effective Date any other regulatory filings relating to Compound or Product owned or controlled by AVENTIS, if any, and AVENTIS shall file a Drug Master File relating to the Nucleus if it is required by INDEVUS or a Regulatory Authority for conducting clinical studies or for obtaining Regulatory Approval for the Product, and Aventis will allow INDEVUS to cross reference any Drug Master File relating to the Nucleus.

3.6 **Trademark.** INDEVUS shall select, own and maintain trademarks for Product in the Territory.

3.7 **Inventory.** AVENTIS represents and warrants that (i) its current inventory is listed on Exhibit 3.7, provided that such inventory will be re–tested and, where applicable re–released, (and the resulting quantities will be less than the quantities listed in Exhibit 3.7) (the “AVENTIS Inventory”) and (ii) the manufacture, testing, delivery and storage of the AVENTIS Inventory will upon re–release, conform to the Specifications set forth in Schedule 1.46 and the specifications set forth in Exhibit 3.7 and, for so long as such Inventory is held for the account of INDEVUS as set forth in the following sentence, shall be held in compliance with cGMPs and all other applicable laws and regulations, Effective as of the Effective Date, all right, title and
interest in the AVENTIS’ Inventory shall be transferred to INDEVUS at AVENTIS’ expense and shall remain at AVENTIS in the name of and for the account of INDEVUS. However, INDEVUS shall bear all risk of partial or total deterioration or loss after transfer of title and interest to INDEVUS, without any recourse against AVENTIS in relation thereto.

3.8 Manufacturing and Supply. INDEVUS shall have all rights and responsibility relating to chemistry, manufacturing and control for clinical and commercial use of Compound or Product such as but not limited to process development, scale up and manufacturing of Compound and Product, subject to the following:

(a) Manufacture of Nucleus. AVENTIS shall retain the right to manufacture and supply or, subject to the provisions of this Section 3.8 (a), have manufactured or have supplied the Nucleus for additional clinical trials and for commercial use by INDEVUS, provided that (i) AVENTIS can manufacture and supply, or any Third Party manufacturer that is a permitted assignee of AVENTIS’ rights under this Section 3.8 (a) can manufacture and supply, the Nucleus in accordance with cGMP and other regulatory requirements; and (ii) AVENTIS shall not have the right to assign its rights under this Section 3.8 (a) to a Third Party manufacturer or supplier of the Nucleus, without INDEVUS’ prior written consent, except with a sale or other divestiture of the manufacturing site where the Nucleus is manufactured; and (iii) any such manufacture and supply is in accordance with the terms of the agreement referred to in the next sentence. INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within [*] days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.

(b) Other Manufacturing. In connection with any other manufacturing and supply of Compound and/or Product, INDEVUS will consider AVENTIS in priority to any Third Party, as such manufacturer and supplier.

ARTICLE IV
CONFIDENTIALITY AND PUBLICITY

4.1 Non−Disclosure and Non−Use Obligations. All Proprietary Information disclosed by one Party to the other Party hereunder shall be maintained in confidence and shall not be disclosed to any Third Party or used for any purpose except as expressly permitted herein without the prior written consent of the Party that disclosed the Proprietary Information to the other Party during the term of this Agreement and for a period of five years thereafter. The foregoing non−disclosure and non−use obligations shall not apply to the extent that such Proprietary Information:

(a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by business records;

(b) is or becomes properly in the public domain or knowledge;

* CONFIDENTIAL TREATMENT REQUESTED
(c) is subsequently disclosed to a receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or

(d) is developed by the receiving Party independently of Proprietary Information received from the other Party, as documented by research and development records.

4.2 Permitted Disclosure of Proprietary Information. Notwithstanding Section 4.1, a Party receiving Proprietary Information of another Party may disclose such Proprietary Information:

(a) to governmental or other agencies in order to obtain patents pursuant to this Agreement, or to gain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain such patents or approvals;

(b) by each of INDEVUS or AVENTIS to its respective agents, consultants, Affiliates, INDEVUS’ sublicensees and/or other Third Parties for the research and development, manufacturing and/or marketing of the Compound and/or Product (or for such parties to determine their interests in performing such activities) on the condition that such Third Parties agree to be bound by confidentiality obligations consistent with this Agreement; provided, however, that except if such disclosure is required by law or is in connection with obtaining any Regulatory Approval, INDEVUS shall inform AVENTIS prior to disclosing to a Third Party AVENTIS Proprietary Information relating to the production of Compound and shall give due consideration to AVENTIS’ reasonable comments or objections to such disclosure; or

(c) if required to be disclosed by law or court order, provided that notice is promptly delivered to the non-disclosing Party in order to provide an opportunity to challenge or limit the disclosure obligations; provided, however, without limiting any of the foregoing, it is understood that the Parties or their Affiliates may make disclosure of this Agreement and the terms hereof in any filings required by the Securities and Exchange Commission (“SEC”), may file this Agreement as an exhibit to any filing with the SEC and may distribute any such filing in the ordinary course of its business, provided, however, that to the maximum extent allowable by SEC rules and regulations, the Parties shall be obligated to maintain the confidentiality obligations set forth herein and shall redact any confidential information set forth in such filings.

(d) Upon execution of this Agreement, either Party may issue a press release, provided that any such Party shall provide the other Party with a draft of such press release for review at least one Business Day prior to its intended release.

4.3 Publication. AVENTIS shall not submit for written or oral publication any manuscript, abstract or the like relating to Compound or Product, without the prior approval of INDEVUS. If AVENTIS proposes to submit such publication, it shall deliver the proposed publication at least thirty (30), or an outline of the oral disclosure at least fifteen (15), Business Days prior to planned submission or presentation. At the request of INDEVUS, the submission of such
4.4 Collaboration Information and Inventions.

(a) Subject to the provisions of Section 4.4(b), the entire right, title and interest in all discoveries, Improvements, processes, formulas, information, data, inventions, know-how and trade secrets, patentable or otherwise, that are primarily used or useful for the development, manufacturing and/or Regulatory Approval of Compound or Product and are obtained, generated, derived, developed or invented in the course of carrying out the Development Program (collectively, “Program Information and Inventions”):

   (i) solely by employees of AVENTIS shall be owned by AVENTIS (“AVENTIS Information and Inventions”);
   (ii) solely by employees of INDEVUS shall be owned solely by INDEVUS (“INDEVUS Information and Inventions”); and
   (iii) jointly by employees of AVENTIS and employees of INDEVUS shall be owned jointly by AVENTIS and INDEVUS (“Joint Information and Inventions”).

Each Party shall promptly disclose to the other Party hereto the development, making, conception or reduction to practice of Program Information and Inventions as soon as practical after such information is obtained. Section 4.1 shall apply to such disclosure.

(b) INDEVUS shall retain all right, title and interest in and to any INDEVUS Information and Inventions and to its interest in all Joint Information and Inventions. AVENTIS shall retain all right, title and interest in and to any AVENTIS Information and Inventions and to its interest in all Joint Information and Inventions, all of which shall be included in the license granted to INDEVUS under this Agreement.

ARTICLE V
PAYMENTS; ROYALTIES AND REPORTS

5.1 License Fee. In consideration of the rights granted by AVENTIS hereunder, INDEVUS shall pay AVENTIS US $[*] within five (5) Business Days after the Effective Date.

5.2 Milestone Payments. Subject to the terms and conditions contained in this Agreement, and in further consideration of the rights granted by AVENTIS hereunder, INDEVUS shall pay AVENTIS the following milestone payments, contingent upon occurrence of the specified event,

[*] CONFIDENTIAL TREATMENT REQUESTED
with each milestone payment to be made no more than once with respect to the achievement of such milestone and no amounts payable for any subsequent or repeated achievement of such milestones, regardless of the number of Products for which such milestone may be achieved (but payable the first time such milestone is achieved) for Product:

5.2.1. For the first IV formulation of the first Product:

(a) US $[*] upon commencement (first dosing of the first patient) of first multiple dose Phase 1 Clinical Trial;

(b) US $[*] upon commencement (first dosing of the first patient) of first Phase 2 Clinical Trial;

(c) US $[*] upon the commencement (first dosing of the first patient) of the first Phase 3 Clinical Trial;

(d) US $[*] upon the FDA’s acceptance for filing of the first NDA;

(e) US $[*] upon the first acceptance for filing of an NDA with the EMEA;

(f) US $[*] upon the first acceptance for filing of an NDA in Japan;

(g) US $[*] upon receipt of first written Regulatory Approval in the United States by the FDA;

(h) US $[*] upon receipt of written Regulatory Approval by the EMEA;

(i) US $[*] upon receipt of written Regulatory Approval by the Regulatory Authority in Japan;

(j) US $[*] upon the achievement of cumulative Net Sales of US $[*];

(k) US $[*] upon the achievement of cumulative Net Sales of US $[*];

(l) US $[*] upon the achievement of cumulative Net Sales of US $[*]; and

(m) US $[*] upon the achievement of cumulative Net Sales of US $[*].

5.2.2. For the first oral formulation of the first Product:

(a) US $[*] upon the commencement (first dosing of the first patient) of the first Phase 3 Clinical Trial;

(b) US $[*] upon the FDA’s acceptance for filing of the first NDA;

* CONFIDENTIAL TREATMENT REQUESTED
upon the first acceptance for filing of an NDA by the EMEA;

upon the first acceptance for filing of an NDA in Japan;

upon receipt of first written Regulatory Approval in the United States by the FDA;

upon receipt of written Regulatory Approval by the EMEA;

upon receipt of written Regulatory Approval by the Regulatory Authority in Japan;

upon the achievement of cumulative Net Sales of US $[*];

upon the achievement of cumulative Net Sales of US $[*];

upon the achievement of cumulative Net Sales of US $[*]; and

upon the achievement of cumulative Net Sales of US $[*].

INDEVUS shall notify AVENTIS in writing within fifteen (15) Business Days after the achievement of each milestone (ninety (90) days for milestones 5.2.1 (j) through (m) and 5.2.2 (h) through (l)), and such notice shall be accompanied by the appropriate milestone payment.

5.3 Royalties and Other Payments.

5.3.1. Royalties Payable By INDEVUS.

(i) Subject to the terms and conditions of this Agreement, and in further consideration of the rights granted by AVENTIS hereunder, INDEVUS shall pay to AVENTIS royalties in the applicable percentage set forth below for Net Sales of Prescription Products in each Royalty Year in the United States by INDEVUS or its Affiliates, as applicable, if the manufacture, use or sale of such Prescription Products would, absent the license granted hereunder, infringe one or more Valid Claims of the AVENTIS Patent Assets in the United States:

<table>
<thead>
<tr>
<th>Annual Net Sales in U.S.</th>
<th>Royalty Rate</th>
</tr>
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<tbody>
<tr>
<td>Up to US$[*]</td>
<td>[*]%</td>
</tr>
<tr>
<td>From US$[*] up</td>
<td>[*]%</td>
</tr>
</tbody>
</table>

* CONFIDENTIAL TREATMENT REQUESTED
(ii) Subject to the terms and conditions of this Agreement, and in further consideration of the rights granted by AVENTIS hereunder, INDEVUS shall pay to AVENTIS royalties equal to the applicable percentage set forth below for total Net Sales of Prescription Products in each country in the Territory other than the United States in each Royalty Year by INDEVUS or its Affiliates where the manufacture, use or sale of such Prescription Product would, absent the license granted hereunder, infringe one or more Valid Claims of the AVENTIS Patent Assets in such country:

<table>
<thead>
<tr>
<th>Total Annual Net Sales outside U.S.:</th>
<th>Royalty Rate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to US$[*]</td>
<td>[*]%</td>
</tr>
<tr>
<td>From US$[*] up</td>
<td>[*]%</td>
</tr>
</tbody>
</table>

(iii) Royalties on Net Sales at the rates set forth in (i) and (ii) above shall accrue as of the date of First Commercial Sale of Product in the applicable country and shall continue and accrue on Net Sales on a country−by−country basis until the expiration of all AVENTIS Patent Assets in such country, provided, however, that no royalties shall be payable in respect of Net Sales of Product in any country during any period in which lawful Generic Competition exists in such country. Thereafter, INDEVUS shall be relieved of any royalty payment under this Section 5.3.

(iv) The payment of royalties set forth above shall be subject to the following conditions:

(a) only one payment shall be due with respect to the same unit of Product; and

(b) no royalties shall accrue on the disposition of Product by INDEVUS, Affiliates or sublicensees as samples (promotion or otherwise) or as reasonable donations (for example, to non−profit institutions or government agencies) or to clinical trials.

(v) In the event that INDEVUS or any INDEVUS Affiliate or sublicensee determines to commercialize Product as an Over−the−Counter Product, the Parties shall negotiate in good faith a royalty payable to AVENTIS on Net Sales of Over−the−Counter Products in countries where the manufacture, use or sale of such Over−the−Counter Product would, absent the license granted hereunder, infringe one or more Valid Claims of the AVENTIS Patent Assets in such country.

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(vi) In those countries in the Territory in which no Valid Claim of the AVENTIS Patent Assets exists as of the date of First Commercial Sale of Product INDEVUS would pay to AVENTIS, in consideration of the license under AVENTIS Know How, royalties on Net Sales of Products in such country(ies) at rates that are [*] of the rates stated in Section 5.3.1(i) or (ii), as applicable (or with respect to Over-the-Counter Products, the rates determined in accordance with Section 5.3.1(v)), for a period expiring on the expiration date of the last to expire United States patent included in the AVENTIS Patent Assets, as long as the AVENTIS Know-How is not in the public domain and provided there is no Generic Competition in such country. Notwithstanding the foregoing, no royalties shall be payable in respect of Net Sales of any Product in any country of the Territory as of and after the date on which Generic Competition exists in the applicable country.

5.3.2. Payments in the Event of Sublicense. In the event INDEVUS enters into one or more sublicense agreement(s) with one or more Third Party or Third Parties under Section 2.3 of this Agreement, the respective percentages of royalties set forth in Section 5.3.1 would no longer be applicable to the Net Sales in the country or countries covered by the sublicense agreement(s) and, in lieu thereof, AVENTIS would receive the following respective percentages of the total Sublicense Royalty Payments for the concerned country(ies):

- [*] percent ([*]%) if the sublicense agreement is entered into [*];
- [*] percent ([*]%) if the sublicense agreement is entered into [*]; and
- [*] percent ([*]%) if the sublicense agreement is entered into [*].

In order to calculate the amounts due to AVENTIS under this Section 5.3.2, it is understood that (i) any payment to INDEVUS by a sublicensee that is triggered by Net Sales (such as but not limited to fees) shall be considered Sublicense Royalty Payments; and (ii) if no royalties or a lower royalty percentage is paid by INDEVUS’ Sublicensee in consideration of an increased margin received by INDEVUS on Compound or Product supply or of higher milestones payments, such excess payments shall be considered Sublicense Royalty Payments.

5.3.3. Affiliate and Sublicensee Sales. In the event that INDEVUS transfers Compound (for conversion to Product) or Product to one of its Affiliates or Sublicensees, there shall be no royalty due at the time of transfer. Subsequent sales of Product by the Affiliate or the Sublicensee to end users such as patients, hospitals, medical institutions, health plans or funds, wholesalers, pharmacies or other retailers, shall be reported as Net Sales hereunder by INDEVUS.

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5.3.4. Compulsory Licenses. If a compulsory license is granted to a Third Party with respect to Product in any country in the Territory with a royalty rate lower than the royalty rate provided by Section 5.3.1, then the royalty rate to be paid by INDEVUS on Net Sales in that country under Section 5.3.1 shall be reduced to the rate paid by the compulsory Third Party licensee, provided Indevus can show appropriate evidence that Indevus has used commercially reasonable efforts (i) to avoid having to grant such Compulsory License and (ii) to obtain the highest possible royalty rate from such Compulsory Licensee.

