UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to .

Commission File Number: 001-33609

SUCAMPO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**30-0520478**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. employer identification no.)*
4520 East-West Highway, Suite 300 Bethesda, MD 20814	**(301) 961-3400**
(Address of principal executive offices, including zip code)	*(Registrant's telephone number, including area code)*

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Class A common stock, par value $0.01	The NASDAQ Global Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o 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 Exchange Act 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 o

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

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

Large accelerated filer o	Accelerated filer ☑	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☑

The aggregate market value of the 11,398,483 shares of class A common stock held by non-affiliates of the registrant (based on the closing price of the registrant's class A common stock on the last business day of the registrant's most recently completed second fiscal quarter) was $122 million.

As of March 5, 2009, there were outstanding 15,651,849 shares of the registrant's class A common stock, par value $0.01 per share, and 26,191,050 of the registrant's class B common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Proxy Statement for its 2009 Annual Meeting of Stockholders to be held on May 28, 2009, which Proxy Statement is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2008, are incorporated by reference in Part III of this Annual Report on Form 10-K.

Sucampo Pharmaceuticals, Inc.

Form 10-K

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PART I

This Annual Report on Form 10-K, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding us and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "should," "would," "could," "will," "may" or other similar expressions. In addition, any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business and other characterizations of future events or circumstances are forward-looking statements. We cannot guarantee that we will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors are described under "Risk Factors" set forth below. In addition, any forward-looking statements we make in this document speak only as of the date of this document, and we do not intend to update any such forward-looking statements to reflect events or circumstances that occur after that date.

ITEM 1. ***BUSINESS***

Overview

We are an international biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. We conduct our business through our subsidiaries based in the United States, the United Kingdom and Japan.

We believe that most prostones function as activators of cellular ion channels. As a result, prostones appear to be effective at promoting fluid secretion and enhancing cell protection, including recovery of barrier function. This activity may give prostones wide-ranging therapeutic potential, particularly for age-related diseases. We are focused on developing prostone-based compounds for the treatment of gastrointestinal, vascular, respiratory, and central nervous system diseases and disorders for which there are unmet or underserved medical needs and significant commercial potential.

The therapeutic potential of prostones was first identified by one of our founders, Dr. Ryuji Ueno. To date, two prostone-based products have received marketing approval: Amitiza® (lubiprostone) for the treatment of chronic idiopathic constipation in adults and irritable bowel syndrome with constipation in adult women and Rescula® (unoprostone isopropyl) for the treatment of glaucoma. Rescula, which was developed by R-Tech Ueno, Ltd, or R-Tech, under the leadership of Dr. Ueno and our other founder, Dr. Sachiko Kuno, was the first commercially available prostone-based drug. Although we do not hold any rights to Rescula, we believe that the successful development of Amitiza and Rescula demonstrates the initial therapeutic potential of prostones.

Amitiza® in the United States and Canada

In January 2006, we received marketing approval from the U.S. Food and Drug Administration, or FDA, for our first product, Amitiza, for the treatment of chronic idiopathic constipation in adults of all ages. Amitiza is the only prescription product for the treatment of chronic idiopathic constipation that has been approved by the FDA for use by adults of all ages and that has demonstrated safety and effectiveness for use beyond 12 weeks. Constipation becomes chronic when a patient suffers specified symptoms for more than 12 non-consecutive weeks within a 12-month period and is idiopathic if it is not caused by other diseases or by use of medications. Studies published in *The American Journal of Gastroenterology* estimate that approximately 42 million people in the United States suffer from constipation. Based on these studies, we estimate that approximately 12 million people can be characterized as suffering from chronic idiopathic constipation.

In April 2008, we received a second marketing approval from the FDA for Amitiza for the treatment of irritable bowel syndrome with constipation in adult women. Irritable bowel syndrome is a disorder of the intestines with symptoms that include severe cramping, pain, bloating and extreme changes of bowel habits, such as diarrhea or constipation. According to the American College of Gastroenterology, irritable bowel syndrome affects

approximately 58 million people in the U.S. and irritable bowel syndrome with constipation accounts for approximately one-third of these cases.

Amitiza increases fluid secretion into the intestinal tract by activating specific chloride channels in cells lining the small intestine. This increased fluid level softens the stool, facilitating intestinal motility and bowel movements. In addition, Amitiza improves symptoms associated with chronic idiopathic constipation, including straining, hard stools, bloating and abdominal pain or discomfort.

In October 2004, we entered into a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, to jointly develop and commercialize Amitiza for chronic idiopathic constipation, irritable bowel syndrome with constipation, and opioid-induced bowel dysfunction and other gastrointestinal indications in the United States and Canada. Commercial sales of Amitiza were initiated in the United States in April 2006 for the treatment of chronic idiopathic constipation and in May 2008 for the treatment of irritable bowel syndrome with constipation. We retained the rights to develop and commercialize Amitiza in the United States and Canada for indications other than gastrointestinal indications.

We are primarily responsible for Amitiza research and development efforts and are the holder of the new drug application, or NDA. Takeda is primarily responsible for the marketing and commercialization of Amitiza in the United States and Canada and markets Amitiza broadly to office-based specialty physicians and primary care physicians in the United States and funds a significant portion of the research and development activities. We have the right to co-promote Amitiza in the U.S. and Canada through a specialty sales force in the institutional marketplace, including specialist physicians based in academic medical centers and long-term care facilities. This institutional market is characterized by a concentration of elderly patients, who we believe to be a key market for Amitiza to treat gastrointestinal indications, and by physicians who are key opinion leaders in the gastrointestinal field.

We are currently pursuing marketing approval for Amitiza for opioid-induced bowel dysfunction in patients with non-malignant pain, a constipation-related gastrointestinal indication. In December 2008, we completed enrollment of two phase 3 pivotal clinical trials of Amitiza for this indication. According to the American Pain Foundation, over 50 million Americans suffer from chronic pain, and nearly 25 million Americans experience acute pain each year due to injuries or surgery. Opioid pain relievers are widely prescribed for these patients, many of whom also develop opioid-induced bowel dysfunction.

Amitiza in Japan

In February 2009, we entered into a license, commercialization and supply agreement with Abbott Japan Co. Ltd., or Abbott, for Amitiza in Japan. Under the terms of the agreement, Abbott received exclusive rights to commercialize lubiprostone for the treatment of chronic idiopathic constipation and also received the right of first refusal to any additional indications for which lubiprostone is developed in Japan. Abbott is responsible for all commercialization expenses and efforts.

We received an upfront payment of $10 million and could receive additional milestone payments based on achieving specified development, regulatory, and sales goals. We are continuing to lead the development of and regulatory activity for lubiprostone in Japan and will continue to be responsible for the costs of lubiprostone development.

Following marketing authorization and pricing approval, Abbott will purchase finished product from us for distribution in Japan. We have retained the right to co-promote lubiprostone in Japan.

In addition, we and Abbott have separately agreed to negotiate in good faith a license, commercialization and supply agreement for lubiprostone for the rest of the world’s markets outside Japan, the U.S., Canada and Western Europe and to use commercially reasonable efforts to enter into such an agreement.

In September 2008, we reported the successful results of a multi-center phase 2b dose-ranging trial in Japan to evaluate the safety and efficacy of lubiprostone for treating chronic idiopathic constipation in adults. Based on the results of this trial, we plan to initiate phase 3 clinical testing of lubiprostone for chronic idiopathic constipation in Japan during the second quarter of 2009.

Amitiza in other territories

We have retained full rights to develop and commercialize Amitiza for the rest of the world's markets outside of the U.S., Canada and Japan. We are pursuing marketing approval for Amitiza in Europe and the Asia-Pacific region for appropriate gastrointestinal indications based on local market disease definitions and the reimbursement environment.

In February 2008, we submitted a marketing authorization application, or MAA, for lubiprostone, 24 micrograms, for the indication of chronic idiopathic constipation in adults. The MAA was filed using the decentralized procedure, with the United Kingdom, through its Medicines and Healthcare Products Regulatory Agency, serving as the reference member state. Additional applications were subsequently filed with the member states of Belgium, Denmark, France, Germany, Ireland, the Netherlands, Spain and Sweden. These applications were received and validated by the individual regulatory authorities and their formal review process of the applications has begun. We also filed a marketing approval application in Switzerland for the same indication.

Other prostone-based product candidates

We are developing other prostone-based compounds for the treatment of a broad range of diseases. The most advanced of these programs are:

- Cobiprostone is currently in a phase 2 clinical trial for the prevention of ulcers induced by non-steroidal anti-inflammatory drugs, or NSAIDs. We completed enrollment of arthritis patients treated with NSAIDs into this trial in December 2008. We continue to pursue pre-clinical studies of cobiprostone for topical ulcers and wounds, and work to finalize an inhaled formulation of cobiprostone as a potential treatment of respiratory symptoms associated with cystic fibrosis, as well as chronic obstructive pulmonary disease.
- SPI-017 is current in clinical and pre-clinical testing to evaluate its potential as a treatment of peripheral arterial and vascular disease and central nervous system disorders. In December 2008, we commenced a first-in-humans phase 1 clinical trial of the intravenous formulation of SPI-017 as a potential treatment for peripheral arterial disease in Japan. We continue additional pre-clinical development of SPI-017 in an oral formulation which we hope to enter into phase 1 clinical trials in the United States in 2009 as a potential treatment for Alzheimer's disease.

Patent and manufacturing arrangements

We hold an exclusive worldwide royalty-bearing license to develop and commercialize Amitiza and other prostone-based compounds covered by patents and patent applications from Sucampo AG, an affiliated Swiss patent-holding company. We are obligated to assign to Sucampo AG all patentable improvements that we make in the field of prostones, which Sucampo AG will in turn license back to us on an exclusive basis. Amitiza, cobiprostone and SPI-017 are covered by perpetual licenses that cannot be terminated unless we default in our payment obligations to Sucampo AG. If we have not committed specified development efforts to any prostone compound other than Amitiza, cobiprostone and SPI-017 by the end of a specified period, which ends on the later of June 30, 2011 or the date upon which Drs. Ryuji Ueno and Sachiko Kuno, our founders and controlling stockholders, no longer control our company, then the commercial rights to that compound will revert to Sucampo AG, subject to a 15-month extension in the case of any compound that we designate in good faith as planned for development within that extension period.

We are party to exclusive supply arrangements with R-Tech Ueno, Ltd., or R-Tech, an affiliated Japanese pharmaceutical manufacturer, to provide us with clinical and commercial supplies of Amitiza and clinical supplies of our product candidates cobiprostone and SPI-017. These arrangements include provisions requiring R-Tech to assist us in connection with applications for marketing approval for these compounds world-wide, including assistance with regulatory compliance for chemistry, manufacturing and controls.

Our two founders, Drs. Ueno and Kuno, together, directly or indirectly, own all of the stock of Sucampo AG and a majority of the stock of R-Tech. Drs. Ueno and Kuno also are controlling stockholders of our company and are married to each other. Dr. Ueno is our chief executive officer and the chairman of our board of directors and Dr. Kuno is a member of our board of directors and also serves as our advisor of international business development.

Product Pipeline

The table below summarizes the development status of Amitiza and our key product candidates. We currently hold all of the commercialization rights to the prostone compounds in our product pipeline, other than for commercialization of Amitiza in the United States and Canada, which is covered by our collaboration and license agreement with Takeda.

Product/ Product Candidate	Target Indication	Development Phase	Next Milestone
Amitiza® (lubiprostone)	Chronic idiopathic constipation (adult)	Marketed in the U.S.	—
		Marketing Authorization Application validated in ten European countries	Completion of the formal review of applications by the European countries' regulatory authorities in 2009 followed by the reimbursement approval process
		Phase 2b dose-ranging study in Japan reported	Initiation of the phase 3 program in Japan in the second quarter of 2009
	Irritable bowel syndrome with constipation (adult women)	Marketed in the U.S.	—
	Chronic idiopathic constipation (pediatric, patients with renal impairment and patients with hepatic impairment)	Phase 4 pediatric, renal impairment and hepatic impairment trials completed	Filings with FDA in 2009
	Opioid-induced bowel dysfunction	Two phase 3 pivotal trials and a safety extension study ongoing, enrollment completed	Filing of supplemental NDA with FDA in early 2010
Cobiprostone	*Gastrointestinal*		
	Prevention of Non-steroidal anti-inflammatory drug (NSAID) induced ulcers	Phase 2 proof of concept trial ongoing, enrollment completed	Phase 2 dose-ranging trial planned to commence in 2010
	Liver		
	Non-alcoholic fatty liver disease	Phase 2 trial completed	Pending availability of new diagnostic tool
	Dermatologic		
	Topical ulcers and wounds	Preclinical	Phase 1 trial planned to commence in 2010
	Pulmonary		
	Cystic fibrosis - respiratory symptoms	Preclinical	Finalize inhaled formulation
	Chronic obstructive pulmonary disease	Preclinical	Finalize inhaled formulation
SPI-017	Peripheral arterial and vascular disease	Phase 1 human clinical safety study initiated in Japan	Completion of phase 1 study in the first quarter 2010 followed by phase 2 proof of concept trial*
	Alzheimer's disease	Preclinical	Phase 1 trials of oral formulation planned to commence in 2009*

* Results from phase 1 trials of both intravenous and oral formulations may be useful in development of any of these indications.

Additionally, we are continuing to conduct pre-clinical studies of six additional preclinical prostone compounds, including two combination candidates, as we focus on development and commercialization of therapies for age-related diseases.

Scientific Background of Prostones

Prostones are a class of compounds derived from functional fatty acids that occur naturally in the human body.

Ion Channel Activation

Based on our preclinical studies, we believe that most prostones work as selective ion channel activators, which means that they promote the movement of specific ions into or out of cells. Ions are charged particles, such as sodium, potassium, calcium and chloride ions. The concentration of specific ions within particular types of cells is important to many vital physiological functions, such as maintenance of the membrane potential and control of the activity levels of enzymes and transport molecules. Because ions cannot move freely across cell membranes, they must enter or exit a cell via specific transporters or through protein structures known as ion channels. Ion channels, which are found in every cell in the body, span the cell membrane and regulate the flow of ions into and out of cells by opening and closing in response to particular stimuli, such as changes in membrane potential, ph, cell volume or binding of particular ligands to the channel. Each kind of ion generally moves through its own specific ion channel. Some prostones have been shown to activate or inhibit ion channels, thereby controlling the concentration of specific ions within cells. We believe that these prostones work selectively on specific ion channels and, as a result, can be targeted to induce very specific pharmacological activities without triggering other cellular activity that could lead to undesirable side effects.

In preclinical *in vitro* tests on human cell lines with the three prostones that we are currently developing, Amitiza, cobiprostone and SPI-017, all three compounds activated a specific ion channel known as the type-2 chloride channel, or ClC-2 channel. The ClC-2 channel is expressed in cells throughout the body and is one of the channels through which chloride ions move into and out of cells. Chloride channels regulate many essential physiological functions within cells, including cell volume, intracellular pH, cellular water and ion balance and regulation of potential difference across the cell membrane (membrane potential) and energy levels. We believe that Amitiza is the first selective chloride channel activator approved by the FDA for therapeutic use in humans.

Potential Beneficial Effects of Prostones

We believe that the mechanism of action of prostones as selective ion channel activators may result in the following beneficial effects:

- *Enhancement of Fluid Secretion.* Activating the movement of specific ions into and out of cells can promote the secretion of fluid into neighboring areas following the osmotic gradient. For example, Amitiza promotes fluid secretion into the small intestine by activating the ClC-2 channel in the cells lining the small intestine. Likewise, Rescula is a potassium channel activator that works to treat glaucoma by increasing aqueous humor outflow in ocular cells in the eyes.
- *Recovery of Barrier Function.* Disruption of the barrier function in human epithelial cells can trigger cell damage by increasing the permeability of cells and tissue, thereby diminishing the body's first line of defense. Recently, tight junctions which are the closely associated areas of two cells whose membranes join together forming a virtually impermeable barrier to fluid have been found to play a critical role in the regulation of barrier function in the body. The ClC-2 channel plays an important role in the restoration of these tight junction complexes and in the recovery of barrier function in the body. CIC-2 channels have been detected at the tight junction complex between adjacent intestinal epithelial cells. In preclinical studies, Amitiza appeared to accelerate the recovery of the disrupted barrier function through the restoration of the tight junction structure. This may be a result of Amitiza's specific effects on the ClC-2 channel. We believe that other prostones that act as ClC-2 channel activators may have a similar barrier recovery function.

- *Localized Activity.* Because most prostones act through contact with cells, their pharmacological activity is localized in those areas where the compound is physically present in its active form. Because some prostones are metabolized relatively quickly to an inactive form, we believe their pharmacological effects are not spread to other parts of the body. These properties allow some prostones to be targeted to specific types of cells in specific organs through different routes of administration. For example, when Amitiza is taken orally, it arrives in the small intestine and liver while it is still active and begins to act on the cells lining those organs. By the time it is passed through to the large intestine, it appears to have been largely metabolized and is no longer active. Similarly, we believe that other formulations, such as an inhaled formulation of prostones would act principally in the lungs without having systemic effects.

Products and Product Candidates

AMITIZA® (lubiprostone)

Overview

We are developing Amitiza for the treatment of multiple constipation-related gastrointestinal disorders. Amitiza functions as an activator of the ClC-2 chloride channel through which negatively charged chloride ions flow out of the cells lining the small intestine and into the intestinal cavity. As these negatively charged chloride ions enter the intestine, positively charged sodium ions move through spaces between the cells into the intestine to balance the negative charge of the chloride ions. As these sodium ions move into the intestine, water is also allowed to pass into the intestine through these spaces between the cells. We believe that this movement of water into the small intestine promotes increased fluid content, which in turn softens the stool and facilitates its movement, or motility, through the intestine.

Chronic Idiopathic Constipation

On January 31, 2006, the FDA approved our NDA for Amitiza for the treatment of chronic idiopathic constipation in adults of both genders and all ages without restriction as to duration of use. In collaboration with Takeda, we initiated commercial sales of Amitiza in the United States for the treatment of chronic idiopathic constipation in April 2006. When used for this indication, Amitiza gelatin capsules are taken orally twice daily in doses of 24 micrograms each.

Disease Overview. Constipation is characterized by infrequent and difficult passage of stool and becomes chronic when a patient suffers specified symptoms for over 12 non-consecutive weeks within a 12-month period. Chronic constipation is idiopathic if it is not caused by other diseases or by use of medications. Symptoms of chronic idiopathic constipation include straining, hard stools, bloating and abdominal pain or discomfort. Factors contributing to the development of chronic idiopathic constipation include a diet low in soluble and insoluble fiber, inadequate exercise, bowel disorders and poor abdominal pressure and muscular weakness.

Current Treatment. Some patients suffering from chronic idiopathic constipation can be successfully treated with lifestyle modification, dietary changes and increased fluid and fiber intake, and these treatments are generally tried first. For patients who fail to respond to these approaches, physicians typically recommend laxatives, most of which are available over-the-counter. The most commonly used laxatives can be categorized as stimulants, stool softeners, bulk-forming agents, osmotics or lubricants. Though somewhat effective in treating chronic idiopathic constipation, stimulants and stool softeners can be habit forming, while bulk-forming agents are often ineffective in patients with moderate-to-severe constipation. Osmotics, such as MiraLax™ (polyethylene glycol 3350) and lactulose are labeled for use only for treating occasional constipation, not chronic idiopathic constipation, and they may cause fluid and electrolyte imbalance, which, if left untreated, can impair normal function of the nerves and muscles. MiraLax was approved in late 2008 for sale as an over-the-counter treatment. In addition, lubricants, such as orally administered mineral oil, can be inconvenient and unpleasant for patients to ingest. For those patients who failed to respond to laxatives, Zelnorm® (tegaserod maleate), a 5-HT4 serotonin-receptor agonist, was often prescribed. However, in March 2007, at the request of the FDA, Zelnorm was withdrawn from the U.S. market by Novartis Pharmaceuticals Corporation, or Novartis. The FDA requested that Novartis discontinue marketing Zelnorm based on a finding of an increased risk of serious cardiovascular adverse events associated with use of the drug. The FDA announced in July 2007 that it would permit the restricted use of Zelnorm under a treatment IND. On

April 2, 2008, after more than eight months of availability, Novartis re-assessed the treatment program and made a decision to close it.

Market Opportunity. Studies published in *The American Journal of Gastroenterology* estimate that approximately 42 million people in the United States suffer from constipation. In an additional study published in *The American Journal of Gastroenterology*, 91% of physicians expressed a desire for better treatment options for constipation.

We believe that Amitiza has a number of advantages over existing treatment options that could help it capture a significant portion of, and potentially expand, the existing market for chronic idiopathic constipation therapies. These advantages include the following:

- Amitiza is approved for administration to adults of all ages, including those over 65 years of age;
- Amitiza is approved without limitation on duration of use; and
- Amitiza has not been associated with the serious side effects observed with some other treatment options, such as ischemic colitis, electrolyte imbalance and cardiovascular ischemic events.

Clinical Trial Results. In connection with obtaining FDA marketing approval of Amitiza, we conducted a comprehensive program of clinical trials of this drug for use in treating chronic idiopathic constipation. This clinical program included two phase 3 pivotal trials and three long-term safety and efficacy trials.

Efficacy Results in Two Pivotal Clinical Trials. In August 2002 and September 2003, we completed two multi-center, double-blind, randomized, placebo-controlled, four-week, phase 3 clinical trials of substantially identical design to assess the safety and efficacy of Amitiza for the treatment of chronic idiopathic constipation. In each of these trials, we enrolled approximately 240 participants aged 18 or older with a history of chronic idiopathic constipation. The primary efficacy endpoint in these trials was the frequency of spontaneous bowel movements during the first week of treatment. Secondary efficacy endpoints included the frequency of spontaneous bowel movements during the second, third and fourth weeks of treatment, the percentage of participants with a spontaneous bowel movement within 24 hours after administration, the time to first spontaneous bowel movement and weekly subjective assessments by participants of average stool consistency, degree of straining, severity of constipation, overall treatment effectiveness and prevalence of other related symptoms, such as bloating and discomfort.

In these trials, Amitiza met its primary efficacy endpoint with statistical significance, increasing the frequency of spontaneous bowel movements from baseline during the first week of treatment by 75% in one pivotal trial and 78% in the second pivotal trial, in each case with a p-value less than 0.0001. In addition, on the basis of combined data from both pivotal trials, Amitiza met all but one of the secondary efficacy endpoints with statistical significance for all treatment weeks. That one secondary efficacy endpoint, abdominal discomfort, showed statistically significant improvements only during the last two weeks of treatment with Amitiza compared to placebo. The results of these trials were consistent in subpopulation analyses for gender, race and patients 65 years of age or older. We determined statistical significance based on a widely used, conventional statistical method that establishes the p-value of clinical results. Under this method, a p-value of 0.05 or less represents statistical significance, meaning that there is a less than one-in-twenty likelihood that the observed results occurred by chance.

Efficacy Results in Long-term Safety Trials. Between November 2001 and January 2005, we conducted three multi-center, open-label, long-term clinical safety and efficacy trials of Amitiza in patients with a history of chronic idiopathic constipation. The trials consisted of one six-month trial and two twelve-month trials and enrolled a total of 881 patients age 18 or older. The primary objective of these trials was to demonstrate the safety of Amitiza when administered to participants in twice-daily doses of 24 micrograms each. A secondary objective was to provide further evidence of the long-term efficacy of Amitiza in treating the symptoms of chronic idiopathic constipation. In these trials, Amitiza produced statistically significant improvements from baseline in subjective assessments of constipation severity, abdominal bloating and abdominal discomfort over both the six-month and the twelve-month treatment periods with a p-value less than or equal to 0.0001. Subjective assessment of constipation severity was improved by an average of 1.47 points on a five-point scale in the six-month trial and 1.38 points in the twelve-month trial; subjective assessment of abdominal bloating was improved by an average of 0.98 points in the six-

month trial and 1.00 points in the twelve-month trial; and subjective assessment of abdominal discomfort was improved by an average of 0.91 points in the six-week trial and 0.87 points in the twelve-month trial.

Safety Profile and Withdrawal Effects. Amitiza was well tolerated in twice-daily doses of 24 micrograms each in an earlier phase 2 trial, the two phase 3 pivotal trials and the three long-term clinical safety and efficacy trials. These trials revealed no apparent increased risk of serious adverse events as a result of treatment with Amitiza. The most common adverse events reported by participants in these six trials were nausea, which was reported by 31% of all trial participants, and diarrhea and headache, which were each reported by 13% of all trial participants. The incidence of nausea was lower among participants 65 years of age or older, with only 18.6% of those participants reporting this side effect. In addition, because Amitiza demonstrated a potential to cause fetal loss in guinea pigs in preclinical studies, its label provides that it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The label further states that women who could become pregnant should have a negative pregnancy test prior to beginning therapy with the drug and should be capable of complying with effective contraceptive measures.

Post-marketing Studies. In connection with our marketing approval for Amitiza for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in pediatric patients, patients with renal impairment and in patients with hepatic impairment. We initiated the studies in January 2007. We completed the study in patients with renal impairment and submitted the clinical study report to the FDA in April 2008. We have completed the study in patients with hepatic impairment and studies in pediatric patients and our analysis of results are under way.

Japanese Studies. In November 2007, we commenced a multi-center phase 2b dose-ranging study in Japan to evaluate the safety and efficacy of lubiprostone for chronic idiopathic constipation in adults. This randomized, parallel group, double-blind, placebo-controlled study compared the dose response of oral lubiprostone with that of placebo in Japanese patients diagnosed with chronic idiopathic constipation. The study evaluated 170 patients who were randomized to one of three twice-daily doses of lubiprostone (8, 16 or 24 micrograms) or placebo. Participants in the study had a statistically significant increase in the mean change in spontaneous bowel movements, or SBM, from baseline after one week on treatment, the study's primary endpoint, for patients taking Amitiza 24 micrograms twice daily versus placebo, with a p. value of less than .0001. Patients taking Amitiza 24 micrograms also had statistically significant improvement versus placebo for several secondary endpoints, including change in SBM after two weeks, mean weekly SBM, percentage of patients having first SBM within 24 and 48 hours, degree of straining and stool consistency, abdominal bloating, abdominal discomfort, global assessment of severity of constipation, global assessment of treatment efficacy as well as quality of life evaluation of treatment satisfaction.

Amitiza was well-tolerated with the most commonly reported adverse events, reported in greater than 5% of patients, being diarrhea, nausea, and stomach discomfort, which are consistent with previously reported Amitiza data.

Irritable Bowel Syndrome with Constipation

On April 29, 2008, the FDA approved our supplemental NDA, or sNDA, for Amitiza for the treatment of irritable bowel syndrome with constipation in adults. In collaboration with Takeda, we initiated commercial sales of Amitiza in the United States for this indication in May 2008. When used for this indication, Amitiza gelatin capsules are taken orally twice daily in doses of 8 micrograms each.

Disease Overview. Irritable bowel syndrome is a disorder of the intestines with symptoms that include severe cramping, pain, bloating and extreme changes of bowel habits, such as diarrhea or constipation. Patients diagnosed with irritable bowel syndrome are commonly classified as having one of three forms: irritable bowel syndrome with constipation, irritable bowel syndrome with diarrhea, or mixed-pattern irritable bowel syndrome alternating between constipation and diarrhea. Currently, irritable bowel syndrome in all its forms is considered to be one of the most common gastrointestinal disorders.

Current Treatment. Most treatment options for irritable bowel syndrome with constipation focus on separately addressing symptoms, such as pain or infrequent bowel movements. Some patients suffering from irritable bowel syndrome with constipation can be successfully treated with dietary measures, such as increasing

fiber and fluid intake, and these treatments are generally tried first. If these measures prove ineffective, laxatives are frequently used for the management of this condition. Zelnorm was the only FDA-approved drug indicated for the treatment of irritable bowel syndrome with constipation before it was withdrawn in March 2007. In December 2005, the European Medicines Agency denied marketing approval for Zelnorm for the treatment of irritable bowel syndrome with constipation in women, citing the inconclusiveness of clinical studies in demonstrating its effectiveness. In March 2006, the agency denied an appeal of that decision.

Market Opportunity. According to the American College of Gastroenterology, irritable bowel syndrome affects approximately 58 million people in the United States, and irritable bowel syndrome with constipation accounts for approximately one-third of these cases.

Development Status. In June 2004, we completed a multi-center, double-blind, randomized, placebo-controlled, dose-response, 12-week phase 2 clinical trial to assess the safety and efficacy of Amitiza for the treatment of irritable bowel syndrome with constipation in daily doses of 16, 32 and 48 micrograms. In this trial, we enrolled approximately 200 participants meeting the International Congress of Gastroenterology's working criteria for the diagnosis of irritable bowel syndrome with constipation, referred to as the Rome II criteria. The objective of this trial was to evaluate the safety and efficacy of multiple dose levels of Amitiza in this patient population in order to select the appropriate dose for phase 3 pivotal studies.

The primary efficacy endpoint for this trial was a subjective assessment of changes in abdominal discomfort and pain during the first month of treatment. Secondary efficacy endpoints included subjective assessments of changes in abdominal discomfort and pain during the second and third months of treatment, frequency of spontaneous bowel movements, subjective assessments of average stool consistency, degree of straining, abdominal bloating, severity of constipation and overall treatment effectiveness and subjective assessment of quality of life.

In this trial, Amitiza demonstrated a statistically significant, dose-dependent trend in improvement in mean change from baseline abdominal discomfort and pain during the first month of treatment with a p-value of 0.0431. The term mean change from baseline refers to differences in patients' condition after treatment with the drug or the placebo compared to their condition before treatment. This dose-dependent trend in improvement in mean change from baseline also was statistically significant during the second month of treatment with a p-value of 0.0336. During the third month of treatment, the trend in favor of Amitiza continued, but was not statistically significant. Several secondary efficacy endpoints, including frequency of spontaneous bowel movements, subjective assessments of average stool consistency, degree of straining, abdominal bloating and severity of constipation, also showed overall dose-dependent trends that were statistically significant for at least two of the three months of treatment.

Although Amitiza was effective and well tolerated at all doses in this trial, the 16 microgram daily dose produced the best overall balance of safety and efficacy, with participants in the 32 and 48 microgram treatment groups generally more likely to discontinue treatment due to adverse events. Adverse events appeared to be dose-dependent between the 16 and 48 microgram Amitiza treatment groups and occurred more frequently in the Amitiza treatment group than in the placebo treatment group.

Based on the results of this phase 2 trial, we initiated two pivotal phase 3 clinical trials of Amitiza in men and women for irritable bowel syndrome with constipation in May 2005, each involving 570 or more participants meeting the Rome II criteria for irritable bowel syndrome with constipation at 65 investigative study sites in the United States. These phase 3 pivotal trials were designed as double-blind, randomized, 12-week clinical trials to demonstrate the efficacy and safety of Amitiza for the treatment of symptoms of irritable bowel syndrome with constipation using twice daily doses of 8 micrograms each, or 16 micrograms total. The primary efficacy endpoint for these trials was a subjective assessment of the participant's overall relief from the symptoms of irritable bowel syndrome with constipation determined by the question "How would you rate your relief of irritable bowel syndrome symptoms (abdominal discomfort/pain, bowel habits, and other irritable bowel syndrome symptoms) over the past week compared to how you felt before you entered the study?" Patient responses were recorded using a seven-point balanced scale. Treatment responders were defined in each month as those reporting at least "significantly relieved", which was the highest scale category, for two out of four weeks or "moderately relieved", the second highest category, for four out of four weeks. To qualify as an overall treatment responder, and count toward the primary efficacy endpoint, patients had to be a monthly treatment responder for at least two out of three months.

The secondary efficacy endpoints were similar to those for our phase 2 clinical trials of Amitiza for this indication and involved subjective assessments of such factors as abdominal discomfort and pain, bloating, straining, stool consistency, severity of constipation and quality of life components. The first of the two pivotal studies was followed by a randomized withdrawal period to assess the effects, if any, associated with withdrawal of Amitiza over a four-week period. We also initiated an additional follow-on open-label safety and efficacy study to assess the long-term use of Amitiza as a treatment for this indication. This study included 476 patients who were treated for an additional 36 weeks following the initial 12 or 16 week treatment period.

In the two pivotal phase 3 trials, participants receiving Amitiza at a dose of 8 micrograms twice daily were more likely to achieve overall relief from symptoms compared to those receiving the placebo, with 17.9% of the Amitiza group achieving overall relief compared to 10.1% for the placebo group, with a p-value of 0.001. In both trials individually, participants receiving Amitiza experienced overall relief from symptoms at higher rates than those receiving the placebo, 18.2% compared to 9.8% with a p-value of 0.009 in one trial and 17.7% compared to 10.4% with a p-value of 0.031 in the other.

In the combined phase 3 trials, the secondary endpoints, which were measured on a five-point scale, were improved with statistical significance in participants receiving Amitiza compared to those receiving the placebo. At the end of the three-month treatment period, subjective assessments of abdominal discomfort and pain by participants receiving Amitiza improved from baseline by an average of 0.45 points, compared to average improvements in participants receiving the placebo of 0.35 points; subjective assessments of stool consistency improved by an average of 0.51 points compared to 0.38 points; subjective assessments of straining improved by an average of 0.60 points compared to 0.47 points; subjective assessments of constipation severity improved by an average of 0.52 points compared to 0.40 points; and subjective assessments of abdominal bloating improved by an average of 0.45 points compared to 0.36 points. At the end of the three-month treatment period, the overall composite score for subjective assessments of quality of life improved from baseline an average of 17.1 points on a 100-point scale for participants receiving Amitiza compared to an average improvement of 14.4 points for those receiving the placebo. Statistical significance was seen for each of these secondary endpoints, with the subjective assessments of abdominal discomfort and pain having a p-value of 0.013, stool consistency having a p- value of 0.006, straining having a p-value of 0.020, constipation severity having a p-value of 0.005, abdominal bloating having a p-value of 0.024 and quality of life having a p-value of 0.021.

The first of the two phase 3 trials also assessed the rebound effect from the withdrawal of Amitiza following 12 weeks of treatment with an 8 microgram dose twice daily. In this trial, withdrawal of Amitiza did not result in a rebound effect. Amitiza was well-tolerated in the phase 2, phase 3, and long-term safety studies. In the combined phase 2 and phase 3 studies and at the recommended dose, there was a similar incidence of serious adverse events, 1% in both the Amitiza group and the placebo group, and treatment-related adverse events, with 26% in the Amitiza groups compared to 21% in the placebo groups. The most common treatment-related adverse events were nausea, which was reported by 8% of participants receiving Amitiza and 4% of those receiving the placebo, and diarrhea, which was reported by 7% of the Amitiza groups and 4% of the placebo groups. Abdominal pain occurred at a similar rate in the placebo groups and the Amitiza groups, with 5% reporting this adverse event.

Opioid-Induced Bowel Dysfunction

Disease Overview. Opioid-induced bowel dysfunction comprises a variety of gastrointestinal side effects originating from the use of narcotic medications such as morphine and codeine, which are referred to as opioids. Physicians prescribe opioids for patients with advanced illnesses, such as cancer and AIDS, patients undergoing surgery and patients who experience chronic pain. Despite their pain-relieving effectiveness, opioids are known to produce gastrointestinal side effects that lead to opioid-induced constipation, including inhibition of large intestine motility, decreased gastric emptying and hard stools.

Current Treatment. There are currently no FDA-approved oral products that are specifically indicated for treatment of opioid-induced bowel dysfunction. Current treatment options for opioid-induced bowel dysfunction include the use of stool softeners, enemas, suppositories and peristaltic stimulants such as senna, which stimulate muscle contractions in the bowel. The effectiveness of these products for the treatment of opioid-induced bowel dysfunction is limited due to the severity of the constipation caused by opioids. In addition, physicians often cannot

prescribe peristaltic stimulants for the duration of narcotic treatment because of the potential for dependence upon these stimulants. The FDA recently approved Relistor (methylnaltrexone bromide) for opioid-induced constipation in patients with late-stage and advanced illness who experience severe constipation. However, Relistor is available only as an injectable medication and is not recommended for patients with known or suspected intestinal obstructions. Common side effects of Relistor include abdominal pain, gas, nausea, dizziness and diarrhea.

Market Opportunity. According to the American Pain Foundation, over 50 million Americans suffer from chronic pain, and nearly 25 million Americans experience acute pain each year due to injuries or surgery. Opioid pain relievers are widely prescribed for these patients, many of whom also develop opioid-induced bowel dysfunction. We believe over three million people in the United States currently suffer from opioid-induced bowel dysfunction.

Opioid drugs are known to increase absorption of electrolytes, including chloride, in the small intestine, contributing to the constipating effects of these analgesics.

We believe that Amitiza, as a chloride channel activator, may directly counteract this side effect without interfering with the analgesic benefits of opioids. As a result, we believe that Amitiza, if approved for the treatment of opioid-induced bowel dysfunction, could hold a competitive advantage over drugs that do not work through this mechanism of action.

Development Status

We have completed preclinical studies of Amitiza as a potential therapy for opioid-induced bowel dysfunction. In a model of morphine-induced constipation in mice, Amitiza was shown to improve intestinal transit time and did not result in any reduction of the analgesic effect of morphine. Based on these preclinical results, we determined to pursue development of Amitiza as a treatment for opioid-induced bowel dysfunction.

We commenced two pivotal phase 3 clinical trials of orally administered Amitiza for the treatment of opioid-induced bowel dysfunction in September 2007. Each trial enrolled approximately 420 participants at 190 participating sites. These phase 3 pivotal trials are designed as double-blind, randomized, 12-week clinical trials to demonstrate the efficacy and safety of Amitiza for the treatment of opioid-induced bowel dysfunction in adults using twice daily doses of 24 micrograms each, or 48 micrograms total. The primary efficacy endpoint for these trials is the change from baseline in SBM frequency at week 8. In addition, several secondary endpoints include change from baseline in SBM frequency at week 12 and overall; percentage of patients with a first post-dose SBM within 24 hours or 48 hours; overall responder rates; overall mean change from baseline in straining, stool consistency, constipation severity, abdominal bloating, abdominal discomfort, and bowel habit regularity; and overall treatment effectiveness. These two pivotal trials, which were fully enrolled in late November 2008, are being followed by a nine month open-label extension trial in approximately 440 participants to assess the long-term safety and efficacy profile of Amitiza in subjects with opioid-induced bowel dysfunction.

Cobiprostone

Overview

We are developing the prostone compound cobiprostone for oral administration to treat various gastrointestinal and liver disorders, including NSAID-induced ulcers and portal hypertension. We also plan to develop an inhaled formulation of cobiprostone for the treatment of respiratory symptoms of cystic fibrosis and chronic obstructive pulmonary disease. We believe that cobiprostone, like Amitiza, is an activator of the chloride ion channel ClC-2, which is known to be present in gastrointestinal, liver and lung cells. We are also developing cobiprostone as a topical preparation for the treatment of ulcers and wounds based on preclinical results from coetaneous tissue blood flow studies and incision wound healing studies.

We completed two phase 1 clinical trials of cobiprostone in healthy volunteers in Japan in 1997. In these trials, orally administered cobiprostone was generally well tolerated both when it was administered three times daily for a period of seven days at doses we expect to be clinically relevant and when it was administered in single doses that were significantly higher than those we expect to be clinically relevant. Several incidents of loose or watery stools were reported, but at doses higher than those we expect to use in planned additional clinical trials. No serious

adverse events were experienced by any participants in these trials, and no participants withdrew from these trials due to adverse events, even at dose levels several times higher than what we expect to be clinically-relevant doses of cobiprostone.

Non-Steroidal Anti-Inflammatory Drug-Induced Ulcers

We commenced a phase 2 clinical trial of cobiprostone for the prevention and treatment of NSAID-induced ulcers in September 2007.

Disease Overview. NSAIDs, such as aspirin and ibuprofen, are among the most commonly prescribed drugs worldwide. They are used to treat common medical conditions, such as arthritis, headaches and fever. In addition, with the recent withdrawal from the marketplace of the COX-2 inhibitors Vioxx® (rofecoxib) and Bextra® (valdecoxib), which were widely prescribed for arthritis patients, an increased number of these patients are returning to NSAID therapy. However, gastrointestinal symptoms, such as gastric, or stomach, ulcers and bleeding, are major limiting side effects of long-term NSAID use.

Current Treatment. Current treatment options for NSAID-induced ulcers include products designed to prevent the formation of gastric ulcers during NSAID use and products that help to repair the damage of ulcers after they have developed. Cytotec® (misoprostol) is currently the only FDA approved product for the prevention of NSAID-induced gastric ulcers. It is sometimes marketed as a combination product with NSAIDs under the brand name Arthrotec®. However, Cytotec has been associated with severe diarrhea, particularly in higher doses, and its label restricts its use in women of childbearing potential, except in very limited circumstances, because it can cause abortion, premature birth and birth defects.

After NSAID-induced ulcers have developed, proton pump inhibitors, such as Nexium® (esomeprazole magnesium) and Prevacid® (lansoprazole), are prescribed to treat most gastric ulcer patients, either alone or in combination with other treatments. H2 receptor blockers, such as Pepcid® (famotidine), Tagamet® (cimetidine) and Zantac® (ranitidine hydrochloride), help to reduce stomach acid and are typically prescribed as a second line of therapy for gastric ulcers, when proton pump inhibitors are not effective, or are used in conjunction with proton pump inhibitors. Although both proton pump inhibitors and H2 blockers can aid in the repair of existing gastric ulcers, neither of these drug categories has been shown to be effective in preventing ulcer development. Furthermore the therapeutic effects of these products are only observed at high doses and in some types of at-risk patients, such as those with a prior history of ulcers or those 65 years of age or older.

Market Opportunity. According to a study published in *Postgraduate Medicine*, approximately 13 million patients in the United States are regular users of NSAIDs. According to the American Chronic Pain Association, as many as 20% of patients who take NSAIDs daily may develop gastric ulcers. We believe that many patients treated with NSAIDs are not prescribed preventative treatment for gastric ulcers due to a combination of high cost, side effects and lack of a well established standard of care. We believe that these factors also limit the use of prescription products for the repair of gastric ulcers after they have developed. Based on cobiprostone's novel mechanism of action and protective activity in animal models, we believe that it may be effective at both preventing and treating NSAID-induced ulcers, but without the safety concerns and restrictions on use associated with existing treatment options.

Development Status. We have completed preclinical studies of cobiprostone as a potential therapy for the prevention of NSAID-induced ulcers. In preclinical tests in rats, cobiprostone protected against formation of ulcers induced by indomethacin, an NSAID, and ulcers induced by stress and demonstrated an acceptable safety profile at what we believe are clinically relevant doses. In the third quarter of 2007, we commenced a phase 2 clinical trial for cobiprostone. This phase 2 multi-center, randomized, placebo-controlled study was fully enrolled at the end of December 2008 with 124 participants at 12 sites. The trial is designed to assess the efficacy and safety of cobiprostone in preventing nonsteroidal anti-inflammatory drug induced gastroduodenal injury in patients taking Naproxen 500mg twice daily. Study patients are randomized to one of three daily doses of cobiprostone (18, 36 or 54 micrograms) or placebo. The efficacy endpoints for the trial include the overall incidence of gastric, duodenal, and gastroduodenal ulcers, the incidence of gastric, duodenal, and gastroduodenal ulcers and erosions at weeks 4, 8, and 12, the changes in numbers of ulcers and erosions, and evaluation of GI mucosa ischemia. We believe that cobiprostone may have utility in preventing other gastric injury in addition to NSAID-induced ulcers. Accordingly,

as we progress through our clinical program for cobiprostone, we may seek to broaden our indication for this compound by exploring other gastrointestinal lesions, including hemorrhages, erosions and ulcerations.

Other Potential Indications

Portal Hypertension. Portal hypertension is the build-up of pressure in the portal vein connecting the intestines and the liver and is caused by a narrowing of the blood vessel as a result of liver cirrhosis. Increased pressure in the portal vein can lead to the development of large, swollen veins in the esophagus, stomach and rectum which, if ruptured, can result in potentially life-threatening blood loss.

In preclinical tests, cobiprostone:

- decreased portal pressure in two rodent models of portal hypertension disease;
- increased cutaneous blood flow in two additional animal models in the presence of chemical agents known to constrict the peripheral vasculature; and
- reduced vascular resistance in the liver induced by a chemical agent in an isolated liver model.

In the third quarter of 2008, we commenced a phase 2 proof-of-concept study of cobiprostone in patients with portal hypertension. The trial was designed to assess the efficacy and safety of an initial single oral dose of cobiprostone at 36 or 54 micrograms, followed by multiple doses of cobiprostone at 36 micrograms/day (12 micrograms three times daily) and 54 micrograms/day (18 micrograms three times daily) over a four — week period. The trial was discontinued in December 2008 due to lower than anticipated enrollment resulting from lack of patient eligibility interest and study compliance. The trial design is being reviewed to determine if future study for this indication is warranted.

Cystic Fibrosis. Cystic fibrosis is a congenital disease that usually develops during childhood and causes pancreatic insufficiency and pulmonary disorder. The gene product responsible for cystic fibrosis is a protein called the cystic fibrosis transmembrane conductance regulator, or CFTR. CFTR is found in cells lining the internal surfaces of the lungs, salivary glands, pancreas, sweat glands, intestine and reproductive organs and acts as a channel transporting chloride ions out of the cell. Cystic fibrosis is caused by a defect in the CFTR protein, which prevents the transport of chloride ions out of cells, causing the body to develop thick, sticky mucus in the lungs, pancreas and liver. According to the Cystic Fibrosis Foundation, cystic fibrosis currently affects approximately 30,000 people in the United States and is usually diagnosed in infants and children.

In preclinical *in vitro* tests on human cell lines, cobiprostone acted as an ion transport modulator, facilitating transport of chloride ions across cell membranes through the ClC-2 chloride channel, a transport process different from that which is defective in cystic fibrosis patients. We believe that the ability of cobiprostone to activate chloride transport using an alternate chloride channel could potentially reverse the effects caused by the defective CFTR, reducing mucus viscosity and allowing increased clearance of mucus in the lungs, pancreas and liver.

In 2003, we conducted an open-label, dose-escalating phase 2 trial of orally administered cobiprostone in 24 participants with documented cystic fibrosis. These participants were assigned to one of three dose cohorts at four sites in the United States and treated with cobiprostone for seven days. Cobiprostone was generally well tolerated by trial participants, although one participant experienced a serious adverse event and was hospitalized for exacerbation, or short-term worsening, of the disease, possibly as a result of treatment with cobiprostone. Although this trial focused primarily on safety, we also examined the effect of cobiprostone on chloride secretion in cells lining the nose and salivary glands as well as overall quality of life as measured by a questionnaire published by the Cystic Fibrosis Foundation. The results for chloride secretion were inconclusive, which we believe was likely due to the rapid metabolization of the drug in the gastrointestinal tract, the short duration of the trial and the limited number of participants enrolled in the trial. As a result, we are focusing our initial development efforts on an inhaled formulation of cobiprostone for the treatment of respiratory symptoms of cystic fibrosis.

Chronic Obstructive Pulmonary Disease. Chronic obstructive pulmonary disease is characterized by the progressive development of airflow limitation in the lungs that is not fully reversible and encompasses chronic bronchitis and emphysema. According to the National Heart, Lung and Blood Institute, or the NHLBI, a division of the National Institutes of Health, approximately 12 million adults 25 years of age or older in the United States are

diagnosed with chronic obstructive pulmonary disease. The NHLBI further estimates that approximately 24 million adults in the United States have evidence of impaired lung function, indicating in their view that this disease is under diagnosed. Anticholinergics, smooth muscle relaxers that can help to widen air passageways to the lungs, have been the primary therapy to treat chronic obstructive pulmonary disease. Recently, combination agents, such as steroid/Beta-2 agonists, have enjoyed increased use as chronic obstructive pulmonary disease treatments. However, these treatments relieve only the symptoms of chronic obstructive pulmonary disease, such as chronic cough or shortness of breath, and have limited effect on reducing the incidence of exacerbation of the disease.

Because we believe that the method of action of cobiprostone involves a barrier protection function resulting from chloride channel activation, we believe that it may be able to address multiple respiratory treatment needs, including treatment of exacerbations, chronic excessive mucus secretion and the mucus component of chronic bronchitis. In pharmacological testing using an inhaled formulation of cobiprostone in a guinea pig model to assess changes in respiratory and pulmonary function, cobiprostone reduced cigarette smoke-induced airway resistance and restored forced expiratory volume. We plan to conduct additional preclinical testing of this inhaled formulation of cobiprostone as a potential treatment for chronic obstructive pulmonary disease.

SPI-017

Overview

We are conducting preclinical development of SPI-017 for the treatment of peripheral arterial and vascular disease, central nervous system disorders. Initially, we are working on the development of an intravenous formulation of SPI-017 for the treatment of peripheral arterial disease and stroke. We also are developing an oral formulation of SPI-017 for the treatment of Alzheimer's disease.

We commenced a phase 1 clinical trial of the intravenous formulation of SPI-017 in December 2008. We also plan to commence a phase 1 clinical trial of the oral formulation in 2009. Results from the phase 1 trials of both the intravenous and the oral formulations may be useful in the development of multiple indications.

In preclinical *in vitro* tests on human cell lines, SPI-017 activated chloride and potassium channels in very low concentrations on a variety of cell types found in the central nervous system and peripheral blood vessels. We are currently evaluating the safety profile of various SPI-017 dosage forms in preclinical toxicology studies.

Potential Indications

Peripheral Arterial and Vascular Disease. Peripheral arterial disease, which also is sometimes referred to as peripheral vascular disease, is a chronic condition that results from narrowing of the vessels that supply blood to the stomach, kidneys, arms, legs and feet. Peripheral arterial disease is caused by the build-up of fatty deposits, or plaque, in the inner walls of the arteries as a result of a vascular condition known as atherosclerosis. This build-up of plaque restricts the flow of blood throughout the body, particularly in the arms and legs, and can lead to painful cramping and fatigue after exercise. The American Heart Association estimates that peripheral arterial disease affects as many as 8 million to 12 million people in the United States.

Anti-platelet medications, vasodilators and prostaglandins represent the most frequently prescribed treatments for peripheral arterial disease, but they have little or no impact on symptoms or the underlying atherosclerotic process. Palux® (alprostadil) and Liple® (alprostadil) are used for the treatment of chronic arterial occlusion in Japan, but alprostadil is not approved for this indication in the United States. In addition, Palux and other prostaglandin E1 drug products should not be administered to patients with bleeding disorders or patients being treated with chronic anti-platelet medications, such as aspirin, due to the detrimental effect of these products on platelet aggregation. Despite the need for additional treatments, we believe that few novel therapies are being explored.

In preclinical animal studies, intravenously administered SPI-017 counteracted blood vessel constriction induced by a chemical agent without significantly affecting blood pressure. In addition, in preclinical animal studies, SPI-017 had no effect on platelet aggregation. We believe that this may suggest that SPI-017, unlike Palux and other prostaglandin E1 drugs, could be used to treat patients with bleeding disorders or patients being treated

with chronic anti-platelet medications. We are planning additional experiments to further test the activity of SPI-017 in animal models of peripheral arterial disease.

Stroke. Ischemic stroke occurs when an artery that supplies blood to the brain becomes blocked due to a blood clot or other blockage or when blood flow is otherwise reduced as a result of a heart condition. During ischemic stroke, a high rate of damage of neuronal cells in the brain usually leads to permanent functional loss. The American Heart Association estimates that approximately 700,000 patients in the Unites States suffer strokes annually, 88% of which are ischemic strokes.

The thrombolytic Activase® (alteplase, recombinant) is the principal drug currently used to treat acute ischemic stroke in the United States. To be effective, treatment with Activase must be initiated within three hours after the onset of stroke symptoms. In addition, because Activase is contraindicated in patients with intracranial hemorrhaging or active internal bleeding, treatment should be initiated only after exclusion of these conditions.

Intravenously administered SPI-017 reduced the extent of cerebral tissue damage in experimentally induced ischemic stroke in rats. In these studies, intravenous SPI-017 administered shortly after the restoration of blood flow also significantly reduced the extent of tissue damage. We are planning additional animal tests to further define the time window for administration of SPI-017 and the concentration range.

Alzheimer's Disease. Alzheimer's disease is a chronic debilitating disease, with patients suffering from a progressive dementia over a number of years, ultimately resulting in severe incapacitation and a shortened lifespan. According to the Alzheimer's Association, there are approximately 4.5 million Alzheimer's disease patients in the United States.

The brain comprises a complex network of neurons that enable memory, sensation, emotion and other cognitive functions. Neurons are highly specialized cells that are capable of communicating with each other through biochemical transmission across junctions called synapses. For this communication to occur, neurons secrete chemicals, known as neurotransmitters, which bind to receptors on neighboring neurons. Coordinated communication across synapses is essential for the formation of memories. The molecular mechanisms and hypotheses of Alzheimer's disease are complex.

Several classes of ion channels play a critical role in both the activation of neurons and in the secretion of neurotransmitters across synapses. In particular, some classes of potassium ion channels, sodium ion channels and calcium ion channels have been shown to be critical in the cascade of events that leads to the secretion of neurotransmitters in key regions of the brain associated with memory. We believe that some of these channels may be important in the process of memory formation and retention.

Preclinical studies of SPI-017 in a cholinergic lesion rat model of Alzheimer's disease suggest that orally administered SPI-017 facilitates memory formation and cognitive behaviour. In addition, the survival and structural integrity of cholinergic neurons in the nucleus basalis magnocellularis were preserved in SPI-017 treated animals. The efficacy of SPI-017 was comparable to Aricept, an acetylcholine esterase inhibitor which is currently marketed for the treatment of moderate to severe Alzheimer's disease. Since the mechanisms of action of SPI-017 are different from inhibition of neuronal acetylcholine esterase we are planning additional studies to further test the activity of SPI-017 in different animal models of Alzheimer's disease.

Marketing and Sales

In 2006, we exercised the co-promotion rights under our collaboration and license agreement with Takeda to begin developing a specialized sales force to market Amitiza to complement Takeda's marketing efforts among primary care physicians. We have implemented a selling model that we believe has produced increased sales growth for Amitiza in geographies covered by a Sucampo representative within the United States.

Takeda markets Amitiza broadly to office-based specialty physicians and primary care physicians in the United States. We complement Takeda's marketing efforts by promoting Amitiza through a specialty sales force in the institutional marketplace, including specialist physicians based in academic medical centers and long-term care facilities. This institutional market is characterized by a concentration of elderly patients, who we believe to be a

key market for Amitiza to treat gastrointestinal indications, and by physicians who are key opinion leaders in the gastrointestinal field.

We intend to evaluate strategic acquisitions, in-licensing or co-promotion opportunities to supplement our existing product pipeline, especially those that would add products complementary to the focus of our specialty sales force.

Takeda Collaboration

In October 2004, we entered into a 16-year collaboration and license agreement with Takeda to jointly develop and commercialize Amitiza for gastrointestinal indications in the United States and Canada. This agreement provides Takeda with exclusive rights within these two countries to develop and commercialize Amitiza for these indications under all relevant patents, know-how and trademarks. Takeda does not have the right to manufacture Amitiza. Instead, Takeda is required to purchase all supplies of the product from R-Tech under a supply and purchase agreement between Takeda and R-Tech.

Development Costs. The agreement provides for development cost-sharing arrangements in which Takeda funds all development costs for the development of Amitiza as a treatment for chronic idiopathic constipation and irritable bowel syndrome with constipation up to $30.0 million, of which we received the full amount in 2005. We are required to fund the next $20.0 million in development costs for these two indications, and all development costs in excess of $50.0 million are shared equally between Takeda and us. In addition, Takeda and we share equally in all external costs of regulatory-required studies up to $20.0 million, with Takeda funding any remaining costs related to such studies. For any additional indications beyond chronic idiopathic constipation and irritable bowel syndrome with constipation and for new formulations of Amitiza, Takeda has agreed to fund all development costs, including regulatory-required studies, to a maximum of $50.0 million for each new indication and $20.0 million for each new formulation. Takeda and we have agreed to share equally all costs in excess of these amounts. With respect to any studies required to modify or expand the label for Amitiza for the treatment of chronic idiopathic constipation or irritable bowel syndrome with constipation, Takeda has agreed to fund 70% of the costs of such studies and we have agreed to fund the remainder. With respect to the development costs for Amitiza for the treatment of chronic idiopathic constipation in pediatric patients, the joint commercialization committee described below has determined that such costs will be funded entirely by Takeda.

Commercialization Funding Commitment. Takeda is obliged to maintain a specific level of funding for activities in relation to the commercialization of Amitiza. If we and Takeda jointly determine to conduct a full-scale direct-to-consumer television advertising campaign for Amitiza, Takeda's funding obligation for commercialization activities will be $80.0 million per year for three years. If there is no full-scale direct to consumer advertising campaign in a 12 month period, then the total commercialization funding commitment will be $40.0 million per year for a three year period following the NDA approval for the irritable bowel syndrome with constipation indication.

Promotion and Marketing. Takeda is required to provide a dedicated sales force of at least 200 people to promote Amitiza and a supplemental sales force of 500 people to promote Amitiza together with one other drug product. In addition, Takeda is required to perform specified minimum numbers of product detail meetings with health care professionals throughout the term of the agreement depending upon the indications for which Amitiza has been approved.

Co-Promotion Rights. Under the agreement, we retained co-promotion rights, which we exercised in February 2006, resulting in a related supplemental agreement. In connection with our exercise of these rights, we agreed to establish our own specialty sales force consisting of a team of approximately 38 field sales representatives. The supplemental agreement provides that Takeda will fund a portion of our sales force costs, for a period of five years from the date we first deploy our sales representatives. We may increase the total number of our sales representatives and receive additional funding from Takeda for any related costs up to a specified annual amount, subject to the unanimous approval of the joint commercialization committee described below.

Medical and Scientific Activities. We also are entitled to receive cost reimbursement from Takeda on a case-by-case negotiated basis for a part of our commercialization efforts with respect to specific medical and

scientific activities undertaken by us. Takeda is to retain overall responsibility for managing these medical and scientific activities. We were responsible for the development of all publications directed at a scientific audience until January 31, 2007, with this work being reimbursed by Takeda up to a specified limit. We retain all intellectual property rights over the material in these publications. After January 31, 2007, Takeda is primarily responsible for the development of these publications.

Licensing Fees, Milestone Payments and Royalties. Takeda made an up-front payment of $20.0 million in 2004 and has paid total development milestone payments of $130.0 million through December 31, 2008. Subject to reaching future development and commercial milestones, we are entitled to receive up to $10.0 million in additional development milestone payments and up to $50.0 million in commercial milestone payments. In addition, upon commercialization of any product covered by the agreement, Takeda is required to pay us a quarterly royalty on net sales revenue on sales of the commercialized product.

Governance. Our collaboration with Takeda is governed by several committees consisting of an equal number of representatives from both companies. These consist of a joint steering committee, which resolves any conflicts arising within the other committees, a joint development committee, a joint commercialization committee and a joint manufacturing committee. In the case of a deadlock within the joint steering committee, our chief executive officer has the determining vote on matters arising from the joint development and manufacturing committees, while Takeda's representative has the determining vote on matters arising from the joint commercialization committee.

New Indications and Additional Territories. Under the agreement, Takeda has a right of first refusal to obtain a license to develop and commercialize Amitiza in the United States and Canada for any new indications that we may develop. In addition, the agreement granted Takeda an option to exclusively negotiate with our affiliated European and Asian operating companies, Sucampo Pharma Europe Ltd., or Sucampo Europe, and Sucampo Pharma Ltd., or Sucampo Japan, to jointly develop and commercialize Amitiza in two additional territories: Europe, the Middle East, and Africa; and Asia. With respect to the negotiation rights for Europe, the Middle East and Africa, Takeda was required to pay Sucampo Europe an option fee of $3.0 million. In the event that these negotiations failed to produce a definitive agreement before we received marketing approval in the United States for Amitiza for the treatment of chronic idiopathic constipation in adults, Sucampo Europe was required to repay Takeda $1.5 million of the original option fee. With respect to the negotiation rights for Asia, Takeda was required to pay Sucampo Japan an option fee of $2.0 million. In the event that these negotiations failed to produce a definitive agreement within twelve months, Sucampo Japan was required to repay Takeda $1.0 million of the original option fee. By the first quarter of 2006, the option rights for both territories had expired without agreement and, accordingly, we repaid Takeda an aggregate of $2.5 million of the original option fees. The amounts we retained were recorded as contract revenue in the statements of operations when the negotiations failed and agreements expired.

Under the agreement, if we wish to use data or information developed under the collaboration with Takeda outside the United States or Canada, for example in support of a regulatory filing in Europe or Asia, we are obligated to pay to Takeda a one-time fee the first time such data or information is used in specified territories. The amount of the fee for each territory is to be agreed between us and Takeda. In February 2008, in connection with our MAA for lubiprostone in Europe, we agreed with Takeda to make a one-time payment of $1.8 million, which will permit us to use in Europe, the Middle East and Africa all data and information developed under the agreement relating to the use of lubiprostone to treat chronic idiopathic constipation.

Term. The Takeda agreement continues until 2020 unless earlier terminated. We may terminate the agreement if Takeda fails to achieve specific levels of net sales revenue or if Takeda comes under the control of another party and launches a product competitive with Amitiza. Alternatively, either party has the right to terminate the agreement in the following circumstances:

- a breach of the agreement by the other party that is not cured within 90 days, or 30 days in the case of a breach of payment obligations;
- a change of control of the other party in which the new controlling party does not expressly affirm its continuing obligations under the agreement; or
- insolvency of the other party.

Intellectual Property

Our success depends in part on our ability, and that of Sucampo AG, to obtain and maintain proprietary protection for the technology and know-how upon which our products are based, to operate without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights.

We hold an exclusive worldwide royalty-bearing license from Sucampo AG to develop and commercialize Amitiza and other prostone compounds covered by patents and patent applications held by Sucampo AG. As of December 31, 2008, we had licensed from Sucampo AG rights to a total of 51 U.S. patents, 19 U.S. patent applications, 22 European patents, 14 European patent applications, 25 Japanese patents and 19 Japanese patent applications. Many of these patents and patent applications are counterparts of each other. Our portfolio of licensed patents includes patents or patent applications with claims directed to the composition of matter, including both compound and pharmaceutical formulation, or method of use, or a combination of these claims, for Amitiza, cobiprostone and SPI-017. Depending upon the timing, duration and specifics of FDA approval of the use of a compound for a specific indication, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act.

The patent rights relating to Amitiza licensed by us consist of nine issued U.S. patents and five issued European patents relating to composition of matter and methods of use. These patent rights also include various U.S., European and Japanese patent applications relating to dosing, pharmaceutical formulation and other claims. The U.S. patents relating to composition of matter expire between 2014 and 2020. The other U.S. and foreign patents expire between 2009 and 2022.

The patent rights relating to cobiprostone licensed by us consist of ten issued U.S. patents, four issued European patents, and six issued Japanese patents relating to composition of matter and methods of use. These patent rights also include various U.S., European and Japanese patent applications relating to dosing regimens, pharmaceutical formulation and other claims. The U.S. patents relating to composition of matter expire between 2011 and 2020. The other U.S. and foreign patents expire between 2010 and 2022.

The patent rights relating to SPI-017 licensed by us consist of ten issued U.S. patents, six issued European patents and six issued Japanese patents relating to methods of use. These patent rights also include various U.S., European and Japanese patent applications relating to composition of matter and methods of use. The U.S. patent relating to composition of matter expires in 2021. The U.S. patents relating to methods of use and the other U.S. and foreign patents expire between 2010 and 2022.

In addition, we share joint ownership of eight U.S. patents with R-Tech. These patents cover prostone compounds, formulations and manufacturing methods.

We are actively seeking to augment the patent protection of our licensed compounds by focusing on the development of new chemical entities, or NCEs, such as Amitiza, cobiprostone and SPI-017, which have not previously received FDA approval. Upon approval by the FDA, NCEs are entitled to market exclusivity in the United States with respect to generic drug products for a period of five years from the date of FDA approval, even if the related patents have expired.

License from Sucampo AG

On June 30, 2006, we entered into a restated license agreement with Sucampo AG. Under this agreement, Sucampo AG has granted to us a royalty-bearing, exclusive, worldwide license, with the right to sublicense, to develop and commercialize Amitiza, cobiprostone and SPI-017 and any other prostone compounds, other than Rescula, subject to Sucampo AG's patents. Under the terms of the restated license agreement, which became effective upon our initial public offering in 2007, we are obligated to assign to Sucampo AG any patentable improvements derived or discovered by us relating to Amitiza, cobiprostone and SPI-017 through the term of the license. In addition, we are obligated to assign to Sucampo AG any patentable improvements derived or discovered by us relating to other licensed prostone compounds prior to the date which is the later of June 30, 2011 or the date on which Drs. Ueno and Kuno cease to control our company. For purposes of this agreement, Drs. Ueno and Kuno will be deemed to control our company as long as either they together own a majority of the voting power of our

stock or at least one of them is a member of our board of directors. All compounds assigned to Sucampo AG under this agreement will be immediately licensed back to us on an exclusive basis.

In consideration of the license, we are required to make milestone and royalty payments to Sucampo AG. The milestone payments include:

- a payment of $500,000 upon the initiation of the first phase 2 clinical trial for each compound in each of three territories covered by the license: North, Central and South America (including the Caribbean), Asia and the rest of the world; and
- a payment of $1.0 million for the first NDA filing or comparable foreign regulatory filing for each compound in each of the same three territories.

Upon payment of the above milestones, no further payments will be required either for new indications or formulations or for further regulatory filings for the same compound in additional countries within the same territory.

In addition, we are required to pay Sucampo AG 5% of any up-front or milestone payments that we receive from sublicensees.

Under the license and an addendum we entered in February 2009, we also are required to pay Sucampo AG, on a country-by-country basis, ongoing patent royalties as follows:

- In the case of products covered by patents existing at the time of our initial public offering in 2007, or pre-IPO patents, a royalty of 2.2% of net sales in the case of sales of Amitiza in North, Central and South America, including the Caribbean, and Asia, Australia and New Zealand; and 4.5% of net sales in the case of sales of Amitiza in other territories or sales of other compounds. These royalties are payable until the last pre-IPO patent covering each relevant compound in the relevant country has expired.
- After the expiration of all pre-IPO patents, in the case of products covered by new patents or improvement patents that were granted after our initial public offering, or post-IPO patents, a royalty of 1.1% of net sales in the case of sales of Amitiza in North, Central and South America, including the Caribbean, and Asia, Australia and New Zealand; and 2.25% of net sales in the case of sales of Amitiza in other territories or sales of other compounds. These royalties are payable until the last post-IPO patent covering each relevant compound has expired.

In addition, we are required to pay Sucampo AG, on a country-by-country basis, a know-how royalty of 1% of net sales in the case of sales of Amitiza in North, Central and South America, including the Caribbean, and Asia, Australia and New Zealand; and 2% of net sales in the case of sales of Amitiza in other territories or sales of other compounds, until the fifteenth anniversary of the first sale of the respective compound. All product royalties required to be paid under the license are based on total product net sales, whether by us or a sublicensee, and not on amounts actually received by us.

The license from Sucampo AG is perpetual as to Amitiza, cobiprostone and SPI-017 and cannot be terminated unless we default in our payment obligations to Sucampo AG. With respect to any other licensed prostone compounds, we are required to perform preclinical testing over a specified period on those compounds and to generate specified pharmacological and toxicity data. The specified period ends on the later of June 30, 2011 or the date upon which Drs. Ueno and Kuno no longer control our company. Following the end of the specified period, Sucampo AG can terminate our license with respect to any compounds as to which we have not performed the required testing, except for any compounds we designate as compounds for which we intend in good faith to perform the required testing within the 15 months following the end of the specified period. At the end of the 15-month extension period, Sucampo AG may terminate our license as to any of the designated compounds for which we have not performed the required testing.