5.3.5. Third Party Licenses. If INDEVUS would be prevented from developing, making, having made, using, selling or importing Product in any country of the Territory on the grounds that by doing so INDEVUS or any sublicensee would infringe a Dominating Patent or other patent rights held by a Third Party in said country, [*] percent ([%]) of any royalties or other payments payable or paid by INDEVUS to such Third Party in such country in any Royalty Year shall be creditable against the royalty or other payments payable to AVENTIS by INDEVUS in such country for such Royalty Year, provided that in such event AVENTIS has been informed of the Dominating Patent and has had an opportunity to provide input on any related discussion.

5.3.6. Combination Product. Notwithstanding the provisions of Section 5.3.1, in the event a Product is sold as a combination product with other biologically active components, Net Sales, for purposes of royalty payments on the combination product, shall be calculated by multiplying the Net Sales of that combination product by the fraction A/B, where A is the gross selling price of the Product sold separately and B is the gross selling price of the combination product. If no such separate sales are made by INDEVUS or its Affiliates, Net Sales for royalty determination shall be calculated by multiplying Net Sales of the combination product by the fraction C/(C+D), where C (excluding the fully allocated cost of the other biologically active component in question) is the fully allocated cost of the Compound and D is the fully allocated cost of such other biologically active components.

5.4 Reports; Payment of Royalty. During the term of the Agreement for so long as royalty or other payments are due, INDEVUS shall furnish to AVENTIS a quarterly written report for the Calendar Quarter showing (i) the Net Sales of all Products sold by INDEVUS or its Affiliates or sublicensees, as applicable, during the reporting period, (ii) the royalties or other payments payable to AVENTIS under this Agreement, (iii) in the case of sales outside the United States the calculation of the conversion to United States dollars as per Section 5.6, and (iv) in the case of a sublicense, Sublicense Royalty Payments received by INDEVUS. Reports shall be due on the [*] day following the close of each Calendar Quarter. Royalties or other payments shown to have accrued by each royalty report, if any, shall be due and payable on the date such report is due. INDEVUS shall keep complete and accurate records in sufficient detail to enable the royalties or other payments hereunder to be determined.

5.5 Audits. Upon the written request of AVENTIS and not more than once in each Calendar Year, INDEVUS shall permit an independent certified public accounting firm selected by

* CONFIDENTIAL TREATMENT REQUESTED
AVENTIS and consented to in writing by INDEVUS, which consent shall not be unreasonably withheld, to have access during normal business hours, upon ten−days notice to INDEVUS, to such of the records of INDEVUS as may be necessary to verify the accuracy of the royalty reports hereunder for any Royalty Year ending not more than [**] months prior to the date of such request. The accounting firm shall disclose to AVENTIS only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies.

5.5.1. If such accounting firm concludes that additional royalties were owed during such Royalty Year, INDEVUS shall pay the additional royalties within [**] days of the date AVENTIS delivers to INDEVUS such accounting firm’s written report so concluding. In the event such accounting firm concludes that amounts were overpaid by INDEVUS during such period, AVENTIS shall repay INDEVUS the amount of such overpayment within [**] days of the date AVENTIS delivers to INDEVUS such accounting firm’s written report so concluding. The fees charged by such accounting firm shall be paid by AVENTIS; provided, however, that if an error in favor of AVENTIS of more than the greater of (i) $[**] or (ii) [**] percent ([**]%) of the royalties due hereunder for the period being reviewed is discovered, then the fees and expenses of the accounting firm shall be paid by INDEVUS.

5.5.2. Upon the expiration of [**] months following the end of any Royalty Year the calculation of royalties payable with respect to such year shall be binding and conclusive upon AVENTIS, and INDEVUS shall be released from any liability or accountability with respect to royalties for such year.

5.5.3. AVENTIS shall treat all financial information subject to review under this Section 5.5 in accordance with the confidentiality provisions of this Agreement and shall cause its accounting firm to enter into a reasonable and mutually satisfactory confidentiality agreement with INDEVUS obligating it to retain all such financial information in confidence pursuant to such confidentiality agreement.

5.6 Payment Exchange Rate. All payments to AVENTIS under this Agreement shall be made in United States dollars. In the case of sales invoiced in a currency other than the US dollar, the rate of exchange to be used in computing Net Sales shall be calculated monthly in accordance with GAAP and based on the conversion rates published in the Wall Street Journal, Eastern edition (if available).

5.7 Late Payment. In case of late payment of any payment due hereunder by INDEVUS (milestones or royalties) or in case of additional payment due by INDEVUS pursuant to Section 5.5.1, INDEVUS shall pay to AVENTIS interest on the unpaid amount until such payment is paid in full, at the LIBOR Rate (as defined below), plus [**], but in no event in excess of the maximum rate permitted by applicable law. “LIBOR Rate” means an interest rate per annum equal to the rate of interest per annum at which deposits in United States dollars are offered by the principal office of Citibank, N.A. in London, England, to prime banks in the London interbank market at 11:00 a.m. (London time) on the Business Day immediately preceding the commencement of such interest period.

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5.8 Tax Withholding. If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Article V, AVENTIS shall provide INDEVUS, prior to any such payment, once each Royalty Year or more frequently if required, with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit thereunder (including, but not limited to United States Internal Revenue Service Form W−8BEN or any successor forms) and INDEVUS shall make such withholding payments as required and subtract such withholding payments from the payments set forth in this Article V. INDEVUS will use commercially reasonable efforts consistent with its usual business practices and cooperate with AVENTIS to reduce any withholding taxes imposed as far as possible under the provisions of the current or any future taxation treaties or agreements between foreign countries. INDEVUS will cooperate and assist AVENTIS in having adequate documentation to claim tax credits for any and all taxes withheld pursuant to this Article V. To that end, within thirty (30) days of remitting any and all taxes withheld to the tax authorities, INDEVUS shall provide to AVENTIS proof of its remittance of taxes withheld from payments made to AVENTIS, and on an annual basis will provide AVENTIS with a United States Internal Revenue Service Form 1042−S and comparable state or local forms, if any, or successor federal forms.

5.9 Exchange Controls. Notwithstanding any other provision of this Agreement, if at any time legal restrictions prevent the prompt remittance of part or all of the royalties with respect to Net Sales in any country, payment shall be made through such lawful means or methods as INDEVUS may determine in consultation with AVENTIS. When in any country the law or regulations prohibit both the transmittal and deposit of royalties on sales in such a country, royalty payments shall be suspended for as long as such prohibition is in effect (and such suspended payments shall not accrue interest), and promptly after such prohibition ceases to be in effect, all royalties or other payments that INDEVUS or its Affiliates would have been obligated to transmit or deposit, but for the prohibition, shall be deposited or transmitted, as the case may be, to the extent allowable (with any interest earned on such suspended royalties which were placed in an interest−bearing bank account in that country, less any transactional costs). If the royalty rate specified in this Agreement should exceed the permissible rate established in any country, the royalty rate for sales in such country shall be adjusted to the highest legally permissible or government−approved rate.

ARTICLE VI
REPRESENTATIONS AND WARRANTIES

6.1 AVENTIS Representations and Warranties. AVENTIS represents and warrants to INDEVUS that as of the Effective Date:

(a) the pending patent applications and the issued patents included in the AVENTIS Patent Assets are in existence and, to the best of AVENTIS’ knowledge, recite patentable subject matter and contain claims that are valid and enforceable, respectively; and AVENTIS will comply and abide by the rules and / or statutes governing the prosecution, issuance and maintenance of such pending patent applications and issued patents in each applicable country of the Territory:
(b) this Agreement has been duly executed and delivered by AVENTIS and constitutes legal, valid, and binding obligations enforceable against AVENTIS in accordance with its terms, except as enforceability is limited by any applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor’s rights generally;

(c) no approval, authorization, consent, or other order or action of or filing with any court, administrative agency or other governmental authority is required for the execution and delivery by AVENTIS of this Agreement or the consummation by AVENTIS of the transactions contemplated hereby;

(d) AVENTIS has the full corporate power and authority to enter into and deliver this Agreement, to perform and to grant the licenses granted under Article II hereof and to consummate the transactions contemplated hereby; all corporate acts and other proceedings required to be taken to authorize such execution, delivery, and consummation have been duly and properly taken and obtained;

(e) AVENTIS has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the AVENTIS Intellectual Property, including the Nucleus, or entered into any agreement with any Third Party which is in conflict with the rights granted to INDEVUS pursuant to this Agreement;

(f) it is the sole owner of the AVENTIS Intellectual Property including the Nucleus, all of which are free and clear of any liens, charges and encumbrances, no other person, corporate or other private entity, or governmental or university entity or subdivision thereof has any claim of ownership or rights with respect to the AVENTIS Intellectual Property, including the Nucleus, whatsoever;

(g) AVENTIS has disclosed to INDEVUS the complete texts of all patents or patent applications relating to Compound or Product that are in existence on the Effective Date and that are the property of AVENTIS as well as all information received by AVENTIS concerning the institution or possible institution of any interference, opposition, re-examination, reissue, revocation, nullification, or any official proceeding involving an AVENTIS Patent Asset, and that it will continue such disclosure with respect to new events during the term of the Agreement;

(h) Schedule 1.5 is a complete and accurate list of all patents and patent applications in the Territory relating to Compound or Product owned or exclusively licensed by AVENTIS and to which AVENTIS has the right to license;

(i) As of the Effective Date, to the best of AVENTIS’ knowledge, the contemplated development, importation, manufacture, use, offer for sale and sale of Compound included in the AVENTIS Patent Assets or Product or Nucleus would not infringe any patent rights owned or possessed by any Third Party;

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
there are no claims, judgments or settlements against or owed by AVENTIS relating to the AVENTIS Patent Assets or pending or, to the best of AVENTIS’ knowledge, threatened claims or litigation against AVENTIS relating to the AVENTIS Patent Assets;

(AVENTIS has disclosed to INDEVUS all relevant information known by it regarding the AVENTIS Intellectual Property and it has no knowledge of the existence of any preclinical or clinical data or information relating to Compound or Product that has not been disclosed to INDEVUS that could materially influence INDEVUS’ decision to enter into this Agreement;

no contract research organization, corporation, business entity or individual which have been involved in any studies conducted for the purpose of obtaining regulatory approvals have been debarred individuals or entities within the meaning of 21 U.S.C. section 335(a) or (b); and

in connection with development of Nucleus, Compound and Product, AVENTIS has complied and is complying in all material respects with applicable U.S. and European laws and regulations including U.S. good laboratory practices in its conduct of toxicology studies on Compound and U.S. good clinical practices in its conduct of clinical studies on Compound.

as of the Effective Date, there are no contracts, agreements and other arrangements between AVENTIS and any Third Parties relating to the research, development or commercialization of the Nucleus, Compound or Product that could impair the exercise of the rights granted to INDEVUS hereunder.

6.2 INDEVUS Representations and Warranties. INDEVUS represents and warrants to AVENTIS that as of the Effective Date:

(a) this Agreement has been duly executed and delivered by it and constitutes legal, valid, and binding obligations enforceable against it in accordance with its terms except as enforceability is limited by any applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor’s rights generally;

(b) it has full corporate power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. All corporate acts and other proceedings required to be taken to authorize such execution, delivery, and consummation have been duly and properly taken and obtained; and

(c) no approval, authorization, consent, or other order or action of or filing with any court, administrative agency or other governmental authority is required for the execution and delivery by it of this Agreement or the consummation by it of the transactions contemplated hereby.
ARTICLE VII
PATENT MATTERS

7.1 Filing, Prosecution and Maintenance of AVENTIS Patent Assets. AVENTIS shall have the first right to file, prosecute and maintain the AVENTIS Patent Assets and patents on AVENTIS Information and Inventions in AVENTIS’ name and shall be responsible for the payment of all patent prosecution and maintenance costs. If AVENTIS elects not to file, prosecute or maintain a patent application or patent included in the AVENTIS Patent Assets in any particular country, it shall provide INDEVUS with written advance notice sufficient to avoid any loss or forfeiture, and INDEVUS shall have the right, but not the obligation, at its expense, to file, prosecute or maintain such patent application or patent in such country in AVENTIS’ name. Thereafter, INDEVUS’ royalty obligations related to that AVENTIS Patent Asset in such country shall terminate and such patent or patent application in such country shall no longer be deemed an AVENTIS Patent Asset. Upon the reasonable request of one Party, the other Party shall reasonably cooperate in the filing, prosecution or maintenance of any patent application or patent included in the AVENTIS Patent Assets. The responsible Party under this Section 7.1 shall solicit the other Party’s review of the nature and text of such patent applications and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and the responsible Party shall take into account the other Party’s reasonable comments related thereto. AVENTIS shall inform INDEVUS of any significant developments in the prosecution of pending patent applications included in the AVENTIS Patent Assets, including the issuance of any final office actions, allowance of claims, or upcoming grant of any domestic or foreign patent based thereon.

7.2 Program Information and Inventions. INDEVUS shall have the first right to file, prosecute and maintain any patent application(s) or patent(s) arising from INDEVUS Information and Inventions and from Joint Information and Inventions and shall be responsible for the payment of all patent prosecution and maintenance costs. Upon INDEVUS’ request, AVENTIS shall reasonably cooperate in the filing, prosecution or maintenance of any such patent application or patent. If INDEVUS elects not to file, prosecute or maintain any such patent application or patent in any particular country in the Territory, it shall provide AVENTIS with written advance notice sufficient to avoid any loss or forfeiture, and AVENTIS shall have the right, but not the obligation, at its sole expense, to file, prosecute or maintain such patent application or patent in such country in AVENTIS’ name, and INDEVUS shall transfer all right, title and interest in such patent application or patent, and the underlying INDEVUS Information and Inventions claimed by such patent application or patent, in such country to AVENTIS. The responsible Party under this Section 7.2 shall solicit the other Party’s review of the nature and text of such patent applications and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and the responsible Party shall take into account the other Party’s reasonable comments related thereto.

7.3 Patent Office and Court Proceedings. Each Party shall inform the other Party of any request for, filing, or declaration of any proceeding before a patent office seeking to protest, oppose, cancel, reexamine, declare an interference proceeding, initiate a conflicts proceeding, or analogous process involving a patent application or patent included in the AVENTIS Patent Assets, or of the filing of an action in a court of competent jurisdiction seeking a judgment that a
subject to any such patent office or court proceeding. Each Party will provide the other with any information or assistance that is reasonable.

7.4 Enforcement and Defense.

(a) Each Party shall promptly give the other Party notice of any infringement in the Territory of any patent application or patent included in the AVENTIS Patent Assets that comes to such Party’s attention. The Parties will thereafter consult and cooperate fully to determine a course of action, including, without limitation, the commencement of legal action by any Party. However, AVENTIS shall have the first right to initiate and prosecute such legal action at its own expense and in the name of AVENTIS and INDEVUS, or to control the defense of any declaratory judgment action relating to the AVENTIS Patent Assets. AVENTIS shall promptly inform INDEVUS if AVENTIS elects not to exercise such first right, and INDEVUS thereafter shall have the right either to initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of INDEVUS and, if necessary, AVENTIS.

(b) If AVENTIS elects not to initiate and prosecute an infringement or defend a declaratory judgment action in any country in the Territory as provided in Subsection 7.4(a), and INDEVUS elects to do so, the cost of any agreed-upon course of action, including the costs of any legal action commenced or any declaratory judgment action defended, shall be borne solely by INDEVUS.