We will need to focus our development resources and funding on a limited number of compounds during the specified period. The decision whether to commit development resources to a particular compound will require us to determine which compounds have the greatest likelihood of commercial success. Dr. Ueno and his staff will be

instrumental in making these decisions on our behalf, although to assist in this determination, we have formed a selection committee consisting of certain members of management other than Drs. Ueno and Kuno.

We retain the rights to any improvements, know-how or other intellectual property we develop that is not related to prostones. We also retain the rights to any improvements, know-how or other intellectual property we develop after the end of the specified period, even if they are related to prostones.

The agreement provides that, until the later to occur of June 30, 2011 or until Drs. Ueno and Kuno cease to control our company, Sucampo AG may not develop or commercialize:

- any products with a primary mode of action substantially the same as that of any licensed compound; or
- any products licensed or approved for an indication for which a licensed compound is approved or under development.

Thereafter, Sucampo AG may undertake development of competing products but may not commercialize these products for an additional two years.

As part of this license, we have assumed the responsibility to pay the patent filing and maintenance costs related to the licensed rights. In return, we have control over patent filing and maintenance decisions. The license agreement also specifies how we and Sucampo AG will allocate costs to defend patent infringement litigation brought by third parties and costs to enforce patents against third parties. As of December 31, 2008, we have not incurred any cost relating to defending or enforcing patents against third parties.

Manufacturing

We do not own or operate manufacturing facilities for the production of commercial quantities of Amitiza or preclinical or clinical supplies of the other prostone compounds that we are testing in our development programs. Instead, we rely, and expect to continue to rely, exclusively on our affiliate R-Tech to supply us with Amitiza, cobiprostone and SPI-017 and any future prostone compounds that we determine to develop or commercialize. Drs. Ueno and Kuno own, directly and indirectly, a majority of the stock of R-Tech.

We have entered into an exclusive supply arrangement with R-Tech. Under the terms of this arrangement, we have granted to R-Tech the exclusive right to manufacture and supply Amitiza to us to meet our commercial and clinical requirements in the Americas, Europe, the Middle East and Africa until 2026. With the exception of the exclusive supply agreements with Takeda described below, R-Tech is prohibited from supplying Amitiza to anyone other than us during this period. Our supply arrangement with R-Tech also provides that R-Tech will assist us in connection with applications for marketing approval for Amitiza in the United States and elsewhere, including assistance with regulatory compliance for chemistry, manufacturing and controls. In consideration of these exclusive rights, R-Tech has paid to us $8.0 million in up-front and milestone payments as of December 31, 2008. Either we or R-Tech may terminate the supply arrangement with respect to us or Sucampo Europe in the event of the other party's uncured breach or insolvency.

In anticipation of the commercial development of Amitiza, we entered into a 16-year supply agreement with Takeda and R-Tech in October 2004, which was supplemented by a definitive supply and purchase agreement in January 2006. Under these agreements, R-Tech agreed to supply and Takeda agreed to purchase all of Takeda's commercial requirements, including product samples, for Amitiza in the United States and Canada. Pursuant to the terms of these agreements, Takeda is required to provide R-Tech with a rolling 24-month forecast of its product and sample requirements and R-Tech is required to keep adequate levels of inventory in line with this forecast. In addition, these agreements require R-Tech to maintain a six-month supply of the active ingredient used in manufacturing Amitiza and a six-month supply of Amitiza in bulk form as backup inventory. Upon a termination of the collaboration and license agreement between Takeda and us, either Takeda or we may terminate these supply agreements by notice to R-Tech.

On February 23, 2009, we entered into an Exclusive Manufacturing and Supply Agreement with R-Tech under which we granted R-Tech the exclusive right to manufacture and supply lubiprostone to meet our commercial and clinical requirements in Asia, Australia and New Zealand. In consideration, R-Tech will make an up-front payment of $250,000 and will be obligated to make milestone payments of $500,000 upon regulatory approval of

lubiprostone in Japan and $250,000 upon the commercial launch in Japan. In addition, R-Tech is required to maintain at least a six-month supply of lubiprostone and a three-month supply of the active ingredient used in manufacturing lubiprostone as a backup inventory.

R-Tech is Takeda's and our sole supplier of Amitiza. In the event that R-Tech cannot meet some or all of Takeda's or our demand, neither Takeda nor we have alternative manufacturing arrangements in place. However, R-Tech has agreed to maintain at least a six-month supply of Amitiza and a six-month supply of the active ingredient used in manufacturing Amitiza as a backup inventory. R-Tech may draw down this backup inventory to supply Amitiza to us in the event that R-Tech is unable or unwilling to produce Amitiza to meet our demand. We also have the right to qualify a back-up supplier for Amitiza. In the event that R-Tech is unwilling or unable to meet our demand, R-Tech will grant to that back-up supplier a royalty-free license to use any patents or know-how owned by R-Tech relating to the manufacturing process for Amitiza and will provide, upon our reasonable request and at our expense, consulting services to the back-up supplier to enable it to establish an alternative manufacturing capability for Amitiza. We may purchase Amitiza from the back-up supplier until R-Tech is able and willing to meet our demand for Amitiza.

R-Tech operates a manufacturing facility near Osaka, Japan that we believe is compliant with current good manufacturing practices, or cGMP. R-Tech received approval from the FDA in October 2005 and from the Medicines and Healthcare Products Regulatory Agency or MHRA in October 2008 to manufacture Amitiza at this facility. In addition, R-Tech manufactures its own prostone product Rescula at this facility and has been the sole supplier of this product to the marketplace since 1994 without interruption.

We have also entered into an exclusive supply arrangement with R-Tech to provide us with clinical supplies of our product candidates cobiprostone and SPI-017, as well as any other prostone compound we may designate, and to assist us in connection with applications for marketing approval for these compounds in the United States and elsewhere, including assistance with regulatory compliance for chemistry, manufacturing and controls. This clinical supply arrangement has a two year term which renews automatically for one-year periods unless we and R-Tech agree not to renew it. Either we or R-Tech may terminate the clinical supply arrangement with respect to us or one of our operating subsidiaries in the event of the other party's uncured breach or insolvency.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and resources provide us with competitive advantages, we face potential competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Amitiza and any other product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are currently approved therapies for the diseases and conditions addressed by Amitiza. For example, the osmotic laxatives MiraLax, which is marketed by Braintree Laboratories, Inc., and lactulose, which is produced by Solvay S.A., have each been approved for the short-term treatment of occasional constipation. MiraLax was recently approved for sale as an over-the-counter treatment.

Several companies also are working to develop new drugs and other therapies for these same diseases and conditions. Some of these potential competitive drug products include:

- Drugs targeting serotonin receptors for the treatment of irritable bowel syndrome with constipation, such as Renzapride, being developed by Alizyme plc. and DDP733, being developed by Dynogen Pharmaceuticals, Inc. currently in phase 2 clinical trials. Based on the limited clinical efficacy in phase 3 clinical trials, Alizyme discontinued further clinical development for Renzapride and in the light of a recent filing under Chapter 7 of U.S. Bankruptcy Code by Dynogen, it is unclear about the future clinical trials for DDP733.
- Opioid antagonists such as methylnaltrexone, being developed by Progenics Pharmaceuticals, Inc., for the treatment of opioid-induced bowel dysfunction. Progenics and its collaboration partner Wyeth Pharmaceuticals received FDA approval of methylaltrexone in 2008 for the subcutaneous formulation of this drug in

treating opioid-induced bowel dysfunction in patients receiving palliative care. Progenics continues to move forward with an oral form of methylaltrexone for similar indications; and

- TD-5108, being developed by Theravance, Inc. for the treatment of chronic constipation, and linaclotide, being developed by Microbia, Inc. for the treatment of irritable bowel syndrome with constipation, both of which have recently completed phase 2 clinical trials.
- Resolor (prucalopride), being developed by Movetis for the treatment of chronic constipation in adults. In May 2008, the European Medicines Agency has accepted the MAA filed by Movetis for Resolor (prucalopride).

We face similar competition from approved therapies and potential drug products for the diseases and conditions to be addressed by cobiprostone, SPI-017 and our other product candidates. The current standard of care for NSAID induced ulcers is the usage of PPI medications.

The key competitive factors affecting the success of all of our product candidates are likely to be their efficacy, safety, price and convenience.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, approval, manufacturing, labeling, post-approval monitoring and reporting, packaging, promotion, storage, advertising, distribution, marketing and export and import of pharmaceutical products such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, as amended, and it's implementing regulations. The FDA has jurisdiction over all of our products and administers requirements covering the safety, effectiveness, manufacturing, quality control distribution, labeling, marketing, advertising, dissemination of information and post-marketing study and surveillance of our pharmaceutical products. Information that must be submitted to the FDA in order to obtain approval to market a drug varies depending upon whether the drug is a new product whose safety and efficacy have not previously been demonstrated in humans or a drug whose active ingredients and certain other properties are the same as those of a previously approved drug. The results of product development, preclinical studies and clinical trials must be submitted to the FDA as part of the approval process. The FDA may deny approval if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the application does not satisfy the criteria for approval.

Obtaining FDA approval for new products and manufacturing processes can take a number of years and involve the expenditure of substantial resources. To obtain FDA approval for the commercial sale of a therapeutic agent, the potential product must undergo testing programs on animals, the data from which is used to file an IND with the FDA. In addition, there are three phases of human testing:

- Phase 1 consists of safety tests for human clinical experiments, generally in normal, healthy people;
- Phase 2 programs expand safety tests and are conducted in people who are sick with the particular disease condition that the drug is designed to treat; and
- Phase 3 programs are greatly expanded clinical trials to determine the effectiveness of the drug at a particular dosage level in the affected patient population.

The data from these tests is combined with data regarding chemistry, manufacturing and animal toxicology and is then submitted in the form of a New Drug Application, or NDA, to the FDA. The preparation of an NDA requires the expenditure of substantial funds and the commitment of substantial resources.

Failures to comply with the applicable FDA requirements at any time during the product development process, approval process or after approval may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a hold on clinical trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA extensively regulates all aspects of manufacturing quality under its current good manufacturing practices (cGMP) regulations. The FDA inspects the facility or the facilities at which drug products are manufactured. The FDA will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the application, manufacturing process or manufacturing facilities, are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

Post-Approval Requirement

After regulatory approval of a product is obtained, we are required to comply with a number of post-approval requirements. For example, the FDA may require post marketing, or phase 4, trials to assess the product's long-term safety or efficacy. In addition, holders of an approved NDA are required to report certain adverse drug reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes certain fiscal, procedural, substantive and recordkeeping requirements.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings, precautions and contraindications. Also, new government requirements, including those resulting from new legislation, may be established that could delay or prevent regulatory approval of our products under development.

Regulation Outside the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions most notably by the European Medicines Agency in the European Union and the Ministry of Health, Labor and Welfare in Japan. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the United States before we can commence clinical trials or marketing of the product in those countries The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country, and the time for approval may be longer or shorter than that required by the FDA.

Europe

In Europe medicinal products are governed by a framework of European Union regulations which apply across all European Union member states. To obtain regulatory approval of a drug under the European Union regulatory system, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes and optional for those which are innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for a member state, known as the reference member state, to assess an application, with one or more other, or concerned, member states subsequently approving that assessment. The European Union also governs among other areas, the authorization and conduct of clinical trials, the marketing authorization process for medical products, manufacturing and import activities, and post-authorization activities including pharmacovigilance. The European Union has established new regulations on pediatric medicines which impose certain obligations on pharmaceutical companies with respect to the investigation of their products in children.

Sucampo's wholly owned subsidiary, Sucampo Pharma Europe Ltd., located in Oxford, UK and Basel, Switzerland is subject to a number of regulatory requirements and inspection by the authorities. The Basel office was inspected in 2008 for compliance with applicable licenses and permits.

Japan

In Japan, pre-marketing approval and clinical studies are required for all pharmaceutical products. The regulatory regime for pharmaceuticals in Japan has in the past been so lengthy and costly that it has been cost-prohibitive for many pharmaceutical companies. Historically, Japan has required that all clinical data submitted in support of a new drug application be performed on Japanese patients. Recently, however, as a part of the global drug harmonization process, Japan has signaled a willingness to accept United States or European Union patient data when submitted along with a bridging study, which demonstrates that Japanese and non-Japanese subjects react comparably to the product. This approach, which is executed on a case-by-case basis, may reduce the time required for approval and introduction of new products into the Japanese market.

Regulation of the Health Care Industry

In addition to the regulatory approval requirements described above, we are or will be directly or indirectly through our customers, subject to extensive regulation of the health care industry by the federal and state government and foreign countries in which we may conduct our business. The laws that directly or indirectly affect our ability to operate our business include the following:

- The federal Medicare and Medicaid Anti-Kickback laws, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- Other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- The federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- The federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- The Foreign Corrupt Practices Act, which prohibits certain payments made to foreign government officials; and
- State and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations.

If our operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation, or if interpretations of the foregoing change, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations.

Pharmaceutical Pricing and Reimbursement

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals, and the drug candidates that we are developing.

Another development that may affect the pricing of drugs is proposed Congressional action regarding drug re-importation into the United States. Proposed legislation would allow the re-importation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs are sold at a lower price. If such legislation or similar regulatory changes were enacted, they could reduce the price we receive for any approved products, which, in turn, could adversely affect our revenues.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions permit products to be marketed only after a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits.

In Japan, the National Health Ministry biannually reviews the pharmaceutical prices of individual products. In the past, these reviews have resulted in price reductions. We expect similar price reviews in the future, in line with the government's previously announced plan for controlling health care costs. It is not possible to predict the outcome of these reviews, and it is possible that Japanese authorities will again reduce drug reimbursement rates, which could adversely affect the reimbursement levels for our products or product candidates.

Executive Officers

The following table lists our executive officers and their ages as of March 5, 2009.

Name	Age	Position
Ryuji Ueno, M.D., Ph.D., Ph.D.	55	Chief Executive Officer, Chief Scientific Officer and Director, Chairman of the Board of Directors
Jan Smilek	42	Chief Financial Officer
Gayle R. Dolecek	66	Senior Vice President of Research and Development
Stanley G. Miele	44	Senior Vice President of Sales and Marketing

Ryuji Ueno, M.D., Ph.D., Ph.D. Dr. Ueno is a founder of our company and has been our Chief Executive Officer since September 2006 and our Chief Scientific Officer since August 2004. Dr. Ueno also became the Chairman of our Board of Directors effective June 1, 2007 following the resignation of Dr. Sachiko Kuno from that position. Dr. Ueno also served as Chief Operating Officer from December 1996 to November 2000 and again from March 2006 to September 2006 and as Chief Executive Officer from December 2000 to September 2003.
Dr. Ueno

has been a director since 1996 and served as Chairman of our Board of Directors from December 2000 to September 2006. Dr. Ueno co-founded our affiliate R-Tech in September 1989 and served as its President from 1989 to March 2003. Dr. Ueno also co-founded Sucampo AG in December 1997 and served as its Chairman of the Board or Vice Chairman of the Board since its inception. Dr. Ueno received his M.D. and a Ph.D. in medical chemistry from Keio University in Japan, and he received a Ph.D. in Pharmacology from Osaka University. Dr. Ueno is married to Dr. Sachiko Kuno, one of our founders and a member of our board of directors.

Jan Smilek. Mr. Smilek joined us in February 2008 as Vice President of Finance and Corporate Controller. He was subsequently promoted to Acting Chief Financial Officer in August 2008 and to Chief Financial Officer in December 2008. Prior to joining our company, he was the Senior Director of Finance at Vanda Pharmaceuticals beginning in January 2006. Before that, he was Senior Director of Financial Reporting, Analysis and General Accounting at McGraw-Hill Companies from January 2005 to January 2006. He also worked at PricewaterhouseCoopers, LLP for 13 years beginning in 1991 in Prague, Miami and Washington, D.C. Mr. Smilek is a Certified Public Accountant in the United States, and is a graduate of the School of Economics, Bratislava, Slovakia and holds an International Executive M.B.A. degree from Georgetown University, McDonough School of Business.

Gayle R. Dolecek. Dr. Dolecek has been our Senior Vice President of Research and Development since May 2006. From August 1995 to April 2006, he was a Senior Consultant at AAC Consulting Group, Inc., a provider of regulatory consulting services to the pharmaceutical industry. Prior to 1995, Dr. Dolecek was an officer with the U.S. Public Health Service where he served in pharmacy and health service related positions. He completed his career with the government in the Food and Drug Administration as Director of Compendial Operations in the Center for Drug Evaluation and Research. Dr. Dolecek received his B.S./P.D. in Pharmacy from the University of Maryland and a M.P.H. in Health Services and Planning from the University of Hawaii.

Stanley G. Miele. Mr. Miele has been our Senior Vice President since October 2008. Prior to his new role, he was our Vice President of Sales and National Director of Sales since February 2006. Prior to joining Sucampo, Mr. Miele, as a Sales Director, managed a national level team of specialty sales representatives and engineering consultants that sold and marketed blood gas analyzers and point of care diagnostic equipment used in acute-care areas within hospitals at Abbott Point of Care beginning October 2005. Prior to that, Mr. Miele held a series of positions at Millennium Pharmaceuticals (and COR Therapeutics prior to its acquisition by Millennium) including National Sales Director, Cardiology where he was responsible for managing the overall hospital-based cardiovascular sales function beginning January 2003. Previously, Mr. Miele was a Division Sales Representative with Abbott Labs' Hospital Products Division, of Abbott Park, Illinois, and a Sales Representative for Syntex Labs, of Palo Alto, California. Mr. Miele earned a B.A. in Management/Communications from the University of Dayton.

Employees

As of March 5, 2009, we had 94 full-time employees, including 34 with doctoral or other advanced degrees. Of our workforce, 30 employees are engaged in research and development, 39 are engaged in sales and marketing and 25 are engaged in business development, legal, finance and administration. None of our employees are represented by a labor union or covered by collective bargaining agreements. We have never experienced a work stoppage and believe our relationship with our employees is good.

Our Dual Class Capital Structure

We have two classes of common stock authorized; class A common stock and class B common stock. Holders of class A common stock and class B common stock have identical rights, except that holders of class A common stock are entitled to one vote per share and holders of class B common stock are entitled to ten votes per share on all matters on which stockholders are entitled to vote.

As of March 5, 2009, we had outstanding 15,651,849 shares of class A common stock and 26,191,050 shares of class B common stock. The class B common stock represents approximately 95% of the combined voting power of our outstanding common stock. All of the shares of class B common stock are owned by S&R Technology Holding, LLC, or S&R, an entity wholly-owned by our founders, Drs. Ueno and Kuno. As a result, Drs. Ueno and Kuno will be able to control the outcome of all matters upon which our stockholders vote, including the election of directors, amendments to our certificate of incorporation and mergers or other business combinations.

We are not authorized to issue additional shares of class B common stock except in limited circumstances, such as a stock split of both classes of common stock or a stock dividend made in respect of both classes of common stock. Shares of class B common stock will automatically be converted into shares of class A common stock upon transfer, with limited exceptions for transfers to family trusts. In addition, all remaining outstanding shares of class B common stock will automatically be converted into shares of class A common stock upon the death, legal incompetence or retirement from our company of both Drs. Ueno and Kuno or at such time as the number of outstanding shares of class B common stock is less than 20% of the number of outstanding shares of class A and class B common stock together.

In this report, we refer to our authorized class A common stock and class B common stock together as our common stock.

Our Corporate Information

Our predecessor was incorporated under the laws of Delaware in December 1996.

In December 2008, we implemented a new holding company structure. In this reorganization, Sucampo Pharmaceuticals, Inc. became a wholly owned subsidiary of a newly formed Delaware holding company, then known as Sucampo Pharma Holdings, Inc., which became the publicly traded company. Each share of Sucampo Pharmaceuticals, Inc. stock was automatically converted into equivalent shares of the holding company with the same rights and privileges as the converted shares.

Immediately after the reorganization, Sucampo Pharmaceuticals, Inc. was renamed Sucampo Pharma Americas, Inc. and the holding company succeeded to the name Sucampo Pharmaceuticals, Inc. Sucampo Pharma Americas, Inc. then distributed to the new holding company the stock of its two wholly owned subsidiaries, Sucampo Pharma Ltd. and Sucampo Pharma Europe Ltd. As a result, those two companies are now also wholly owned subsidiaries of the new holding company.

The final corporate structure consists of a public holding company named Sucampo Pharmaceuticals, Inc., which has three wholly owned subsidiaries: Sucampo Pharma Ltd., based in Tokyo and Osaka, Japan, in which we conduct our Asian operations; Sucampo Pharma Americas, Inc., based in Bethesda, Maryland, in which we conduct operations in North and South America; and Sucampo Pharma Europe Ltd., based in Oxford, U.K., and Basel, Switzerland, in which we conduct operations in Europe and the rest of the world.

Our principal executive offices are located at 4520 East-West Highway, Suite 300, Bethesda, Maryland 20814, and our telephone number is (301) 961-3400.

Website Access to U.S. Securities and Exchange Commission Reports

Our Internet address is http://www.sucampo.com. Through our website, we make available, free of charge, access to all reports filed with the U.S. Securities and Exchange Commission, or the SEC, including our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and amendments to these reports, as filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Copies of any materials we file with, or furnish to, the SEC can also be obtained free of charge through the SEC's website at http://www.sec.gov or at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

ITEM 1A. ***RISK FACTORS***

In addition to the other information set forth in this report, the following factors should be considered carefully in evaluating our business and our company.

Risk Related to Current Worldwide Economic Downturn

The recent downturn in the global economy and the recent pressure on capital markets increases the possibility of and may exacerbate the impact of any adverse effects on our financial position and business prospects.

The recent downturn in the U.S. economy and economies around the world and the extraordinary pressure being placed on both debt and equity markets have led to significant retraction in U.S. businesses, sudden and severe decreases in the prices of U.S. equities generally and a severe shortage in available credit. These factors have made it more difficult, in general, for companies to expand or maintain their current operations and have increased the likelihood that companies will fail. Although we cannot say with certainty the impact the current economic crises has had on us to date or may have on us in the future, continued pressure on the U.S. economy and its capital markets may have the effect of, among other things, reducing demand for Amitiza and other medicines, imposing significant pricing pressure, compromising the ability of our collaborators to timely satisfy their performance obligations, increasing the cost to manufacture our products, or making it more difficult for us to raise capital or enter into strategic relationships, each of which could hurt our business and business prospects. If the economic downturn in foreign economies is prolonged, this could harm our ability to pursue our strategy of developing and commercializing Amitiza and other compounds in Europe, Japan and other territories. The economic downturn may also lead to, or accelerate, a decrease in the trading price of our class A common stock.

We recently implemented a cost saving initiative by reducing our headcount and refocusing our research and development plans and our sales and marketing efforts.

To conserve cash and more closely align our spending towards our strategic objectives, we implemented a cost reduction initiative in early 2009, including a workforce reduction in our administrative, research and development and sales and marketing staffs and a refocusing of our research and development plans. These reductions could make it more difficult to manage our business and might compromise our ability to pursue our development and commercialization strategies.

Risks Related to Our Limited Commercial Operations

Although we reported profit for three consecutive years ending December 31, 2008, we may not maintain operating profitability in the future.

We initiated commercial sales of our first product, Amitiza, for the treatment of chronic idiopathic constipation in adults in April 2006 and for the treatment of irritable bowel syndrome with constipation in May 2008 and we first generated product royalty revenue in the quarter ended June 30, 2006. Although we had net income of $25.0 million in 2008 and our retained earnings turned positive to $14.8 million in 2008 as compared to $10.2 million deficit in 2007, this was primarily attributable to our development milestones of $50.0 million and $30.0 million earned in 2008 and 2007, respectively. Our primary cost drivers result from expenses incurred in our research and development programs and from our general and administrative expenses. We expect to continue to incur significant and increasing expenses for at least the next several years as we continue our research activities and conduct development of, and seek regulatory approvals for, additional indications for Amitiza and for other drug candidates. Whether we are able to achieve sustainable operating profitability in the future will depend upon our ability to generate revenues that exceed our expenses. Changes in market conditions, including the failure or approval of competing products, may require us to incur more expenses or change the timing of expenses such that we may incur unexpected losses. We may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to maintain profitability, the market value of our class A common stock may decline.

If we are unable to continue successful commercialization of our first product, Amitiza, for the treatment of chronic idiopathic constipation in adults and irritable bowel syndrome with constipation and other indications for which we are developing this drug, or experience significant delays in doing so, our ability to generate product-based revenues and achieve profitability will be jeopardized.

In the near term, our ability to increase product-based revenues will depend on the continued growth in commercialization and continued development of Amitiza. The growth in sale of Amitiza will depend on several factors, including the following:

- the effectiveness of Takeda's sales force, as supplemented by our internal specialty sales force, in marketing and selling Amitiza in the United States;
- our ability to complete clinical trials and secure regulatory approval of lubiprostone in Japan and the ability of Abbott to commercialize it if we do so;
- the ability of R-Tech, which has the exclusive right to manufacture and supply Amitiza, or any substitute manufacturer to supply quantities sufficient to meet market demand and at acceptable levels of quality and price;
- continued and growing acceptance of the product within the medical community and by third-party payors;
- successful completion of clinical trials of Amitiza for the treatment of other constipation-related gastrointestinal indications beyond chronic idiopathic constipation and irritable bowel syndrome with constipation, and acceptance of the results of these trials by regulatory authorities; and
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities for other indications.

If we are not successful in maintaining continued growth in commercializing Amitiza or are significantly delayed in doing so, our business will be materially harmed.

We have limited experience commercializing drug products. If we are not successful in maintaining the transition from a pre-commercial stage company to a commercial company, our ability to continue profitability will be compromised.

For most of our operating history, we have been a pre-commercial stage company. Our operations to date have been limited largely to organizing and staffing our company, developing prostone technology, undertaking preclinical and clinical trials of our product candidates and coordinating the U.S. regulatory approval process for Amitiza. To make the transition to a commercial company, we will need to continue to develop internally, or contract with third parties to provide us with, the capabilities to manufacture a commercial scale product and to conduct the sales and marketing activities necessary for successful product commercialization. While we are currently utilizing R-Tech to perform these manufacturing functions and Takeda to perform many of these sales and marketing functions with respect to the sale of Amitiza in the United States, we may nevertheless encounter unforeseen expenses, difficulties, complications and delays as we establish these commercial functions for Amitiza and for other products for which we may receive regulatory marketing approval. As we continue to develop and seek regulatory approval of additional product candidates and additional indications for Amitiza, and to pursue regulatory approvals for Amitiza and other products outside the United States, it could be difficult for us to obtain and devote the resources necessary to successfully manage our commercialization efforts. If we are not successful in completing our transition to a commercial company, our ability to remain profitable will be jeopardized and the market price of our class A common stock is likely to decline.

Risks Related to Employees and Managing Growth

If we are unable to retain our chief executive and chief scientific officer and other key executives, we may not be able to successfully develop and commercialize our products.

We are highly dependent on Dr. Ryuji Ueno, our chief executive officer and chief scientific officer, and the other principal members of our executive and scientific teams, including Jan Smilek, our chief financial officer, Stanley Miele, our senior vice president of sales and marketing and Gayle Dolecek, our senior vice president of

research and development. The loss of the services of any of these persons might impede the achievement of our product development and commercialization objectives and it might be difficult to recruit a replacement executive for any of their positions. We have employment agreements with these executives, but these agreements are terminable by the employees on short or no notice at any time without penalty to the employee. We do not maintain key-man life insurance on any of our executives.

If we fail to attract, retain and motivate qualified personnel, we may not be able to pursue our product development and commercialization programs.

Recruiting and retaining qualified scientific and commercial personnel, including clinical development, regulatory, and marketing and sales executives and field personnel, will be critical to our success. If we fail to recruit and then retain these personnel, our ability to pursue our clinical development and product commercialization programs will be compromised. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions.

We may encounter difficulties in managing growth, which could disrupt our operations.

To manage future growth in our business, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. This may become more challenging as a result of our recent headcount reductions, which affected our administrative staff. Due to our limited resources, we may not be able to effectively manage any expansion of our operations or recruit and train additional qualified personnel. Expansion of our operations could lead to significant costs and might divert our management and business development resources. The challenges of managing our growth will become more significant as we expand the operations of Sucampo Europe and Sucampo Japan. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

The requirements of being a public company may strain our resources and distract management.

We completed our initial public offering in August 2007. As a public company, we will incur significant legal, accounting, corporate governance and other expenses that we did not incur as a private company. We are subject to the requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, The NASDAQ Global Market, and other rules and regulations. These rules and regulations may place a strain on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Sarbanes-Oxley requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. The first time that we and our external auditors were required to issue a report on the design and operating effectiveness of our internal controls over financial reporting was as of December 31, 2008. We currently do not have an internal audit group. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to devote significant resources and management oversight. As a result, management's attention may be diverted from other business concerns. In addition, we might need to hire additional accounting staff with appropriate public company experience and technical accounting knowledge and we cannot assure you that we would be able to do so in a timely fashion. These strains may become more acute as a result of our recent headcount reductions, which affected our administrative and accounting staff.

The rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

We may experience material weaknesses in our internal controls over financial reporting, which could result in delays of our public filings and be costly to correct.

We have in the past identified material weaknesses in our internal controls over financial reporting. Although we have remediated these material weaknesses, if we identify other material weaknesses in the future and are unable

to remediate them, we may not be able to accurately and timely report our financial position, results of operations or cash flows as a public company. Becoming subject to the public reporting requirements of the Securities Exchange Act upon the completion of the initial public offering intensified the need for us to report our financial position, results of operations and cash flows on an accurate and timely basis. If we are not able to prepare complete and accurate financial statements on a timely basis, this could result in delays in our public filings and ultimately delisting of our class A common stock from its principal trading market.

Risks Related to Product Development and Commercialization

Commercial rights to some prostone compounds will revert back to Sucampo AG in the future unless we devote sufficient development resources to those compounds during the next several years; if any of the compounds that revert back to Sucampo AG subsequently become valuable compounds, we will have lost the commercial rights to those compounds and will not be able to develop or market them, and the reverted compounds could ultimately compete with compounds we are developing or marketing.

Sucampo AG has granted to us an exclusive worldwide license to develop and commercialize products based upon Sucampo AG's extensive portfolio of U.S. and foreign patents and patent applications relating to prostone technology. To retain our license rights to any prostone compounds other than Amitiza, cobiprostone and SPI-017, which are perpetual, we are required to perform preclinical testing over a specified period on those compounds and to generate specified pharmacological and toxicity data. The specified period ends on the later of June 30, 2011 or the date upon which Drs. Ueno and Kuno no longer control our company. For purposes of this agreement, Drs. Ueno and Kuno will be deemed to control our company as long as either they together own a majority of the voting power of our stock or at least one of them is a member of our board of directors. Following the end of the specified period, Sucampo AG can terminate our license with respect to any compounds as to which we have not performed the required testing, except for any compounds we designate as compounds for which we intend in good faith to perform the required testing within 15 months following the expiration of the specified period. At the end of that 15-month period, Sucampo AG may terminate our license as to any of the designated compounds for which we have not performed the required testing. Dr. Ueno and his wife, Dr. Kuno, indirectly own all the stock of Sucampo AG.

We will need to focus our development resources and funding on a limited number of compounds during the specified period. The decision whether to commit development resources to a particular compound will require us to determine which compounds have the greatest likelihood of commercial success. Dr. Ueno and his staff will be instrumental in making these decisions on our behalf, although to assist in this determination, we have formed a selection committee consisting of certain members of management that exclude Drs. Ueno and Kuno. In this process, we will likely commit resources to some compounds that do not prove to be commercially feasible and we may overlook other compounds that later prove to have significant commercial potential. If we do not identify and commit resources to one of these valuable compounds, the commercial rights with respect to the compound will eventually revert back to Sucampo AG. After the reversion of these rights to Sucampo AG, we will have no ability to develop or commercialize the compound. Although Sucampo AG will be prohibited from developing products that compete with our products prior to the end of the specified period, thereafter they will be free to develop competitive products. In addition, although Sucampo AG will be prohibited from marketing products that compete with our products for 24 months after the end of the specified period, after that date Sucampo AG will be permitted to market products, including products covered by the reverted license rights, in competition with us.

If our preclinical studies do not produce successful results or if our clinical trials do not demonstrate safety and efficacy in humans, our ability to develop additional indications for Amitiza and to develop and commercialize other product candidates will be impaired.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Preclinical and clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous

unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and as a result we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we consider to be promising. For example, the efficacy results in two of our phase 2 trials of cobiprostone, specifically the trials for the treatment of non-alcoholic fatty liver disease and for the treatment of symptoms associated with cystic fibrosis, were inconclusive. Therefore, further clinical testing will be required in connection with the development of this compound for these indications;
- design of or enrollment in our clinical trials may be slower than we currently anticipate, resulting in significant delays, or participants may drop out of our clinical trials at rates that are higher than we currently anticipate;
- we might have to suspend or terminate our clinical trials, or perform additional trials, if we discover that the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we currently anticipate;
- we might have difficulty obtaining sufficient quantities of the product candidate being tested to complete our clinical trials;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable; and
- the effects of our product candidates may not be the desired or anticipated effects or may include undesirable side effects, or the product candidates may have other unexpected characteristics. For example, in preclinical tests of Amitiza, the drug demonstrated a potential to cause fetal loss in guinea pigs and, as a result, its label includes cautionary language as to its use by pregnant women.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing or if the results of these trials or tests are not positive or are only modestly positive, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not be able to obtain marketing approval; or
- obtain approval for indications that are not as broad as those for which we apply.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

We are required to conduct supplemental post-marketing clinical trials of Amitiza and we may elect to perform additional clinical trials for other indications or in support of applications for regulatory marketing approval in jurisdictions outside the United States. These supplemental trials could be costly and could result in findings inconsistent with or contrary to our historic U.S. clinical trials.