(c) For any such legal action or defense, in the event that any Party is unable to initiate, prosecute, or defend such action solely in its own name, the other Party will join such action voluntarily and will execute all documents necessary for the Party to prosecute, defend and maintain such action. In connection with any such action, the Parties will cooperate fully and will provide each other with any information or assistance that either reasonably may request.

(d) Any recovery obtained by INDEVUS or AVENTIS shall be shared as follows:

(i) the Party that initiated and prosecuted, or maintained the defense of, the action shall recoup all of its costs and expenses (including reasonable attorneys’ fees) incurred in connection with the action, whether the recovery is by settlement or otherwise;

(ii) the other Party then shall, to the extent possible, recover its costs and expenses (including reasonable attorneys’ fees) incurred in connection with the action;

(iii) if AVENTIS initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining then shall be retained by AVENTIS; and
if INDEVUS initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining shall be retained by
INDEVUS, except that AVENTIS shall receive a portion equivalent to the royalties it would have received in accordance with the terms of this
Agreement if such amount were deemed Net Sales.

(c) the foregoing subsections (a), (b), (c) and (d) shall apply on reciprocal basis regarding the INDEVUS Patent Assets and joint patents.

7.5 AVENTIS shall inform INDEVUS of any certification regarding any AVENTIS Patent Assets it has received pursuant to either 21 U.S.C. §§ 355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) or under Canada’s Patented Medicines (Notice of Compliance) Regulations Article 5 and shall provide INDEVUS with a copy of such certification within five (5) Business Days of receipt. AVENTIS’ and INDEVUS’ rights with respect to the initiation and prosecution, or defense, of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be allocated as defined in Subsections 7.4(d)(i) through (iv); provided, however, that INDEVUS shall exercise the first right to initiate and prosecute, or defend, any action and shall inform AVENTIS of such decision within fifteen (15) days of receipt of the certification, after which time, if INDEVUS has not advised AVENTIS of its intention to initiate and prosecute, or defend, such action, AVENTIS shall have the right to initiate and prosecute, or defend, such action.

7.6 Patent Term Extensions or Restorations and Supplemental Protection Certificates. The Parties shall cooperate with each other in obtaining patent term extensions or restorations or supplemental protection certificates or their equivalents in any country in the Territory where applicable. If elections with respect to obtaining such extension or supplemental protection certificates are to be made, INDEVUS shall have the right to make the election and AVENTIS shall abide by such election. AVENTIS shall notify INDEVUS of (a) the issuance of each U.S. patent included within the AVENTIS Patent Assets, giving the date of issue and patent number for each such patent, and (b) each notice pertaining to any patent included within the AVENTIS Patent Assets pursuant to the United States Drug Price Competition and Patent Term Restoration Act of 1984 (hereinafter called the “1984 Act”), including notices pursuant to §§ 101 and 103 of the 1984 Act from persons who have filed an abbreviated NDA (“ANDA”). Such notices shall be given promptly, but in any event within five (5) Business Days of each such patent’s date of issue or receipt of each such notice pursuant to the Act, whichever is applicable. AVENTIS shall notify INDEVUS of each filing for patent term extension or restoration under the 1984 Act, any allegations of failure to show due diligence and all awards of patent term restoration (extensions) with respect to the AVENTIS Patent Assets. Likewise, AVENTIS shall inform INDEVUS of patent extensions in the rest of the world regarding Compound or Product.
Expiration of the last to expire patent included in the AVENTIS Patent Assets in such country. Expiration of this Agreement under this provision shall not preclude INDEVUS from continuing to develop, make, have made, use, sell, offer for sale, and import Product in the Territory without further remuneration to AVENTIS.

8.2 Termination by Notice. Notwithstanding anything contained herein to the contrary, INDEVUS shall have the right to terminate this Agreement at any time after completion of a [*]:

(a) by giving [*] days advance written notice to AVENTIS, if INDEVUS believes that the results of such trial (such as toxicology studies) lead to the conclusion that there is no reasonable likelihood to obtain Regulatory Approval, provided that such conclusion shall be submitted to the Committee and the decision to terminate the Development Program and consequently the Agreement, shall be made by the Committee; or

(b) by giving [*] days advance notice to AVENTIS, provided that: (i) INDEVUS will, if requested by AVENTIS, cooperate with AVENTIS or AVENTIS’ designee during such [*] day period to transfer to AVENTIS or AVENTIS’ designee the supervision of any ongoing clinical trial in such a way that no delay incurs in such clinical trial, if the termination of such trial would materially adversely affect the development of Product and AVENTIS has advised INDEVUS that it intends to continue development of Product; (ii) INDEVUS will promptly upon having sent such notice transfer to AVENTIS or AVENTIS’ designee all data, files, Regulatory Approvals, if any, and information, data, know−how, etc. in the possession of INDEVUS and related to Compound or Product; (iii) AVENTIS will be entitled to start negotiations with Third Parties in relation to Compound or Product immediately upon receipt of such notice; and (iv) INDEVUS will provide AVENTIS with reasonable assistance that AVENTIS may request in responding to due diligence requests by Third Parties that AVENTIS is negotiating with as potential licensees for Compound or Product, provided that INDEVUS shall not be required to disclose to such Third Parties INDEVUS Proprietary Information that does not relate to Compound or Product.

Except as otherwise set forth in this Agreement, in the event of such termination, (i) the rights and obligations hereunder, excluding any payment obligation that has accrued as of the termination date and excluding rights and obligations relating to confidentiality, shall terminate immediately, and (ii) the provisions of Section 8.4 shall be applicable.

* CONFIDENTIAL TREATMENT REQUESTED
8.3 Termination.

8.3.1. Termination for Cause. Either Party may terminate this Agreement by notice to the other Party at any time during the term of this Agreement as follows:

(a) if the other Party is in breach of any material obligation hereunder by causes and reasons within its control, or has breached, in any material respect, any representations or warranties set forth in Article VI, and has not cured such breach within (i) [*] Business Days in case the breach is a non payment of any amount due under this Agreement and (ii) within [*] days for other cases of breach, after notice requesting cure of the breach, provided, however, that if a breach other than a non payment is not capable of being cured within [*] days of such written notice, the Agreement may not be terminated sooner than [*] days of such written notice so long as the breaching Party commences and is taking commercially reasonable actions to cure such breach as promptly as practicable; or

(b) Upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, under any re-organization or insolvency law of any jurisdiction, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or upon the rejection of this Agreement by either Party under section 365 of 11 U.S.C. §101 et seq. (the “Bankruptcy Code”); provided, however, that in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if the Party consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof.

8.3.2. Licensee Rights Not Affected.

(a) All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code licenses of rights to “intellectual property” as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that INDEVUS and AVENTIS shall retain and may fully exercise all of their respective rights, remedies and elections under the Bankruptcy Code.

(b) The Parties further agree that, in the event of the commencement of a bankruptcy or reorganization case by or against AVENTIS under the Bankruptcy Code, INDEVUS shall be entitled to all applicable rights under Section 365 (including 365(n)) of the Bankruptcy Code. Upon rejection of this Agreement by AVENTIS or a trustee in bankruptcy for AVENTIS, pursuant to Section 365(n), INDEVUS may elect (i) to treat this Agreement as terminated by such rejection or (ii) to retain its rights (including any right to enforce any exclusivity provision of this Agreement) to intellectual property (including any embodiment of such intellectual property) under this Agreement and under any agreement supplementary to this Agreement for the duration of this Agreement and any period for which this Agreement could have been extended by INDEVUS. Upon written request to the trustee in bankruptcy or AVENTIS, the trustee or AVENTIS, as

* CONFIDENTIAL TREATMENT REQUESTED
applicable, shall (i) provide to INDEVUS any intellectual property (including such embodiment) held by the trustee or AVENTIS and shall provide to INDEVUS a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property and (ii) not interfere with the rights of INDEVUS to such intellectual property as provided in this Agreement or any agreement supplementary to this Agreement, including any right to obtain such intellectual property (or such embodiment or duplicates thereof) from a Third Party.

8.4 Effect of Expiration or Termination.

(a) Except as set forth in this Agreement, in the event of termination of this Agreement, the rights and obligations hereunder, excluding any payment obligation that has accrued as of the termination date and excluding rights and obligations relating to confidentiality, shall terminate immediately, except that INDEVUS and its Affiliates and sublicensees shall have the right to sell or otherwise dispose of the stock of any Product subject to this Agreement then on hand or in process of manufacture. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. In addition to any other provisions of this Agreement which by their terms continue after the expiration of this Agreement, the provisions of Article IV shall survive the expiration or termination of this Agreement and shall continue in effect for five (5) years from the date of expiration or termination. In addition, any other provision required to interpret and enforce the Parties’ rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement. Any expiration or early termination of this Agreement shall be without prejudice to the rights of any Party against the other accrued or accruing under this Agreement prior to termination. Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, or at law.

(b) Upon termination of this Agreement pursuant to Section 8.2 or upon termination by AVENTIS pursuant to Section 8.3.1(a), INDEVUS shall, if requested to do so in writing by AVENTIS, grant a license to AVENTIS of INDEVUS Patent Assets and INDEVUS Know−How including any Regulatory Approval, if any, held by INDEVUS for Products at the time of termination. The Parties shall negotiate in good faith to enter into a mutually acceptable license provided, however, that such license shall be royalty−free if the termination is by INDEVUS under Section 8.2.

ARTICLE IX
MISCELLANEOUS

9.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement during the period of time when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, fire, flood, embargo, war, acts of war (whether war be declared or not),
insurrection, riot, civil commotion, strike, lockout or other labor disturbance, act of God or act, omission or delay in acting by any governmental authority, provided the affected Party has promptly notified the other Party of such force majeure circumstances as soon as reasonably practicable, and makes reasonable efforts to overcome force majeure and minimize the consequences of the force majeure, and resumes the performance of its obligations as soon as force majeure terminates.

9.2 Assignment. The Agreement may not be assigned or otherwise transferred without the prior written consent of the other Party; provided, however, that without such consent (i) either Party may assign this Agreement to an Affiliate, or in connection with the transfer or sale of all or substantially all of its business or assets or in the event of a merger, consolidation, change in control or similar corporate transaction and (ii) AVENTIS may assign this Agreement in connection with the transfer or sale of all or substantially all of its business or assets to which the Compound or Product relate, and provided further that the provisions of Section 2.4 may not be assigned by AVENTIS except to a Qualified Assignee of AVENTIS’ business and assets to which Compound or Product relate. For purposes of this Section 9.2, a Qualified Assignee shall mean a company that, at the time of exercise of the Right of First Negotiation, is actively engaged in the marketing of pharmaceutical products in those countries of the European Community where such Right of First Negotiation is meant to be implemented at that time and has the internal capability to achieve substantial market penetration and optimize sales of Product in such countries, taking into account the market potential of the Product and the status of the market as well as all relevant factors at that time. The Agreement shall be binding and inure to the successors of either Party thereto, in particular in the event of a merger, consolidation, change in control or similar corporate transaction. Any successor or permitted assignee shall assume all obligations of its assignor under this Agreement.

9.3 Severability. In the event that any of the provisions contained in this Agreement are held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the invalid provisions are of such essential importance for this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions. In such event, the Parties shall substitute such invalid provisions by valid ones, which in their economic effect come so close to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement also with those substituted provisions.

9.4 Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to INDEVUS to:

INDEVUS PHARMACEUTICALS, INC.
99 Hayden Avenue, Suite 200
Lexington, MA, United States 02421
Attention: President
Fax No.: 1-781-862-3859
if to AVENTIS to:

AVENTIS PHARMA SA
20 avenue Raymond Aron
92165 Antony Cedex
France
Attention: General Counsel
Fax No.: 33 1 55 71 66 50

or to such other address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered or sent by facsimile on a Business Day, upon confirmed delivery by nationally-recognized overnight courier if so delivered and on the third Business Day following the date of mailing if sent by registered or certified mail.

9.5 Applicable Law and Dispute Resolution. The Agreement shall be governed by and construed in accordance with the laws of New York, without reference to any rules of conflict of laws, except matters of intellectual property law, which shall be determined in accordance with the national intellectual property laws relevant to the intellectual property in question.

(a) The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a “Dispute”) by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within thirty (30) Business Days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of each Party. Such Chief Executive Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within thirty (30) Business Days after such notice is received by the Party to whom the notice was sent. With the exception of issues subject to the provisions of Section 3.3.2, if the Chief Executive Officers are unable to settle the Dispute between them within thirty (30) Business Days, they shall so report to the Parties in writing. The Dispute shall then be referred to mediation as set forth in the following subsection (b).

(b) Upon the Parties receiving the Chief Executive Officers’ report that the Dispute referred to them pursuant to subsection (a) has not been resolved, the Dispute shall be referred to mediation by written notice from either Party to the other. The mediation shall be conducted pursuant to the LCIA Mediation Procedure. In the event INDEVUS is the claimant, the mediation shall be held in London, England; in the event AVENTIS is the claimant, the mediation shall be held in Geneva, Switzerland. If the Parties have not reached a settlement within twenty (20) Business Days of the date of the notice of mediation, the Dispute shall be referred to arbitration pursuant to subsection (c) below.
If after the procedures set forth in subsections (a) and (b) above, the Dispute has not been resolved, a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. The Parties shall refrain from instituting the arbitration proceedings for a period of sixty (60) days following such notice. During such period, the Parties shall continue to make good faith efforts to amicably resolve the dispute without arbitration. If the Parties have not reached a settlement during that period the arbitration proceedings shall go forward and be governed by the LCIA Arbitration Rules then in force. Each such arbitration shall be conducted by a panel of three arbitrators with appropriate experience in the biotechnology or pharmaceutical industry: one arbitrator shall be appointed by each of AVENTIS and INDEVUS and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two Party-appointed arbitrators. In the event INDEVUS is the claimant, the arbitration shall be held in London, England; in the event AVENTIS is the claimant, the arbitration shall be held in the Geneva, Switzerland. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the mediation and arbitration levied by the LCIA. Any mediation or arbitration proceeding entered into pursuant to this Section 9.5 shall be conducted in the English language.

9.6 Entire Agreement. This Agreement, including the exhibits and schedules hereto, contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes all previous writings and understandings. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by all Parties hereto.

9.7 Independent Contractors. It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of such other Party.

9.8 Waiver. The waiver by a Party hereto of any right hereunder or the failure to perform or of a breach by another Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

9.9 Headings. The captions to the several Articles and Sections hereof are not a part of the Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.
9.10 **Counterparts.** The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

9.11 **LIMITATION OF LIABILITY.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

[Remainder of page intentionally left blank]
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

AVENTIS PHARMA SA

By: /s/ GILLES BRISSON
Name: Gilles Brisson
Title: President and Chief Executive Officer

INDEVUS PHARMACEUTICALS, INC.

By: /s/ GLENN L. COOPER
Name: Glenn L. Cooper, M.D.
Title: President and Chief Executive Officer
SCHEDULE 1.5
AVENTIS PATENT ASSETS
[*]

* CONFIDENTIAL TREATMENT REQUESTED
# SCHEDULE 1.6
## BANK HOLIDAYS IN FRANCE AND IN U.S.A.