In connection with our marketing approval for Amitiza for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies of the product in pediatric patients, in patients with renal impairment and in patients with hepatic impairment. In the future, we may be required, or we may elect, to conduct additional clinical trials of Amitiza. In addition, if we seek marketing approval from regulatory

authorities in jurisdictions outside the United States, such as the European Medicines Agency, they may require us to submit data from supplemental clinical trials in addition to data from the clinical trials that supported our U.S. filings with the FDA. Any requirements to conduct supplemental trials would add to the cost of developing our product candidates. Additional or supplemental trials could also produce findings that are inconsistent with the trial results we have previously submitted to the FDA, in which case we would be obligated to report those findings to the FDA. This could result in new restrictions on Amitiza's existing marketing approval or could force us to stop selling Amitiza altogether. Inconsistent trial results could also lead to delays in obtaining marketing approval in the United States for other indications for Amitiza or for other product candidates, could cause regulators to impose restrictive conditions on marketing approvals and could even make it impossible for us to obtain marketing approval. Any of these results could materially impair our ability to generate revenues and to achieve or maintain profitability.

If we are unable to establish sales and marketing capabilities or successfully use third parties to market and sell our products, we may be unable to generate sufficient product revenues to become profitable.

We currently have limited sales and distribution capabilities and little experience in marketing and selling pharmaceutical products. To achieve commercial success for Amitiza and any other approved products, we must either further develop our internal sales and marketing organization or continue to outsource these functions to third parties. There are risks associated with either of these alternatives. For example, expanding a sales force would be expensive and time consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing capabilities were delayed, we would incur related expenses too early relative to the product launch. This may be costly, and our investment would be lost if we could not retain our sales and marketing personnel.

We have entered into a joint collaboration and license agreement with Takeda for the commercialization of Amitiza for gastrointestinal indications in the United States and Canada. Takeda markets Amitiza to office-based specialty physicians and primary care physicians in the United States. The Takeda sales force dedicated to selling Amitiza is significantly larger than our internal sales force, and we are therefore heavily dependent on the marketing and sales efforts of Takeda. If our internal sales force is not effective, or if Takeda is less successful in selling Amitiza than we anticipate, our ability to generate revenues and achieve profitability will be significantly compromised. We have also entered into an agreement with Abbott for the development and commercialization of lubiprostone to treat chronic idiopathic constipation in Japan and we are currently negotiating with Abbott to expand their territory to other parts of the world. If we achieve regulatory approval for lubiprostone in Japan or other countries where Abbott has rights to commercialization our compounds, we will be dependent upon their marketing and sales efforts.

We face substantial competition which may result in others discovering, developing or commercializing products earlier or more successfully than we do.

The development and commercialization of pharmaceutical products is highly competitive. We expect to face intense competition with respect to Amitiza and our other product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than Amitiza or the other product candidates that we are developing or that would render Amitiza or our other product candidates obsolete or uncompetitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours or achieve product commercialization before we do. A competitive product might become more popular if it is approved for sale over the counter. If any of our competitors develops a product that is more effective, safer or more convenient for patients, or is able to obtain FDA approval for commercialization before we do, we may not be able to achieve market acceptance for our products, which would impair our ability to generate revenues and recover the substantial developments costs we have incurred and will continue to incur.

There are currently approved therapies for the diseases and conditions addressed by Amitiza. For example, the osmotic laxatives MiraLax, which is marketed by Braintree Laboratories, Inc., and lactulose, which is produced by Solvay S.A., have each been approved for the short-term treatment of occasional constipation. MiraLax was recently approved for sale as an over-the-counter treatment.

Several companies also are working to develop new drugs and other therapies for these same diseases and conditions. Some of these potential competitive drug products include:

- Drugs targeting serotonin receptors for the treatment of irritable bowel syndrome with constipation, such as Renzapride, being developed by Alizyme plc. and DDP733, being developed by Dynogen Pharmaceuticals, Inc. currently in phase 2 clinical trials. Based on the limited clinical efficacy in phase 3 clinical trials, Alizyme discontinued further clinical development for Renzapride and in the light of a recent filing under Chapter 7 of U.S. Bankruptcy Code by Dynogen, it is unclear about the future clinical trials for DDP733.
- Opioid antagonists such as methylnaltrexone, being developed by Progenics Pharmaceuticals, Inc., for the treatment of opioid-induced bowel dysfunction. Progenics and its collaboration partner Wyeth Pharmaceuticals received FDA approval of methylaltrexone in 2008 for the subcutaneous formulation of this drug in treating opioid-induced bowel dysfunction in patients receiving palliative care. Progenics continues to move forward with an oral form of methylaltrexone for similar indications; and
- TD-5108, being developed by Theravance, Inc. for the treatment of chronic constipation, and linaclotide, being developed by Microbia, Inc. for the treatment of irritable bowel syndrome with constipation, both of which have recently completed phase 2 clinical trials.
- Resolor (prucalopride), being developed by Movetis for the treatment of chronic constipation in adults. In May 2008, the European Medicines Agency has accepted the MAA filed by Movetis for Resolor (prucalopride).

Many patients are treated for chronic idiopathic constipation with competing over-the-counter products that are sold for occasional or infrequent use or for recurring use and that are directly competitive with our products.

We face similar competition from approved therapies and potential drug products for the diseases and conditions addressed by cobiprostone and SPI-017, and are likely to face significant competition for any other product candidates we may elect to develop in the future.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The commercial success of Amitiza and any other products that we may develop will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

Amitiza and any other products that we bring to the market may not gain acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate sufficient product revenues to become profitable. The degree of market acceptance of Amitiza and any other products approved for commercial sale will depend on a number of factors, including:

- the prevalence and severity of any side effects. For example, the most common side effects reported by participants in our clinical trials of Amitiza for the treatment of chronic idiopathic constipation were nausea, which was reported by 31% of trial participants, and diarrhea and headache, both of which were reported by 13% of trial participants;
- the efficacy and potential advantages over alternative treatments;
- the competitiveness of the pricing of our products;

- relative convenience and ease of administration of our products compared to other alternatives;
- the timing of the release of our products to the public compared to alternative products or treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- the level of third-party coverage or reimbursement.

The withdrawal of Zelnorm from the U.S. market might adversely affect market acceptance of Amitiza. The FDA requested that Novartis discontinue marketing Zelnorm based on a finding of an increased risk of serious cardiovascular adverse events associated with use of the drug. Although the mechanism of action of Amitiza is different from that of Zelnorm, and although Amitiza has not been associated with serious adverse cardiovascular events, nonetheless the withdrawal of Zelnorm may result in heightened concerns in the minds of some patients or physicians about the safety of using alternative treatments such as Amitiza.

In addition, Adolor Corporation, the developer of an opioid antagonist, Entereg® (alvimopan), for the treatment of opioid-induced bowel dysfunction, recently announced that it was withdrawing its protocol for an additional phase 3 clinical trial of Entereg to treat this condition, which had previously been filed with the FDA. This decision was reportedly based upon preliminary phase 3 trial safety results that suggest potential links between use of Entereg and adverse cardiovascular events, tumor development and bone fractures. It is possible that this development, coming so shortly after the withdrawal of Zelnorm, could further confuse patients and physicians and lead to reluctance on their part to use and to prescribe new drugs to treat gastrointestinal conditions, even those with different mechanisms of action such as Amitiza.

If we are unable to obtain adequate reimbursement from third-party payors for Amitiza and any other products that we may develop, or acceptable prices for those products, our revenues and prospects for profitability will suffer.

Our revenues and ability to become profitable will depend heavily upon the availability of adequate reimbursement for the use of our products from governmental and other third party payors, both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some product uses that are approved by the FDA or comparable authorities. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. If we are not able to obtain coverage and profitable reimbursement promptly from government-funded and private third-party payors for our products, our ability to generate revenues and become profitable will be compromised.

Recent federal legislation will increase the pressure to reduce prices of prescription drugs paid for by Medicare, which could limit our ability to generate revenues.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we will be required to sell products to Medicare recipients through drug procurement organizations operating pursuant to this legislation. These organizations will negotiate prices for our products, which are likely to be lower than those we might otherwise obtain. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs, in particular through cost-effectiveness evaluations. Future legislation could limit payments for pharmaceuticals such as Amitiza and the other product candidates that we are developing.

Legislation has been proposed from time to time that would permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices at which we sell our products and impair our ability to derive revenues from these products.

Legislation has been introduced from time to time in the U.S. Congress that would permit more widespread re-importation of drugs from foreign countries into the United States. This could include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decrease in the price we receive for any approved products, which, in turn, could impair our ability to generate revenues. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales.

Foreign governments tend to impose strict price controls, which may limit our ability to generate revenues.

In some foreign countries, particularly Japan and the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable in particular countries or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenue and profitably distribute products in these countries could be compromised.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure, both from the testing of our product candidates in human clinical trials and from the sale of Amitiza and any other drugs we may sell in the future. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for Amitiza or any other product that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to continue to commercialize Amitiza or to commercialize any other product that we may develop.

We currently have worldwide product liability insurance that covers our clinical trials and our commercial sales of Amitiza up to an annual aggregate limit of $20.0 million. The amount or scope of our product liability insurance may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost, and we may not be able to obtain insurance coverage that will be adequate to cover any liability that may arise. We may not have sufficient resources to pay for any liabilities resulting from a claim beyond the limits of our insurance coverage. If we cannot protect against product liability claims, we or our collaborators may find it difficult or impossible to commercialize our products.

Our strategy of generating growth through acquisitions and in-licenses may not be successful if we are not able to identify suitable acquisition or licensing candidates, to negotiate the terms of any such transaction or to successfully manage the integration of any acquisition.

As part of our business strategy, we intend to pursue strategic acquisitions and in-licensing opportunities with third parties to complement our existing product pipeline. We have no experience in completing acquisitions with third parties to date and we may not be able to identify appropriate acquisition or licensing candidates or to successfully negotiate the terms of any such transaction. The licensing and acquisition of pharmaceutical and biological products is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products in the pharmaceutical field, and they may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. If we are unable to successfully complete acquisitions or in-licensing transactions for suitable products and product candidates, our prospects for growth could suffer.

Even if we are successful in completing one or more acquisitions, the failure to adequately address the financial, operational or legal risks of these transactions could harm our business. To finance an acquisition, we could be required to use our cash resources, issue potentially dilutive equity securities or incur or assume debt or contingent liabilities. Accounting for acquisitions can require impairment losses or restructuring charges, large write-offs of in-process research and development expense and ongoing amortization expenses related to other intangible assets. In addition, integrating acquisitions can be difficult, and could disrupt our business and divert management resources. If we are unable to manage the integration of any acquisitions successfully, our ability to develop new products and continue to expand our product pipeline may be impaired.

We may need substantial additional funding and be unable to raise capital when needed, which could force us to delay, reduce or abandon our commercialization efforts or product development programs.

We expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution of Amitiza. In addition, we expect our research and development expenses to increase in connection with our ongoing activities. We may need substantial additional funding and be unable to raise capital when needed or on attractive terms, which would force us to delay, reduce or abandon our commercialization efforts or development programs.

We have financed our operations and internal growth principally through private placements and a public offering of equity securities, payments received under our collaboration agreement with Takeda and milestone and other payments from Sucampo AG and R-Tech. We believe that our existing cash and cash equivalents and internally generated funds that we anticipate from Amitiza product sales, will be sufficient to enable us to fund our operating expenses for the foreseeable future. Our future funding requirements, however, will depend on many factors, including:

- actual levels of Amitiza product sales;
- the cost of commercialization activities, including product marketing, sales and distribution;
- the scope and results of our research, preclinical and clinical development activities;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the costs involved in obtaining and maintaining proprietary protection for our products, technology and know-how, including litigation costs and the results of such litigation;

- our ability to recruit and retain internal staff resources to conduct these activities;
- the extent to which we acquire or invest in businesses, products and technologies;
- the success of our collaboration with Takeda; and
- our ability to establish and maintain additional collaborations.

If we are required to raise additional funds from external sources, we might accomplish this through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities, current stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights and related intellectual property to our technologies, research programs, products or product candidates.

Risks Related to Our Dependence on Third Parties, Including Related Parties

We have no manufacturing capabilities and are dependent upon R-Tech to manufacture and supply us with our product and product candidates. If R-Tech does not manufacture Amitiza or our other product candidates in sufficient quantities, at acceptable quality levels and at acceptable cost and if we are unable to identify a suitable replacement manufacturer, our sales of Amitiza and our further clinical development and commercialization of other products could be delayed, prevented or impaired.

We do not own or operate manufacturing facilities and have little experience in manufacturing pharmaceutical products. We currently rely, and expect to continue to rely, exclusively on R-Tech to supply Takeda and us with Amitiza, cobiprostone and SPI-017 and any future prostone compounds that we may determine to develop or commercialize. We have granted R-Tech the exclusive right to manufacture and supply Amitiza to meet our commercial and clinical requirements throughout the world and we do not have an alternative source of supply for Amitiza. We also do not have an alternative source of supply for cobiprostone or SPI-017, which R-Tech manufactures and supplies to us. If R-Tech is not able to supply Amitiza or these other compounds on a timely basis, in sufficient quantities and at acceptable levels of quality and price and if we are unable to identify a replacement manufacturer to perform these functions on acceptable terms, sales of Amitiza would be significantly impaired and our development programs could be seriously jeopardized.

The risks of relying solely on R-Tech for the manufacture of our products include:

- we rely solely on R-Tech for quality assurance and their continued compliance with regulations relating to the manufacture of pharmaceuticals;
- R-Tech's manufacturing capacity may not be sufficient to produce commercial quantities of our product, or to keep up with subsequent increases in the quantities necessary to meet potentially growing demand;
- R-Tech may not have access to the capital necessary to expand its manufacturing facilities in response to our needs;
- in light of the complexity of the manufacturing process for prostones, if R-Tech were to cease conducting business, or if its operations were to be interrupted, it would be difficult and time consuming for us to find a replacement supplier and the change would need to be submitted to and approved by the FDA;
- R-Tech has substantial proprietary know-how relating to the manufacture of prostones and, in the event we must find a replacement or supplemental manufacturer or we elect to contract with another manufacturer to supply us with products other than Amitiza, we would need to transfer this know-how to the new manufacturer, a process that could be both time consuming and expensive to complete;
- R-Tech may experience events, such as a fire or natural disaster, that force it to stop or curtail production for an extended period; and
- R-Tech could encounter significant increases in labor, capital or other costs that would make it difficult for R-Tech to produce our products cost-effectively.

In addition, R-Tech currently uses one supplier for the primary ingredient used in the manufacture of prostones. R-Tech could experience delays in production should it become necessary to switch its source of supply for this ingredient to another supplier or to manufacture the ingredient itself.

Our current and anticipated future dependence upon R-Tech for the manufacture of our products and product candidates may adversely affect our future revenues, our cost structure and our ability to develop product candidates and commercialize any approved products on a timely and competitive basis. In addition, if R-Tech should cease to manufacture prostones for our clinical trials for any reason, we likely would experience delays in advancing these trials while we seek to identify and qualify replacement suppliers. We may be unable to obtain replacement supplies on a timely basis, on terms that are favorable to us or at all.

We and R-Tech are dependent upon a single contract manufacturer to complete the final stage of manufacture of Amitiza.

R-Tech has subcontracted with a single contract manufacturer to encapsulate the bulk form Amitiza supplied by R-Tech into gelatin capsules and to package the final product for distribution in the United States. If this subcontractor experiences difficulties or delays in performing these services for any reason, our ability to deliver adequate supplies of finished product to physicians and patients will be impaired during the period in which R-Tech seeks a replacement manufacturer, which could cause us to lose revenues. In addition, any change in the party providing encapsulation of Amitiza would need to be approved by the FDA, and any change in the party packaging the product would need to be submitted to and reviewed by the FDA, which could increase the time required to replace this subcontractor should that become necessary.

R-Tech and any other third-party manufacturer of our products and product candidates are subject to significant regulations governing manufacturing facilities and procedures.

R-Tech, R-Tech's subcontractors and suppliers and any other potential manufacturer of our products or product candidates may not be able to comply with the FDA's cGMP regulations, other U.S. regulations or similar regulatory requirements in force outside the United States. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products approved for sale. In addition, the FDA or other regulatory agencies outside the United States may at any time audit or inspect a manufacturing facility to ensure compliance with cGMP or similar regulations. Our failure, or the failure of R-Tech, R-Tech's subcontractors and suppliers or any other third-party manufacturer we use, to comply with applicable manufacturing regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates.

If it were to become necessary for us to replace R-Tech as contract manufacturer of our product and product candidates, we would compete with other products for access to appropriate manufacturing facilities and the change would need to be submitted to and approved by the FDA. Among manufacturers that operate under cGMP regulations, there are a limited number that would be both capable of manufacturing for us and willing to do so.

We depend significantly on our collaborations with Takeda and Abbott, and may depend in the future on collaborations with other third parties, to develop and commercialize our product candidates.

A key element of our business strategy is to collaborate where appropriate with third parties, particularly leading pharmaceutical companies, to develop, commercialize and market our products and product candidates. We are currently party to a 16-year joint collaboration and license agreement with Takeda for the development and commercialization of Amitiza for gastrointestinal indications in the United States and Canada. We are also party to an agreement with Abbott for the development and commercialization of lubiprostone in Japan.

The success of our collaboration arrangement will depend heavily on the efforts and activities of Takeda and Abbott. The risks that we face in connection with this collaboration and that we anticipate being subject to in any future collaborations, include the following:

- our agreements with Takeda and Abbott are, and any future collaboration agreements that we may enter into are likely to be, subject to termination under various circumstances;
- Takeda, Abbott and other future collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us;
- Takeda, Abbott and other future collaborators may underfund or not commit sufficient resources to the testing, marketing, distribution or other development of our products or may use committed resources inefficiently;
- Takeda, Abbott and other future collaborators may not properly maintain or defend our intellectual property rights or may utilize our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential liability; and
- Takeda, Abbott and other future collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities from time to time, including following mergers and consolidations, which have been common in recent years in these industries.

The ability of our products and product candidates to reach their potential could be limited if Takeda, Abbott or any other future collaborators decrease or fail to increase spending relating to such products, fail to dedicate sufficient resources to developing or promoting our products or change their business focus.

Because we rely upon third parties to provide the sales representatives marketing Amitiza, we may face increased risks arising from their misconduct or improper activities, which would harm our business.

Because we will have only limited capacity to monitor the sales efforts of Takeda's sales force, we may be exposed to increased risks arising from any misconduct or improper activities of these sales representatives, including the potential off-label promotion of our products or their failure to adhere to standard requirements in connection with product promotion. In addition, we will be exposed to similar risks arising from our previous use of a third-party contractor's employees to market Amitiza. Although we amended our agreement with the contractor and ceased to use its employees effective July 1, 2007, any misconduct or inappropriate activities by those employees prior to termination could create future liabilities for us, and any misconduct or inappropriate activities might not come to light for an extended period after the termination. Any such improper activities could hurt our reputation, cause us to become subject to significant liabilities and otherwise harm our business.

We may not be successful in establishing additional collaborations, which could compromise our ability to develop and commercialize products.

If we are unable to reach new agreements with suitable collaborators, we may fail to meet our business objectives for the affected product or program. We face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish additional collaborations or other alternative arrangements. The terms of any additional collaborations or other arrangements that we establish may not be as favorable to us as we anticipate. Moreover, these collaborations or other arrangements may not be successful.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily or may fail to meet established deadlines for the completion of these trials.

We generally do not have the independent ability to conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions, and clinical investigators, to perform this function. For example, approximately 130 separate clinical

investigators participated in our trials for irritable bowel syndrome with constipation. We use multiple contract research organizations to coordinate the efforts of our clinical investigators and to accumulate the results of our trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not carry out their contractual duties or meet expected deadlines, we will be delayed in obtaining, or may not be able to obtain, regulatory approvals for our product candidates and will be delayed in our efforts to, or may not be able to, successfully commercialize our product candidates.

In addition, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

Conflicts of interest may arise between Sucampo AG or R-Tech and us, and these conflicts might ultimately be resolved in a manner unfavorable to us.

Our founders, Dr. Sachiko Kuno and Dr. Ryuji Ueno, together wholly own Sucampo AG and own a majority of the stock of R-Tech. Drs. Kuno and Ueno are married to each other. Ownership interests of our founders in the stock of R-Tech or Sucampo AG, and Dr. Ueno's service as a director and executive officer of our Company and Dr. Kuno's service as a director of our Company, could give rise to conflicts of interest when faced with a decision that could favor the interests of one of the affiliated companies over another. In addition, conflicts of interest may arise with respect to existing or possible future commercial arrangements between us and R-Tech or Sucampo AG in which the terms and conditions of the arrangements are subject to negotiation or dispute. For example, conflicts of interest could arise over matters such as:

- disputes over the cost or quality of the manufacturing services provided to us by R-Tech with respect to Amitiza, cobiprostone and SPI-017;
- a decision whether to engage R-Tech in the future to manufacture and supply compounds other than Amitiza, cobiprostone and SPI-017;
- decisions as to which particular prostone compounds, other than Amitiza, cobiprostone or SPI-017, we will commit sufficient development efforts to so that commercial rights to those compounds will not revert back to Sucampo AG at the end of the specified period;
- a decision whether to renegotiate the terms of our existing agreements with R-Tech or Sucampo AG; or
- business opportunities unrelated to prostones that may be attractive both to us and to the other company.

If tax authorities disagree with our transfer pricing policies or other tax positions, we could become subject to significant tax liabilities.

We are a member of an affiliated group of entities, including Sucampo AG and R-Tech, each of which is directly or indirectly controlled by Drs. Ueno and Kuno. We have had and will continue to have significant commercial transactions with these entities. Furthermore, we operate two foreign subsidiaries, Sucampo Japan and Sucampo Europe. We expect to enter into commercial transactions with each of these entities on an ongoing basis. As a result of these transactions, we will be subject to complex transfer pricing regulations in both the United States and the other countries in which we and our affiliates operate. Transfer pricing regulations generally require that, for tax purposes, transactions between our subsidiaries and affiliates and us be priced on a basis that would be comparable to an arm's length transaction and that contemporaneous documentation be maintained to support the related party agreements. To the extent that United States or any foreign tax authorities disagree with our transfer pricing policies, we could become subject to significant tax liabilities and penalties related to prior, existing and future related party agreements. As of December 31, 2008, we performed updated tax analyses wherein liabilities for uncertain tax positions were recorded for certain state jurisdictions based on nexus related to the sourcing of

revenues. Should the tax authorities in one or more of these states have different interpretations than us, we may be subject to additional tax liabilities.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain proprietary protection for the intellectual property relating to our technology and products, the value of our technology and products will be adversely affected and our ability to derive revenue from our products would be impaired.

Our success depends in part on our ability, and that of Sucampo AG, to obtain and maintain proprietary protection for the technology and know-how upon which our products are based, to operate without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights. The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our intellectual property will depend on our success, in conjunction with Sucampo AG, in obtaining effective claims and enforcing those claims once granted. The scope of protection afforded by a set of patent claims is subject to inherent uncertainty unless the patent has already been litigated and a court has ruled on the meaning of the claim language and other issues affecting how broadly a patent claim can be enforced. In some cases, we license patent applications from Sucampo AG instead of issued patents, and we do not know whether these patent applications will result in the issuance of any patents. Our licensed patents may be challenged, invalidated or circumvented, which could limit the term of patent protection for our products or diminish our ability to stop competitors from marketing related products. In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of Sucampo AG's patents and our intellectual property or narrow the scope of the protection provided by these patents. Accordingly, we cannot determine the degree of future protection for our proprietary rights in the licensed patents and patent applications. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, a related patent may expire or may remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

The patents we license from Sucampo AG also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor Sucampo AG can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

Confidentiality agreements with our employees and other precautions may not be adequate to prevent disclosure of our proprietary information and know-how.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how developed both by Sucampo AG and by us. We and Sucampo AG seek to protect our respective proprietary technology and processes, in part, by confidentiality agreements with our respective employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. These agreements or security measures may be breached, and we and Sucampo AG may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we or Sucampo AG are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could compromise our ability to produce revenue and achieve profitability.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Our research, development and commercialization

activities and those of Sucampo AG, as well as any products or product candidates resulting from these activities, may infringe or be alleged to infringe patents or patent applications owned or controlled by other parties. These third parties could bring claims against us or one of our collaborators that would require us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or one of our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or one of our collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or a collaborator were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or one of our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

We may be subject to other patent related litigation or proceedings that could be costly to defend and uncertain in their outcome.

In addition to infringement claims against us, we may become a party to other patent litigation and proceedings, including interference proceedings declared by the United States Patent and Trademark Office or opposition proceedings in the European Patent Office regarding intellectual property rights with respect to our products and technology, as well as other disputes with licensees, licensors or others with whom we have contractual or other business relationships for intellectual property. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could negatively affect our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management resources.

Risks Related to Regulatory Approval and Oversight

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate.

Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have undesirable side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited in scope or subject to restrictions or post-approval commitments that render the

product not commercially viable. If any regulatory approval that we obtain is delayed or is limited, we may decide not to commercialize the product candidate after receiving the approval.

Even if we receive regulatory approval for a product, the product could be subject to regulatory restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with ongoing regulatory requirements.

Amitiza and any other product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

We may experience unanticipated safety issues with our products after they are approved for marketing, which could harm our business and our reputation.

Because Amitiza and our other product candidates are based on newly discovered prostone technology with novel mechanisms of action, there may be long-term safety risks associated with these products that are not identifiable or well-understood at early stages of development and commercialization. Later discovery of previously unknown problems with our products, manufacturers or manufacturing processes may result in:

- restrictions on such products, manufacturers or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit; and
- voluntary or mandatory product recalls.

Because we rely on Takeda to provide a significant portion of the sales force that is selling Amitiza, we are dependent to some degree on Takeda to promptly and properly report any safety issues encountered in the field. If Takeda or their sales representatives fail to provide timely and accurate reporting of any safety issues that arise in connection with Amitiza, our business and reputation could be harmed.

Failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our products outside the United States and could adversely affect our reputation and our product marketing activities within the United States.

We intend to market our products both domestically and outside the United States. In order to market our products in the European Union, Japan and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

We may not be able to obtain orphan drug exclusivity for our product candidates. If our competitors are able to obtain orphan drug exclusivity for a product that is competitive with one or more of our product candidates and we cannot show that our product candidate is clinically superior, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including Europe and the United States, may designate drugs that target relatively small patient populations as orphan drugs. We have received an orphan drug designation from the FDA for our product candidate cobiprostone for the treatment of disorders associated with cystic fibrosis and we may pursue orphan drug designation for additional product candidates. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity. The exclusivity applies only to the indication for which the drug has been designated and approved. The applicable exclusivity period is seven years in the United States, but this period may be interrupted if a sponsor of a competitive product that is otherwise the same drug for the same use can show that its drug is clinically superior to our orphan drug candidate. The European exclusivity period is ten years, but may be reduced to six years if a drug no longer meets the criteria for orphan drug designation, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified. In addition, European regulations establish that a competitor's marketing authorization for a similar product with the same indication may be granted if there is an insufficient supply of the product or if another applicant can establish that its product is safer, more effective or otherwise clinically superior. If a competitor obtains orphan drug exclusivity for a product competitive with cobiprostone before we do and if the competitor's product is the same drug with the same indication as ours, we would be excluded from the market, unless we can show that our drug is safer, more effective or otherwise clinically superior. Even if we obtain orphan drug exclusivity for cobiprostone for these indications, we may not be able to maintain it if a competitor with a product that is otherwise the same drug can establish that its product is clinically superior.

We must comply with federal, state and foreign laws, regulations, and other rules relating to the health care business, and, if we are unable to fully comply with such laws, regulations and other rules, we could face substantial penalties.

We are or will be directly or indirectly through our customers, subject to extensive regulation by the federal government, the states and foreign countries in which we may conduct our business. The laws that directly or indirectly affect our ability to operate our business include the following:

- the federal Medicare and Medicaid Anti-Kickback law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;
- other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- the federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the Foreign Corrupt Practices Act, which prohibits certain payments made to foreign government officials; and
- state and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations.

If our operations are found to be in violation of any of the laws, regulations, rules or policies described above or any other law or governmental regulation to which we or our customers are or will be subject, or if the interpretation of the foregoing changes, we may be subject to civil and criminal penalties, damages, fines, exclusion from the

Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations would harm our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions may be open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert management resources from the operation of our business and damage our reputation.

Risks Related to Our Common Stock

Our founders, who are also members of our board of directors, maintain the ability to control all matters submitted to stockholders for approval, which could result in actions of which you or other stockholders do not approve.

Our founders, Dr. Sachiko Kuno, one of our directors, and Dr. Ryuji Ueno, our chief executive officer, chief scientific officer and a director, together beneficially own 1,893,885 shares of class A common stock and 26,191,050 shares of class B common stock, representing approximately 95% of the combined voting power of our outstanding common stock. As a result, Drs. Ueno and Kuno, who are married, acting by themselves, are able to control the outcome of all matters that our stockholders vote upon, including the election of directors, amendments to our certificate of incorporation, and mergers or other business combinations. The concentration of ownership and voting power also may have the effect of delaying or preventing a change in control of our company and could prevent stockholders from receiving a premium over the market price if a change in control is proposed.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our class A common stock may be lower as a result.

There are provisions in our certificate of incorporation and by-laws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our class A common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents contain other provisions that could have an anti-takeover effect, including:

- the high-vote nature of our class B common stock;
- following the conversion of all shares of class B common stock into class A common stock, only one of our three classes of directors will be elected each year;
- following the conversion of all shares of class B common stock into class A common stock, stockholders will not be entitled to remove directors other than by a 75% vote and for cause;
- following the conversion of all shares of class B common stock into class A common stock, stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and

could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our class A common stock. These provisions may also prevent changes in our management.

Our class A common stock is thinly traded and our stock price is volatile; investors in our class A common stock could incur substantial losses.

The public trading market for our class A common stock is characterized by small trading volumes and a highly volatile stock price. The stock market in general and the market for pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their class A common stock at or above the price they paid, and may have difficulty selling their shares at any price. The market price for our class A common stock may be influenced by many factors, including:

- failure of Amitiza or other approved products, if any, to achieve commercial success;
- results of clinical trials of our product candidates or those of our competitors;
- the regulatory status of our product candidates;
- the success of competitive products or technologies;
- regulatory developments in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- the ability of R-Tech to manufacture our products to commercial standards in sufficient quantities;
- actual or anticipated fluctuations in our quarterly financial results;
- variations in the financial results of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations; and
- general economic, industry and market conditions.

We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on our capital stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our class A common stock will be your sole source of gain for the foreseeable future.

A significant portion of our total outstanding shares are eligible to be sold into the market. This could cause the market price of our class A common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our class A common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our class A common stock in the public market, the market price of our class A common stock could decline significantly. Virtually all of our outstanding shares of common stock are eligible to be resold in the public markets, including approximately 37.5 million shares that first became available for sale in the public market in February 2008 following the expiration of lock-up agreements between our stockholders and the underwriters of our public offering, subject in some cases to volume limitations imposed by federal securities laws. Moreover, holders of an aggregate of approximately 6,751,609 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also registered the 13,900,900 shares of class A common stock

that we may issue in the future under our equity compensation plans, and they can be freely sold in the public market upon issuance.

Due to recent uncertainties in the credit markets, we may be unable to liquidate some holdings of our auction rate securities and as a result, may suffer losses from these investments. In addition, given the complexity of auction rate securities and their valuations, our estimates of their fair value may differ from the actual amount we would be able to collect in an ultimate sale.

As of December 31, 2008, we had $19.4 million invested in auction rate securities, or ARS. ARS are long-term debt instruments that provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined calendar intervals, generally every seven to 49 days. This mechanism generally allows existing investors to roll-over their holdings and continue to own their respective securities or liquidate their holdings by selling their securities at par value.

Historically, we invested in ARS for short periods of time as part of our cash management program. Recent uncertainties in the credit markets have prevented us from liquidating some of our holdings of ARS during the year because the amount of securities submitted for sale during the auction exceeded the amount of purchase orders.

On October 16, 2008, we accepted a settlement rights offer from the broker UBS, AG of Auction Rate Security Rights. This offer permits us to require UBS to purchase our ARS at par value between June 30, 2010 and July 2, 2012. In exchange, we granted UBS the right, at their sole discretion, to sell or otherwise dispose of our ARS at any time during the same period.

It is uncertain as to when the liquidity issues relating to these investments will improve. Although we do not currently anticipate having to sell these securities in order to operate our business, if that were to change, or if such liquidity issues continue over a prolonged period, we might be unable to liquidate some holdings of our ARS and, as a result, might suffer losses from these investments. In addition, given the complexity of ARS and their valuations, our estimates of their fair value may differ from the actual amount we would be able to collect in an ultimate sale. Although our arrangement with UBS provides some comfort that we will eventually be able to liquidate our ARS holdings, we cannot provide any assurance that UBS will be in a position to honor its commitment to repurchase our ARS during the specified period.

ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

None.

ITEM 2. ***PROPERTIES***

Our corporate headquarters, including our principal executive office, and some of our commercial, administrative and research and development activities, are located in Bethesda, Maryland. Our lease for this facility, which comprises approximately 25,000 square feet of office space, expires in February 2017. In addition, we have a short-term lease in Fuquay-Varina, North Carolina to house our national sales office.

In July 2007, we vacated our previous headquarters in Bethesda, Maryland. We sublet 1,600 square feet of space under a lease that expires in December 2010 and sublet 11,166 square feet of space under a lease that expires in November 2009. We remain obligated to make rent payments under both leases.

We lease our Asian and European headquarters, located in Tokyo and Osaka, Japan and Oxford, England, under short-term leases, which comprises an aggregate of approximately 3,626 square feet of space.

We believe that our current facilities are sufficient to meet our needs for at least the next 12 months.

ITEM 3. ***LEGAL PROCEEDINGS***

We are not currently a party to any legal proceedings of which the ultimate outcome, in our judgment, would have a material adverse effect on our business, financial condition or results of operations.

ITEM 4. ***SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS***

No matters were submitted to a vote of security holders during the quarter ended December 31, 2008.

PART II

ITEM 5. ***MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES***

Our class A common stock is traded on The NASDAQ Global Market under the symbol "SCMP". The following table sets forth, for the periods indicated, the range of high and low sale prices of our class A common stock as reported on The NASDAQ Global Market since our initial public offering on August 2, 2007.