### FRANCE

<table>
<thead>
<tr>
<th>Day</th>
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<tr>
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<td>Easter Monday</td>
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<tr>
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<td>May 1 (*)</td>
<td>Labour Day</td>
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<tr>
<td>Thursday</td>
<td>May 8 (*)</td>
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<tr>
<td>Thursday</td>
<td>May 29 (**)</td>
<td>Ascension</td>
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<tr>
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<tr>
<td>Tuesday</td>
<td>November 11 (*)</td>
<td>End of World War I</td>
</tr>
<tr>
<td>Thursday</td>
<td>December 25 (*)</td>
<td>Christmas</td>
</tr>
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(*) Every year on same date  
(**) Dates are for 2003, but for following years, since they are catholic religious feasts, they are worldwide identical dates,

### U.S.A.

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<th>Day</th>
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<tr>
<td>Wednesday</td>
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<td>May 26 — (4)</td>
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<tr>
<td>Thursday</td>
<td>December 25 — (1)</td>
<td>Christmas Day</td>
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</table>

Notes:  
ALL dates listed are for 2003

(1) Occur every year on the same date

(2) Occurs on the third Monday in January every year

(3) Occurs on the third Monday in February every year

(4) Occurs on the fourth Monday in May every year

(5) Occurs on the first Monday in September every year

(6) Occurs on the second Monday in October every year

(7) Occurs on the fourth Thursday in November every year

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
SCHEDULE 1.46
SPECIFICATIONS OF NUCLEUS
Preliminary Specification
(based on [*] data)
[*]

* CONFIDENTIAL TREATMENT REQUESTED
AVENTIS; 
[*] 
INDEVUS; 
[*] 

* CONFIDENTIAL TREATMENT REQUESTED
EXHIBIT 3.3.5
ANNUAL DEVELOPMENT PLAN — YEAR 1
[*]

* CONFIDENTIAL TREATMENT REQUESTED
EXHIBIT 3.7
AVENTIS INVENTORY
(BEFORE RE-TESTING AND RE-RELEASE)
[*]

* CONFIDENTIAL TREATMENT REQUESTED
* The exact amount to be provided by AVENTIS to INDEVUS in writing within ten (10) Business Days after the Effective Date

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
EXHIBIT C
LETTERS OF EXTENSION FOR AVENTIS SUPPLY OF NUCLEUS
[See attached]
Dear David,

Further to our review of aminocandin, I am informing you that sanofi-aventis is not interested in pursuing further this project. Therefore, our 90 days period for evaluating our interest in submitting an indicative offer is over.

I would like to thank you and your team for the pleasant exchanges we had on this project.

I hope we will have other opportunities to work together in the future.

Best regards,

Sebastien

Corporate Licenses, Sanofi-aventis
174 Av. de France, 75013 Paris
Tel. +33 1 53774659
Mob. +33608961586
Fax. +33 153774994

11/15/2006
Thomas D. Forrester  
Corporate Counsel−Legal Corporate Development  
Aventis Pharmaceuticals  
Mail Code: RX2−71650  
200 Crossing Boulevard  
PO Box 6890  
Bridgewater, NJ 08807−0890

Re: Amendment No.1 of License Agreement between Indevus Pharmaceuticals, Inc. (“Indevus”) and Aventis Pharma SA (“Aventis”) dated April 18, 2003 (“the License Agreement”)

Dear Tom:

We refer to Section 3.8(a) of the License Agreement. The two parties agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: “INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within one hundred fifty (150) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.” Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

Please indicate your acceptance of this amendment by having the appropriate Aventis representative sign both of these originals in the space indicated and return one original to us for our files.

Very truly yours,

Accepted and Agreed  
this 15th day of July, 2003

INDEVUS PHARMACEUTICALS, INC.  

By: /s/ Mark S. Butler  
Name: Mark S. Butler  
Title: Executive Vice President, Chief Administrative Officer & General Counsel

AVENTIS PHARMA SA

By: /s/ Gilles Brisson  
Name: Gilles Brisson  
Title: President of Management Board

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
Amendment No. 2, dated as of September 12, 2003, to License Agreement between Indevus Pharmaceuticals, Inc. (“Indevus”) and Aventis Pharma SA (“Aventis”) dated April 18, 2003 (“License Agreement”)

Whereas Indevus and Aventis desire to amend the last sentence of Section 3.8(a) of the License Agreement;

NOW, THEREFORE, for good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Indevus and Aventis hereby agree as follows:

1. Indevus and Aventis agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: “INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within two hundred forty (240) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.”

2. Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Indevus and Aventis have caused this Amendment No.2 of the License Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMA SA

By: /s/ Alain Chevallier
Name: Alain Chevallier
Title: General Manager and Member of Management Board

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Mark S. Butler
Name: Mark S. Butler
Title: EVP
Amendment No. 3, dated as of December 10, 2003, to License Agreement between Indevus Pharmaceuticals, Inc. ("Indevus") and Aventis Pharma SA ("Aventis") dated April 18, 2003 ("License Agreement")

Whereas Indevus and Aventis desire to amend the last sentence of Section 3.8(a) of the License Agreement;

NOW, THEREFORE, for good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Indevus and Aventis hereby agree as follows:

1. Indevus and Aventis agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: “INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within three hundred sixty (360) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.”

2. Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Indevus and Aventis have caused this Amendment No.3 of the License Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMA SA

By: /s/ Alain Chevallier
Name: Alain Chevallier
Title: Chief Financial Officer and Member of Management Board

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Mark S. Butler
Name: Mark S. Butler
Title: Executive Vice President, Chief Administrative Officer & General Counsel
Whereas Indevus and Aventis desire to amend the last sentence of Section 3.8(a) of the License Agreement;

NOW, THEREFORE, for good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Indevus and Aventis hereby agree as follows:

1. Indevus and Aventis agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: “INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within four hundred fifty (450) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.”

2. Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Indevus and Aventis have caused this Amendment No. 4 of the License Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMA SA

By: /s/ Alain Chevallier
Name: Alain Chevallier
Title: Chief Financial Officer

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Mark S. Butler
Name: Mark S. Butler
Title: Executive Vice President, Chief Administrative Officer & General Counsel
Amendment No. 5, dated as of July 1, 2004, to License Agreement between Indevus Pharmaceuticals, Inc. (“Indevus”) and Aventis Pharma SA (“Aventis”) dated April 18, 2003 (“License Agreement”)

Whereas Indevus and Aventis desire to amend the last sentence of Section 3.8(a) of the License Agreement;

NOW, THEREFORE, for good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Indevus and Aventis hereby agree as follows:

1. Indevus and Aventis agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: “INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within five hundred thirty three (533) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.”

2. Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Indevus and Aventis have caused this Amendment No. 5 of the License Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMA SA

By: /s/ Alain Chevallier
Name: Alain Chevallier
Title: Chief Financial Officer

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Mark S. Butler
Name: Mark S. Butler
Title: Executive Vice President, Chief Administrative Officer & General Counsel

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
Amendment No. 6, dated as of September 28, 2004, to License Agreement between Indevus Pharmaceuticals, Inc. ("Indevus") and Aventis Pharma SA ("Aventis") dated April 18, 2003 ("License Agreement")

Whereas Indevus and Aventis desire to amend the last sentence of Section 3.8(a) of the License Agreement;

NOW, THEREFORE, for good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Indevus and Aventis hereby agree as follows:

1. Indevus and Aventis agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: "INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within seven hundred thirty (730) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus."

2. Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Indevus and Aventis have caused this Amendment No. 6 of the License Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMA SA

By: /s/ O. Jacquesson
Name: O. Jacquesson
Title:

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Mark S. Butler
Name: Mark S. Butler
Title: Executive Vice President
Amendment No. 7, dated as of April 20, 2005, to License Agreement between Indevus Pharmaceuticals, Inc. (“Indevus”) and Aventis Pharma SA (“Aventis”) dated April 18, 2003 (“License Agreement”)

Whereas Indevus and Aventis desire to amend the last sentence of Section 3.8(a) of the License Agreement;

NOW, THEREFORE, for good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Indevus and Aventis hereby agree as follows:

1. Indevus and Aventis agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: “INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within eight hundred twenty (820) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.”

2. Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Indevus and Aventis have caused this Amendment No. 7 of the License Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMA SA

By: /s/ Gilles Lhernould
Name: Gilles Lhernould
Title: President

By: /s/ Gerard Touratier
Name: Gerard Touratier
Title: Financial Director

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Mark S. Butler
Name: Mark S. Butler
Title: Executive Vice President
Amendment No. 8, dated as of July 20, 2005, to License Agreement between Indevus Pharmaceuticals, Inc. ("Indevus") and Aventis Pharma SA ("Aventis") dated April 18, 2003 ("License Agreement")

Whereas Indevus and Aventis desire to amend the last sentence of Section 3.8(a) of the License Agreement;

NOW, THEREFORE, for good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Indevus and Aventis hereby agree as follows:

1. Indevus and Aventis agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: "INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms within nine hundred and forty (940) days after the Effective Date, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus."

2. Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Indevus and Aventis have caused this Amendment No. 7 of the License Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMA SA

By: /s/ Gilles Lhernould
Name: Gilles Lhernould
Title: President

By: /s/ Gerard Touratier
Name: Gerard Touratier
Title: Financial Director

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Mark S. Butler
Name: Mark S. Butler
Title: Executive Vice President

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
Whereas Indevus and Aventis desire to amend the last sentence of Section 3.8(a) of the License Agreement;

NOW, THEREFORE, for good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Indevus and Aventis hereby agree as follows:

1. Indevus and Aventis agree to amend the License Agreement by deleting the last sentence of Section 3.8(a) in its entirety and substituting therefor the following sentence: “INDEVUS and AVENTIS shall negotiate in good faith to enter into a manufacturing and supply agreement between the Parties containing mutually acceptable terms on or before July 1, 2007, which shall set forth the terms and conditions of the manufacturing and supply of the Nucleus.”

2. Except as provided herein, all terms in the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Indevus and Aventis have caused this Amendment No. 7 of the License Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMA SA

By: /s/ Gilles Lhernould
Name: Gilles Lhernould
Title: President

By: /s/ Gerard Touratier
Name: Gerard Touratier
Title: Financial Director

INDEVUS PHARMACEUTICALS, INC.

By: /s/ Mark S. Butler
Name: Mark S. Butler
Title: Executive Vice President
API SUPPLY AGREEMENT

This API Supply Agreement (this “Agreement”) is made as of this 22nd day of November, 2006 (“Effective Date”), by and between INDEVUS PHARMACEUTICALS INC., a corporation organized and existing under the laws of the State of Delaware, United States of America, and having an office at 33 Hayden Avenue, Lexington, MA 02421–7971, United States (“Indevus”) and HELSINN CHEMICALS SA and HELSINN ADVANCED SYNTHESIS SA, both corporations organized and existing under the law of Switzerland and having their registered office at Via Industria 24, 6710 Biasca, Switzerland (“Helsinn”). Indevus and Helsinn hereinafter are collectively referred to as the “Parties” and individually as a “Party”.

WHEREAS, Indevus holds certain rights to manufacture, market and sell pharmaceutical products containing the API (as defined below);

WHEREAS, Indevus wishes to purchase from Helsinn API In Bulk (as defined below) for subsequent formulation, tableting, packaging, and commercial sale by Indevus or Indevus’ designee and for certain clinical and other purposes; and

WHEREAS, Helsinn has suitable facilities and equipment and sufficient qualified personnel to manufacture API In Bulk, and is willing to provide such API supply on the terms and conditions set forth below.

NOW, THEREFORE, the Parties hereto, intending to be legally bound, agree as follows:

I. DEFINITIONS

As used in this Agreement:

1.1 “Act” means the United States Food, Drug, and Cosmetic Act of 1938, as amended, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.

1.2 “Active Pharmaceutical Ingredient” or “API” means the compound [*] which is more commonly known as TROPIUM CHLORIDE, described in and conforming to the Specifications.

1.3 “Adverse Experience” or “AE” means any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with any use of a product or of a derivative thereof containing API, whether or not the adverse experience is considered to be related to the use of such product, including but not limited to any of the following: an unexpected side effect, injury, toxicity or sensitivity reaction, which may include an experience of unexpected incidence and severity; an adverse

[*] CONFIDENTIAL TREATMENT REQUESTED
experience occurring in the course of the use of a drug product in professional practice; an adverse experience occurring in clinical studies; an adverse experience occurring from drug overdose, whether accidental or intentional; an adverse experience occurring from drug abuse; an adverse experience occurring from drug withdrawal; and any significant failure of expected pharmacological action; but in any event shall mean adverse drug experiences, as defined by 21 CFR Section 314.80.

1.4 "Affiliate" means with respect to a Party, any corporation or other business entity which, directly or indirectly, is controlled by, controls, or is under common control with such Party. For this purpose, “control” shall be deemed to mean direct or indirect ownership of fifty percent (50%) or more of the stock or other equity of such entity.

1.5 “Batch” means a specific quantity of API that is produced according to a single manufacturing order during the same cycle of manufacture.

1.6 “Business Day” shall mean any day that is not a Saturday, a Sunday, a day on which the New York Stock Exchange is closed, or other day on which banks are required or authorized by law to be closed in Biasca, Switzerland.


1.8 “Commercially Reasonable Efforts” means, with respect to a Party, the efforts and resources which would be used (including without limitation the promptness in which such efforts and resources would be applied) by such Party, consistent with generally-accepted industry standards for a company of comparable size and business in the industry, with regard to the diligent manufacture and commercialization of pharmaceutical products of similar market and profit potential at a similar stage in development or product life. The term “Commercially Reasonable” shall have a corresponding meaning.

1.9 “Confidential Information” means all information, data, know-how and all other business, technical and financial data disclosed hereunder by one Party or any of its Affiliates to the other Party or any of its Affiliates, except any portion thereof which:

(a) at the time of disclosure, is public knowledge;

(b) after disclosure, becomes public knowledge by publication or otherwise, except by breach of this Agreement by the recipient;

(c) the recipient can demonstrate by its written records was in the recipient’s possession at the time of such disclosure, and which was not acquired, directly or indirectly, from the disclosing Party or its Affiliates;

(d) is lawfully disclosed to the recipient on a non-confidential basis by a third party who is not obligated to the disclosing Party or any other third party to retain such Confidential Information in confidence;

(e) results from research and development by the recipient independent of such disclosure as shown by competent evidence; or
(f) is required to be disclosed by legal process; provided, in each case the Party so disclosing information timely informs the other Party and uses its reasonable efforts to limit the disclosure and maintain confidentiality to the extent possible and, if possible, permits the other Party to attempt by appropriate legal means to limit such disclosure, subject to the provisions of Section 4.6.

All information exchanged pursuant to this Agreement shall be considered Confidential Information. Confidential Information disclosed orally, visually and/or in another intangible form shall be identified by the disclosing Party to the receiving Party as confidential at the time of such disclosure and confirmed in writing to the receiving party within thirty (30) days after such disclosure.

1.10 “Current Good Manufacturing Practices” or the letters “GMP,” or “cGMP” means current good manufacturing practice and standards as provided for (and as amended from time to time) in European Community Directive 91/356/EEC (Principles and guidelines of good manufacturing practice for medicinal products for human use) and in the Current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 C.F.R. Parts 210 and 211) in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, and applicable ICH Harmonised Tripartite Guideline Q7a, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, and subject to any arrangements, additions or clarifications agreed in writing from time to time between the Parties in the Quality Technical Agreement.

1.11 “DMF” means a Drug Master File as defined in 21 C.F.R. §314.420 in the United States, including all supplements and amendments thereto or any foreign counterpart of a U.S. DMF.

1.12 “FDA” means the United States Food and Drug Administration and any successor agency having substantially the same functions.

1.13 “Finished Product” means any drug product containing or comprising API, in its finished, labeled and packaged form, ready for sale to the market, including all samples thereof.

1.14 “HCT” means [*], an Affiliate of Helsinn.

1.15 “Helsinn Facility(ies)” means any Helsinn or HCT manufacturing facility(ies) that is qualified or approved in the NDA to manufacture API and that is used for the manufacture of API pursuant to this Agreement.

1.16 “Helsinn Payment” means [*].

1.17 “In Bulk” means quantities of API formulated and packaged in non–retail size containers.

1.18 “Launch Period” means the period commencing on the launch date of SANCTURA XR™ in the United States and expiring on (a) December 31 of the calendar year in which such launch date occurs if the launch date occurs in the first three months of

[*] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
such year; or (b) December 31 of the calendar year immediately following the calendar year in which the launch date occurs if the launch date occurs after the first three months of such year.

1.19 “Losses” means any and all damages, awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties (including penalties imposed by any governmental authority), costs, fees, liabilities, obligations, taxes, liens, losses, and expenses (including without limitation court costs, interest and reasonable fees of attorneys, accountants and other experts) awarded or otherwise paid or payable to third parties.

1.20 “NDA” means a New Drug Application pursuant to Section 505 of the Act submitted to the FDA or any successor application or procedure or any foreign counterpart of a U.S. New Drug Application for approval to market, including, where applicable, applications for pricing and reimbursement approval.

1.21 “Purchase Price” shall have the meaning set forth in Section 6.3 hereof.

1.22 “Quality Technical Agreement” means the quality assurance/quality control agreement to be entered into by Indevus and Helsinn in accordance with Schedule 1.22 and as contemplated by Section 3.7 and to be appended to this Agreement as Exhibit 1.22.

1.23 “Regulatory Authority” means (i) the FDA and/or (ii) any regulatory body with similar regulatory authority in any other jurisdiction anywhere in the Territory.

1.24 “Regulatory Standards” means (i) obtaining and maintaining any and all permits, licenses, filings and certifications required by the FDA or other Regulatory Authorities, and compliance with cGMPs, applicable to the Helsinn Facilities or Helsinn’s activities hereunder, and (ii) any laws, rules, regulations and standards of any Regulatory Authority, whether within or outside the United States that apply to such activities.

1.25 “SANCTURA XR™” means the once-daily formulation of SANCTURA® currently under development by Indevus.

1.26 “Specifications” means the quality assurance and quality release specifications for API as set forth on Schedule 1.26, subject to such modifications to the Specifications agreed between Indevus and Helsinn in writing and set forth in an amendment to this Agreement as a restated Schedule 1.26.

1.27 “Territory” means worldwide.

Where words and phrases are used herein in the singular, such usage is intended to include the plural forms where appropriate to the context, and vice versa. The words “including”, “includes” and “such as” are used in their non-limiting sense and have the same meaning as “including without limitation” and “including but not limited to”. References to Articles, Sections, subsections, and clauses are to the same with all their subparts as they appear in this Agreement.

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
II. PURCHASE AND SALE

2.1 Purchase and Sale. Subject to the terms and conditions of this Agreement, (a) Indevus hereby agrees to purchase from Helsinn an [*] per year of API for each rolling [*] period of the Initial Term commencing after the [*] and expiring after Indevus has purchased from Helsinn [*] of API (the “Minimum Purchase Requirement”), and (b) Helsinn agrees to manufacture and supply API exclusively to Indevus and/or Indevus’ designee, pursuant to purchase orders placed by Indevus from time to time, for all purposes, including without limitation, subsequent formulation, encapsulating, tableting, packaging and commercial sale by Indevus and/or Indevus’ designee and for certain clinical and other purposes in the Territory. Helsinn shall supply the API in appropriate bulk containers. Subject to the last sentence of this Section 2.1, in the event that for any calendar year commencing on the [*] anniversary of the [*] of the [*] (the [*] Contract Year”), Indevus purchases [*], but during the prior calendar year Indevus had purchased at least [*]. Indevus will have satisfied the Minimum Purchase Requirement for the [*] Contract Year and no Helsinn Payment would be due for the [*] Contract Year. If however, for the prior calendar year Indevus had purchased [*], Indevus would not have satisfied the Minimum Purchase Requirement for the [*] Contract Year and a Helsinn Payment for [*] would be due for the [*] Contract Year. In the event that before the end of any calendar year commencing on the [*] anniversary of the [*] of the [*], Indevus notifies Helsinn of its inability to purchase, by the end of each rolling two year period, the number of batches required to meet in aggregate the Minimum Purchase Requirement for the applicable period, Indevus shall pay Helsinn [*] percent ([*]%) of the Helsinn Payment on the number of batches required to meet the Minimum Purchase Requirement that are not purchased by Indevus in the next calendar year if Helsinn [*] said Helsinn Payment [*].

2.2 Cooperation. Indevus and Helsinn will cooperate with each other as may be necessary and customary in consideration of industry practice, and will disclose all material information necessary to enable each other to perform their duties under this Agreement in a timely fashion.

2.3 Specific Duties. In addition to its general obligations relating to the manufacture and supply of API, Helsinn shall be responsible for performing the following services at Helsinn’s cost:

(a) quality control and testing of all API in order to monitor compliance with all applicable Regulatory Standards, the Specifications and this Agreement;

(b) conducting stability testing of API in accordance with the procedures set forth in the Quality Technical Agreement;

(c) summarizing implemented changes and supplying latest versions of approved critical documentation, and providing other information necessary for Indevus to prepare, submit, obtain and maintain all regulatory filings relating to the manufacture of the API under the terms of this Agreement; and

(d) performing such other services as agreed upon in writing by the Parties.

[*] CONFIDENTIAL TREATMENT REQUESTED
III. API QUANTITY, QUALITY AND MANUFACTURING PROCESSES; TECHNICAL ASSISTANCE

3.1 **Quantity.** Subject to the terms and conditions of this Agreement, Helsinn will manufacture and supply to Indevus or Indevus’ designee quantities of API ordered by Indevus or Indevus’ designee. Helsinn agrees to reserve capacity for the quantities of API as defined in **Schedule 3.1.** Helsinn shall have no obligation to supply quantities in excess of those set forth in **Schedule 3.1,** but shall use its Commercially Reasonable Efforts to accommodate Indevus demand for excess quantities.

3.2 **Quality.** All API manufactured and sold by Helsinn to Indevus under this Agreement will meet the Specifications, as well as the quality assurance standards established in the Quality Technical Agreement. Such Specifications, as well as the terms and conditions of the Quality Technical Agreement, are subject to modification from time to time by mutual written agreement of the Parties. Subject to the terms of this Section 3.2 and Section 6.3, prior to implementation of any such changes to the Specifications, the Parties agree to negotiate in good faith in an attempt to reach agreement on (a) the new Purchase Price for any API manufactured and supplied hereunder by Helsinn which embodies such changes, based solely on the effect of such changes on Helsinn’s manufacturing costs for the API (including, if applicable, any decrease in the Purchase Price in the event of any decrease in the costs of starting and raw materials used in the manufacture of the API) and (b) any other amendments to this Agreement which may be necessitated by such changes (e.g., an adjustment to the lead time for purchase orders).

3.3 **Improvements**

(a) Except as set forth in sub−section 3.3 (b), for changes, including, but not limited to process changes, site changes and supplier changes intended to improve operational efficiency, effectiveness and risk−management (the “Improvements”), both Parties shall agree in writing whether to implement such Improvement or not. If the Parties agree to implement such Improvement, the Parties shall also agree in writing on an Improvement program including an assessment of the costs of implementation of the program and of the expected financial impact of the Improvement. Upon completion of the Improvement program, should the Improvement have been demonstrated to be feasible, the Parties shall agree in writing which Party will be responsible to pay documented costs and expenses for the implementation of said Improvement, being understood that should Indevus be responsible for all such costs and expenses the Purchase Price will be reduced by an amount equal to [*]% of the amount of the decrease, if any, in the costs of starting and raw materials due to the implementation of the Improvement, while should Helsinn be responsible for all such costs and expenses the Purchase Price will be reduced by an amount equal to [*]% of the amount of the decrease, if any, in the costs of starting and raw materials.

(b) The Parties acknowledge that (i) [*], and (ii) [*]/kg (the “[*]”). Helsinn agrees to use its best efforts to [*] and to [*]. The Purchase Prices set forth on Part B of **Schedule 6.3** shall be effective [*]; provided, however, that in the event that the actual [*], the Purchase Prices set forth on Part B of Schedule 6.3 [*]. For example, if the [*] is [*], the Purchase Price set forth on Part B of Schedule 6.3 [*]

[CONFIDENTIAL TREATMENT REQUESTED]
3.4 **Manufacturing Processes.** Helsinn has furnished and will continue to furnish to Indevus during the term of this Agreement a copy of its current production procedures and in the Quality Technical Agreement the Parties will agree upon the equipment to be used to produce the API. Except as otherwise set forth in this Agreement, costs incurred by Helsinn as a result of any such changes or modifications requested by the FDA or by Indevus and relating solely to the production of the API will be borne by Indevus; costs for other changes affecting Helsinn’s compliance with cGMP or affecting other products generally will be borne by Helsinn.

3.5 **Documentation.** Indevus shall provide Helsinn with initial methods and Specifications for manufacturing the API as set forth in the attached Schedule 1.26. Indevus shall also promptly provide Helsinn with all available safety data and information concerning the API, process and related materials, including without limitation all material safety data sheets (“MSDS’s”).

3.6 **Communication.** Helsinn and Indevus will respond to requests for support, information and approvals within ten (10) Business Days. If a complete response is not possible within such ten (10)−day period, the Party owing the response shall communicate within such ten (10)−day period the reason for the delay and when the response will be available.

3.7 **Quality Technical Agreement.** Within sixty (60) days after the Effective Date, the Parties shall enter into a Quality Technical Agreement outlining responsibilities and key contacts for API quality and compliance related issues. Helsinn will provide Indevus with certain production and control information for review prior to release as specified in the Quality Technical Agreement. The Quality Technical Agreement will also address, without limitation, annual product reviews, returned goods, regulatory audits, compliance with Current Good Manufacturing Practices, and such other quality related concerns deemed appropriate. The final agreed Quality Technical Agreement will be attached to this Agreement as Exhibit 1.22 and deemed a part of this Agreement. In the event that the Quality Technical Agreement contains material provisions that substantially differ from applicable comparable Regulatory Standards, the Regulatory Standards shall control.

IV. CONFIDENTIAL INFORMATION

4.1 The Parties acknowledge that they have provided Confidential Information to each other in connection with the manufacture and supply of the API, and further acknowledge that all such Confidential Information (as well as any additional Confidential Information provided by one Party to the other hereunder) shall be subject to the provisions of this Section IV. Any and all confidential information, knowledge, technology and trade secrets relating to the API and provided by Indevus and/or Helsinn to the other shall be deemed Confidential Information.

4.2 During the term of this Agreement and for ten (10) years thereafter, all Confidential Information disclosed and confirmed in writing and designated as confidential by the disclosing party within thirty (30) days from oral disclosure, including confidential information so designated that was disclosed by either Party prior to the Effective Date, shall be held in confidence by the receiving party, shall not be used by the receiving party for any purpose except as provided hereunder and

[†] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
shall not be disclosed to third parties except for disclosure to its Affiliates or governmental authorities, in connection with pre-clinical or clinical development activities or the manufacturing of Finished Product, or except as otherwise necessary to carry out the receiving party’s obligations under this Agreement. If a receiving party finds it necessary to disclose such Confidential Information to a third party, the receiving party will not do so without first obtaining the written consent of the disclosing party (which shall not be unreasonably withheld) and entering into an agreement with the third party which binds the third party to obligations of restricted use and disclosure no less stringent than those undertaken by the Parties in this Agreement.

4.3 Neither Party shall distribute any Confidential Information of the other except to its employees, agents or consultants who have a need to know exclusively in connection with the performance of their duties in satisfying the obligations of such Party hereunder. Any employee, agent or consultant who receives Confidential Information shall be advised as to the confidential nature thereof and the prohibitions contained herein. All copies of any portions of any Confidential Information distributed as provided in this Section will be identified as confidential. Upon termination of this Agreement, and upon the request of the disclosing party, the receiving party shall return or destroy all such Confidential Information and any copies thereof in its possession, except that each Party may retain one copy of Confidential Information solely for archival purposes.

4.4 Termination of this Agreement shall not operate to extinguish either Party’s obligation to treat Confidential Information as provided herein, and the same shall continue in effect in accordance with this Section.

4.5 Nothing contained herein shall be deemed to grant to either Party, either expressed or implied, a license or other right or interest in the Confidential Information of the other or in any patent, trademark or other similar property of the other.

4.6 Neither Party shall use the name of the other, nor disclose the existence of this Agreement for any purpose, without the prior written consent of the other, which shall not be unreasonably withheld or delayed provided, however, it is understood that Indevus may make disclosure of this Agreement and the terms hereof, in any filings required by the United States Securities and Exchange Commission (“SEC”) and may file this Agreement as an exhibit to any filing with the SEC. In connection with any such filing, Indevus shall endeavor to obtain confidential treatment of economic and trade secret information and shall deliver to Helsinn in advance of any filing a redacted copy of this Agreement to enable Helsinn to give comments and suggestions on economic and trade secret information to be kept confidential.

V. FORECASTS AND ORDERS

5.1 Forecasts.

(a) Not later than [*] prior to the estimated launch date of SANCTURA XR ™[*], Indevus shall provide Helsinn with a forecast of its estimated requirements for API for the period [*] calendar quarters from the estimated launch date, broken down on a quarterly basis. Within [*] prior to the estimated launch date of
SANCTURA XR™, Indevus shall provide Helsinn with an updated forecast of its estimated requirements of API for the [*] calendar quarters commencing after [*] after the launch date, broken down on a quarterly basis. Within [*] days after the launch date, and thereafter on a quarterly basis during the term of this Agreement, Indevus shall provide Helsinn with a rolling forecast of its estimated requirements of API, broken down on a quarterly basis, for [*] consecutive calendar quarters (commencing at the beginning of the [*] complete calendar quarter that commences after the date of such forecast).

(b) The first [*] calendar quarters of each forecast provided after the launch date of SANCTURA XR™ (the “Binding Portion”) shall represent a binding forecast and the remaining [*] calendar quarters of each forecast shall be non-binding and shall represent Indevus’s reasonable estimates only. Except as set forth in the preceding sentence and the first sentence of Section 5.2, all forecasts made hereunder shall be made to assist Helsinn in planning its production and shall not be binding purchase orders, and shall be without prejudice to Indevus’s subsequent purchase orders for the API in accordance with the terms of this Agreement. Each forecast provided by Indevus shall supersede any previous forecast and may be expressed in a reasonable range.

5.2 Purchase Orders. Subject to the terms and conditions of this Agreement, Indevus shall be bound to order [*] percent ([*]%) of the forecasted quantities of API that are subject to a Binding Portion of the most recent rolling forecast referred to in Section 5.1. Indevus agrees to purchase API in not less than full lot quantities, which as of the Effective Date are approximately [*] kg ([*] kilograms) per batch. Indevus or its designee shall provide Helsinn with purchase orders on the standard purchase order forms of Indevus or its designee of its requirements for API at least [*] days before it requires each delivery of API, specifying the required delivery date in each purchase order. Provided Indevus’s purchase orders do not exceed Helsinn’s reserve capacity set forth in Schedule 3.1, Helsinn shall accept all Indevus purchase orders and shall supply Indevus in accordance with them, provided, however, that in case of any conflict or inconsistency between the terms of said orders and the terms and conditions of this Agreement, the terms of this Agreement shall prevail. Indevus can increase or decrease its firm order quantities with Helsinn’s prior agreement and Helsinn can adjust its shipping quantities with Indevus’s prior agreement. Both parties shall use their Commercially Reasonable Efforts to accommodate reasonable change requests from the other. Helsinn shall use Commercially Reasonable Efforts to prevent an interruption of supply to Indevus and to execute all orders received and accepted pursuant to Article V within [*] days from the date of receipt and acceptance of the relevant order by Helsinn.