Quarters Ended:	High	Low
September 30, 2007 (beginning August 2, 2007, our initial public offering date)	$ 14.50	$ 10.75
December 31, 2007	$ 19.75	$ 10.16
March 31, 2008	$ 18.01	$ 8.00
June 30, 2008	$ 14.32	$ 8.29
September 30, 2008	$ 12.88	$ 6.88
December 31, 2008	$ 8.44	$ 2.84

As of March 5, 2009, we had 15,651,849 shares of class A common stock outstanding held by 13 stockholders of record. The number of holders of record of our class A common stock is not representative of the number of beneficial holders because many shares are held by depositories, brokers or nominees. As of March 5, 2009, the closing price of our class A common stock was $3.88. As of March 5, 2009, we had 26,191,050 shares of class B common stock outstanding held by one stockholder of record.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, to support our growth strategy and do not anticipate paying cash dividends in the foreseeable future.

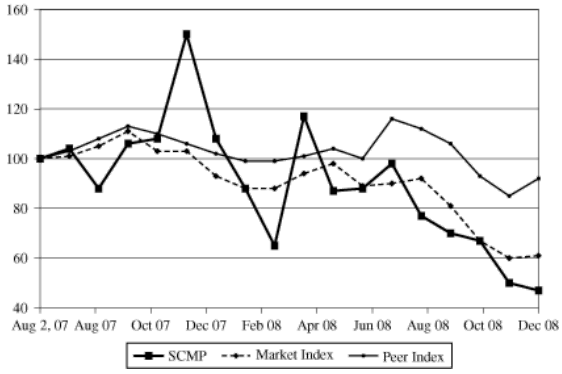
On December 9, 2008 our board of directors authorized and approved a stock repurchase program, under which we may use up to $10 million to purchase shares of our class A common stock from time to time in open-market transactions, depending on market conditions and other factors. We did not repurchase any of our equity securities in 2008.

The equity compensation plan information required under this Item is incorporated by reference to the information provided under the heading "Equity Compensation Plan Information" in our proxy statement to be filed within 120 days after the fiscal year end of December 31, 2008.

Stock Performance Graph

The information included under this heading "Stock Performance Graph" is "furnished" and not "filed" and shall not be deemed to be "soliciting material" or subject to Regulation 14A, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph compares the cumulative total return, assuming the investment of $100 on August 2, 2007, the date on which our class A common stock began trading on The NASDAQ Global Market, in each of (1) our class A common stock, (2) The NASDAQ Composite Index (U.S. and Foreign) and (3) the NASDAQ Pharmaceutical Index, assuming reinvestment of any dividends. These comparisons are required by the SEC and are not intended to forecast or be indicative of possible future performance of our class A common stock.



ITEM 6. ***SELECTED CONSOLIDATED FINANCIAL DATA***

We have derived the following consolidated financial data as of December 31, 2005, 2006, 2007 and 2008 and for the years then ended from our audited consolidated financial statements. Consolidated balance sheets as of December 31, 2007 and 2008 and the related consolidated statements of operations and comprehensive income, changes in stockholders' equity and cash flows for each of the three years ended December 31, 2006, 2007 and 2008 and notes thereto appear elsewhere in this Annual Report. We have derived the following consolidated financial data as of December 31, 2004 from our unaudited consolidated balance sheet and consolidated financial data as of December 31, 2005 and for the two years then ended, from audited consolidated financial statements, which are not included in this Annual Report. The information set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related footnotes appearing elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
(In thousands, except per share data)	2004	2005	2006	2007	2008
Statement of operations data					
Revenues	$ 3,839	$ 40,205	$ 59,266	$ 91,891	$ 112,123
Operating expenses:					
Research and development	14,036	31,167	19,204	31,697	46,181
General and administrative	8,216	7,760	11,699	21,423	14,400
Selling and marketing	—	295	11,179	13,474	10,895
Milestone royalties — related parties	1,000	1,500	1,250	2,000	3,531
Product royalties — related parties	—	—	1,171	4,890	6,045
Total operating expenses	23,252	40,722	44,503	73,484	81,052
(Loss) income from operations	(19,413)	(517)	14,763	18,407	31,071
Total non-operating (expense) income, net	(56)	990	2,141	2,616	2,043
(Loss) income before income taxes	(19,469)	473	16,904	21,023	33,114
Income tax (provision) benefit	—	(789)	4,897	(7,833)	(8,163)
Net (loss) income	$ (19,469)	$ (316)	$ 21,801	$ 13,190	$ 24,951
Basic net (loss) income per share	$ (0.60)	$ (0.01)	$ 0.63	$ 0.35	$ 0.60
Diluted net (loss) income per share	$ (0.60)	$ (0.01)	$ 0.63	$ 0.35	$ 0.59
Weighted average common shares outstanding — basic	32,600	32,601	34,383	37,778	41,787
Weighted average common shares outstanding — diluted	32,600	32,601	34,690	38,226	41,973

(In thousands)	As of December 31, 2004 (Unaudited)	2005	2006	2007	2008
Balance sheet data:					
Cash and cash equivalents	$ 21,918	$ 17,436	$ 22,481	$ 25,559	$ 11,536
Short-term investments	3,000	28,435	29,399	51,552	93,776
Working capital	7,850	10,051	40,623	84,313	98,229
Total assets	25,837	47,985	67,084	110,027	150,794
Notes payable — related parties, current	4,040	848	—	—	—
Notes payable — related parties, net of current portion	2,326	2,546	—	—	—
Total liabilities	39,375	58,225	28,551	23,499	37,004
Convertible preferred stock	20,288	20,288	20,288	—	—
Accumulated (deficit) surplus	(44,852)	(45,167)	(23,366)	(10,176)	14,775
Total stockholders' equity (deficit)	(13,538)	(10,240)	38,533	86,528	113,790

ITEM 7. ***MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

You should read the following discussion and analysis together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that are based on our current expectations, estimates and projections about our business and operations. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors, including those we discuss under Item 1A — "Risk Factors" and elsewhere in this Annual Report.

Overview

We generate revenue mainly from product development milestone payments, product royalties, and research and development activities. Although we reported net income for the years ended December 31, 2008, 2007 and 2006, we have incurred operating losses in the past, resulting principally from costs incurred in our research and development programs and from our general and administrative expenses. We expect to continue to incur significant expenses for the next several years as we continue to expand our research and development activities, seek regulatory approvals for additional indications for Amitiza and for other compounds in the United States and abroad and expand our international operations. While we expect future profitability, whether we are able to sustain profitability will depend upon our ability to generate sufficient revenues and receive payments under our contracts with Takeda, Abbott and similar future arrangements. In the near term, our ability to generate product revenues will depend primarily on the growth in our product commercialization, continued development of additional indications for Amitiza and success in new clinical developments currently in progress.

In August 2007, we completed our initial public offering, consisting of 3,125,000 shares of class A common stock sold by us, 625,000 shares of class A common stock sold by a stockholder and 562,500 shares of class A common stock sold under an overallotment option by S&R, at a public offering price of $11.50 per share, resulting in gross proceeds to us of approximately $35.9 million. After deducting underwriters' discounts and commissions and expenses of the offering, including costs of $3.1 million incurred in 2006, we raised net proceeds of $28.2 million.

Financial Terms of our Collaboration with Takeda

We entered into a 16-year collaboration agreement with Takeda in October 2004 to jointly develop and commercialize Amitiza for gastrointestinal indications in the United States and Canada. We also entered into a related supplemental agreement with Takeda in February 2006. Under the terms of these agreements, we have received a variety of payments and will have the opportunity to receive additional payments in the future.

Up-front Payment

Upon signing the original collaboration agreement with Takeda, we received a non-refundable up-front payment of $20.0 million. We deferred $2.4 million of this up-front payment associated with our obligation to participate in joint committees with Takeda and we are recognizing this amount as collaboration revenue ratably over the 16-year life of the agreement. We recognized the remaining $17.6 million as research and development revenue ratably over the estimated development period associated with the chronic idiopathic constipation and irritable bowel syndrome with constipation indications, which was completed in June 2007 as evidenced by the filing with the FDA of a supplement to our existing NDA for Amitiza relating to the treatment of irritable bowel syndrome with constipation.

Product Development Milestone Payments

We have received the following non-refundable payments from Takeda reflecting our achievement of specific product development milestones, which we recognized either ratably over the estimated development period associated with the chronic idiopathic constipation and irritable bowel syndrome with constipation indications, which was completed in June 2007 or upon completion of performance obligations in case where milestone payments were received after the associated development period.

- $10.0 million upon the filing of the NDA for Amitiza to treat chronic idiopathic constipation in March 2005;
- $20.0 million upon the initiation of our phase 3 clinical trial related to Amitiza for the treatment of irritable bowel syndrome with constipation in May 2005;
- $20.0 million upon the receipt of approval from the FDA for Amitiza for the treatment of chronic idiopathic constipation in adults in January 2006;
- $30.0 million as a result of submission of supplement to our existing NDA for Amitiza to the FDA seeking marketing approval for Amitiza for the treatment of irritable bowel syndrome with constipation in June 2007; and
- $50.0 million upon the receipt of approval from the FDA for Amitiza for the treatment of irritable bowel syndrome with constipation in women 18 years and older in May 2008.

Subject to our achieving further product development milestones, we are potentially entitled to receive up to $10.0 million in additional payments from Takeda.

Research and Development Cost-Sharing for Amitiza

Our collaboration agreement and related supplemental agreement with Takeda provides for the sharing with Takeda the costs of our research and development activities for Amitiza in the United States and Canada as follows:

Research and development expense related to Amitiza for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation:

- Pursuant to the agreement, Takeda is responsible for first $30.0 million in research and development expenses we incurred after October 2004 related to Amitiza for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. We received reimbursement payments from Takeda of $28.5 million in 2005 and $1.5 million in 2004. We recognized these payments as research and development revenue ratably over the development period associated with the chronic idiopathic constipation and irritable bowel syndrome with constipation indications, which was completed in June 2007. We were responsible for the next $20.0 million in research and development expenses related to Amitiza for these indications, of which we incurred $14.5 million of related research and development expense as of December 31, 2008. Based on the agreement, any additional research and development expense in excess of the $50.0 million shall be shared equally between Takeda and us. As of December 31, 2008, the related aggregate research and development expense incurred was $44.5 million.

- For research and development expenses relating to changing or expanding the labeling of Amitiza to treat chronic idiopathic constipation and irritable bowel syndrome with constipation, Takeda is responsible for 70% of these expenses and we are responsible for 30%. In connection with our marketing approval for Amitiza for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in patients with renal impairment and patients with hepatic impairment. We initiated these studies in January 2007. The expenses of these studies, which we began to incur in the quarter ended September 30, 2006, are being shared 70% by Takeda and 30% by us. Through December 31, 2008, we had incurred $2.2 million of these expenses, of which the agreement requires we be reimbursed approximately $1.5 million by Takeda.
- The expense of phase 4 clinical trials of Amitiza for the treatment of chronic idiopathic constipation in pediatric patients that we initiated in January 2007 will be borne by Takeda in full. As of December 31, 2008, we had incurred $7.1 million of these expenses, all of which have been or will be reimbursed by Takeda.
- For expenses in connection with additional clinical trials required by regulatory authorities relating to Amitiza to treat chronic idiopathic constipation or irritable bowel syndrome with constipation, Takeda and we are responsible to share these expenses equally. We have not incurred any expenses of this nature to date.

Research and development expense related to Amitiza for the treatment of gastrointestinal indications other than chronic idiopathic constipation and irritable bowel syndrome with constipation:

- Takeda is responsible for the first $50.0 million in expenses we incur related to the development of Amitiza for each gastrointestinal indication other than chronic idiopathic constipation and irritable bowel syndrome with constipation and any expenses in excess of $50.0 million are shared equally between Takeda and us. We initiated clinical trials of Amitiza for the treatment of opioid-induced bowel dysfunction in September 2007 and we began incurring expenses for these trials in the third quarter of 2006. Currently, we anticipate the aggregate expenses necessary to complete our development of Amitiza for this indication will be approximately $54.0 million, of which Takeda will be responsible for $52.0 million and we will be responsible for $2.0 million. As of December 31, 2008 we had incurred $32.7 million of these expenses, all of which have been or will be reimbursed by Takeda.
- Takeda is responsible for the first $20.0 million in expenses we incur related to the development of each new formulation of Amitiza, and any expenses in excess of $20.0 million are shared equally between Takeda and us. We have not incurred any expenses of this nature to date.

Co-Promotion Expense Reimbursements

In connection with our exercise of our co-promotion rights under the collaboration agreement and our entry into a related supplemental agreement in February 2006, Takeda agreed to reimburse us for a portion of our expenses related to our specialty sales force. We recognized $4.8 million, $4.3 million and $3.4 million of co-promotion revenue reflecting these reimbursements for the years ended December 31, 2008, 2007 and 2006 respectively.

Takeda also agreed to reimburse us for all of the costs we incur in connection with specified miscellaneous marketing activities related to the promotion of Amitiza. During the years ended December 31, 2007 and 2006, we recognized $158,000 and $779,000, respectively, as co-promotion revenue reflecting these reimbursements. We completed the miscellaneous marketing activities, to which these reimbursements relate, during the year ended December 31, 2007 and, accordingly, we did not recognize any co-promotion revenue towards miscellaneous marketing activities in 2008 and we do not expect to recognize additional co-promotion revenue related to these activities in the future.

Product Royalty Revenue

Takeda is obligated to pay us a varying royalty based on a percentage of the net sales revenue from the sale of Amitiza in the United States and Canada. The actual percentage depends on the level of net sales revenue attained each calendar year. All sales of Amitiza in the United States and Canada, including those arranged by our specialty

sales force, will be made through Takeda. During the years ended December 31, 2008, 2007 and 2006, we recognized a total of $34.4 million, $27.5 million and $6.6 million, respectively, as product royalty revenue.

Commercialization Milestone Payments

Our collaboration agreement also requires Takeda to pay us up to an additional aggregate of $50.0 million conditioned upon the achievement of specified targets for annual net sales revenue from Amitiza in the United States and Canada. We had not met these targets as of December 31, 2008.

Takeda Cash Flows and Revenue

The following table summarizes the cash streams and related collaboration and research and development revenue recognized under the Takeda Agreements:

(In thousands)	Cash Received through December 31, 2008	Revenue Recognized for the Year Ended December 31, 2004	2005	2006	2007	2008	Accounts Receivable at December 31, 2008*	Amount Deferred at December 31, 2008
Collaboration revenue:								
Up-front payment associated with our obligation to participate in joint committees with Takeda	$ 2,375	$ 23	$ 147	$ 147	$ 147	$ 147	$ —	$ 1,764
Research and development revenue:								
Up-front payment — remainder	$ 17,624	$ 1,356	$ 8,134	$ 6,157	$ 1,977	$ —	$ —	$ —
Development milestones	130,000	—	16,154	28,237	35,609	50,000	—	—
Reimbursement of research and development expenses	82,577	1,482	14,672	11,988	21,793	22,293	4,406	14,755
Total	$ 230,201	$ 2,838	$ 38,960	$ 46,382	$ 59,379	$ 72,293	$ 4,406	$ 14,755

* Includes billed and unbilled accounts receivable.

Financial Terms of our License from Sucampo AG

We paid Sucampo AG the following milestone royalty payments that were expensed as incurred and recorded as milestone royalties — related parties in the respective periods.

- $1.0 million, reflecting 5% of a $20.0 million development milestone payment that we received from Takeda, and $250,000 upon marketing approval of Amitiza by the FDA for the treatment chronic idiopathic constipation in adults in 2006;
- $1.5 million, reflecting 5% of a $30.0 million milestone payment received from Takeda as a result of our submission to the FDA in June 2007 of the supplement to our existing NDA for Amitiza seeking marketing approval for Amitiza for the treatment of irritable bowel syndrome with constipation;
- $500,000 upon the initiation of the first phase 2b dose-ranging study in Japan in 2007;
- $2.5 million, reflecting 5% of a $50.0 million development milestone payment that we received from Takeda as a result of our submission to the FDA in May 2008 of the supplement to our existing NDA for Amitiza seeking marketing approval for Amitiza for the treatment of irritable bowel syndrome with constipation; and
- $1.0 million milestone royalty payment in connection with our MAA filed in the United Kingdom in February 2008, representing the first such filing for the rest-of-the-world territory.

Additionally, we expensed $6.0 million, $4.9 million and $1.2 million in product royalties to Sucampo AG during the years ended December 31, 2008, 2007 and 2006 respectively, reflecting 3.2% of Amitiza net sales during each of these years, which we recorded as product royalties — related parties on the consolidated statements of operations and comprehensive income.

Supply Agreement with R-Tech

We entered into an exclusive supply arrangement with our affiliate, R-Tech, in March 2003. In return for the exclusive right to manufacture and supply clinical and commercial supplies of Amitiza and a second prostone compound that we are no longer developing in North, Central and South America, including the Caribbean, R-Tech agreed to make the following milestone payments to us:

- $1.0 million upon entry into the arrangement, which we received in March 2003;
- $2.0 million upon commencement of a first phase 2 clinical trial relating to Amitiza to treat irritable bowel syndrome with constipation, which we received in April 2003; and
- $3.0 million upon commencement of a first phase 2 clinical trial for the other compound, which we received in 2003. On March 31, 2005, after evaluating the phase 2 study results, we determined to discontinue any further research and development related to this compound and will not receive any further payments in respect of this compound.

We evaluated the $6.0 million in cash receipts from R-Tech and determined these payments were made for the exclusive right to supply inventory to us and, accordingly, should be deferred until commercialization of the drugs begins. We also were unable to accurately apportion value between Amitiza and the other compound based on the information available to us and determined that the full $6.0 million deferred amount should be amortized over the contractual life of the relationship, which we concluded was equivalent to the commercialization period of Amitiza and the other compound. Accordingly, we began recognizing this revenue during the year ended December 31, 2006 and will continue recognizing it ratably on a straight-line basis over the remaining life of our supply agreement with R-Tech through 2026. We recognized $418,000 for the years ended December 31, 2008 and 2007 and $404,000 for the year ended December 31, 2006 as contract revenue — related parties under this exclusive supply arrangement with R-Tech.

In June 2005, Sucampo Europe entered into an exclusive supply agreement with R-Tech. In return for the exclusive right to manufacture and supply clinical and commercial supplies of Amitiza in Europe, the Middle East and Africa. R-Tech agreed to pay us $2.0 million in anticipation of entering into this agreement, which we received in March 2005. We determined that this payment should be deferred until commercialization of Amitiza begins within the specified territories in Europe, the Middle East and Africa and, accordingly, the entire $2.0 million is reflected as deferred revenue at December 31, 2008.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect our reported assets, liabilities, revenues and expenses. Actual results may differ significantly from those estimates under different assumptions and conditions.

We regard an accounting estimate or assumption underlying our financial statements as a critical accounting estimates if:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are described in more detail in Note 2 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Current and Non-Current Investments

Current and non-current investments consist primarily of U.S. Treasury bills, notes and auction rate securities. We account for these investments under the guidance of Statement of Financial Accounting Standards, or SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. We classify these investments

into current and non-current based on their maturities and our reasonable expectation to recognize these investments in cash. Interest and dividend income is recorded when earned and included in interest income. During the years ended December 31, 2008, 2007 and 2006, there were no current or non-current investments that were purchased at a premium or discount. We use the specific identification method in computing realized gains and losses on sale of our securities. There were no gains or losses realized on the sale of these investments during 2008, 2007 and 2006.

Auction rate securities

As of December 31, 2008, all of our auction rate securities, or ARS, consisted of AAA or A rated non-mortgage related ARS. Although the ARS have variable interest rates which typically reset every seven to 49 days through a competitive bidding process known as a "Dutch auction," they have long-term contractual maturities usually exceeding ten years, and therefore are not classified as cash equivalents. As a result of recent liquidity issues in the global credit and capital markets, it has been difficult to sell these securities in the open market.

On October 16, 2008, we accepted a settlement rights offer from the broker UBS, AG of Auction Rate Security Rights. This offer permits us to require UBS to purchase our ARS at par value between June 30, 2010 and July 2, 2012. In exchange, we granted UBS the right, at their sole discretion, to sell or otherwise dispose of our ARS at any time during the same period. As of December 31, 2008, we have recorded an asset of $2.8 million for the fair value of settlement rights offered by UBS for redemption of our outstanding ARS at par value.

The unique circumstances associated with the auction rate securities markets and the settlement rights has resulted in the reclassification of our investment in auction rate securities from available-for-sale securities to trading securities, which requires us to record an unrealized gain or loss in the consolidated statement of operations and comprehensive income. Accordingly, we recognized $3.2 million of unrealized losses on auction rate securities for the year ended December 31, 2008. We will continue to record fair value changes for the trading securities as a gain or loss in the statement of operations and comprehensive income.

Other current and non-current investments

Our other investments consist primarily of money market instruments such as U.S. Treasury bills and treasury funds. These investments are classified as available-for-sale securities.

Fair Value Estimates

We adopted the provisions of Statement of Financial Accounting Standards or SFAS No. 157 *Fair Value Measurements*, effective January 1, 2008 for our financial assets and liabilities. Our financial assets and liabilities subject to the disclosure requirements of SFAS 157 include investments-current and non-current and ARS related settlement rights asset. We determined the fair market value of other financial assets and liabilities to be the carrying values as of yearend.

Fair value estimate for auction rate securities

ARS have historically been long-term notes that acted like short-term debt, because their coupon rates reset in regular and frequent Dutch auctions, typically every seven to 49 days. The recent uncertainties in the credit markets have disrupted the liquidity of this process resulting in failed auctions. The breakdown in the auction process affects our estimate of term to maturity in valuing these investments.

The current lack of marketability prevented us from comparing our ARS directly to securities with quoted market prices or finding secondary market indications of the prices at which investors are willing to buy and sell auction rate securities. Therefore, we used the income approach model as the primary quantitative valuation technique for valuing the ARS during the year ended December 31, 2008. We used the income approach consistently during the year and there are no changes in the valuation technique.

In developing the valuation model, we determined expected cash flows, expected period coupon rate, market rate of return or margin and the expected term of investments as key inputs. The value of the ARS was then determined as equal to the value of the principal plus return on investment discounted at the required market rate of return over the life of our investment. In simulating the estimated coupon rate and other variables, we relied on

information obtained from the market interest rate data provided by Barclays Capital (formerly Lehman Brothers), Goldman Sachs, Deutsche Bank, UBS, Merrill Lynch, JP Morgan, Thomson Financial, US Bancorp, and Bloomberg; trade data available from Bloomberg and Municipal Securities Rulemaking Board; and asset appropriate credit transition matrices and recovery rates for any non-government guaranteed assets as provided by Standard & Poor's, Moody's, Fitch, and Standard & Poor's J.J. Kenny PERFORM Municipal Index.

The fair value model calculated market-required rates of return that included a risk-free interest rate and a credit spread. The model discounted the expected coupon rates at the calculated required rate of return to arrive at the price. The model used the market data most recently available as of the valuation date. The cash flows for each security depend on the contractual terms of the security. We estimated the coupon rates for each of the securities by a regression analysis in which the dependent variable was the hypothetical monthly calculated maximum rate over the previous five years of successful auctions and the independent variable was the swap rate. The regression relationship and the current swap rate were used to estimate the future coupon rate. The credit adjustment to the discount rate was calculated as the difference between two interest rates, mainly the interest rate index provided by an investment bank, Barclays Capital or UBS, which was designed to reflect the risk of the security, subtracted from the coupon rate for the most recent successful auction. This credit adjustment was then added to the current value of the index to create a discount rate. We did not use broker quotes or pricing services as the basis for fair value estimate of any ARS.

The valuation model also took into effect the counterparty credit risk and lack of marketability effect in arriving at the fair value of the ARS. We estimated the effect of the counterparty credit risk adjustment and the amount of unrealized gain or loss that would affect the consolidated statement of operations and comprehensive income on account of improvement or decline in counterparty credit rating and concluded it was not material as of December 31, 2008.

Reflecting the settlement rights offer from UBS, we assumed the remaining life of our investment in ARS to be two years as of December 31, 2008. We indentify the expected life of ARS, an input in the estimate of fair value, as one of the key elements to measure the sensitivity of the fair value of ARS. A change in the expected life from two years to four years would result in a $2.2 million decrease in fair value of ARS outstanding as on December 31, 2008. We measured sensitivity for a range of two to four years in line with exercise period available under the UBS settlement agreement for par value redemption.

Fair value estimate for Settlement Rights under UBS agreement

We voluntarily adopted the provisions of SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115* (SFAS 159), which permits entities to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis, to record the settlement rights related to the auction rate securities at fair value. Accordingly, we recorded $2.8 million within other assets in the consolidated balance sheet as of December 31, 2008 for the fair value of the settlement rights and the corresponding amount as a gain within other expense, net in the consolidated statements of operations and comprehensive income. Subsequent changes in the initial recognition of the fair value of settlement rights will be recorded as other income (loss) in the statement of operations and comprehensive income. The fair value estimate of the settlement rights has been derived from the par value of our investment in ARS and the fair value of ARS as on the recognition date, since the settlement rights obligate UBS to redeem the ARS at par.

Revenue Recognition

Collaboration and License Agreements

Our primary sources of revenue include up-front payments, product development milestone payments, reimbursements of research and development expenses, reimbursement of co-promotion costs related to our specialty sales force and miscellaneous marketing activities, and product royalties. We recognize revenue from these sources in accordance with Staff Accounting Bulletin, or SAB, 104, *Revenue Recognition*, Emerging Issues Task Force, or EITF, Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21. The application of EITF 00-21 requires subjective analysis and requires us to make estimates and assumptions about whether deliverables within

multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and, if so, to determine the fair value to be allocated to each unit of accounting.

We evaluated the multiple deliverables within our joint collaboration and license agreement and the related supplemental agreement with Takeda in accordance with the provisions of EITF 00-21 to determine whether our deliverables have value to Takeda on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. We separately evaluate deliverables that meet these criteria for the purposes of revenue recognition. We combine deliverables that do not meet these criteria and account for them as a single unit of accounting.

In accordance with EITF 00-21, we recognized the cash flows associated with the individual units of accounting from the joint collaboration and license agreement as revenue using a time-based model that recognizes the revenue ratably over the period in which we complete our performance requirements. However, revenue is limited to amounts that are non-refundable and that Takeda is contractually obligated to pay. With respect to the portion of the up-front payment we attributed to our obligation to participate in joint committees with Takeda, which we present as collaboration revenue, the performance period is the 16-year term of the collaboration agreement. With respect to the remainder of the up-front payment, as well as the product development milestone payments and the reimbursement of research and development expenses, all of which we present as research and development revenue, the performance period is the estimated development period for Amitiza to treat chronic idiopathic constipation and irritable bowel syndrome with constipation. The performance period was completed in June 2007 as evidenced by the filing with the FDA of a supplement to our existing NDA for Amitiza relating to the treatment of irritable bowel syndrome with constipation. We have determined that we are acting as a principal under the collaboration agreement and, as such, we record these amounts on a gross basis as collaboration revenue and as research and development revenue.

We have other obligations with Takeda to perform research and development activities, for which Takeda reimburses us after the services have been performed. We recognize these reimbursable costs as research and development revenue using a similar time-based model over the estimated performance period. The research and development revenue for these obligations is limited to the lesser of the actual reimbursable costs incurred or the straight-line amount of revenue recognized over the estimated performance period. In cases where milestone payments are received after the completion of the associated development period, we recognize revenue upon completion of the performance obligation. Revenues are recognized for reimbursable costs only if those costs are supported by an invoice or final contract with a vendor.

Reimbursements of co-promotion costs under the supplemental agreement with Takeda, including costs associated with our specialty sales force and miscellaneous marketing activities, are recognized as co-promotion revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts. We have determined that we are acting as a principal under the supplemental agreement and, as such, we record reimbursements of these amounts on a gross basis as co-promotion revenue.

Product royalty revenue is based on third-party sales of licensed products. We record these amounts on the accrual basis when earned in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met.

We do not immediately recognize as revenue option fees received for other potential joint collaboration and license agreements with Takeda because the transactions do not represent a separate earnings process. Our policy is to recognize revenue immediately upon expiration of the option or to commence revenue recognition upon exercise of the option and continue recognition over the estimated performance period because we will have contingent performance obligations if and when the options are exercised. We record option fees as contract revenue when they are recognized.

We recognize contract revenue related to development activities with related parties under the time-based method and we recognize contract revenue related to consulting activities with related parties as performance is rendered. We record cost-sharing payments received in advance as deferred revenue and recognize these payments as revenue over the applicable clinical trial period.

Accrued Research and Development Expenses

As part of our process of preparing our consolidated financial statements, we are required to estimate an accrual for research and development expenses. This process involves reviewing and identifying services which have been performed by third parties on our behalf and determining the value of these services. Examples of these services are payments to clinical investigators and contracted service organizations. In addition, we make estimates of costs incurred to date but not yet invoiced to us in relation to external contract research organizations and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs, when evaluating the adequacy of the accrued liabilities for research and development. We must make significant judgments and estimates in determining the accrued balance in any accounting period.

Stock-Based Compensation

On January 1, 2006, we adopted SFAS 123(R) *Share Based Payments*, or SFAS 123(R) using the modified prospective method of implementation. According to the modified prospective method, we have been recognizing compensation expense for all share-based payment awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

For recording our stock-based compensation expense under SFAS 123(R), we have chosen to use:

- the straight-line method of allocating compensation cost under SFAS 123(R);
- the Black-Scholes-Merton option pricing formula as our chosen option-pricing model;
- the simplified method to calculate the expected term for options as discussed under SAB No. 107, *Share-Based Payment;* and
- an estimate of expected volatility based on the historical volatility of similar entities whose share prices are publicly available.

We account for transactions with non-employees in which services are received in exchange for equity instruments under EITF 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services*. Under this guidance, the transactions are based on the fair value of the services received from the non-employees or the fair value of the equity instruments issued, whichever is more reliably measured. The three factors which most affect stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded, the vesting term of the options and the volatility of such fair value of common stock. Accounting for these equity instruments requires us to determine the fair value of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating stock-based compensation expenses.

Prior to the completion of our initial public offering in August 2007, our board of directors determined the fair value of our class A common stock for stock option awards given the lack of an active market for our class A common stock. In establishing the estimates of fair value, our board of directors considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation,* and made retrospective determinations of fair value. The board of directors gave significant consideration to the price of the class A common stock sold to unrelated third parties in the first half of 2006 in determining fair value for purposes of the stock options granted to employees shortly after the sales occurred.

Determining the fair value of our class A common stock required making complex and subjective judgments. Our approach to valuation was based on a discounted future cash flow approach that used our estimates of revenue, driven by assumed market growth rates, and estimated costs as well as appropriate discount rates. These estimates were consistent with the plans and estimates that we used to manage our business. There was inherent uncertainty in making these estimates.

Income Taxes

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. We follow SFAS No. 109, *Accounting for Income Taxes.* This process requires us to estimate our actual current tax exposure while assessing our temporary differences resulting from the differing treatment of items, such as deferred revenue, for tax and accounting purposes. These differences have resulted in deferred tax assets and liabilities, which are included in our consolidated balance sheets. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We consider forecasted earnings, future taxable income, the mix of earnings in the jurisdictions in which we operate, and prudent and feasible tax planning strategies in determining the need for a valuation allowance. Considerable judgment is involved in developing such estimates. In the event we were to determine that we would not be able to realize all or part of our net deferred tax assets in the future, we would charge an adjustment to earnings for the deferred tax assets in the period in which we make that determination. Likewise, if we later determine that it is more likely than not that the net deferred tax assets would be realized, we would reverse the applicable portion of the previously provided valuation allowance. In order for us to realize our deferred tax assets we must be able to generate sufficient taxable income in the tax jurisdictions in which our deferred tax assets are located.

Significant judgment is required in determining the provision for income taxes and, in particular, any valuation allowance recorded against our deferred tax assets. We recorded a valuation allowance of $5.7 million and $10.8 million as of December 31, 2008 and 2007, respectively, which resulted in a net deferred tax asset of $5.0 million and $639,000 as of December 31, 2008 and 2007, respectively. The increase in the net deferred tax asset is due primarily to the reversal of valuation allowance on the remaining net deferred tax assets in the United States. Significant future events, including continued success in commercialization of products in U.S. markets, regulatory approvals for products in international markets, not in our control could affect our future earnings potential and consequently the amount of deferred tax assets that will be utilized. We determined the amount of the valuation allowance based on our estimates of income in the jurisdictions in which we operate over the periods in which the related deferred tax assets are recoverable.

As of December 31, 2008, we had foreign net operating loss carry forwards of $14.4 million. The foreign net operating loss carry forwards will begin to expire on December 31, 2011.

On January 1, 2007, we adopted Financial Accounting Standards Board, or FASB, Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48. FIN 48 requires application of a more likely than not threshold to the recognition and derecognition of uncertain tax positions. If the recognition threshold is met, FIN 48 permits us to recognize a tax benefit measured at the largest amount of the tax benefit that, in our judgment, is more than 50 percent likely to be realized upon settlement.

We have recorded a non-current income tax liability of $517,000 for uncertain tax positions as of December 31, 2008. The amount represents the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in our consolidated financial statements, and are reflected in other liabilities in the accompanying consolidated balance sheets. The liability for uncertain tax positions as of December 31, 2008 mainly pertains to our interpretation of nexus in certain states related to certain revenue sources for state income tax purposes.

We recognize interest and penalties accrued related to uncertain tax positions as a component of the income tax provision. There were no interest and penalties recorded in 2008. We have identified no uncertain tax position for which it is reasonably possible that the total amount of liability for unrecognized tax benefits will significantly increase or decrease within 12 months, except for recurring accruals on existing uncertain tax positions.

We are still open to examination by tax authorities from 2005 forward, although research and experimentation tax attributes that were generated prior to 2005 may still be adjusted upon examination by tax authorities. We are currently under examination for 2005, 2006 and 2007 by the U.S. tax authorities.

Related Party Transactions

As part of our operations, we enter into transactions with our affiliates. At the time of the transaction, we estimate the fair market value of the transaction based upon estimates of net present value or comparable third party information. For material transactions with our foreign subsidiaries and affiliates, we have evaluated the terms of transactions similar to those that would have prevailed had the entities not been affiliated.