5.3 Shortages. Helsinn shall acknowledge and provide Indevus, subject to Section 5.2 above, with a written acceptance of each purchase order within five (5) Business Days following Helsinn’s receipt thereof, provided, that Helsinn shall immediately notify Indevus of any problems or unusual production situations which may adversely affect production or quality of API or its timely delivery to Indevus or its designee. In addition, if, at any time Helsinn becomes aware or anticipates that it will not be able to satisfy Indevus’s forecasts or ordered requirements for API in whole or in part, due to any reason then Helsinn shall: (i) give Indevus notice thereof within five (5) Business Days of receipt of a particular forecast or purchase order (or upon Helsinn’s
reasonable belief that it cannot fulfill the forecast or purchase order if such date is after such five (5) Business Day period), (ii) if such inability is partial, fulfill purchase orders with such quantities of API as are available and supply the remaining quantities of API through HCI on a timely basis and (iii) if such inability is total, fulfill purchase orders of API through HCI, provided that all API manufactured and supplied by HCI is in accordance with the Specifications, applicable Regulatory Standards, and the terms and conditions of this Agreement and the Quality Technical Agreement. In addition, in the event neither Helsinn nor HCI can fulfill such purchase orders in accordance with such requirements, Helsinn shall take all Commercially Reasonable steps including as set forth under Section 5.4, to enable Indevus to procure adequate quantities of API from a second source. In the event of any failure to supply by Helsinn, Indevus shall be relieved from its obligations under this Agreement to purchase any quantities of API identified in any Binding Portion of a forecast or outstanding purchase orders and of the Minimum Purchase Requirements. Nothing in this Section 5.3, Section 5.4 or Section 7.7, shall limit any contractual rights or remedies that may be available to Indevus on account of any failure to supply API pursuant to the terms of this Agreement.

5.4 Second Source.
At the request of Indevus, Helsinn shall take all Commercially Reasonable steps to procure all necessary licenses, permits, certifications and approvals relating to the qualification of HCI and/or another Helsinn Facility as a second manufacturer of API, and to comply and cause HCI or such other Helsinn Facility, as applicable, to comply with such other requirements, obligations and responsibilities as are necessary to fully enable HCI or such other Helsinn Facility, as applicable to undertake the manufacturing and supply of API in accordance with the Specifications, applicable Regulatory Standards, and the terms and conditions of this Agreement and the Quality Technical Agreement. Such alternative production site and all related costs and expenses shall be approved by Indevus before commencement of routine production and all actions required to have a DMF for API approved by the FDA will be put in place and agreed between both Parties. Costs and expenses related to obtainment and maintenance of the above mentioned licenses, permits, certifications and approvals shall be borne by Indevus, provided, however, that Helsinn shall bear or reimburse Indevus for all such costs and expenses incurred in the event or as a result of Helsinn’s inability to supply or fulfill its requirements under this Agreement.

5.5 API Inventory. Indevus may use any API produced by Helsinn and delivered prior to the date of this Agreement, including validation batches of API ("API Inventory"), as launch stocks and/or to satisfy Indevus’s requirements to order any API quantities subject to any Binding Portion of a forecast or purchase order requirements provided under this Agreement including the Minimum Purchase Requirements, subject to compliance with applicable laws and other provisions of this Agreement. In such event, the quantities of API Inventory used to satisfy the Binding Portion of a forecast or purchase order requirement shall be offset against the requirements to purchase the comparable quantities of API subject to any such Binding Portion of a forecast or purchase order requirement.
VI. PRICE, SHIPMENT AND PAYMENT

6.1 **Helsinn’s Responsibilities.** Helsinn will properly manufacture the API so that it may be lawfully and safely shipped to Indevus or its designee worldwide. Helsinn will prepare and execute all reasonably necessary shipping documents, consisting of Packing List, Dangerous Goods Declaration, MSDS, Certificate of Analysis and Certificate of GMP compliance. Indevus will choose the carrier and the designee by indicating both on its purchase order provided to Helsinn.

6.2 **Terms of Shipment.** Upon receipt from Indevus of an authorization for release as set forth in Section 7.1, Helsinn will invoice API [*] (Incoterms 2000). Transportation to final destination will be carried out at the care of Helsinn, according to Indevus’s written instructions, by common carrier designated by Indevus. If Indevus does not designate a common carrier, Helsinn may select the common carrier. Risk of loss shall pass from Helsinn to Indevus [*]. All transport and insurance costs will be borne by [*]. All API to be delivered pursuant to this Agreement shall be delivered in accordance with this Section 6.2, suitably packed in bulk containers for shipment, and marked for shipment to the final destination point indicated in Indevus’ purchase order. The shipping packaging used in connection with API deliveries shall be in accordance with cGMP with respect to protection of the API during transportation, taking into consideration the mode(s) of transport Indevus has elected to use for each such shipment, the final destination point of each such shipment and reasonable expectations regarding shipment time duration and possible delays associated therewith.

6.3 **Price.** Helsinn shall invoice Indevus the Purchase Price for all API delivered as set forth in Schedule 6.3 attached hereto, as such schedule is amended as provided for herein and therein. Helsinn shall send its invoice at the time of shipment. For purchase orders and invoices during any particular year, the Purchase Price shall be calculated on a cumulative basis based on the quantities of API purchased during that year up to and including API purchased under the purchase order for which the calculation is being made, giving effect to any applicable credit due to volume discounts, provided, however, that within [*] days after the end of each year, the Parties shall calculate the actual Purchase Price for such year based on a calculation of the total quantities of API purchased for that year and the applicable Purchase Price for such quantities of API in accordance with Schedule 6.3 and, at Indevus’ request, Helsinn shall either refund to Indevus within ten (10) days after such reconciliation or credit against future purchases of API any amounts due Indevus for any excess payment of the Purchase Price.

6.4 **Terms of Payment.** Indevus will pay Helsinn the Purchase Price within [*] days after the date on which Indevus receives the invoice from Helsinn. All payments required by this Agreement shall be made in United States dollars. In the event of any late payment of any payment due hereunder, the amount of the late payment shall bear interest at the Prime Rate commencing on the date such payment is due until such date as the payment is made. “Prime Rate” for purposes of this Section 6.4 shall mean the prime rate of Citibank, N.A. in New York, New York as published in the Wall Street Journal computed on a daily basis and shall change when and as the Prime Rate changes.

6.5 **Tax Withholding.** If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Agreement, Helsinn shall provide Indevus, prior to any such payment, annually or more frequently if required, with all

[*] CONFIDENTIAL TREATMENT REQUESTED
forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary (including, but not limited to, Form W8−BEN and any successor form) and Indevus shall make such withholding payments as required and subtract such withholding payments from the payments set forth in this agreement. Indevus shall submit appropriate proof to Helsinn of payment of the withholding taxes within a reasonable period of time. Indevus will use efforts consistent with its usual business practices to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future taxation treaties or agreements between foreign countries, and Helsinn shall cooperate with such efforts.

VII. INSPECTION AND ANALYSIS

7.1 Inspection by Helsinn. Helsinn will analyze each API lot for compliance with the Specifications. Helsinn will send to Indevus a certificate of analysis and a certificate of compliance (together with any other documentation required under the Quality Technical Agreement) prior to each shipment of API and will not release any shipment for delivery unless and until it receives from Indevus an authorization for release based on such certificates and other documents required under the Quality Technical Agreement.

7.2 cGMP Records. In this regard, Helsinn agrees to maintain and retain complete and accurate records and documents, including all manufacturing, analytical, stability testing, batch records, validation data, quality control and all records of shipment, relating to the API, necessary to comply with cGMP and fulfill the requirements established by all applicable Regulatory Authorities to the extent and for the time periods required by applicable Regulatory Standards. As required under Section 7.1 or as otherwise requested by Indevus, Helsinn shall provide Indevus with such documentation promptly.

7.3 Notice of Failure to Meet Specifications. Upon Helsinn’s discovery that any batch or lot of API fails to conform to the Specifications, Helsinn will notify Indevus within three (3) Business Days of such failure to meet the Specifications and of the nature thereof in detail, and will supply to Indevus such information related thereto as Indevus may reasonably request, including, but not limited to, all investigatory reports, data, and communications, out−of−specification reports and data and the results of all outside laboratory testing and conclusions, if any. At its expense, Helsinn shall investigate all such failures promptly, and cooperate with Indevus in determining the cause for the failure and a corrective action to prevent future failures.

7.4 Inspection by Indevus. Indevus or its authorized representative will inspect all shipments upon their receipt in order to perform acceptance testing according to applicable cGMP requirements and will report any reasonably discernible defects in the API to Helsinn within [*] days of its receipt of the API and related records. Any latent defects or defects not reasonably discernible will be reported to Helsinn by Indevus within [*] days of Indevus’s discovery of the same.

7.5 Non−Conforming API. If any API produced and delivered to Indevus or invoiced by Helsinn does not meet the Specifications and/or the warranties set forth in Article IX and Indevus has notified Helsinn of such non−compliance within [*] of its receipt of the API and related records, then at its option Indevus may require that Helsinn
(i) replace said API with API that meets the Specifications and the warranties set forth in Article IX as soon as practicable at no charge to Indevus and Helsinn shall pay all round-trip shipping and other charges to and from the destination of the original shipment, (ii) refund the Purchase Price to Indevus, or (iii) credit Indevus’s account in an amount equal to the Purchase Price for the rejected API. Helsinn shall reimburse Indevus for the reasonable costs incurred by Indevus in properly disposing of such non-conforming API. Any notice given hereunder shall specify the manner in which the API fails to conform to the purchase order therefor or fails to meet such warranty or the Specifications.

7.6 Independent Testing. If Indevus notifies Helsinn that any API does not meet the Specifications and/or the warranties in Article IX, and Helsinn does not agree with Indevus’s position, the Parties will attempt to reach a mutually acceptable resolution of the dispute. If they are unable to do so after a reasonable period of time (such period not to exceed [*] days from the date of original notification), the matter will be submitted to an independent qualified testing laboratory acceptable to both parties. Both parties will accept the judgment of the independent laboratory. The cost of such testing will be borne by the Party whose position is determined to have been in error. If the API is determined by said independent laboratory to have been conforming, then the provisions of Section 7.5 hereof shall not apply, and Indevus shall not be relieved of its obligations to pay Helsinn for such API. In the event the test results indicate that the API in question does not conform to the Specifications and/or the warranties in Article IX, Helsinn shall replace such API with API that meet the Specifications and the warranties set forth in Article IX at no additional cost to Indevus as soon as reasonably possible after receipt of such results.

7.7 Replacement API. In the event that Helsinn is unable to supply acceptable replacement API within [*] days of receipt of Indevus’ notice under Section 7.5 or of the results of the independent testing under Section 7.6, as applicable, then Helsinn shall fulfill such requirements through HCI, provided that all API manufactured and supplied by HCI is in accordance with the Specifications, applicable Regulatory Standards, and the terms and conditions of this Agreement and the Quality Technical Agreement.

VIII. REGULATORY MATTERS; REGULATORY FILINGS AND APPROVALS

8.1 General.

(a) Helsinn shall (i) be responsible for obtaining and maintaining all site licenses and registrations for the manufacture of the API at the Helsinn Facility where the API is manufactured and will make copies of such registrations and all related documents available to Indevus and its designee for inspection upon Indevus’ reasonable request; (ii) take all steps necessary to pass inspection by and shall comply with other applicable regulations promulgated by, but not limited to, the FDA and [*] and any other applicable Regulatory Authority in connection with Helsinn’s manufacture of the API; and (iii) file with the FDA and any other applicable Regulatory Authority DMFs relating to the API. Helsinn hereby grants Indevus and/or Indevus’ designees the rights to reference any such DMF in Indevus’ and/or Indevus’ designees regulatory submissions and, upon Indevus’ request, will provide Indevus and/or Indevus’ designees with a letter of authorization authorizing Indevus and/or Indevus’ designees to reference such DMF.

[*] CONFIDENTIAL TREATMENT REQUESTED
(b) Indevus shall be responsible for obtaining and maintaining all regulatory approvals for the use of the product incorporating the API for all the purposes set forth in Section 2.1 above.

IX. REPRESENTATIONS AND WARRANTIES

9.1 General.

(a) Helsinn represents and warrants to Indevus that (i) it has the full corporate power and authority to enter into this Agreement and to perform its obligations hereunder; (ii) it has and will maintain throughout the term of this Agreement, the expertise, with respect to personnel and equipment, to fulfill the obligations established hereunder; (iii) the production facility, equipment and personnel to be employed will be qualified to manufacture API according to cGMP at the time each such batch of API is produced, and that the production facility to be employed is in compliance with all applicable material laws and regulations; (iv) neither Helsinn nor any of its employees engaged in performing Helsinn’s obligations under this Agreement, is, nor shall it or any of such individuals be at the time of performing any of the activities to be performed by Helsinn hereunder, disqualified or debarred by the FDA or any other Regulatory Authority for any purpose pursuant to 21 U.S.C Section 355a or any foreign equivalent thereof; (v) there are no pending or uncorrected citations or adverse conditions noted in any inspection of the production facility to be employed which would cause the API to be misbranded or adulterated within the meaning of the Act or other applicable laws; (vi) the execution, delivery and performance of this Agreement by Helsinn does not conflict with, or constitute a breach of any order, judgment, agreement, or instrument to which Helsinn is a party; (vii) the execution, delivery and performance of this Agreement by Helsinn does not require the consent of any person or the authorization of (by notice or otherwise) any governmental or Regulatory Authority (other than those relating to the granting of approval to commercialize the product containing the API); and (viii) to Helsinn’s knowledge, the use by Helsinn, complying with the terms and conditions of this Agreement, of Helsinn Confidential Information, of any information related to the API that was not supplied by Indevus to Helsinn, or of any procedures, processes and/or other manufacturing know−how that were independently known by Helsinn or that were invented, discovered or developed by Helsinn or any Helsinn Affiliate or agent, does not infringe upon any third party’s intellectual property rights.

(b) Indevus represents and warrants to Helsinn that (i) it has the full corporate power and authority to enter into this Agreement and to perform its obligations hereunder; (ii) the execution, delivery and performance of this Agreement by Indevus including the delivery and disclosure to Helsinn of the Specifications, the Confidential Information, Indevus’ know−how and any other information disclosed by Indevus in writing specifically for use in connection with the manufacture of the API does not conflict with, or constitute a breach of any order, judgment, agreement, or instrument to which Indevus is a party; (iii) the execution, delivery

[*] CONFIDENTIAL TREATMENT REQUESTED
and performance of this Agreement by Indevus including the delivery and disclosure to Helsinn of the Specifications, the Confidential Information, Indevus’ know–how and any other information disclosed by Indevus in writing specifically for use in connection with the manufacture of the API does not require the consent of any third party or the authorization of (by notice or otherwise) any governmental or regulatory authority (other than those relating to the granting of approval to commercialize the product containing the API); (iv) all Indevus Confidential Information (including but not limited to Indevus’ know–how) necessary to allow Helsinn to manufacture the API has been made available to Helsinn, subject to confidentiality obligations and solely for the purpose of manufacturing such API; such Confidential Information is accurate and complete in all material respects and Indevus has not, up to and including the Effective Date, omitted to furnish Helsinn with any information in its possession concerning the API or the transactions contemplated by this Agreement, which would be material to Helsinn’s decision to enter into this Agreement and to undertake the commitments and obligations set forth herein; (v) to Indevus’ knowledge, the use by Helsinn, complying with the terms and conditions of this Agreement, of the Specifications, the Indevus Confidential Information (including but not limited to Indevus’ know–how) or any other information supplied by Indevus to Helsinn in writing specifically for use in connection with the manufacture of the API and that was not independently known or invented, discovered or developed by Helsinn or any Helsinn Affiliate or agent, does not infringe upon any third party’s intellectual property rights; and (vi) any and all materials (including raw materials) supplied by or on behalf of Indevus to Helsinn specifically for use in connection with the manufacture of the API comply with all applicable specifications, laws and regulations (including any applicable regulatory requirements) and fit for the purpose of allowing Helsinn to perform the activities provided for hereunder.