Founders' Awards

On June 19, 2007, the Compensation Committee of our board of directors authorized a one-time stock and cash award to each of our founders, Drs. Ueno and Kuno. These awards were granted on June 29, 2007 when the founders agreed to their terms and were settled on August 2, 2007 upon the effectiveness of our initial public offering. The Compensation Committee intended for these awards to compensate the founders for the lost value of stock options that had been granted to them in 2001 and 2002 and had been understood by them to have ten-year terms, but which had expired in 2006 and early 2007 as a result of the terms of our 2001 stock incentive plan. The expired options would have entitled the founders to purchase an aggregate of 578,000 shares of class A common stock at a price of $0.21 per share and 136,000 shares at a price of $2.95 per share. These awards were fully vested at the grant date.

Upon the completion of the initial public offering, these stock and cash awards had an aggregate value equal to the difference between the value of the shares that could have been purchased under each of the expired options, determined on the basis of the public offering price per share of $11.50 in the initial public offering, and the respective aggregate exercise prices for such shares as provided in the option agreements.

These awards consisted of a combination of cash and shares of class A common stock. Of the aggregate value of each award, 40% was payable in cash and 60% in stock. For purposes of determining the number of shares of class A common stock to be issued in connection with each award, the stock was valued on the basis of the public offering price per share in the initial public offering.

We determined the estimated fair value of these founders' awards, totaling $10.2 million on grant date, using the Black-Scholes-Merton option pricing formula, as allowed under SFAS 123(R). For the six months ended June 30, 2007, we recorded $10.2 million of general and administrative expense for these awards, of which $4.1 million was recorded as other liabilities — related parties for the cash settlement portion and $6.1 million as additional paid-in capital for the stock settlement portion. The liability portion of the awards would then be adjusted based upon the final cash settlement amount, but the equity portion was fixed upon the grant date.

When the initial public offering was completed in August 2007, the awards were settled and 401,133 shares of class A common stock were issued to the founders. In addition, as a result of the lower public offering price compared to the estimated public offering price at June 30, 2007, we recorded an adjustment of $1.0 million to reduce the amount of expense and related cash portion of the awards, which was paid to the founders.

Results of Operations

Comparison of years ended December 31, 2008 and December 31, 2007

Revenues

The following table summarizes our revenues for the years ended December 31, 2008 and 2007:

	Year Ended December 31,	
(In thousands)	**2008**	**2007**
Research and development revenue	$ 72,293	$ 59,379
Product royalty revenue	34,438	27,536
Co-promotion revenue	4,826	4,411
Contract and collaboration revenue	566	565
Total	$ 112,123	$ 91,891

Total revenues were $112.1 million in 2008 compared to $91.9 million in 2007, an increase of $20.2 million or 22.0%.

Research and development revenue

Research and development revenue was $72.3 million in 2008 compared to $59.4 million in 2007, an increase of $12.9 million or 21.7%. This increase was primarily the result of the $50.0 million research and development milestone payment earned from Takeda in 2008 upon the FDA's approval of the sNDA of Amitiza for irritable bowel syndrome with constipation as compared to the $30.0 million development milestone payment earned in 2007 when the sNDA was filed, partially offset by a reduction in research and development revenue related to reimbursements for certain ongoing trials during the year ended December 31, 2008.

The research and development revenue for 2008 of $22.3 million as reimbursement from Takeda relates to the following three ongoing activities during the year: post-marketing studies to evaluate the safety of Amitiza in patients with renal and hepatic impairment, phase 4 clinical trials of Amitiza for the treatment of chronic idiopathic constipation in pediatric patients and clinical trials of Amitiza for the treatment of opioid-induced bowel dysfunction. The research and development revenue in 2007 includes $21.7 million towards cost reimbursement for research and development payments from Takeda and $7.7 million in upfront payments and additional milestone payments associated with the completion of development of Amitiza which were recognized ratably over the performance period which was completed in June 2007.

Product royalty revenue

Product royalty revenue represents royalty revenue we earned from Takeda on net sales of Amitiza. In 2008, we recognized $34.4 million of product royalty revenue compared to $27.5 million in 2007, an increase of $6.9 million or 25.1%, reflecting increased sales of Amitiza. The increase reflects the continuing acceptance by patients and physicians of Amitiza 24 mcg for the treatment of chronic idiopathic constipation in adults and sales of Amitiza 8 mcg for irritable bowel syndrome with constipation in adult women, which became available in the second quarter of 2008.

Co-promotion revenue

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force and costs associated with miscellaneous marketing activities in connection with the commercialization of Amitiza. In 2008, we recognized $4.8 million of co-promotion revenues towards reimbursement of sales force costs. In 2007, we recognized $4.4 million as co-promotion revenues, of which approximately $0.1 million was for reimbursement of costs for miscellaneous marketing activities and $4.3 million was for reimbursement of sales force costs.

Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2008 and 2007:

	Year Ended December 31,	
(In thousands)	**2008**	**2007**
Direct costs:		
Amitiza	$ 33,303	$ 23,758
Cobiprostone	4,648	4,398
SPI — 017	4,377	1,961
Other	1,625	(36)
Total	43,953	30,081
Indirect costs	2,228	1,616
Total	$ 46,181	$ 31,697

Total research and development expenses in 2008 were $46.2 million compared to $31.7 million in 2007, an increase of $14.5 million or 45.7%. These costs primarily reflect our ongoing clinical development programs of Amitiza for the treatment of opioid-induced bowel dysfunction and chronic idiopathic constipation in Japan and cobiprostone for the treatment of non-steroidal anti-inflammatory drug-induced ulcers and portal hypertension in patients with liver cirrhosis, as well as preclinical and basic development costs associated with SPI-017. In 2008, we also incurred filing and data purchase costs of approximately $2.5 million, which were necessary to submit our European MAAs for lubiprostone, 24 micrograms, for the indication of chronic idiopathic constipation in adults.

General and Administrative Expenses

The following summarizes our general and administrative expenses for years ended December 31, 2008 and 2007:

	Year Ended December 31,	
(In thousands)	**2008**	**2007**
Salaries, benefits and related costs	$ 4,315	$ 4,092
Legal and consulting expenses	2,900	2,967
Stock-based compensation	199	47
Founders' stock-based awards	—	9,188
Lease loss	172	432
Other operating expenses	6,814	4,697
Total	$ 14,400	$ 21,423

General and administrative expenses were $14.4 million in 2008 compared to $21.4 million in 2007, a decrease of $7.0 million or 32.8%. The decrease in the general and administrative expenses for 2008 was primarily the result of the absence of an expense of $9.2 million that was recorded in 2007 for a one-time cash and stock-based award granted to our founders for stock options previously granted and terminated, offset by an increase in expenses associated with our new office space in the United States and an increase in overall cost associated with the compliance and regulatory requirements of being a publicly traded company with international operations.

Selling and Marketing Expenses

Selling and marketing expenses represent costs we incur to co-promote Amitiza, including salaries, benefits and related costs for our sales force and other sales and marketing personnel, costs of market research and analysis and other selling and marketing expenses. Selling and marketing expenses were $10.9 million in 2008 compared to $13.5 million in 2007, a decrease of $2.6 million or 19.1%. This decrease was primarily due to reduced marketing expense in the long term care market and cost savings related to utilization of our own internal dedicated sales force to provide Amitiza to patients in long-term care facilities, medical schools and university hospitals.

Product Royalties — Related Parties

Product royalties — related parties expense represent royalty payments to our affiliate Sucampo AG based on net sales of Amitiza. In 2008, our product royalty expense was $6.0 million compared to $4.9 million in 2007, an increase of $1.1 million, or 23.6%, which was consistent with the increase of product royalty revenue of 25.1%.

Milestone Royalties — Related Parties

Milestone royalties — related parties expense was $3.5 million in 2008 compared to $2.0 million in 2007, a decrease of $1.5 million, or 76.6%. In 2008, we paid Sucampo AG a $1.0 million milestone in connection with our European MAA's filed in February 2008. As a result of our sNDA approval for Amitiza to treat irritable bowel syndrome with constipation, we paid SAG $2.5 million, reflecting 5% of the $50.0 million development milestone payment that we received from Takeda in May 2008. In 2007, we paid Sucampo AG $1.5 million reflecting the 5%

we owed them for the $30.0 million development milestone earned from Takeda during that period and a $0.5 million milestone for the initiation of a phase 2 trial in Japan.

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the years ended December 31, 2008 and 2007:

(In thousands)	Year Ended December 31, 2008	2007
Interest income	$ 2,442	$ 2,465
Other (expense) income, net	(399)	151
Total non-operating income, net	$ 2,043	$ 2,616

Interest income during 2008 and 2007 remained flat as interest earned on higher investment balances during 2008 as compared to 2007 was offset by a decrease in yield earned by our investments during 2008 as interest rates declined generally and as the mix of our investment portfolio moved from ARS to lower interest rate U.S. government securities during the year.

Other expenses primarily include an unrealized loss of $3.2 million on trading securities offset by a $2.8 million unrealized gain on settlement rights on our investments in auction rate securities.

Income Taxes

For the years ended December 31, 2008 and 2007, our consolidated effective tax rate was 24.7% and 37.3%, respectively. For the years ended December 31, 2008 and 2007, we recorded a tax provision of $8.2 million and $7.8 million, respectively. The decrease in the effective tax rate in 2008 from 2007 was attributable to the release of valuation allowance on our U.S. deferred tax assets largely due to the recognition of $50.0 million in development milestone revenue during 2008, as well as an increase in projected profits in the United States. As of December 31, 2008, our remaining valuation allowance against our deferred tax assets was $5.7 million solely relating to foreign jurisdictions.

Comparison of years ended December 31, 2007 and December 31, 2006

Revenues

The following table summarizes our revenues for the years ended December 2007 and 2006:

(In thousands)	Year Ended December 31, 2007	2006
Research and development revenue	$ 59,379	$ 46,382
Product royalty revenue	27,536	6,590
Co-promotion revenue	4,411	4,243
Contract and collaboration revenue	565	2,051
Total	$ 91,891	$ 59,266

Total revenues were $91.9 million in 2007 compared to $59.3 million in 2006, an increase of $32.6 million, or 55.0%. This increase was primarily due to an increase in payments received from Takeda for research and development services performed by us and product royalties from Amitiza sales.

Research and development revenue was $59.4 million in 2007 compared to $46.4 million in 2006, an increase of $13.0 million, or 28.0%. This increase was due to the recognition of the $30.0 million research and development milestone payment for the completion of our development of Amitiza to treat chronic idiopathic constipation and irritable bowel syndrome with constipation and the recognition of payments previously received from Takeda,

offset in part by a decline of $17.0 million of research and development revenue reflecting the recognition of Amitiza -related deferred revenue previously received from Takeda for only six months in 2007 compared with twelve months in 2006. We recognized revenue for this development work ratably over the estimated performance period associated with the development of Amitiza, which was completed in June 2007.

The specific revenue streams associated with research and development revenue for the years ended December 31, 2007 and 2006 were as follows:

- In October 2004, we received an up-front payment of $20.0 million from Takeda, of which $17.6 million was associated with the development of Amitiza. This amount was recognized ratably over the estimated performance period, resulting in $2.0 million and $6.2 million of research and development revenue in 2007 and 2006, respectively. The smaller amount of revenue recognized in 2007 is a result of the inclusion in 2006 of a full year of revenue recognition compared to 2007, which only included revenue recognition through the first six months. It also reflects our determination in June 2006 to extend the estimated completion of the development period to June 2007, which had the effect of spreading out the remaining revenue over a longer period of time with a smaller amount thus being recognized after that point in each reporting period.
- In March and May 2005, we received development milestone payments from Takeda totaling $30.0 million related to our efforts to develop Amitiza. We recognized these payments as research and development revenue ratably over the performance period, resulting in $3.4 million of research and development revenue in 2007 and $10.5 million in 2006. The smaller amount of revenue recognized in 2007 is a result of a full year of revenue recognized in 2006 compared to a partial year of revenue recognized in 2007, reflecting the completion of the development period in June 2007.
- In January 2006, we received a $20.0 million development milestone payment from Takeda related to our efforts to develop Amitiza, which we recognized as research and development revenue ratably over the performance period, resulting in $2.2 million of research and development revenue in 2007 and $17.8 million in 2006. We recognized a significant portion of this milestone payment in the three months ended March 31, 2006, the quarter in which it was received, reflecting the fact that we were then well into the estimated development period. The smaller amount of revenue recognized in 2007 is a result of a full year of revenue recognized in 2006 compared to a partial year of revenue recognized in 2007, reflecting the completion of the development period in June 2007.
- Since inception of our agreement with Takeda, we have received a total of $30.0 million of reimbursement payments for research and development costs from Takeda related to our efforts to develop Amitiza, which we recognized as research and development revenue ratably over the performance period, resulting in $3.4 million of research and development revenue in 2007 and $10.5 million in 2006. The smaller amount of revenue recognized in 2007 is a result of the full year of revenue recognition in 2006 and also reflects our determination in June 2006 to extend the estimated completion of the development period to June 2007.
- We also began to perform services and receive payments from Takeda during the third quarter of 2006 for the following three deliverables: post-marketing studies to evaluate the safety of Amitiza in patients with renal impairment and patients with hepatic impairment, phase 4 clinical trials of Amitiza for the treatment of chronic idiopathic constipation in pediatric patients and clinical trials of Amitiza for the treatment of opioid-induced bowel dysfunction. Total research and development revenue associated with these three deliverables in 2007 and 2006 was $18.3 million and $1.1 million, respectively.

We began to recognize product royalty payments from Takeda as revenue in the second quarter of 2006 following the product launch of Amitiza. In 2007, we recognized $27.5 million of product royalty revenue compared to $6.6 million in 2006, reflecting increased sales of Amitiza.

We began to receive reimbursement of costs for our sales force in the second quarter of 2006 following the product launch of Amitiza. In 2007, we recognized $4.4 million of co-promotion revenues, of which approximately $158,000 was for reimbursement of costs for miscellaneous marketing activities and approximately $4.3 million was for reimbursement of sales force costs. In 2006, we recognized $4.2 million as co-promotion revenues, of which approximately $291,000 was for reimbursement of costs for miscellaneous marketing activities and $3.5 million was for reimbursement of sales force costs.

Contract revenue — related parties represents reimbursement of costs incurred by us on behalf of affiliated companies for research and development consulting, patent maintenance and certain administrative costs. These revenues are recognized in accordance with the terms of the contract or project to which they relate. We had no contract revenue in 2007 compared to $1.5 million in 2006. Contract revenue represents amounts released from previously deferred revenue that we recognized upon the expiration in January 2006 of the option we had previously granted to Takeda for joint development and commercialization rights for Amitiza in Europe, Africa and the Middle East.

Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2007 and 2006:

	Year Ended December 31,	
(In thousands)	**2007**	**2006**
Direct costs:		
Amitiza	$ 23,758	$ 13,757
Cobiprostone	4,398	903
SPI-017	1,961	3,290
Other	(36)	211
Total	30,081	18,161
Indirect costs	1,616	1,043
Total	$ 31,697	$ 19,204

Total research and development expenses in 2007 were $31.7 million compared to $19.2 million in 2006, an increase of $12.5 million or 65.1%. The higher costs in 2007 reflect the significant research and development expenses incurred by us during that period in connection with the filing of the sNDA for the treatment of irritable bowel syndrome with constipation; the initiation of post-marketing safety studies in pediatric patients, in patients with renal impairment and in patients with hepatic impairment; the initiation of phase 3 studies for opioid-induced bowel dysfunction; and the initiation of a phase 2 study of NSAID-induced ulcers. In 2006, our research and development expenses were primarily those associated with the ongoing phase 3 clinical trials of Amitiza for the treatment of irritable bowel syndrome with constipation. In September 2007, we enrolled our first patient in a phase 3 study for opioid-induced bowel dysfunction and our first patient in a multi-center phase 2 study of NSAID-induced ulcers.

General and Administrative Expenses

The following summarizes our general and administrative expenses for years ended December 31, 2007 and 2006:

	Year Ended December 31,	
(In thousands)	**2007**	**2006**
Salaries, benefits and related costs	$ 4,092	$ 2,730
Legal and consulting expenses	2,967	3,357
Stock-based compensation	47	2,708
Founders' stock-based awards	9,188	—
Lease loss	432	—
Other operating expenses	4,697	2,904
Total	$ 21,423	$ 11,699

General and administrative expenses were $21.4 million in 2007 compared to $11.7 million in 2006, an increase of $9.7 million or 83.1%. This increase was due primarily to the founders' stock-based award of $9.2 million granted in June 2007, comprising of $6.1 million non-cash compensation expense and $3.1 million in cash settlement expense, offset in part by the decline in stock-based compensation expenses from the $2.7 million recorded in the prior year. This increase also reflected increases in operational headcount, rent for additional leased office space, lease loss related to the abandonment of our former office in Bethesda, Maryland in 2007 and additional costs associated with being a publicly-traded company.

We recorded a cumulative out-of-period adjustment of approximately $358,000 in 2007 to reduce an overstatement of additional paid-in capital and general administrative expenses that had been recorded as of and for the year ended December 31, 2006 in connection with employee stock options awarded in 2006. The error resulted from applying the incorrect contractual term for to the employee stock options. The impacts of this adjustment were not material to the consolidated financial statements for the year ended December 31, 2006, for the corresponding interim periods or for the period in which it was recorded, as the adjustment consisted of insignificant amounts related to each of the quarterly reporting periods dating back to the quarter ended September 30, 2006.

Selling and Marketing Expenses

Selling and marketing expenses were $13.5 million in 2007 compared to $11.2 million in 2006, an increase of $2.3 million or 20.5%. This increase was due to increased costs for market research and analysis, marketing and promotional materials and other costs, reflecting the operation of our sales and marketing function for twelve months in 2007 compared to only nine months in 2006.

Product Royalties — Related Parties

We began to incur product royalty expenses for net sales of Amitiza in the second quarter of 2006 following the product launch of Amitiza. In 2007, we expensed $4.9 million in product royalties — related parties compared to $1.2 million in 2006, reflecting higher product sales in 2007.

Milestone Royalties — Related Parties

Milestone royalties — related parties expense were $2.0 million and $1.3 million in 2007 and 2006, respectively. These royalties were paid to Sucampo AG, reflecting the 5% we owed them for the $30.0 million development milestone earned from Takeda during that period and a $500,000 milestone for the initiation of a phase 2 trial in Japan. The milestone royalties — related parties of $1.3 million for the year ended December 31, 2006 were paid to Sucampo AG, reflecting the 5% we owed them for the $20.0 million development milestone payment we received from Takeda during that period, and a $250,000 milestone payment for regulatory approval of Amitiza.

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the years ended December 31, 2007 and 2006:

	Year Ended December 31,	
(In thousands)	**2007**	**2006**
Interest income	$ 2,465	$ 1,976
Other (expense) income, net	151	165
Total non-operating income, net	$ 2,616	$ 2,141

Interest income was $2.5 million in 2007 compared to $2.0 million in 2006, an increase of $0.5 million or 22.2%. The increase was primarily due to an increase in the funds available for investment as a result of our receipt of development milestone payments from Takeda in June 2007 and the closing of our initial public offering in

August 2007. Interest expense was nil in 2007 compared to $90,000 in 2006, a decrease of $90,000. This decrease reflected our repayment in full in June 2006 of related party debt instruments.

Income Taxes

For the years ended December 31, 2007 and 2006, our consolidated effective tax rate was 37.3% and 29.0%, respectively. We recorded a tax provision of $7.8 million for 2007 and a tax benefit of $4.9 million for 2006. The increase in the effective tax rate in 2007 from 2006 was due to a partial release of the valuation allowance on the U.S. deferred tax assets in 2006 that did not recur in 2007. As of December 31, 2007, our remaining valuation allowance against our deferred tax assets was $10.8 million.

Reportable Geographic Segments

We have determined that we have three reportable geographic segments based on our method of internal reporting, which disaggregates business by geographic location. These segments are the United States, Europe and Japan. We evaluate the performance of these segments on the basis of income from operations. The following is a summary of financial information by reportable segment.

(In thousands)	United States	Europe	Japan	Intercompany Eliminations	Consolidated
Year Ended December 31, 2008					
Total revenues	$ 112,123	$ —	$ 840	$ (840)	$ 112,123
Income (loss) from operations	39,875	(3,499)	(5,305)	—	31,071
Identifiable assets	163,660	568	4,469	(17,903)	150,794
Year Ended December 31, 2007					
Total revenues	$ 91,891	$ —	$ 840	$ (840)	$ 91,891
Income (loss) from operations	21,681	(1,127)	(2,155)	8	18,407
Identifiable assets	114,490	2,381	1,987	(8,831)	110,027
Year Ended December 31, 2006					
Total revenues	$ 57,676	$ 1,500	$ 161	$ (71)	$ 59,266
Income (loss) from operations	13,974	980	(190)	(1)	14,763
Identifiable assets	68,943	496	2,556	(4,899)	67,084

Liquidity and Capital Resources

Sources of Liquidity

We require cash principally to meet our operating expenses. Historically, we have financed our operations with a combination of up-front payments, milestone and royalty payments and research and development expense reimbursements received from Takeda and other parties, private placements of equity securities and our initial public offering.

Our cash, cash equivalents and investments consist of the following:

(In thousands)	December 31, 2008	December 31, 2007
Cash and cash equivalents	$ 11,536	$ 25,559
Investments, current	93,776	51,552
Investments, non-current	16,222	9,400
	$ 121,534	$ 86,511

Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity at time of purchase of 90 days or less.

As of December 31, 2008, our short term investments consist of money market funds, U.S. Treasury notes and bills which have short term maturities. Our non-current investments primarily consist of investments in ARS.

ARS are long-term debt instruments that provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined calendar intervals, generally every seven to 49 days. This mechanism generally allows existing investors to roll-over their holdings and continue to own their respective securities or liquidate their holdings by selling their securities at par value. The disruption of liquidity in short-term fixed income markets resulting in failed auctions prevented us from liquidating certain holdings of ARS during the year.

During October 2008, we accepted the settlement rights offer from the broker UBS, AG of our ARS. This right permits us to require UBS to purchase our ARS at par value between June 30, 2010 and July 2, 2012. We do not anticipate having to sell these securities in order to operate our business before the expected redemption dates.

To conserve cash and more closely align our spending towards our strategic objectives, we implemented cost reduction initiatives in early 2009, including a workforce reduction and a refocusing of our research and development plans. We expect these initiatives will result in reduced costs of approximately $3.0 million during 2009. However, there is no assurance that we will be successful in achieving these cost savings if actual spending varies from our budget, or that these cost savings will not hurt our business and our ability to pursue our development and commercialization strategies.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2008, 2007 and 2006:

	Year Ended December 31,		
(In thousands)	**2008**	**2007**	**2006**
Cash provided by (used in):			
Operating activities	$ 37,192	$ 5,649	$ (10,914)
Investing activities	(52,546)	(33,784)	(1,413)
Financing activities	878	31,341	17,421
Effect of exchange rates	453	(128)	(49)
Net increase (decrease) in cash and cash equivalents	$ (14,023)	$ 3,078	$ 5,045

Year ended December 31, 2008

Net cash provided by operating activities was $37.2 million for the year ended December 31, 2008. This reflected net income of $25.0 million, which included a non-cash unrealized loss on trading securities of $3.2 million, an increase in deferred revenue of $14.0 million offset by a non cash deferred tax benefit of $4.4 million, a non-cash unrealized gain on settlement rights on auction rate securities of $2.8 million and an increase in prepaid and income tax receivable and payable, net of $1.8 million. The increase in deferred revenue primarily related to the prepayments received from Takeda towards research and development expense reimbursement and $3.9 million of additional deferral of revenue due to change in the estimated development period of Amitiza for opioid-induced bowel dysfunction.

Net cash used in investing activities of $52.5 million for the year ended December 31, 2008 primarily reflected our net purchases of investments as a result of our investment of the $50.0 million milestone payment received from Takeda during the year.

Net cash provided by financing activities of $878,000 for the year ended December 31, 2008 resulted mainly from the exercise of stock options and proceeds from the employee stock purchase plan during the year.

Year ended December 31, 2007

Net cash provided by operating activities was $5.6 million for the year ended December 31, 2007. This reflected net income of $13.2 million, which included non-cash deferred tax provision of $4.3 million and non-cash

stock-based compensation of $6.7 million, offset by an increase in product royalties receivable of $6.6 million and in accounts receivable of $5.9 million and a decrease in deferred revenue of $11.0 million. The decrease in deferred revenue primarily related to the amortization of deferred research and development revenue over the performance period of the development of Amitiza.

Net cash used in investing activities was $33.8 million for the year ended December 31, 2007. This primarily reflected our purchases of short-term investments and of property and equipment associated with the move of our offices in the United States in July 2007 offset by proceeds from the sale of short-term investments.

Net cash provided by financing activities was $31.3 million for the year ended December 31, 2007. This reflected the net proceeds from the issuance of class A common stock in our initial public offering, which was consummated in August 2007. We had prepaid $3.1 million of offering expenses prior to 2007.

Year ended December 31, 2006

Net cash used in operating activities was $10.9 million for the year ended December 31, 2006. This reflected net income of $21.8 million, which included a non-cash charge of $3.3 million of stock-based compensation expense. We also had a decrease in deferred tax provision of $4.0 million and a decrease in deferred revenue of $26.8 million. The decrease in deferred revenue primarily related to the amortization of deferred research and development revenue over the performance period of the development of Amitiza.

Net cash used in investing activities was $1.4 million for the year ended December 31, 2006. This reflected our purchases of short-term investments and property and equipment of $2.5 million, offset in part by proceeds received from sales and maturities of short-term investments of $1.3 million.

Net cash provided by financing activities was $17.4 million for the year ended December 31, 2006. This reflected $23.9 million in net proceeds raised in a private placement sale of 2,398,759 shares of class A common stock, $1.2 million in funds received from borrowings under related party debt instruments, $2.9 million of payments incurred for our completed initial public offering and $4.8 million of repayments under related party debt instruments.

Commitments and Contingencies

As of December 31, 2008, our principal outstanding contractual obligations related to our office leases in Bethesda, Maryland, England and Japan. The following table summarizes these significant contractual obligations at December 31 for the indicated year:

(In thousands)	
2009	$ 1,537
2010	1,051
2011	938
2012	963
2013	992
2014 and thereafter	3,297
Total minimum lease payments	$ 8,778

The above table does not include:

- Contingent milestone and royalty obligations under our license agreement with Sucampo AG to pay:
  - 5% of every milestone payment we receive from a sublicensee;
  - $500,000 upon initiation of the first phase 2 clinical trial for each compound in each of the three territories covered by the license;
  - $1.0 million for the first NDA filing or comparable foreign regulatory filing for each compound in each of these three territories covered by the license; and

- royalty payments ranging from 2.1% to 6.5% of net sales of products covered by patents licensed to us by Sucampo AG.

- Our share of research and development costs for Amitiza for the treatment of opioid-induced bowel dysfunction, which will not be reimbursed by Takeda. We expect to incur approximately $2.0 million of research and development costs in connection with the development of Amitiza.
- Expenses under agreements with contract research organizations for clinical trials of our product candidates. The timing and amount of these disbursements are based on a variety of factors, such as the achievement of specified milestones, patient enrollment, services rendered or the incurrence of expenses by the contract research organization. As a result, we estimate that as of December 31, 2008, our current commitments to contract research organizations will be $11.8 million during 2009 and 2010.

Funding Requirements

We will need substantial amounts of capital to continue growing our business. We will require this capital, among other things, to:

- fund our 30% share of the two post-marketing studies of Amitiza to evaluate its safety in patients with renal impairment and patients with hepatic impairment;
- fund regulatory efforts in Europe and Japan for Amitiza;
- fund development and regulatory activities for cobiprostone and SPI-017;
- fund research and development activities for prostone compounds other than Amitiza, cobiprostone and SPI-017;
- fund the expansion of our commercialization activities in the United States and the initiation of commercialization efforts in non-U.S. markets;
- fund costs for capital expenditures to support the growth of our business; and
- fund the purchase shares of Class A common stock up to $10.0 million, if we elect to do so, pursuant to our board-approved stock repurchase program.

The timing of these funding requirements is difficult to predict due to many factors, including the outcomes of our research and development programs and when those outcomes are determined, the timing of obtaining regulatory approvals and the presence and status of competing products. Our capital needs may exceed the capital available from our future operations, collaborative and licensing arrangements and existing liquid assets. Our future capital requirements and liquidity will depend on many factors, including, but not limited to:

- the revenue from Amitiza;
- the future expenditures we may incur to increase revenue from Amitiza;
- the cost and time involved to pursue our research and development programs;
- our ability to establish collaborative arrangements and to enter into licensing agreements and contractual arrangements with others; and
- any future change in our business strategy.

To the extent that our capital resources may be insufficient to meet our future capital requirements, we may need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements.

Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain

product candidates that we might otherwise seek to develop or commercialize independently. In addition, any future equity funding would dilute the ownership of our stockholders.

Effects of Foreign Currency

We currently incur a portion of our operating expenses in the United Kingdom and Japan. The reporting currency for our consolidated financial statements is U.S. Dollars. As such, our results of operations could be adversely affected by changes in exchange rates either due to transaction losses, which are recognized in the statement of operations, or translation losses, which are recognized in comprehensive income. We currently do not hedge foreign exchange rate exposure.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. SFAS 157 outlines a common definition of fair value and the new standard intends to make the measurement of fair value more consistent and comparable and improve disclosures about those measures. We adopted SFAS 157 as of January 1, 2008 for financial assets and liabilities that are subject to recurring fair value measurements and the adoption did not have a material impact on the consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 permits entities to measure many financial instruments and certain other assets and liabilities at fair value, with unrealized gains and losses related to these financial instruments reported in earnings at each subsequent reporting date. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We adopted SFAS 159 as of January 1, 2008 for measuring the fair value of settlement rights pursuant to the offer agreement with UBS on our investments in auction rate securities. As a result of this fair value adoption, we recorded $2.8 million as a non-current asset included within other assets in our consolidated balance sheets for the fair value of the settlement rights and the corresponding amount as a gain within other expense, net in the consolidated statements of operations and comprehensive income.

In June 2007, the Emergency Issue Task Force, or EITF, issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3, which provides guidance to research and development companies on how to account for the nonrefundable portion of an advance payment made for research and development activities. We adopted EITF 07-3 as of January 1, 2008 and there was no material impact upon its adoption.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, or SFAS 141(R), and SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of Accounting Research Bulletin No. 51*, or SFAS 160. SFAS 141(R) will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141(R) and SFAS 160 will be applied to acquisitions that close in years beginning after December 15, 2008. Early adoption is not permitted. SFAS 141(R) and SFAS 160 will not have any impact on our future consolidated financial statements unless we undertake an acquisition in the future.

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. The consensus prohibits the equity method of accounting for collaborative arrangements under APB 18, *The Equity Method of Accounting for Investments in Common Stock*, unless a legal entity exists. Payments between the collaborative partners will be evaluated and reported in the income statement based on applicable GAAP.

Absent specific GAAP, the participants to the arrangement will apply other existing GAAP by analogy or apply a reasonable and rational accounting policy consistently. The guidance in EITF 07-1 is effective for periods that begin after December 15, 2008 and will apply to arrangements in existence as of the effective date. The effect of the new consensus will be accounted for as a change in accounting principle through retrospective application. We are currently evaluating the potential impact, if any, of the adoption of EITF 07-1 on the consolidated financial statements.

In February 2008, the FASB issued Financial Staff Positions, or FSP, SFAS 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2, which delays the effective date of SFAS 157, for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. FSP 157-2 partially defers the effective date of SFAS 157 to fiscal years beginning after November 15, 2008. FSP 157-2 is effective for us beginning January 1, 2009. We are currently evaluating the potential impact, if any, of the adoption of FSP 157-2 on the consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States of America. SFAS 162 will be effective for fiscal years beginning after November 15, 2008. We are currently evaluating the potential impact, if any, of the adoption of SFAS 162 on the consolidated financial statements.

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset in a Market That is Not Active*, or FSP FAS 157-3. FSP FAS 157-3 clarifies the application of SFAS 157 in a market that is not active. FSP FAS 157-3 addresses how management should consider measuring fair value when relevant observable data does not exist. FSP FAS 157-3 also provides guidance on how observable market information in a market that is not active should be considered when measuring fair value, as well as how the use of market quotes should be considered when assessing the relevance of observable and unobservable data available to measure fair value. FSP 157-3 is effective upon issuance, for companies that have adopted SFAS No. 157. Revisions resulting from a change in the valuation technique or its application shall be accounted for as a change in accounting estimate in accordance with SFAS 154. The application of the provisions of FSP 157-3 did not materially impact our consolidated financial statements.

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

Foreign Exchange Risk

Our sales generally are denominated in U.S. Dollars and our expenses generally are denominated in the respective functional currencies, and are, therefore, not exposed materially to changes in foreign currency exchange rates.

Interest Rate Risk

Our exposure to market risks associated with changes in interest rates relates primarily to the increase or decrease in the amount of interest income earned on our investment portfolio. We ensure the safety and preservation of invested funds by limiting default risks, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. A hypothetical one percentage point decline in interest rates would not have materially affected the fair value of our interest-sensitive financial instruments as of December 31, 2008.

We do not use derivative financial instruments for trading or speculative purposes. However, we regularly invest excess cash in overnight repurchase agreements that are subject to changes in short-term interest rates. We believe that the market risk arising from holding these financial instruments is minimal.

Credit Risk

Our exposure to credit risk consists of cash and cash equivalents, restricted cash, investments and receivables. We place our cash and cash equivalents, restricted cash and investments with what we believe to be highly rated financial institutions. Our uninsured cash, cash equivalents and investments as of December 31, 2008 consist primarily of $42.7 million of U.S. Treasury and notes, $18.9 million of money market funds guaranteed under the

U.S. Treasury's Temporary Guarantee Program and $32.2 million of other money market funds. We have not experienced any losses on these accounts related to amounts in excess of insured limits.