9.2 Manufacturing Warranty. Helsinn warrants that all API supplied to Indevus will be manufactured in accordance with and conform to the Specifications, cGMPs, the Quality Technical Agreement in effect at the time of manufacture, other applicable Regulatory Standards and such quality assurance and quality control practices as are standard in the pharmaceutical manufacturing industry; Helsinn makes no warranty, and shall have no responsibility of any kind whatsoever, in connection with any Finished Product, except to the extent attributable to the API and subject to the provision of Section 14.1.

9.3 Warranty Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ANY WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. EXCEPT FOR THIRD PARTY CLAIMS COVERED BY ARTICLE XIV, THE REMEDIES SET FORTH IN SECTION 7.5, 7.6 AND 7.7 SHALL BE THE SOLE REMEDIES AVAILABLE TO INDEVUS WITH RESPECT TO ANY DEFECT IN QUALITY THAT IS DISCOVERED AND REPORTED PURSUANT TO THE PROVISIONS OF SECTION 7.4, 7.5 OR 7.6, AS APPLICABLE.
X. QUALITY CONTROL, RECORDS AND INSPECTIONS

10.1 Retained Samples. Helsinn will maintain a sample of API from each lot as required by applicable regulatory standards or as otherwise mutually agreed by Indevus and Helsinn. Helsinn will be responsible for maintaining and storing retention samples of the API as may be required by applicable regulatory standards and the Quality Technical Agreement. Helsinn shall provide Indevus with reasonable access to and portions of the retained samples upon Indevus’ request. Preservation samples/retained samples, as referred to herein, do not include samples retained for purposes of stability testing.

10.2 Validation. Helsinn will validate all process, methods, equipment, utilities, facilities and computers used in the formulation, storage, testing and release of API in conformity with all applicable laws and regulations. Indevus will have the right to review the results of said validation upon request.

10.3 Quality Compliance. Helsinn will provide Indevus with timely notification of all significant deviations, notes to file, and other deficiencies that may reasonably be expected to impact the quality of the API, as well as all FDA or other applicable Regulatory Authority reports regarding testing, manufacture, bulk packaging or labeling of the API.

10.4 Manufacturing Records. Helsinn will maintain complete and accurate records relating to the API and the manufacture, bulk packaging, labeling and testing thereof for the period required by applicable Regulatory Standards, and Helsinn shall provide copies thereof to Indevus upon Indevus’ request. The records shall be subject to audit and inspection under this Article X.

10.5 Batch Records. Records which include the information relating to the manufacturing, bulk packaging and quality operation for each lot of API will be prepared by Helsinn at the time such operations occur. Helsinn will prepare such records in accordance with cGMP’s, the Specifications and the Quality Technical Agreement.

10.6 Records Retention. Helsinn will retain records and documents for periods meeting all applicable regulations of the FDA, or other applicable regulatory authority and make such records and documents available to Indevus upon Indevus’ reasonable request.

10.7 Regulatory Communications and Inspections. Helsinn will promptly, but in any event not later than three (3) Business Days after notice or the same day as any unannounced contact, inspection or audit commences, inform Indevus of any contact, inspection or audit by any Regulatory Authority or governmental agency (other than ISO 14001 and FCOS inspections), related to or affecting the API or a Helsinn Facility where the API is manufactured. Authorized representatives of Indevus shall have the right to be present during the inspection and/or during the close−out session with any Regulatory Authority inspectors. Helsinn will promptly provide Indevus with copies of any government−issued inspection observation reports (including without limitation FDA Form 483s, warning letters, citations and/or equivalent or similar forms from other Regulatory Authorities) and/or agency correspondence that may reasonably be expected to affect the API or a Helsinn Facility where the API is manufactured, or that

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
relates to any related license or permit issued to Helsinn in connection with the API manufacture. Helsinn and Indevus will cooperate in resolving any concerns with any Regulatory Authority and Helsinn will provide Indevus with a written copy of any proposed response at least five (5) Business Days prior to submitting such response and of the actual responses submitted to any Regulatory Authority and with a summary of the corrective action(s) taken or planned by Helsinn. Helsinn will do all its best efforts to rectify or resolve any deficiencies noted by any Regulatory Authority that relate to Helsinn’s ability to supply API hereunder. Helsinn will also inform Indevus of any action taken by any governmental agency against Helsinn or any of its officers and employees which may reasonably be expected to adversely affect the API or Helsinn’s ability to supply API hereunder within 24 hours after the action is taken. Helsinn will also provide Indevus with copies of all other communications or correspondence between Helsinn and any Regulatory Authority relating to Helsinn’s activities under this Agreement within forty−eight (48) hours after receiving or providing such communication or correspondence.

10.8 Indevus Inspections and Audits. Indevus employees or Indevus authorized representatives will have the right during normal business hours, at reasonable intervals and upon giving Helsinn at least thirty (30) Business Days advance notice (two (2) Business Days in the event of a recall attributable to the API) to inspect and audit at Indevus’s sole expense, (a) the Helsinn Facilities used in the manufacturing, bulk packaging, storage, testing, shipping or receiving of API and (b) manufacturing and quality control records and other documentation relating to such activities for the purpose of verifying the compliance of the API manufacture with the requirements provided for in this Agreement, the Quality Technical Agreement and with current Good Manufacturing Practices, provided, however that, if circumstances arise that in Indevus’s reasonable judgment require that its representatives inspect the Helsinn Facilities more than once per calendar year, the Parties shall discuss such circumstances and agree in good faith upon additional inspections and appropriate means for addressing such circumstances. All such employees and representatives shall be bound by the same confidentiality obligations as contained herein and shall abide at all times with Helsinn’s rules and regulations, including without limitation safety rules and regulations. Such inspections may include cGMP inspections and system audits. Persons conducting such inspections will have access only to documents, records, reports, data, procedures, facilities, regulatory submissions and communications, and all other information required to be maintained by applicable government regulations relating to the API. Helsinn shall take appropriate actions to adopt reasonable suggestions of Indevus to correct any deficiencies identified by such inspection or audit and shall provide Indevus with reasonable documentary and other evidence of such correction. The duration of each inspection or audit will be limited to no more than five (5) days, being however understood that in any case said inspections and audits may not interfere with Helsinn’s normal operations.

XI. COMPLAINTS, ADVERSE EVENTS AND RECALLS

11.1 API Complaints and AEs. Indevus shall maintain complaint files with respect to the product containing API in accordance with cGMPs. In the event that Helsinn should receive any API complaints and/or AEs notices from third parties, Helsinn will promptly notify Indevus by facsimile or other electronic transmission within two (2) Business Days of its receipt thereof. All such notices shall be sent to the attention of James Shipley, M.D.,
Senior Vice President–Clinical Development and Regulatory Affairs at Indevus, facsimile number 781−761−0559. Indevus shall promptly provide Helsinn with copies of any complaints received by Indevus relating to the manufacture or bulk packaging of the API. Indevus shall have the exclusive responsibility for responding to all complaints, and for promptly providing Helsinn with a copy of any responses to complaints relating to the manufacture or bulk packaging of the API. Indevus or its affiliates shall have responsibility for reporting all complaints relating to the product containing API to the FDA and any other Regulatory Authorities, including, but not limited to, complaints relating to the manufacture or bulk packaging of the API as well as adverse experience (AE) reports. Indevus will correspond with complainants as to any complaints associated with product containing API, whether received during or after the term hereof. Helsinn will reasonably assist Indevus in investigating API complaints relating to the manufacture or bulk packaging of the API by analyzing API and manufacturing processes to determine the nature and cause of an alleged API manufacturing defect or alleged API failure. Helsinn will also reasonably assist Indevus, if so expressly required by Indevus from time to time, in the investigation of any Adverse Experience (AE) reported to either Party when such AEs are reasonably believed to be attributable to the manufacture or bulk packaging of the API. If Indevus determines that any reasonable physical, chemical, biological or other evaluation should be conducted in relation to an AE or API complaint relating to the manufacture or bulk packaging of the API, Helsinn will reasonably conduct the evaluation and use its reasonable effort to provide Indevus with a written report of such evaluation within thirty (30) days from receipt of Indevus’s written request for same, together with samples of the API from the relevant lot. The obligations and responsibility in connection with the above AEs and the management of the same shall pertain exclusively to Indevus.

11.2 Recall Action. If Indevus should elect or be required to initiate a recall, withdrawal, stock recovery or field correction (each, or collectively, a “Recall”) of API or product containing API because of supply by Helsinn of API that does not conform to the Specifications and warranties established by this Agreement, subject in any case to Section 14.1 hereunder, Indevus will notify Helsinn and provide Helsinn a copy of its recall letter prior to initiation of the recall. Helsinn will assist Indevus (and its designee) in an investigation to determine the cause and extent of the problem. All regulatory authority contacts and coordination of any recall activities will be initiated by, and will be the sole responsibility of, Indevus.

11.3 Recall Expenses. If a Recall of any product containing API is necessary, requested by any Regulatory Authority or otherwise advisable for any reason, Helsinn and Indevus shall each bear the costs of the Recall in proportion to each Party’s responsibility for the error necessitating the recall or withdrawal. For purposes of this Agreement, such costs shall include the expenses of notification and destruction or return of the recalled or withdrawn API or Finished Product and all other documented out−of−pocket costs incurred in connection with such Recall but shall not include lost profits or opportunity costs of either Party.

11.4 Recall Records. Helsinn will maintain complete and accurate records for such periods as may be required by applicable law or regulation.

11.5 Discontinuation of Sales. Indevus, at any time and without liability to Helsinn, shall be entitled to cease, permanently or temporarily, sales of Finished Product in any country if continued sales of Finished Product in such country would be in violation of any applicable laws or regulations, or if Indevus determines that there is an ethically valid reason to cease such sales based on medical or scientific concerns relating to such Finished Product.

Source: INDEVUS PHARMACEUTIC, 10−K, December 07, 2006
XII. INSURANCE

12.1 During the term hereof, Helsinn shall maintain in full force and effect valid and effective insurance policies, including product liability insurance policies, in connection with its obligations, liabilities, representations and warranties as contemplated herein. In particular, Helsinn’s product liability coverage shall be not less than US$ [*] (United States Dollars [*]) (or the equivalent amount in other currency) per loss occurrence and per aggregated loss occurrences per year provided such coverage is available at commercially reasonable rates. If such coverage is not so available, Helsinn will immediately provide notice thereof to Indevus. Helsinn will provide to Indevus, upon Indevus’s written request, evidence of liability insurance coverage and the amounts thereof. Such coverage shall be maintained for not less than seven (7) years following expiration or termination of this Agreement for any reason.

12.2 During the term hereof, Indevus agrees to maintain in full force and effect valid and effective insurance policies, including product liability insurance policies, in connection with its obligations, liabilities, representations and warranties as contemplated herein. In particular, Indevus’s product liability coverage shall be not less than US$ [*] (United States Dollars [*]) per loss occurrence and per aggregated loss occurrences per year provided such coverage is available at commercially reasonable rates. If such coverage is not so available, Indevus will immediately provide notice thereof to Helsinn. Indevus will provide to Helsinn, upon Helsinn’s written request, evidence of adequate liability insurance coverage and the amounts thereof. Such coverage shall be maintained for not less than seven (7) years following expiration or termination of this Agreement for any reason.

XIII. INVENTIONS

13.1 Subject to Section 13.2 hereunder, any information, inventions, improvements or the like derived or coming from Indevus’ Confidential Information or from any other information related to the API, howsoever gained or obtained by Helsinn, will be automatically considered as Confidential Information under the terms of the Section IV and will have to be immediately communicated and delivered to Indevus, and will be considered the exclusive property of, and all right, title and interest will be owned by, Indevus.

13.2 It is expressly agreed that Section 13.1 above is not applicable to those works, information and improvements (and relevant intellectual property rights) related exclusively to procedures, processes and manufacturing know−how of Helsinn’s factories which may be developed by Helsinn in the course of API manufacture hereunder but which relate to manufacturing operations generally. In this case, therefore, any resulting information, and the relevant intellectual property rights, shall belong to Helsinn.

[*] CONFIDENTIAL TREATMENT REQUESTED
XIV. INDEMNIFICATION

14.1 By Helsinn.

(A) Helsinn will indemnify and hold harmless Indevus, its Affiliates, directors, officers, employees, agents, successors, and assigns (collectively, “Indevus Indemnified Parties”) from and against any and all Losses arising out of, attributable to or resulting from any third party claim, suit or action related to or alleging (i) any failure of the quality of the API supplied hereunder, including any failure of the API to conform to the Specifications; (ii) any negligent or wrongful act or any breach by Helsinn of any of its obligations, representations and/or warranties hereunder; or (iii) the infringement of third parties’ intellectual property rights due to the use by Helsinn of any Helsinn Confidential Information in each case except to the extent caused by the negligence or willful misconduct of Indevus or any breach by Indevus of any of its obligations, representations and/or warranties hereunder.

[*]

14.2 By Indevus.

(A) Indevus will indemnify and hold harmless Helsinn, its Affiliates, directors, officers, employees, agents, successors, and assigns (collectively, “Helsinn Indemnified Parties”) from and against any and all Losses arising out of, attributable to or resulting from any third party claim, suit or action in any way related to or alleging (i) any failure in the quality of the API supplied hereunder which (a) is due to any defect in the Indevus Confidential Information, or the Specifications supplied to Helsinn by or on behalf of Indevus for use in connection with the manufacture of the API, or (b) results from any API quantities which have been adulterated or otherwise mistreated by Indevus; (ii) the processing of said API into Finished Product and/or the distribution and sale of said Finished Product to clients; (iii) any negligent or wrongful act or any breach by Indevus of any of its obligations, representations and/or warranties hereunder, or (iv) the infringement of third parties’ intellectual property rights due to the use by Helsinn, in accordance with the terms and conditions of this Agreement, of the Specifications and/or of the Indevus Confidential Information (including but not limited to Indevus’ know−how) supplied by Indevus to Helsinn for use in connection with the manufacture of the API, in each case except to the extent caused by the negligence or willful misconduct of Helsinn, or any breach by Indevus of any of its obligations, representations and/or warranties hereunder.

[*]

14.3 By Each Party. In the event that negligence or willful misconduct of both Helsinn and Indevus contribute to or is determined to have contributed to, any such loss, damage, claim, injury, cost or expense, Helsinn and Indevus will each indemnify and hold harmless the other with respect to that portion of the loss, damage, claim, injury, cost or expense (including costs of defense thereof) attributable to its negligence or willful misconduct.

14.4 Procedures. In the event that one Party receives notice of a claim, lawsuit, or liability for which it is entitled to indemnification by the other Party, the Party receiving notice shall give prompt notification to the indemnifying party, provided that the failure to give such notice shall not excuse the indemnifying party from its indemnity obligations hereunder unless the indemnifying party is materially prejudiced by such failure. The Party being
indemnified shall cooperate fully with the indemnifying party throughout the pendency of the claim, lawsuit or liability, and the indemnifying party shall have complete control over the conduct and disposition of the claim, lawsuit, or liability including the retention of legal counsel engaged to handle such matter provided, however, that, (a) neither Party shall, without the written consent of the other Party, which shall not be unreasonably withheld, as part of any settlement (i) admit to liability on the part of the other Party; (ii) agree to an injunction against the other Party; or (iii) settle any matter in a manner that separately apportions fault to the other Party and (b) the indemnified party shall be entitled to participate in any such action, suit or proceeding with counsel of its own choice, but as its own expense. If the indemnifying Party fails to assume the defense within a reasonable time, the indemnified party may assume such defense and the reasonable fees and expenses of its attorneys will be covered by the indemnifying party pursuant to the indemnity provisions provided for herein. Neither Party shall be liable for any costs resulting from any settlement made by a Party without the prior consent of the other Party to such settlement, which consent shall not be unreasonably withheld or delayed.