(In thousands)	December 31, 2008
Cash and cash equivalents	$ 11,536
Investments	109,998
Restricted cash	213
Less: amounts subject to federally insured limits	(3,099)
Total amounts in excess of federally insured limits	$ 118,648

As of December 31, 2008, we had $16.2 million invested in ARS. These investments consist of AAA or A -rated non-mortgage related auction rate securities and are insured against loss of principal and interest by bond insurers. Recent uncertainties in the credit markets have prevented us from liquidating certain holdings of auction rate securities during 2008. Pursuant to the acceptance of settlement rights offered by our broker, we have the right to require the redemption of all of our outstanding investments in auction rate securities at par value at any time during the two-year period beginning June 30, 2010. In addition, given the complexity of auction rate securities and their valuations, our estimates of their fair value may differ from the actual amount we would be able to collect at the time of redemption under the settlement right offer or ultimate sale.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

The consolidated financial statements and related financial statement schedules required by this item are included beginning on page F-1 of this report.

ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***

None.

ITEM 9A. ***CONTROLS AND PROCEDURES***

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of December 31, 2008. In designing and evaluating such controls, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer has concluded that, as of December 31, 2008, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified under applicable rules of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended) for the Company. Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control-Integrated Framework.* Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2008.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Ryuji Ueno, M.D., Ph.D., Ph.D.
Chief Executive Officer, Chief Scientific Officer and Chairman of the Board of Director (Principal Executive Officer)

Jan Smilek
Vice President, Finance and Chief Financial Officer (Principal Accounting Officer)

ITEM 9B. ***OTHER INFORMATION***

None.

PART III

ITEM 10. ***DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

The information regarding our executive officers required by this item will be set forth under Item 1 to this Annual Report on Form 10-K.

The following information will be included in our proxy statement to be filed within 120 days after the fiscal year end of December 31, 2008, and is incorporated herein by reference:

- Information regarding our directors required by this item will be set forth under the heading "Election of Directors";
- Information regarding our Audit Committee and designated "audit committee financial experts" will be set forth under the heading "Corporate Governance Principles and Board Matters, Board Structure and Committee Composition — Audit Committee;" and
- Information regarding Section 16(a) beneficial ownership reporting compliance will be set forth under the heading "Section 16(a) Beneficial Ownership Reporting Compliance."

Code of Ethics

We have adopted a code of ethics and business conduct that applies to our employees, including our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. Our code of ethics and business conduct can be found posted in the investor relations section on our website at http://www.sucampo.com.

ITEM 11. ***EXECUTIVE COMPENSATION***

The information required by this item is incorporated by reference to the information provided under the heading "Executive Compensation" of the Proxy Statement.

ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

The information required by this Item is incorporated by reference to the information provided under the heading "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" of the Proxy Statement.

ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE***

The information required by this item is incorporated by reference to the information provided under the heading "Certain Relationships and Related Transactions" of the Proxy Statement.

ITEM 14. ***PRINCIPAL ACCOUNTING FEES AND SERVICES***

The information required by this item is incorporated by reference to the information provided under the heading "Principal Accounting Fees and Services" of the Proxy Statement.

PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENT SCHEDULE***

(a) The following financial statements, financial statement schedule and exhibits are filed as part of this report or incorporated herein by reference:

(1) Consolidated Financial Statements. See index to consolidated financial statements on page F-1.

(2) Financial Statement Schedule: Schedule II — Valuation and Qualifying Accounts on page F-39. All other schedules are omitted because they are not applicable, not required or the information required is shown in the financial statements or notes thereto.

(3) Exhibits. See subsection (b) below.

(b) Exhibits. The following exhibits are filed or incorporated by reference as part of this report.

Exhibit Number	Description	Reference
2.1	Agreement and Plan of Reorganization	Exhibit 2.1 to the Company's Current Report on Form 8-K (filed December 29, 2008)
3.1	Certificate of Incorporation	Exhibit 3.1 to the Company's Current Report on Form 8-K (filed December 29, 2008)
3.2	Certificate of Amendment	Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2008)
3.3	Restated Bylaws	Exhibit 3.3 to the Company's Current Report on Form 8-K (filed December 29, 2008)
4.1	Specimen Stock Certificate evidencing the shares of class A common stock	Exhibit 4.1 to Registration Statement No. 333-135133, Amendment No. 5 (filed February 1, 2007)
10.1^	Amended and Restated 2001 Stock Incentive Plan	Exhibit 10.1 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.2^	Amended and Restated 2006 Stock Incentive Plan	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (filed November 14, 2007)
10.3^	2006 Employee Stock Purchase Plan	Exhibit 10.3 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.4^	Form of Incentive Stock Option Agreement for 2006 Stock Incentive Plan	Exhibit 10.4 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.5^	Form of Nonstatutory Stock Option Agreement for 2006 Stock Incentive Plan	Exhibit 10.5 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.6^	Form of Restricted Stock Agreement for 2006 Stock Incentive Plan	Exhibit 10.6 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.7^	Non-employee Director Compensation Summary	Exhibit 10.7 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.8^	Employment Agreement, dated June 16, 2006, between the Company and Ryuji Ueno	Exhibit 10.9 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.9^	Form of Executive Employment Agreement	Exhibit 10.10 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.10	Indemnification Agreement, dated May 26, 2004, between the Company and Sachiko Kuno	Exhibit 10.11 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.11	Indemnification Agreement, dated May 26, 2004, between the Company and Ryuji Ueno	Exhibit 10.12 to Registration Statement No. 333-135133, (filed June 19, 2006)

Exhibit Number	Description	Reference
10.12	Indemnification Agreement, dated May 26, 2004, between the Company and Michael Jeffries	Exhibit 10.13 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.13	Indemnification Agreement, dated May 26, 2004, between the Company and Hidetoshi Mine	Exhibit 10.14 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.14	Form of Investor Rights Agreement	Exhibit 10.16 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.15	Lease Agreement, dated September 16, 1998, between the Company and Plaza West Limited Partnership, successor in interest to Trizechahn Plaza West Limited Partnership, as amended	Exhibit 10.17 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.16	Sublease Agreement, dated October 26, 2005, between the Company and First Potomac Realty Investment L.P.	Exhibit 10.18 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.17	Amended and Restated Patent Access Agreement, dated June 30, 2006, among the Company, Sucampo Pharma Europe Ltd., Sucampo Pharma, Ltd. and Sucampo AG	Exhibit 10.19 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.18*	Exclusive Manufacturing and Supply Agreement, dated June 23, 2004, between the Company and R-Tech Ueno, Ltd., as amended on October 2, 2006	Exhibit 10.20 to Registration Statement No. 333-135133, Amendment No. 3 (filed October 25, 2006)
10.19*	Collaboration and License Agreement, dated October 29, 2004, between the Company and Takeda Pharmaceutical Company Limited	Exhibit 10.21 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.20*	Agreement, dated October 29, 2004, among the Company, Takeda Pharmaceutical Company Limited and Sucampo AG	Exhibit 10.22 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.21*	Supply Agreement, dated October 29, 2004, among the Company, Takeda Pharmaceutical Company Limited and R-Tech Ueno, Ltd.	Exhibit 10.23 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.22*	Supply and Purchase Agreement, dated January 25, 2006, among the Company, Takeda Pharmaceutical Company Limited and R-Tech Ueno, Ltd.	Exhibit 10.24 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.23*	Supplemental Agreement, dated February 1, 2006, between the Company and Takeda Pharmaceutical Company Limited	Exhibit 10.25 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.24*	Services Agreement, dated February 9, 2006, between the Company and Ventiv Commercial Services, LLC	Exhibit 10.26 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.25	Indemnification Agreement, dated September 7, 2006, between the Company and Timothy Maudlin	Exhibit 10.27 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.26	Indemnification Agreement, dated September 7, 2006, between the Company and Sue Molina	Exhibit 10.28 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.27*	Exclusive Manufacturing and Supply Agreement, dated June 24, 2005, between Sucampo Pharma Europe Ltd. and R-Tech Ueno, Ltd., as amended on October 2, 2006	Exhibit 10.29 to Registration Statement No. 333-135133, Amendment No. 3 (filed October 25, 2006)
10.28*	SPI-8811 and SPI-017 Exclusive Clinical Manufacturing and Supply Agreement, dated October 4, 2006, between the Company and R-Tech Ueno, Ltd.	Exhibit 10.31 to Registration Statement No. 333-135133, Amendment No. 3 (filed October 25, 2006)

Exhibit Number	Description	Reference
10.29	Lease Agreement, dated December 18, 2006, between the Company and EW Bethesda Office Investors, LLC	Exhibit 10.29 to the Company's Annual Report on Form 10-K (filed March 27, 2008)
10.30^	Amendment to Employment Agreement, dated November 20, 2006, between the Company and Ryuji Ueno	Exhibit 10.35 to Registration Statement No. 333-135133, Amendment No. 5 (filed February 1, 2007)
10.31	Letter agreement, dated January 29, 2007, between the Company and Takeda Pharmaceutical Company Limited	Exhibit 10.36 to Registration Statement No. 333-135133, Amendment No. 6 (filed May 14, 2007)
10.32^	Employment Agreement, effective June 1, 2007, between the Company and Sachiko Kuno	Exhibit 10.37 to Registration Statement No. 333-135133, Amendment No. 8 (filed July 17, 2007)
10.34	Indemnification Agreement, dated October 18, 2007, between the Company and Anthony C. Celeste	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (filed November 14, 2007)
10.38^	Amendment, dated December 6, 2007, to Employment Agreement between the Company and Gayle Dolecek	Exhibit 10.4 to the Company's Current Report on Form 8-K (filed December 14, 2007)
10.40^	Amendment, dated November 26, 2007, to Employment Agreement between the Company and Ryuji Ueno	Exhibit 10.6 to the Company's Current Report on Form 8-K (filed December 14, 2007)
10.41	Credit Line Agreement, dated March 5, 2008, between the Company and UBS Bank USA	Exhibit 10.41 to the Company's Current Report on Form 10-K (filed March 27, 2008)
10.42	Amended and Restated Patent Access Agreement, dated February 18, 2009, among the Company, Sucampo Pharma Europe, Ltd., Sucampo Pharma, Ltd. and Sucampo AG	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed February 19, 2009)
10.43*	Supply Agreement, dated February 19, 2009, between Sucampo Pharma Ltd and Abbott Japan Co. Ltd.	Included herewith
10.44*	Exclusive Manufacturing and Supply Agreement, dated February 23, 2009, between Sucampo Pharma, Ltd and R-Tech Ueno, Ltd.	Included herewith
10.45	Indemnification Agreement by and between the Company and Andrew J. Ferrara	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed July 22, 2008)
10.46	Separation Agreement and General Release by and between the Company and Mariam E. Morris	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed July 28, 2008)
10.47	Consulting Agreement by and between the Company and Mariam E. Morris	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed July 28, 2008)
21	Subsidiaries of the Company	Included herewith
23.1	Consent of PricewaterhouseCoopers LLC, Independent Registered Public Accounting Firm	Included herewith
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith

Exhibit Number	Description	Reference
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith

^ Compensatory plan, contract or arrangement.

* Confidential treatment has been requested for portions of this exhibit.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Sucampo Pharmaceuticals, Inc.

By: /s/ RYUJI UENO
Ryuji Ueno, M.D., Ph.D., Ph.D.
Chief Executive Officer,
Chief Scientific Officer and
Chairman of the Board of Directors

March 16, 2009

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ RYUJI UENO Ryuji Ueno, M.D., Ph.D., Ph.D.	Chief Executive Officer (Principal Executive Officer), Chief Scientific Officer and Director	March 16, 2009
/s/ JAN SMILEK Jan Smilek	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2009
/s/ ANTHONY C. CELESTE Anthony C. Celeste	Director	March 16, 2009
/s/ GAYLE R. DOLECEK Gayle R. Dolecek Ph.D.	Director	March 16, 2009
/s/ ANDREW J. FERRARA Andrew J. Ferrara	Director	March 16, 2009
/s/ SACHIKO KUNO Sachiko Kuno Ph.D.	Director	March 16, 2009
/s/ TIMOTHY I. MAUDLIN Timothy I. Maudlin	Director	March 16, 2009
/s/ V. SUE MOLINA V. Sue Molina	Director	March 16, 2009
/s/ JOHN C. WRIGHT John C. Wright	Director	March 16, 2009

SUCAMPO PHARMACEUTICALS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Sucampo Pharmaceuticals, Inc.

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Sucampo Pharmaceuticals, Inc. and its subsidiaries at December 31, 2008 and December 31, 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's report on internal control over financial reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our audits (which was an integrated audit in 2008). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland
March 16, 2009

SUCAMPO PHARMACEUTICALS, INC.

Consolidated Balance Sheets

(In thousands, except share data)	December 31, 2008	2007
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 11,536	$ 25,559
Investments, current	93,776	51,552
Product royalties receivable	9,725	8,667
Unbilled accounts receivable	4,373	5,883
Accounts receivable	878	1,525
Prepaid and income taxes receivable	133	1,922
Deferred tax assets, net	963	88
Prepaid expenses and other current assets	3,641	2,222
Total current assets	125,025	97,418
Investments, non-current	16,222	9,400
Property and equipment, net	2,275	2,265
Deferred tax assets, non-current, net	4,026	551
Other assets	3,246	393
Total assets	$ 150,794	$ 110,027
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 1,433	$ 3,313
Accrued expenses	9,764	8,730
Deferred revenue, current	15,599	1,062
Total current liabilities	26,796	13,105
Deferred revenue, net of current portion	8,061	8,626
Other liabilities	2,147	1,768
Total liabilities	37,004	23,499
Commitments		
Stockholders' equity:		
Preferred stock, $0.01 par value; 5,000,000 shares authorized at December 31, 2008 and 2007; no shares issued and outstanding at December 31, 2008 and 2007	—	—
Class A common stock, $0.01 par value; 270,000,000 shares authorized at December 31, 2008 and 2007; 15,651,849 and 15,538,518 shares issued and outstanding at December 31, 2008 and 2007, respectively	156	155
Class B common stock, $0.01 par value; 75,000,000 shares authorized at December 31, 2008 and 2007; 26,191,050 shares issued and outstanding at December 31, 2008 and 2007	262	262
Additional paid-in capital	98,243	96,680
Accumulated other comprehensive income (loss)	354	(393)
Retained earnings (accumulated deficit)	14,775	(10,176)
Total stockholders' equity	113,790	86,528
Total liabilities and stockholders' equity	$ 150,794	$ 110,027

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

SUCAMPO PHARMACEUTICALS, INC.

Consolidated Statements of Operations and Comprehensive Income

(In thousands, except per share data)	Year Ended December 31, 2008	2007	2006
Revenues:			
Research and development revenue	$ 72,293	$ 59,379	$ 46,382
Product royalty revenue	34,438	27,536	6,590
Co-promotion revenue	4,826	4,411	4,243
Contract and collaboration revenue	566	565	2,051
Total revenues	112,123	91,891	59,266
Operating expenses:			
Research and development	46,181	31,697	19,204
General and administrative	14,400	21,423	11,699
Selling and marketing	10,895	13,474	11,179
Milestone royalties — related parties	3,531	2,000	1,250
Product royalties — related parties	6,045	4,890	1,171
Total operating expenses	81,052	73,484	44,503
Income from operations	31,071	18,407	14,763
Non-operating income (expense):			
Interest income	2,442	2,465	1,976
Other expense, net	(399)	151	165
Total non-operating income, net	2,043	2,616	2,141
Income before income taxes	33,114	21,023	16,904
Income tax (provision) benefit	(8,163)	(7,833)	4,897
Net income	$ 24,951	$ 13,190	$ 21,801
Net income per share:			
Basic net income per share	$ 0.60	$ 0.35	$ 0.63
Diluted net income per share	$ 0.59	$ 0.35	$ 0.63
Weighted average common shares outstanding — basic	41,787	37,778	34,383
Weighted average common shares outstanding — diluted	41,973	38,226	34,690
Comprehensive income:			
Net income	$ 24,951	$ 13,190	$ 21,801
Other comprehensive income:			
Unrealized gain on investments, net of tax expense	79	—	—
Foreign currency translation	668	(99)	(200)
Comprehensive income	$ 25,698	$ 13,091	$ 21,601

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

SUCAMPO PHARMACEUTICALS, INC.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(In thousands, except share data)	Series A Convertible Preferred Stock		Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2005	3,780	$ 20,288	6,392,127	$ 64	26,191,050	$ 262	$ 14,407	$ (94)	$ (45,167)	$ (10,240)
Stock issued upon exercise of stock options	—	—	2,398,758	24	—	—	23,872	—	—	23,896
Exercise of 8,500 options for 8,500 shares of class A common stock	—	—	8,500	—	—	—	2	—	—	2
Foreign currency translation	—	—	—	—	—	—	—	(200)	—	(200)
Employee stock option expense	—	—	—	—	—	—	3,274	—	—	3,274
Net income	—	—	—	—	—	—	—	—	21,801	21,801
Balance at December 31, 2006	3,780	20,288	8,799,385	88	26,191,050	262	41,555	(294)	(23,366)	38,533
Stock issued upon exercise of stock options	—	—	3,125,000	31	—	—	28,191	—	—	28,222
Conversion of series A convertible preferred stock to class A common stock	(3,780)	(20,288)	3,213,000	32	—	—	20,256	—	—	—
Foreign currency translation	—	—	—	—	—	—	—	(99)	—	(99)
Employee stock option expense	—	—	401,133	4	—	—	6,678	—	—	6,682
Net income	—	—	—	—	—	—	—	—	13,190	13,190
Balance at December 31, 2007	—	—	15,538,518	155	26,191,050	262	96,680	(393)	(10,176)	86,528
Stock issued upon exercise of stock options	—	—	111,880	1	—	—	869	—	—	870
Employee stock option expense	—	—	—	—	—	—	686	—	—	686
Stock issued under Employee stock purchase plan	—	—	1,451	—	—	—	8	—	—	8
Foreign currency translation	—	—	—	—	—	—	—	668	—	668
Unrealized gain on investments, net of tax effect	—	—	—	—	—	—	—	79	—	79
Net income	—	—	—	—	—	—	—	—	24,951	24,951
Balance at December 31, 2008	—	$ —	15,651,849	$ 156	26,191,050	$ 262	$ 98,243	$ 354	$ 14,775	$ 113,790

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

SUCAMPO PHARMACEUTICALS, INC.

Consolidated Statements of Cash Flows

(In thousands)	Year Ended December 31, 2008	2007	2006
Cash flows from operating activities:			
Net income	$ 24,951	$ 13,190	$ 21,801
Adjustments to reconcile net income to net cash provided by (used in) operating activities:			
Depreciation and amortization	450	251	69
Loss on disposal of property and equipment	—	63	—
Deferred tax provision (benefit)	(4,401)	4,262	(4,035)
Stock-based compensation	686	6,682	3,274
Unrealized loss on trading securities	3,178	—	—
Unrealized gain on settlement rights on auction rate securities	(2,818)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	718	(23)	(813)
Product royalties receivable	(1,058)	(6,638)	(2,029)
Unbilled accounts receivable	1,510	(5,883)	—
Prepaid and income taxes receivable and payable, net	1,789	431	(4,007)
Accounts payable	(2,018)	924	437
Accrued expenses	1,074	3,341	3,023
Deferred revenue	13,972	(11,028)	(26,829)
Other assets and liabilities, net	(841)	77	(1,805)
Net cash provided by (used in) operating activities	37,192	5,649	(10,914)
Cash flows from investing activities:			
Purchases of investments	(172,705)	(88,647)	(2,309)
Proceeds from sales of investments	58,125	57,094	1,345
Maturities of investments	62,485	—	—
Purchases of property and equipment	(451)	(2,231)	(236)
Investments in restricted cash	—	—	(213)
Net cash used in investing activities	(52,546)	(33,784)	(1,413)
Cash flows from financing activities:			
Issuance of common stock, net of offering costs	—	31,341	23,896
Payments of initial public offering costs	—	—	(2,923)
Issuance of notes payable — related parties	—	—	1,200
Payments on notes payable — related parties	—	—	(4,754)
Proceeds from exercise of stock options	870	—	2
Proceeds from employee stock purchase plan	8	—	—
Net cash provided by financing activities	878	31,341	17,421
Effect of exchange rates on cash and cash equivalents	453	(128)	(49)
Net (decrease) increase in cash and cash equivalents	(14,023)	3,078	5,045
Cash and cash equivalents at beginning of year	25,559	22,481	17,436
Cash and cash equivalents at end of year	$ 11,536	$ 25,559	$ 22,481
Supplemental cash flow disclosures:			
Cash paid for interest	$ —	$ —	$ 86
Tax refunds received	$ 1,957	$ 1,361	$ —
Tax payments made	$ 11,370	$ 4,500	$ 3,161

Upon the completion of the Company's initial public offering in August 2007, $3.1 million of initial public offering costs incurred in 2006 were reclassified from deposits and other assets to additional paid-in capital.

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

1. Business Organization and Basis of Presentation

Description of the Business

Sucampo Pharmaceuticals, Inc. (Sucampo or the Company) is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. Sucampo is focused on developing prostones for the treatment of gastrointestinal, respiratory, vascular and central nervous system diseases and disorders for which there are unmet or underserved medical needs and significant commercial potential. Sucampo was established in December 1996.

In January 2006, the Company received marketing approval from the U.S. Food and Drug Administration, or FDA, for its first product, Amitiza® (lubiprostone), to treat chronic idiopathic constipation in adults. In April 2008, the Company received a second marketing approval from the FDA for Amitiza to treat irritable bowel syndrome with constipation in women 18 years of age or older. Amitiza is being marketed and developed under a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, for gastrointestinal indications in the United States and Canada.

Sucampo and Takeda initiated commercial sales of Amitiza in the United States for the treatment of chronic idiopathic constipation in April 2006 and for the treatment of irritable bowel syndrome with constipation in May 2008. In December 2008, the Company completed enrollment of two phase 3 pivotal clinical trials of Amitiza for the treatment of opioid-induced bowel dysfunction, or OBD.

In February 2009, Sucampo entered into a license and commercialization agreement with Abbott Japan Co. Ltd., or Abbott, for Amitiza in Japan. Under the terms of the agreement, Abbott received exclusive rights to commercialize lubiprostone in Japan for the treatment of chronic idiopathic constipation and received the right of first refusal to any additional indications for which lubiprostone is developed in Japan. Abbott is responsible for all commercialization expenses and efforts. The Company received an upfront payment of $10 million and could receive additional milestone payments based on achieving specified development regulatory, and commercialization goals. The Company continues to lead the development of and regulatory activity for lubiprostone in Japan and will continue to be responsible for the costs of lubiprostone development. Following marketing authorization and pricing approval, Abbott would purchase finished product from Sucampo for distribution in Japan. The Company has retained the right to co-promote lubiprostone in Japan. In addition, Sucampo and Abbott Japan or their respective affiliates have separately agreed to negotiate in good faith a license, commercialization and supply agreement for lubiprostone in markets outside Japan, the U.S., Canada and Western Europe and to use commercially reasonable efforts to enter into such an agreement.

In early 2008, Sucampo submitted marketing authorization applications, or MAAs, for lubiprostone, 24 micrograms, for the indication of chronic idiopathic constipation in adults in ten European countries, using a decentralized procedure with the United Kingdom serving as a reference state. In September 2008, the Company reported the successful results of a multi-center phase 2b dose-ranging study in Japan to evaluate the safety and efficacy of lubiprostone for treating chronic idiopathic constipation in adults.

In addition, the Company is developing other prostone compounds for the treatment of a broad range of diseases. The most advanced of these programs are:

- Cobiprostone for the treatment of ulcers induced by non-steroidal anti-inflammatory drugs, or NSAIDs, portal hypertension, non-alcoholic fatty liver disease, disorders associated with cystic fibrosis and chronic obstructive pulmonary disease. Sucampo completed enrollment in a phase 2 clinical trial of cobiprostone for the treatment and prevention of NSAID-induced ulcers in December 2008 in the United States. In July 2008, the Company initiated a phase 2 proof-of-concept study of cobiprostone in patients with portal hypertension in the United States.

- SPI-017 for the treatment of peripheral arterial and vascular disease and central nervous system disorders. Initially, the Company is working on the development of an intravenous formulation of SPI-017 for the treatment of peripheral arterial disease and commenced its first phase 1 clinical trial in December 2008 in Japan. Sucampo is also developing an oral formulation of SPI-017 for the treatment of Alzheimer's disease in United States.

The Company's founders own directly or indirectly the majority holdings in Sucampo as well as in other companies that have significant contractual relationships with Sucampo as described more fully in Note 9. One of the Company's founders serves as the chairman of the board of directors, chief executive officer and chief scientific officer of the Company and the second founder also serves as a director and employee of the Company, serving as executive advisor of international business development.

In December 2008, the Company implemented a new holding company structure. In this reorganization, Sucampo Pharmaceuticals, Inc. became a wholly owned subsidiary of a newly formed Delaware holding company, then known as Sucampo Pharma Holdings, Inc., which became the publicly traded company. Each share of Sucampo Pharmaceuticals, Inc. stock was automatically converted into equivalent shares of the holding company with the same rights and privileges as the converted shares.

Immediately after the reorganization, Sucampo Pharmaceuticals, Inc. was renamed Sucampo Pharma Americas, Inc. and the holding company succeeded to the name Sucampo Pharmaceuticals, Inc. Sucampo Pharma Americas, Inc. then distributed to the new holding company the stock of its two wholly owned subsidiaries, Sucampo Pharma Ltd. and Sucampo Pharma Europe Ltd. As a result, those two companies are now also wholly owned subsidiaries of the new holding company.

The final corporate structure consists of a public holding company named Sucampo Pharmaceuticals, Inc., which has three wholly owned subsidiaries: Sucampo Pharma Ltd., based in Tokyo and Osaka, Japan, in which the Company conducts Asian operations; Sucampo Pharma Americas, Inc., based in Bethesda, Maryland, in which the Company conducts operations in North and South America; and Sucampo Pharma Europe Ltd., based in Oxford, U.K., and Basel, Switzerland, in which the Company conducts operations in Europe and the rest of the world.

In August 2007, the Company completed its initial public offering of 3,125,000 shares of class A common stock at a public offering price of $11.50 per share, resulting in gross proceeds to the Company of approximately $35.9 million and net proceeds of $28.2 million after deducting underwriter's discounts, commission and other related expenses of the offering. An additional 625,000 shares of class A common stock were sold by a selling stockholder of the company and 562,500 shares were sold under an overallotment option by S&R Technology Holdings, LLC, or S&R.

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). The consolidated financial statements include the accounts of Sucampo and its wholly owned subsidiaries. All significant inter-company balances and transactions have been eliminated.

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Reclassifications

Certain amounts in the previously issued financial statements have been reclassified to conform to the current year presentation. The Company reclassified expenses that have been previously included within general and

administrative expenses to research and development expenses. Such expenses primarily include salaries and other employee benefits of personnel who oversee the research and development process, and allocated depreciation and rent expenses and insurance costs. The Company also reclassified allocated depreciation and rent expenses and insurance costs from general and administrative expenses to selling and marketing expenses. For the year ended December 31, 2007, the Company reclassified $3.4 million and $245,000 of general and administrative expenses to research and development expenses and selling and marketing expenses, respectively. For the year ended December 31, 2006, the Company reclassified $2.8 million and $76,000 of general and administrative expenses to research and development expenses and selling and marketing expenses, respectively.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For the purpose of the consolidated balance sheets and statements of cash flows, cash equivalents include all highly liquid investments with an original maturity of 90 days or less at the time of purchase.

Restricted Cash

Restricted cash recorded within other assets on the consolidated balance sheets consists of approximately $213,000 at December 31, 2008 and 2007 of cash securing a letter of credit related to a lease agreement for the Company's principal office premises at Bethesda, Maryland. This letter of credit renews automatically each year and is required until the lease expires on February 15, 2017.

Current and Non-Current Investments

Current and non-current investments consist primarily of U.S. Treasury bills and notes and auction rate securities. The Company classifies its investment into current and non-current, based on its maturities and management's reasonable expectation to realize these investments in to cash. These investments are accounted for under the guidance of SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* Investments in U.S. Treasury bills and notes are classified as available for sale securities and unrealized gain or losses, net of related tax effects, are reported in other comprehensive income.

On October 16, 2008, the Company accepted the settlement rights offered by the Company's broker UBS, AG (UBS) for auction rate securities. The settlement rights allow the Company to redeem auction rate securities at par within a specified period. In exchange, UBS is granted the right, at their sole discretion, to sell or otherwise dispose of the Company's auction-rate securities investments at any time between June 30, 2010 and July 2, 2012 (the Exercise Period). Based on this settlement, the Company received $3.5 million on November 3, 2008, representing the par value of its tax-exempt auction rate securities and has the right to request as of December 31, 2008, the redemption of the remaining auction rate securities at par value of $19.4 million during the Exercise Period.

The unique circumstances associated with the auction rate securities markets and the settlement rights has resulted in the reclassification of the Company's investment in auction rate securities from available-for-sale securities to trading securities, which requires the Company to record an unrealized gain or loss in the statements of operations and comprehensive income. Accordingly, the Company recognized $3.2 million of unrealized losses on auction rate securities for the year ended December 31, 2008. The Company will continue to record fair value changes for these trading securities as a gain or loss in the consolidated statements of operations and comprehensive income.

The Company voluntarily adopted the provisions of SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115* (SFAS 159), which permits entities to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis, to record the settlement rights related to the auction rate securities at fair value. Accordingly, the Company recorded $2.8 million within other assets in the consolidated balance sheet as of December 31, 2008 for the fair value of the settlement rights and the corresponding amount as a gain in the consolidated statements of

operations and comprehensive income. Subsequent changes in the fair value of the settlement rights will be recorded as other income (loss) in the consolidated statements of operations and comprehensive income. The fair value estimate of the settlement right has been derived from the par value of the Company's investment in ARS and the fair value of ARS as of the recognition date, since the settlement rights obligate UBS to redeem the ARS at par value.

Certain Risks, Concentrations and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents, restricted cash, investments and receivables. The Company places its cash and cash equivalents, restricted cash and investments with highly rated financial institutions. At December 31, 2008 and 2007, the Company had approximately $118.6 million and $85.9 million, respectively, of cash and cash equivalents, restricted cash and investments in excess of government insured limits. The Company's uninsured cash, cash equivalents and investments as of December 31, 2008 consist primarily of $42.7 million of T-bills and notes, of $18.9 million of money market funds guaranteed under the U.S. Treasury's Temporary Guarantee Program and of $32.2 million of other money market funds. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

As of December 31, 2008, all of the Company's auction rate securities consisted of AAA or A rated non-mortgage related auction rate securities. The settlement rights between the Company and the auction rate securities broker obligates the broker to redeem the outstanding auction rate securities at par during a two-year period beginning June 30, 2010 if the Company exercises its related settlement rights. The Company does not anticipate having to sell the remaining securities in order to operate its business before the expected redemption dates. Although our arrangement with UBS provides some comfort that the Company will eventually be able to liquidate our ARS holdings, the Company cannot provide any assurance that UBS will be in a position to honor its commitment to repurchase ARS during the exercise period.

The Company's product, Amitiza, and other candidates under development require approval from the FDA or other international regulatory agencies prior to commercial sales. For those product candidates that have not yet been approved by the FDA, or international regulatory agencies, there can be no assurance the products will receive the necessary approval. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company.

The Company's product, Amitiza, competes in a rapidly changing, highly competitive market, which is characterized by advances in scientific discovery, changes in customer requirements, evolving regulatory requirements and developing industry standards. Any failure by the Company to anticipate or to respond adequately to scientific developments in its industry, changes in customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services could have a material adverse effect on the Company's business, operating results and future cash flows.

The Company's expected activities may necessitate significant uses of working capital. The Company's working capital requirements will depend on many factors, including the successful sales of Amitiza, research and development efforts to develop new products, payments received under contractual agreements with other parties, the status of competitive products and market acceptance of the Company's new products by physicians and patients. The Company plans to continue financing operations with product royalty revenue as well as with cash received from milestones and other revenue related to its joint collaboration and license agreement and the supplemental agreement entered into with Takeda and plans to finance its research and development activities in its subsidiary in Japan with cash received from upfront payments and development milestones related to its license and supply agreement with Abbott Japan entered into in February 2009 (Note 14).

The Company depends significantly upon the collaboration with Takeda and the Company's activities may be affected if this relationship is disrupted. Revenues from Takeda accounted for 100%, 100% and 98% of the

Company's total revenues for the years ended December 31, 2008, 2007 and 2006, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 97% and 99% of the Company's accounts and product royalty receivables at December 31, 2008 and 2007, respectively (Note 10).

The Company has an exclusive supply arrangement with R-Tech Ueno, Ltd (R-Tech), a Japanese manufacturing and research and development company that is majority owned by the Company's founders, to provide it with commercial and clinical supplies of its product and product candidates. R-Tech also provides certain preclinical and other research and development services. Any difficulties or delays in performing the services under these arrangements may cause the Company to lose revenues, delay research and development activities or otherwise disrupt the Company's operations (Note 9).

The Company has previously entered into a restated license agreement with Sucampo AG (SAG) to grant the Company a royalty-bearing, exclusive, worldwide license to develop prostone compounds, including Amitiza and cobiprostone. SAG is a Swiss-patent holding company and an entity wholly owned by the Company's founders. The Company's success depends, in part, on SAG's ability to obtain and maintain proprietary protection for the intellectual property rights relating to the prostone technology and products (Note 9).

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, restricted cash, current and non-current investments, receivables, accounts payable and accrued liabilities, approximate their fair values based on their short maturities, independent valuations or internal assessments.

Accounts Receivable and Unbilled Accounts Receivable

Accounts receivable represent amounts due under the joint collaboration and licensing agreement with Takeda (Note 10). Unbilled accounts receivable represent the research and development expenses that are reimbursable by Takeda but have not been billed to Takeda as of the balance sheet date. The Company did not record an allowance for doubtful accounts at December 31, 2008 or 2007 because it believes that its accounts receivable are fully collectible and it does not have a history of credit losses or write-offs of its accounts receivable.

Product Royalties Receivable

Product royalties receivable represent amounts due from Takeda for the Company's royalties on sales of Amitiza, which are based on reports obtained directly from Takeda.