XV. LIMITATION OF LIABILITY

NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL HELSINN OR INDEVUS BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS OR REVENUES, ARISING OUT OF OR IN ANY WAY RELATED TO THIS AGREEMENT WITH THE EXCEPTION OF DAMAGES ARISING OUT OF AND/OR CONNECTED WITH: (A) BREACH BY INDEVUS OF SECTION 9.1(b) POINTS (ii) AND (v) OR (B) BREACH BY HELSINN OF SECTION 9.2 DUE TO THE NON COMPLIANCE OF THE API PRODUCED BY HELSINN WITH THE SPECIFICATIONS, cGMPs AND THE QUALITY TECHNICAL AGREEMENT IN EFFECT AT THE TIME OF MANUFACTURE.

XVI. TERMINATION

16.1 Term. This Agreement shall become effective and remain in effect for a period of [*] years from the Effective Date (the “Initial Term”) and, unless either Party gives written notice of non-renewal at least 1 (one) year prior to the end of the Initial Term (or any renewal term), this Agreement shall be renewed for consecutive terms of 2 (two) years.

16.2 Breach. If either Party hereto commits a material breach of any of its obligations hereunder, the non-breaching Party may, at its option, without prejudice to any other legal remedy available to the non-breaching Party, terminate this Agreement by giving the other Party at least [*] days prior written notice of its intent to terminate this Agreement, which notice shall specify the breach and the termination date, unless the breaching Party cures said breach prior to the specified termination date (or prior to the expiration of a longer period as may be reasonably necessary to cure a breach, provided that the breaching Party is making diligent efforts to cure such breach, and provided further that such longer period shall not in any event exceed [*] days from the date of notice).

[*] CONFIDENTIAL TREATMENT REQUESTED
16.3 **Termination by Indevus.** Indevus shall have the right to terminate this Agreement at any time by giving [*] days’ written notice if the FDA or any other Regulatory Authority takes any action which would prohibit or materially restrict the manufacture, sale or use of Product in the United States or if the Product is otherwise withdrawn from the market in the United States.

16.4 **Insolvency.** Either Party may terminate this Agreement immediately in its entirety if the other Party files a petition of bankruptcy, is adjudged bankrupt, takes advantage of any insolvency act, or executes a bill of sale, deed of trust, or assignment for the benefit of creditors.

16.5 **Survival.** Sections 9.1, 9.2, 12.1, 12.2 and Articles IV and XIV covering representations and warranties, insurance, confidentiality and indemnification will survive termination of this Agreement on the terms set forth therein. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Termination will not affect the liability of either Party by reason of any act, default, or occurrence prior to said termination.

16.6 Upon termination or expiration of this Agreement, Helsinn shall return to Indevus or Indevus’ nominee any and all materials in its stock and belonging to Indevus and shall deliver to Indevus, any remaining API subject to outstanding purchase orders or any Binding Portion of a forecast. Indevus shall pay Helsinn [*] of the applicable Purchase Price of such API if [*] or [*] of the Purchase Price [*].

XVII. GOVERNING LAW AND ALTERNATIVE DISPUTE RESOLUTION

17.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York, United States, without giving effect to the conflict of laws provisions thereof.

17.2 The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a “Dispute”) by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within sixty (60) days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officers of the Parties. Such persons shall negotiate in good faith to achieve a resolution of the Dispute referred to them within thirty (30) days after such notice is received by the Party to whom the notice was sent. If such persons are unable to settle the Dispute between them within thirty (30) days, they shall so report to the Parties in writing. The Dispute shall then be referred to arbitration as set forth below. Any Dispute, controversy or claim arising out of or in connection with this Agreement, including the validity, invalidity, breach or termination thereof, which cannot be settled amicably by the Parties, shall be settled by arbitration in accordance with the rules of the International Chamber of Commerce, Paris (“ICC”) in force on the date when the Notice of Arbitration is submitted in accordance with these rules.

The arbitration proceedings shall be held in the English language in New York City (NY, USA). The arbitral tribunal shall consist of three arbitrators with appropriate experience in the pharmaceutical industry: one arbitrator shall be appointed by each

[*] CONFIDENTIAL TREATMENT REQUESTED

Source: INDEVUS PHARMACEUTIC, 10–K, December 07, 2006
of Helsinn and Indevus and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two Party-appointed arbitrators. The arbitrators shall not have the power to award or assess punitive damages against either Party. The arbitrators shall have the authority to grant specific performance. Any award so rendered shall be final and binding and judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such Dispute would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the costs of the arbitration levied by the ICC.

XVIII. MISCELLANEOUS

18.1 Headings. The headings and captions used herein are for the convenience of the parties only and are not to be construed to define, limit or affect the construction or interpretation hereof.

18.2 Severability. In the event that any provision of this Agreement is found to be invalid or unenforceable, then the offending provision shall not render any other provision of this Agreement invalid or unenforceable, and all other provisions shall remain in full force and effect and shall be enforceable, unless the provisions which have been found to be invalid or unenforceable, to the fullest extent permitted by law. If any such affected provision materially affects the commercial basis of this Agreement, the Parties shall negotiate in good faith so as to amend the provisions of this Agreement so as to preserve and afford to each Party the full extent of benefits that this Agreement is intended to provide, failing which amendment this Agreement may be terminated upon 10 (ten) days written notice by either Party.

18.3 Entire Agreement. This Agreement, including all those Schedules and Exhibits appended hereto, contains the entire agreement of the Parties regarding the subject matter hereof and supersedes all prior agreements, understandings or conditions (whether oral or written) regarding the same except for the Confidential Disclosure Agreement dated April 22, 2005 which shall remain in full force and effect on the terms set forth therein. Further, this Agreement may not be changed, modified, amended or supplemented except by a written instrument signed by the duly authorized representatives of the Parties. Neither Party has relied on any representation except as may be expressly set forth herein.

18.4 Assignability. This Agreement and the rights hereunder may not be assigned or transferred by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, provided, however, that either Party may assign this Agreement to an Affiliate without such consent, and provided further that in the event of a merger, acquisition or sale of substantially all of the assets of Indevus relating to or including the Finished Product, or similar corporate transaction, this Agreement or all or any portion of the rights and obligations of Indevus under this Agreement may be assigned to the surviving or acquiring entity in that transaction without such consent. In the event that this Agreement is assigned, it shall be binding upon and inure to the benefit of the Parties and their respective successors and assigns.
18.5 **Further Assurances.** Each Party hereto agrees to execute, acknowledge and deliver such further instruments, and to take such other actions, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

18.6 **Waiver.** The failure of a Party to insist upon strict performance of any of the terms and conditions of this Agreement by the other Party shall not constitute a waiver of any of the provisions hereof and no waiver by either Party of any of said terms and conditions shall be deemed to have been made unless expressed in writing and signed by such waiving Party.

18.7 **Force Majeure.** A Party shall not be liable for nonperformance or delay in performance (other than of obligations regarding any payments or of confidentiality) caused by any event reasonably beyond the control of, and not caused by the negligence, intentional conduct or misconduct of, such Party including, without limitation, wars, hostilities, revolutions, riots, civil disturbances, national emergencies, strikes, lockouts, unavailability of supplies, epidemics, fires, floods, earthquakes, other forces of nature, explosions, embargoes, or any other Acts of God, or any laws, proclamations, regulations, ordinances, or other acts or orders of any court, government or governmental agency, to the extent of and for so long as such Force Majeure continues, provided that the affected Party uses Commercially Reasonable Efforts to avoid or remove the causes of such Force Majeure with the utmost dispatch. Any occurrence of Force Majeure shall be reported promptly to the other Party and the affected Party shall regularly update the other Party as to its efforts to remove the causes. A Party whose performance has been excused will perform such obligation as soon as is reasonably practicable after the termination or cessation of such event or circumstance. In the event that Force Majeure preventing performance shall continue for more than six (6) months, either Party may terminate this Agreement with a written notice to the other without any liability hereunder, except the obligation to make payments due to such date and except for any obligations that survive termination.

18.8 **Remedies.** Each Party agrees and acknowledges that its disclosure of Confidential Information in breach of this Agreement may cause irreparable harm to other Party, and therefore that any such breach or threatened breach may entitle such Party to seek injunctive relief, in addition to any other legal remedies available in a court of competent jurisdiction.

18.9 **Good Faith.** The Parties agree to perform this Agreement in a spirit of good faith and fair dealing, and each will seek to avoid intentionally doing anything that would deprive the other of the full benefits contemplated hereunder. Neither Party will use any affiliate or third party as a means of avoiding its responsibilities under this Agreement. The Parties agree to communicate openly and in a spirit of co-operation to insure that all services are rendered in accordance with the highest degree of professional competence, current Good Manufacturing Practices and any other applicable Regulatory Standards.
18.10 **Independent Contractors.** The Parties are independent contractors under this Agreement. Nothing contained in this Agreement is to be construed so as to constitute Indevus and Helsinn as partners, agents or employees of the other, including with respect to this Agreement, or as establishing a joint venture. Neither Party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party or to bind the other Party to any contract, agreement or undertaking with any third party unless expressly so authorized in writing by the other Party.

18.11 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

18.12 **Notices.** Except as otherwise expressly stated herein, all notices, consents or approvals required by this Agreement shall be in writing and sent by overnight courier service, certified or registered air mail, postage prepaid, or by facsimile or cable (confirmed by such certified or registered mail) to the Parties at the following addresses or such other addresses as may be designated in writing by the respective parties. Notices shall be deemed effective on the date of mailing.

If to Indevus:

Indevus Pharmaceuticals, Inc.
33 Hayden Avenue
Lexington, MA 02421−7971, United States
Attn: Chief Executive Officer
Fax: +1 781. 862. 3859

All Helsinn invoices and/or charges in billing should be directed to the Accounting Department at:

Indevus Pharmaceuticals, Inc.
33 Hayden Avenue
Lexington, MA 02421−7971, United States
Attn: Corporate Controller
Fax: +1 781. 674. 2448

If to Helsinn:

Helsinn Chemicals SA
Via Industria 24
6710 Biasca
Switzerland
Attention: Commercial Division
Facsimile: + 41 91 873 01 11

All Indevus purchase orders shall be sent to:

Helsinn Chemicals SA
Via Industria 24
6710 Biasca
Switzerland
Attention: Commercial Division
Facsimile: + 41 91 873 01 11

[Remainder of page intentionally left blank]
IN WITNESS WHEREOF, the undersigned Parties have caused this Agreement to be executed as of the date first above written.

HELSINN CHEMICALS SA

/s/ Dr. Paolo Guainazzi
By: Dr. Paolo Guainazzi
General Manager

INDEVUS PHARMACEUTICALS, INC.

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

HELSINN ADVANCED SYNTHESIS SA

/s/ Dr. Enrico Braglia
By: Dr. Enrico Braglia
Managing Director

Source: INDEVUS PHARMACEUTIC, 10-K, December 07, 2006
Helsinn undertakes to comply with cGMP, where applicable, the Specifications, the relevant DMF in the country to which API shall be delivered, the know−how and any other requirements agreed in writing between the Parties applicable to the manufacture, storage (including raw materials) and delivery of the API. The respective responsibilities of Helsinn and Indevus with regard to applicable cGMP regulations shall be defined in detail in the Quality Technical Agreement, which shall be attached hereto as Exhibit 1.22.
The Parties have agreed upon the Specifications for the API as set forth herein. The Parties shall agree upon any modifications to the Specifications set forth herein in writing.

I. Specifications

[*]

II. Specifications

[*]

[*] CONFIDENTIAL TREATMENT REQUESTED
Schedule 3.1
Helsinn Reserve Capacity

The minimum annual capacity to be reserved by Helsinn for the Initial Term of this Agreement is the greater of [*] batches (approximately [*] kg per batch) or [*] of the Binding Portion of any forecast. [*] months before the expiry of the Initial Term the Parties shall meet and discuss to seek an agreement in good faith on the minimum annual capacity to be reserved by Helsinn for the further term of this Agreement following the Initial Term.

[*] CONFIDENTIAL TREATMENT REQUESTED
Subject to the terms and conditions of this Agreement, the Purchase Price/kg of API [*] shall be as follows:

A. Assuming [*]:
   
   Number of Batches purchased per year: [*]  
   Purchase Price/kg: [*]

B. Assuming [*]:
   
   Number of Batches purchased per year: [*]  
   Purchase Price/kg: [*]

(2) The Parties agree to amend this schedule to provide for appropriate Purchase Prices, consistent with the overall terms and conditions of this Agreement, for purchases of other than [*] batches of API as soon as practicable after [*]

[*] CONFIDENTIAL TREATMENT REQUESTED
Name of Subsidiary | State of Incorporation
---|---
CPEC LLC | Delaware
InterNutria, Inc. | Delaware
IPI Management Corp. | Massachusetts
CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S−3 (File Nos. 33−75826, 333−01273, 333−03131, 333,18001, 333−76338, 333−109263, and 333−130741) and on Form S−8 (File Nos. 33−58742, 33−76652, 33−94730, 33−24969, 33−94736, 333−40315, 333−48911, 333−40572, 333−104094, 333−104095, 333−115921, 333−127987, and 333−137848) of Indevus Pharmaceuticals, Inc., of our report dated December 14, 2005 relating to the financial statements, management’s assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting, which appears in this Annual Report on Form 10−K. We also consent to the reference to us under the heading "Selected Financial Data" in this Form 10−K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

December 7, 2006
PRINCIPAL EXECUTIVE OFFICER CERTIFICATION

I, Glenn L. Cooper, Chief Executive Officer of Indevus Pharmaceuticals, Inc. certify that:

1. I have reviewed this Annual Report on Form 10-K of Indevus Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the issuer and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the issuer’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the issuer’s internal control over financial reporting that occurred during the issuer’s most recent fiscal quarter (the issuer’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the issuer’s internal control over financial reporting;

5. The issuer’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer’s auditors and the audit committee of the issuer’s board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer’s ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer’s internal control over financial reporting.

Date: December 7, 2006

By: /s/ GLENN L. COOPER

Chief Executive Officer
I, Michael W. Rogers, Chief Financial Officer of Indevus Pharmaceuticals, Inc. certify that:

1. I have reviewed this Annual Report on Form 10-K of Indevus Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a−15(e) and 15d−15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a−15(f) and 15d−15(f) for the issuer and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the issuer’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the issuer’s internal control over financial reporting that occurred during the issuer’s most recent fiscal quarter (the issuer’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the issuer’s internal control over financial reporting; and

5. The issuer’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer’s auditors and the audit committee of the issuer’s board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer’s ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer’s internal control over financial reporting.

Date: December 7, 2006

By: /s/ M ICHAEL W. R O G E R S

Chief Financial Officer
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES–OXLEY ACT OF 2002

In connection with the Annual Report of Indevus Pharmaceuticals, Inc. (the “Company”) on Form 10–K for the period ended September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Glenn L. Cooper, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes–Oxley Act of 2002, that to the best of my knowledge: (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

By: /s/ GLENN L. COOPER

Chief Executive Officer

December 7, 2006
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES−OXLEY ACT OF 2002

In connection with the Annual Report of Indevus Pharmaceuticals, Inc. (the “Company”) on Form 10−K for the period ended September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Michael W. Rogers, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes−Oxley Act of 2002, that to the best of my knowledge: (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

By: /s/ MICHAEL W. ROGERS
Chief Financial Officer
December 7, 2006

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