Property and Equipment

Property and equipment are recorded at cost and consist of computer and office machines, furniture and fixtures and leasehold improvements. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Computer and office machines are depreciated over four years and furniture and fixtures are depreciated over seven years. Leasehold improvements are amortized over the shorter of ten years or the life of the lease. Significant additions and improvements are capitalized. Expenditures for maintenance and repairs are charged to earnings as incurred. When assets are sold or retired, the related cost and accumulated depreciation are removed from the respective accounts and any resulting gain or loss is included in earnings.

Impairment of Long-lived Assets

When necessary, the Company assesses the recoverability of its long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value.

There have been no impairment charges recorded during the years ended December 31, 2008, 2007 or 2006 because there have been no indicators of impairment during those years.

Revenue Recognition

Collaboration and License Agreements

The Company's primary sources of revenue include up-front payments, development milestone payments, reimbursements of development and co-promotion costs and product royalties. The Company recognizes revenue from these sources in accordance with Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* (SAB 104), Emerging Issues Task Force (EITF) No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), and EITF No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). The application of EITF 00-21 requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separate units of accounting and to determine the fair value to be allocated to each unit of accounting.

The Company entered into a 16-year joint collaboration and license agreement with Takeda in October 2004 (Takeda Agreement) and a supplemental agreement to the Takeda Agreement (Supplemental Agreement) in February 2006. The Company evaluated the multiple deliverables within the Takeda Agreement and the Supplemental Agreement in accordance with the provisions of EITF 00-21 to determine whether the delivered elements that are the obligation of the Company have value to Takeda on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate recognition of revenue is then applied to each separate unit of accounting.

The Company's deliverables under the Takeda Agreement and the Supplemental Agreement, including the related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 10.

The Takeda Agreement consists of the following key funding streams: an up-front payment, product development milestone payments, reimbursements of development costs and product royalty payments. The cash flows associated with the individual units of accounting from the Takeda Agreement are recognized as revenue using a time-based model when the Company has obligations to perform. Under this model, cash flow streams related to each unit of accounting are recognized as revenue over the estimated performance period. Upon receipt of cash payments, revenue is recognized to the extent the accumulated service time, if any, has occurred. The remainder is deferred and recognized as revenue ratably over the remaining estimated performance period. A change in the period of time expected to complete the deliverable is accounted for as a change in estimate on a prospective basis. Revenue is limited to amounts that are nonrefundable and that Takeda is contractually obligated to pay to the Company.

The Company has other obligations with Takeda to perform research and development activities, for which Takeda reimburses the Company after the services have been performed. The Company recognizes these reimbursable costs as research and development revenue using a similar time-based model over the estimated performance period. The research and development revenue for these obligations is limited to the lesser of the actual reimbursable costs incurred or the straight-line amount of revenue recognized over the estimated performance period. Revenues are recognized for reimbursable costs only if those costs are supported by an invoice or final contract with a vendor.

Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal under the Takeda Agreement and, as such, records these amounts as collaboration revenue and research and development revenue.

Royalties from licensees are based on third-party sales of licensed products and are recorded on the accrual basis when earned in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met.

The Supplemental Agreement consists of the following key funding streams: reimbursements of co-promotion costs based upon a per-day rate and reimbursements of the costs of miscellaneous marketing activities.

Reimbursements of co-promotion costs for the Company's sales force efforts and reimbursements of miscellaneous marketing costs under the Supplemental Agreement are recognized as revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts. Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal as it relates to these activities under the Supplemental Agreement and, as such, records reimbursements of these amounts as co-promotion revenue.

Option fees received for other potential joint collaboration and license agreements with Takeda are not recognized as revenue immediately because the transactions do not represent a separate earnings process. Because there are contingent performance obligations by the Company when and if the options are exercised, the Company's policy is to recognize revenue immediately upon expiration of the option or to commence revenue recognition upon exercise of the option and continue recognition over the estimated performance period. When recognized, option fees are recorded as contract revenue.

Contract Revenue

Contract revenue related to development and consulting activities with related parties is also accounted for under the time-based model.

Deferred Revenue

Deferred revenue represents payments received or receivables for licensing fees, option fees, consulting, research and development contracts and related cost sharing and supply agreements that are deferred until revenue can be recognized under the Company's revenue recognition policy. Deferred revenue is classified as current if management believes the Company will be able to recognize the deferred amount as revenue within 12 months of the balance sheet date. During the second quarter of 2008, the Company agreed to receive quarterly prepayments from Takeda for its research and development expenses under the agreements with Takeda. As of December 31, 2008, approximately $10.9 million of deferred revenue relates to these prepayments. At December 31, 2008 and 2007, total deferred revenue was approximately $23.7 million and $9.7 million, respectively.

Total deferred revenue consists of the following as of:

(In thousands)	December 31, 2008	2007
Deferred revenue — current	$ 15,599	$ 1,062
Deferred revenue, net of current portion	8,061	8,626
	$ 23,660	$ 9,688
Deferred revenue to related parties — current	$ 419	$ 419
Deferred revenue to related parties, net of current portion	6,444	6,862
Deferred revenue to related parties, included above	$ 6,863	$ 7,281

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses from third parties who conduct research and development activities pursuant to development and

consulting agreements on behalf of the Company. Costs related to the acquisition of intellectual property are expensed as incurred in research and development expenses since the underlying technology associated with such acquisitions is unproven, has not received regulatory approval at its early stage of development and does not have alternative future uses. Milestone payments due under agreements with third-party contract research organizations (CROs) are accrued when it is deemed probable that the milestone event will be achieved.

General and Administrative Expenses

General and administrative costs are expensed as incurred and consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, information technology and human resource functions. Other costs include facility costs and professional fees for legal and accounting services.

Selling and Marketing Expenses

Selling and marketing expenses represent costs the Company incurs to co-promote Amitiza, including salaries, benefits and related costs of the Company's sales force and other sales and marketing personnel, costs of market research and analysis and other selling and marketing expenses.

Milestone Royalties — Related Parties

The milestone royalties — related parties expense represent royalties paid or due to SAG. The milestone royalty is 5% of milestone payments received under any sublicensing agreements for Amitiza. In addition, for each indication for Amitiza for which the Company obtains regulatory approval, the Company must pay a $250,000 milestone. The Company must also pay a $500,000 milestone upon the initiation of the first phase 2 clinical trial for each compound in each of the three territories covered by the license: (1) North, Central and South America, including the Caribbean, (2) Asia and (3) the rest of the world, and a $1.0 million milestone for the first NDA filing or comparable foreign regulatory filing for each compound in each of the same three territories. Milestone royalties — related parties are expensed as incurred immediately when the related milestones become probable under the guidance of SFAS No. 5, *Accounting for Contingencies*. For the years ended December 31, 2008 and 2007, the Company expensed $3.5 million and $2.0 million in milestone royalties — related parties, respectively.

Product Royalties — Related Parties

Product royalties — related parties expense represent the Company's obligation to SAG for 3.2% of Amitiza net sales and are expensed as incurred. For the years ended December 31, 2008 and 2007, the Company expensed approximately $6.0 million and $4.9 million in product royalties, respectively.

Interest Income

Interest income consists of interest earned on the Company's cash and cash equivalents and current and non-current investments.

Accrued Research and Development Expenses

As part of the process of preparing consolidated financial statements, the Company is required to estimate accrual, for research and development expenses. This process involves reviewing and identifying services which have been performed by third parties on the Company's behalf and determining the value of these services. Examples of these services are payments to clinical investigators and contracted service organizations. In addition, the Company makes estimates of costs incurred to date but not yet invoiced, in relation to external contract research organizations and clinical site costs. The Company analyzes the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs, when evaluating the adequacy of the accrued liabilities

for research and development. The Company makes significant judgments and estimates in determining the accrued balance in any accounting period.

Employee Stock-Based Compensation

The Company applied SFAS No. 123(R), *Share-Based Payments* (SFAS 123(R)), which requires the measurement and recognition of expense for all share-based compensation of employees and directors to be based on estimated fair values of the share-based awards. SFAS 123R requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service period in the Company's consolidated statement of operations.

The Company adopted SFAS 123(R) utilizing the modified prospective method. Under this method, the Company's consolidated financial statements for prior periods were not restated to reflect, and do not include, the impact of SFAS 123(R). Upon adoption of SFAS 123(R), the Company decided to utilize the straight-line method of allocating stock-based compensation expense over the vesting term of the stock-based awards and continued to use the Black-Scholes-Merton option pricing formula which was previously used for the Company's pro-forma information required under SFAS No. 123, *Accounting for Stock-Based Compensation.* The Company's determination of fair value of share-based awards on the date of grant using an option-pricing model is affected by the Company's stock price and assumptions regarding a number of highly complex and subjective variables.

The assumptions used to estimate the fair value of stock options granted for the three years ended December 31, 2008 were as follows:

	Year Ended December 31,		
	2008	2007	2006
Expected volatility	53% - 56%	39% - 60%	54% -76%
Risk-free interest rate	2.78% - 3.45%	2.99% - 3.59%	4.72% - 4.93%
Expected term (in years)	6.25	3.25 - 6.25	2.63 - 5.75
Expected dividend yield	0%	0%	0%

Expected Volatility: The Company evaluated the assumptions used to estimate expected volatility, including whether implied volatility of its options appropriately reflects the market's expectations of future volatility. The Company determined that it would calculate the expected volatility rate using historical stock prices obtained from comparable publicly-traded companies due to the limited history of the Company's common stock activity.

Risk-Free Interest Rate: The risk-free interest rate is based on the market yield currently available on U.S. Treasury securities with maturity that approximates the expected term of the share-based awards.

Expected Term: Due to the limited history of employee stock options granted by the Company, the Company elected to use the "simplified" method allowed under SAB No. 107, *Share-Based Payment* (SAB 107), to calculate its expected term as the share-based awards meet the "plain vanilla" definition described in SAB 107. Under this method, the expected term is the weighted average of the vesting term and the contractual term.

Expected Dividend Yield: The Company has not paid, and does not anticipate paying, any dividends in the foreseeable future.

Employee stock-based compensation expense for the three years ended December 2008 has been reduced for estimated forfeitures as such expense is based upon awards expected to ultimately vest. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. During the years ended December 31, 2008, 2007 and 2006, the estimated forfeiture rate ranged from 8.0% to 12.0%.

Employee stock-based compensation expense under SFAS 123R recorded in the Company's consolidated statements of operations and comprehensive income for the three years ended December 31, 2008 was as follows:

(In thousands)	Year Ended December 31, 2008	2007	2006
Research and development expense	$ 245	$ 190	$ 1,001
General and administrative expense	199	405	1,707
Selling and marketing expense	242	333	566
Founders' stock-based awards (Note 9)	—	6,112	—
Cumulative out-of-period adjustment	—	(358)	—
Total	686	6,682	3,274
Employee stock-based compensation expense per basic share of common stock	$ 0.02	$ 0.18	$ 0.10
Employee stock-based compensation expense per diluted share of common stock	$ 0.02	$ 0.17	$ 0.09

The Company recorded a cumulative out-of-period adjustment of approximately $358,000 during the year ended December 31, 2007 to reduce an overstatement of additional paid-in capital and general and administrative expenses that had been recorded as of and for the year ended December 31, 2006 in connection with certain employee stock options awarded in 2006. The error resulted from applying the incorrect contractual term for certain employee stock options. The impacts of this adjustment were not material to the consolidated financial statements for the years ended December 31, 2007 and 2006.

Income Taxes

The Company accounts for income taxes under the liability method in accordance with provisions of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109), which requires companies to account for deferred income taxes using the asset and liability method. Under the asset and liability method, current income tax provision or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Tax rate changes are reflected in the income tax provision during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

Significant judgment is required in determining the provision for income taxes and, in particular, any valuation allowance recorded against the Company's net deferred tax assets. The Company has recorded a valuation allowance, which resulted in a net deferred tax asset of $5.0 million and $639,000 as of December 31, 2008 and December 31, 2007, respectively. The amount of the valuation allowance has been determined based on management's estimates of income by jurisdiction in which the Company operates, over the periods in which the related deferred tax assets are recoverable.

For all significant transactions between Sucampo US, Sucampo Europe and Sucampo Japan, the Company's management has evaluated the terms of the transactions using significant estimates and judgments to ensure that each significant transaction would be on similar terms if the Company completed the transaction with an unrelated party. Although the Company believes there will be no material tax liabilities to the Company as a result of multi-jurisdictional transactions, there can be no assurance that taxing authorities will not assert that transactions were entered into at monetary values other than fair values. If such assertions were made, the Company's intention would

be to vigorously defend its positions; however, there can be no assurance that additional liabilities may not occur as a result of any such assertions.

Uncertain Tax Positions

On January 1, 2007, the Company adopted Financial Accounting Standards Board, or FASB, Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 requires the application of a more likely than not threshold to the recognition and derecognition of uncertain tax positions. If the recognition threshold is met, FIN 48 permits us to recognize a tax benefit measured at the largest amount of the tax benefit that, in our judgment, is more than 50 percent likely to be realized upon settlement.

The Company has recorded a non-current income tax liability of $517,000 for uncertain tax positions as of December 31, 2008. The amount represents the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in the Company's consolidated financial statements, and are reflected in other liabilities in the accompanying consolidated balance sheets. The liability for uncertain tax positions as of December 31, 2008 mainly pertains to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes.

The Company recognizes interest and penalties accrued related to uncertain tax positions as a component of the income tax provision. The Company has identified no uncertain tax position for which it is reasonably possible that the total amount of liability for unrecognized tax benefits will significantly increase or decrease within 12 months, except for recurring accruals on existing uncertain tax positions.

Foreign Currency

The Company translates the assets and liabilities of its foreign subsidiaries, Sucampo Europe and Sucampo Japan, into U.S. dollars at the current exchange rate in effect at the end of the year and maintains the capital accounts of these subsidiaries at the historical exchange rates. The revenue, income and expense accounts of the foreign subsidiaries are translated into U.S. dollars at the average rates that prevailed during the relevant period. The gains and losses that result from this process are included in accumulated other comprehensive income in the stockholders' equity section of the balance sheet.

Realized and unrealized foreign currency gains or losses on assets and liabilities denominated in a currency other than the functional currency are included in net income.

Other Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive income be reported in the financial statements during the period in which they are recognized. Comprehensive income is net income plus certain other items that are recorded directly to stockholders' equity. The Company has reported comprehensive income in the consolidated statements of operations and comprehensive income.

As of December 31, 2008, the Company has outstanding intercompany loans and investments between its subsidiaries which are eliminated for purposes of the consolidated financial statements. These intercompany loans are not expected to be repaid or settled in the foreseeable future. Accordingly the currency transaction gains or losses on these intercompany loans are recorded as part of other comprehensive income in the consolidated financial statements.

Segment Information

Management has determined that the Company has three reportable segments, which are based on its method of internal reporting by geographical location. The Company's reportable segments are the United States, Europe and Japan.

Change in Estimate

The preparation of consolidated financial statements requires the Company to make estimates that affect assets, liabilities, revenues and expenses, including financial disclosures for the respective reporting periods.

During 2008, as a result of lower-than-expected patient enrollment in one of the studies, the Joint Commercialization Committee approved an increase in funding for patient recruitment. Additionally, the Company concluded that the estimated completion of certain ongoing trials would be extended from June 2009 to December 2009. Accordingly, the Company determined that the recognition period for associated research and development revenue should be extended. As a result of the extended completion date and an increase of total expected reimbursable costs, the Company deferred approximately $3.9 million in research and development revenue for the year ended December 31, 2008. The Company expects to recognize the deferred revenue of $3.9 million in 2009. Under the provision of SFAS No. 154, *Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3* (SFAS 154), the Company recognized this as a change in estimate during the year.

This change in estimate had the following impact on net income and basic and diluted net income per share for the year ended December 31, 2008:

In thousands, except per share data)	
Decrease in revenue and income before income taxes	$ (3,855)
Impact on basic net income per share	(0.02)
Impact on diluted net income per share	(0.02)

During 2006, as a result of new study evaluation requirements released by the Rome III Committee on Functional Gastrointestinal Disorders, an international committee of gastroenterologists, management of the Company concluded that the completion of the final analysis of data from its clinical trials of Amitiza for the treatment of irritable bowel syndrome with constipation would be extended from December 2006 to mid 2007. Accordingly, the Company determined in June 2006 that the recognition period for associated research and development revenue should be extended. The Company deferred the remaining $11.0 million as of December 31, 2006 and recognized the revenues ratably through the completion date of June 2007. Under the provisions of SFAS 154, the Company recognized this as a change in estimate on a prospective basis from June 1, 2006. The effect on net income and basic and diluted net income per share for the year ended December 31, 2006 was as follows:

(In thousands, except for per share data)	
Decrease in revenue and income before income taxes	$ 10,951
Impact on basic net income per share	(0.32)
Impact on diluted net income per share	(0.32)

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. SFAS 157 outlines a common definition of fair value and the new standard intends to make the measurement of fair value more consistent and comparable and improve disclosures about those measures. The Company adopted SFAS 157 as of January 1, 2008 for financial assets and liabilities that are subject to recurring fair value measurements and the adoption did not have a material impact on the consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 permits entities to measure many financial instruments and certain other assets and liabilities at fair value, with unrealized gains and losses related to these financial instruments reported in earnings at each subsequent reporting date. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company adopted SFAS 159 as of January 1, 2008 for measuring the fair value of settlement rights pursuant to the offer agreement with UBS on the Company's

investments in auction rate securities. As a result of this fair value adoption, the Company recorded $2.8 million as a non-current asset included within other assets in the consolidated balance sheets for the fair value of the settlement rights and the corresponding amount as a gain within other expense, net in consolidated statements of operations and comprehensive income.

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3, which provides guidance to research and development companies on how to account for the nonrefundable portion of an advance payment made for research and development activities. The Company adopted EITF 07-3 as of January 1, 2008 and there was no material impact upon its adoption.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, or SFAS 141(R), and SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of Accounting Research Bulletin No. 51*, or SFAS 160. SFAS 141(R) will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141(R) and SFAS 160 will be applied to acquisitions that close in years beginning after December 15, 2008. Early adoption is not permitted. SFAS 141(R) and SFAS 160 will not have any impact on the Company's future consolidated financial statements unless the Company undertakes an acquisition in the future.

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. The consensus prohibits the equity method of accounting for collaborative arrangements under APB 18, *The Equity Method of Accounting for Investments in Common Stock*, unless a legal entity exists. Payments between the collaborative partners will be evaluated and reported in the income statement based on applicable GAAP. Absent specific GAAP, the participants to the arrangement will apply other existing GAAP by analogy or apply a reasonable and rational accounting policy consistently. The guidance in EITF 07-1 is effective for periods that begin after December 15, 2008 and will apply to arrangements in existence as of the effective date. The effect of the new consensus will be accounted for as a change in accounting principle through retrospective application. The Company is currently evaluating the potential impact, if any, of the adoption of EITF 07-1 on the consolidated financial statements.

In February 2008, the FASB issued Financial Staff Positions, or FSP, SFAS 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2, which delays the effective date of SFAS 157, for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. FSP 157-2 partially defers the effective date of SFAS 157 to fiscal years beginning after November 15, 2008. FSP 157-2 is effective for the Company beginning January 1, 2009. The Company is currently evaluating the potential impact, if any, of the adoption of FSP 157-2 on the consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States of America. SFAS 162 will be effective for fiscal years beginning after November 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of SFAS 162 on the consolidated financial statements.

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset in a Market That is Not Active*, or FSP FAS 157-3. FSP FAS 157-3 clarifies the application of SFAS 157 in a market that is not active. FSP FAS 157-3 addresses how management should consider measuring fair value when relevant observable data does not exist. FSP FAS 157-3 also provides guidance on how observable market information in a market that is not active should be considered when measuring fair value, as well as how the use of market quotes

should be considered when assessing the relevance of observable and unobservable data available to measure fair value. FSP 157-3 is effective upon issuance, for companies that have adopted SFAS No. 157. Revisions resulting from a change in the valuation technique or its application shall be accounted for as a change in accounting estimate in accordance with SFAS 154. The application of the provisions of FSP 157-3 did not materially impact the Company's consolidated financial statements.

3. Net Income per Share

Basic net income per share is computed by dividing net income by the sum of the weighted average class A and B common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average common shares and potential dilutive common shares outstanding, except when their inclusion would be anti-dilutive.

The computation of net income per share for the three years ended December 31, 2008, is shown below:

	Year Ended December 31,		
(In thousands, except per share data)	2008	2007	2006
Basic net income per share:			
Net income	$ 24,951	$ 13,190	$ 21,801
Weighted average class A and B common shares outstanding	41,787	37,778	34,383
Basic net income per share	$ 0.60	$ 0.35	$ 0.63
Diluted net income per share:			
Net income	$ 24,951	$ 13,190	$ 21,801
Weighted average class A and B common shares outstanding for diluted net income per share	41,787	37,778	34,383
Assumed exercise of stock options under the treasury stock method	186	448	307
	41,973	38,226	34,690
Diluted net income per share	$ 0.59	$ 0.35	$ 0.63

For the years listed above, the potentially dilutive securities used in the calculations of diluted net income per share as of December 31, 2008, 2007 and 2006 are as follows:

	December 31,		
(In thousands)	2008	2007	2006
Series A preferred stock	—	—	4
Employee stock options	5	908	826
Non-employee stock options	470	510	510

Each share of series A preferred stock was converted into 850 shares of class A common stock in connection with the initial public offering, which was completed in August 2007.

The following securities were excluded from the computation of diluted net income per share as their effect would be anti-dilutive as of December 31, 2008, 2007 and 2006:

	December 31,		
(In thousands)	2008	2007	2006
Employee stock options	772	11	15

4. Current and Non-Current Investments

At December 31, 2008 and 2007, current and non-current investments consisted of the following securities:

	December 31, 2008			
(In thousands)	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
U.S. Treasury bills and notes	$ 42,620	$ 130	$ —	$ 42,750
Money market funds	51,026	—	—	51,026
Total	$ 93,646	$ 130	$ —	$ 93,776
Non-current:				
Auction rate securities	$ 19,400	$ —	$ (3,178)	$ 16,222

	December 31, 2007			
(In thousands)	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Auction rate securities	$ 51,500	$ —	$ —	$ 51,500
Money market funds	52	—	—	52
Total	$ 51,552	$ —	$ —	$ 51,552
Non-current:				
Auction rate securities	$ 9,400	$ —	$ —	$ 9,400

The Company's assets measured at fair value on a recurring basis, which are subject to the disclosure requirements of SFAS 157, at December 31, 2008 were as follows:

	Fair Value Measurements at Reporting Date Using			
(In thousands)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total as of December 31, 2008
U.S. Treasury bills and notes	$ 42,750	$ —	$ —	$ 42,750
Auction rate securities	—	—	16,222	16,222
Settlement rights for auction rate securities*	—	—	2,818	2,818
Other available-for-sale securities	51,026	—	—	51,026
Total assets measured at fair value	$ 93,776	$ —	$ 19,040	$ 112,816

* *included in non-current other assets in the accompanying consolidated balance sheets.*

Based on market conditions, the Company changed its valuation methodology for auction rate securities to a valuation method that includes market and income approaches during the first quarter of 2008. Accordingly, these securities changed from Level 1 to Level 3 within SFAS 157's valuation hierarchy at the time of the Company's initial adoption of SFAS 157 at January 1, 2008. The Level 2 securities consist of the auction rate securities that were redeemed at par during 2008. The following table presents the Company's assets measured at fair value on a

recurring basis using significant observable inputs (Level 2) and significant unobservable inputs (Level 3) as defined in SFAS 157 during the year ended December 31, 2008:

(In thousands)	Auction Rate Securities
Balance at January 1, 2008	$ 9,400
Transfers to Level 2	(3,900)
Transfers to Level 3	51,500
Total gains (losses) (realized or unrealized) included in earnings	(3,178)
Purchases	5,100
Settlements	(42,700)
Balance at December 31, 2008	$ 16,222

As a result of reclassification of the investment in auction rate securities from available-for-sale securities to trading securities, the Company transferred $3.2 million of the unrealized loss on investments in auction rate securities from accumulated other comprehensive loss to other expense, net in the consolidated statements of operations and comprehensive income.

5. Property and Equipment

Property and equipment consists of the following as of:

(In thousands)	December 31, 2008	2007
Computer and office machines	$ 1,494	$ 1,036
Furniture and fixtures	348	348
Leasehold improvements	1,282	1,270
Total cost	3,124	2,654
Less: accumulated depreciation and amortization	(849)	(389)
	$ 2,275	$ 2,265

Depreciation and amortization expense for the years ended December 31, 2008, 2007 and 2006 was $450,000, $251,000 and $69,000, respectively.

The leasehold improvements as of December 31, 2008 are related to tenant improvements to the Company's headquarters in Bethesda, Maryland, to which the Company relocated in July 2007.

6. Accrued Expenses

Accrued expenses consist of the following as of:

(In thousands)	December 31, 2008	2007
Research and development costs	$ 7,086	$ 4,422
Employee compensation	1,748	1,867
Selling and marketing costs	346	384
Legal service fees	322	226
Product royalty liability — related party	—	1,536
Other accrued expenses	262	295
	$ 9,764	$ 8,730

7. Other Liabilities

Other liabilities consist of the following as of:

(In thousands)	December 31, 2008	2007
Deferred leasehold incentive	$ 962	$ 1,080
Deferred rent expense	468	397
Lease loss liability	176	286
Other liabilities	541	5
	$ 2,147	$ 1,768

In July 2007, the Company relocated to new offices (Note 8). Under the terms of the new lease, the Company received $1.1 million in associated leasehold incentives in the form of reimbursements for leasehold improvement expenditures. The Company recorded a liability for the cash incentives and is amortizing these incentives as reductions of rental expense over the term of the lease, which expires in February 2017, using the straight-line method.

8. Commitments

Operating Leases

The Company leases office space in the United States, United Kingdom and Japan under operating leases through 2017. Total future minimum, non-cancelable lease payments under operating leases, which do not include future sublease receipts of $249,000, are as follows as of December 31, 2008:

(In thousands)	
2009	1,537
2010	1,051
2011	938
2012	963
2013	992
2014 and thereafter	3,297
Total minimum lease payments	$ 8,778

Rent expense for all operating leases was $1.2 million, $1.1 million and $572,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

The Company is party to a non-cancelable operating lease agreement for office space in the United States, which expires in November 2009. The Company vacated these premises in July 2007 to relocate to its new leased facility. According to SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146), a liability for costs that will continue to be incurred under a lease for its remaining term without economic benefit to the Company shall be recognized and measured when the Company ceases using the right conveyed by the lease, reduced by estimated sublease rentals that could be reasonably obtained. In accordance with SFAS 146, the Company recorded non-cash charges relating to the abandonment of its former office of approximately $432,000 during the year ended December 31, 2007. This is reflected in general and administrative expenses in the accompanying consolidated statement of operations and comprehensive income.

Research and Development Costs

The Company routinely enters into agreements with third-party CROs to oversee clinical research and development studies provided on an outsourced basis and assist in other research and development activities. The Company generally is not contractually obligated to pay the third party if the service or reports are not provided. Total future estimated costs under these agreements as of December 31, 2008 were approximately $11.8 million.

9. Related Party Transactions

R-Tech Ueno, Ltd.

On March 7, 2003, the Company entered into an exclusive supply agreement with R-Tech. This agreement grants R-Tech the exclusive right to manufacture and supply RUG-015, a prostone compound, and lubiprostone in the United States and Canada, and in consideration for such right R-Tech agreed to pay the Company as follows: $1.0 million upon execution of the agreement, $2.0 million upon commencement of a first phase 2 lubiprostone trial, $3.0 million upon commencement of a first phase 2 RUG-015 trial and $2.0 million upon commencement of the earlier of a second phase 2 or a first phase 3 RUG-015 trial. Upon execution of the agreement, the Company had already commenced phase 2 clinical trials for RUG-015 and lubiprostone, which resulted in an immediate payment of $6.0 million — $1.0 million for the agreement execution, $2.0 million for the commencement of the first phase 2 lubiprostone trial, and $3.0 million for the commencement of the first phase 2 RUG-015 trial. The Company evaluated the $6.0 million in cash receipts from R-Tech and determined the payments were made for the exclusive right to supply inventory to the Company and determined that the amounts should be deferred until commercialization of the drugs begins since this is the point at which the underlying services would commence. Management also was unable to adequately assign value between the two compounds based on the information available to the Company and determined that the full $6.0 million deferred amount would be amortized over the contractual life of the relationship which was equivalent to the estimated commercialization periods of both RUG-015 and lubiprostone (estimated to be through December 2020).

During the year ended December 31, 2005, the Company ceased the development of RUG-015 due to less than satisfactory phase 2 results and the Company's Board of Directors approved the Company's decision to discontinue the development of RUG-015. In addition to the Company's Board of Directors, R-Tech also formally approved the abandonment of RUG-015, which was a requirement in the supply agreement terms. Because the Company was unable to assign value to the compounds at the time the agreement was executed and the $6.0 million was received from R-Tech, the full $6.0 million remained deferred at the abandonment of RUG-015.

The abandonment of RUG-015 changed the amortization period of the $6.0 million deferred revenue to the commercialization period of Amitiza, which began April 2006. The Company has recognized revenue of $419,000 for the years ended December 31, 2008 and 2007, which is recorded as contract revenue — related parties. During the years ended December 31, 2008, 2007 and 2006, Sucampo purchased from R-Tech $58,000, $1.6 million and

$608,000, respectively, of clinical supplies under the terms of this agreement. Commercial supplies of Amitiza in the United States are subject to a three-party agreement among the Company, RTU and Takeda and are not reflected in the Company's financial statements (Note 10).

On June 24, 2005, the Company entered into a 20-year exclusive manufacturing and supply agreement with R-Tech to manufacture and supply lubiprostone for clinical and commercial supplies within Europe. In consideration of the exclusive rights, R-Tech paid the Company $2.0 million prior to the execution of the agreement on March 31, 2005. Management has determined that the amount should be deferred until such time as the commercial benefit to R-Tech can be realized. As lubiprostone has not been approved within Europe, the $2.0 million has been recorded as non-current deferred revenue as of December 31, 2008 and 2007. During the year ended December 31, 2007, Sucampo Europe purchased from R-Tech $336,000 million of clinical supplies under the terms of this agreement. There were no such clinical supply purchases in 2008 or 2006.

On September 7, 2006, the Company's Board of Directors approved an agreement which amends the exclusive manufacturing agreement with R-Tech. This agreement allows the Company to elect a back-up supplier for the supply of drug substance and drug product. In addition, the agreement provides that R-Tech shall maintain at least a six-month inventory of drug substance and at least a six-month inventory of intermediate drug product. Sucampo had no clinical supply purchases from a back-up supplier in 2008, 2007 or 2006.

On October 4, 2006, the Company entered into a two-year exclusive clinical manufacturing and supply agreement with R-Tech for two of its drug compounds, cobiprostone and SPI-017. Under the terms of this agreement, R-Tech agreed to manufacture and supply the necessary drug substance and drug product for the purpose of clinical development. Pricing for clinical supplies will be determined on a batch-by-batch basis and shall not exceed a certain mark-up percentage. Unless this agreement is terminated by mutual written consent within 90 days of expiration, it will automatically be renewed for an additional two years. During the years ended December 31, 2008, 2007 and 2006, Sucampo purchased from R-Tech $1.9 million, $1.8 million and $0.5 million, respectively, of clinical supplies under the terms of this agreement.

In February 2009, the Company entered into an Exclusive Manufacturing and Supply Agreement with R-Tech under which the Company granted R-Tech the exclusive right to manufacture and supply lubiprostone to meet its commercial and clinical requirements in Asia, Australia and New Zealand. In consideration, R-Tech made an up-front payment of $250,000 and is obligated to make milestone payments of $500,000 upon regulatory approval of lubiprostone in Japan and $250,000 upon the commercial launch in Japan. In addition, R-Tech is required to maintain at least a six-month supply of lubiprostone and a three-month supply of the active ingredient used in manufacturing lubiprostone as a backup inventory.

Sucampo AG License Agreements

On June 30, 2006, the Company entered into a restated license agreement with SAG. Under this agreement, SAG has granted to the Company a royalty-bearing, exclusive, worldwide license, with the right to sublicense, to develop and commercialize Amitiza, cobiprostone and SPI-017 and any other prostone compounds, other than Rescula, subject to SAG's patents. This agreement supersedes all previous license and data sharing arrangements between the parties and functions as a master license agreement with respect to SAG's prostone technology. The license is perpetual as to Amitiza, cobiprostone and SPI-017 and cannot be terminated unless the Company defaults in its payment obligations to SAG. If the Company has not committed specified development efforts to any prostone compound other than Amitiza, cobiprostone and SPI-017 by the end of a specified period, which ends on the later of June 30, 2011 or the date upon which the founders, no longer control our company, then the commercial rights to that compound will revert to SAG, subject to a 15-month extension in the case of any compound designate by the Company in good faith as planned for development within that extension period. Under the terms of the license, the Company is obligated to assign to SAG any patentable improvements derived or discovered by the Company relating to Amitiza, cobiprostone and SPI-017 through the term of the license. In addition, the Company is obligated to assign to SAG any patentable improvements derived or discovered by the Company relating to other licensed

prostone compounds prior to the date which is the later of June 30, 2011 or the date on which the founders cease to control the Company. All compounds assigned to SAG under this agreement will be immediately licensed back to the Company on an exclusive basis.

In consideration of the license, the Company is required to make milestone and royalty payments to SAG. The milestone payments include:

- a payment of $500,000 upon the initiation of the first phase 2 clinical trial for each compound in each of three territories covered by the license: North, Central and South America (including the Caribbean), Asia and the rest of the world; and
- a payment of $1.0 million for the first NDA filing or comparable foreign regulatory filing for each compound in each of the same three territories.

Upon payment of the above milestones, no further payments will be required either for new indications or formulations or for further regulatory filings for the same compound in additional countries within the same territory. In addition, the Company is required to pay SAG 5% of any up-front or milestone payments that are received from sublicensees.

In addition, the Company is required to pay SAG, on a country-by-country basis, ongoing patent royalties as follows:

- In the case of products covered by patents existing at the time of our initial public offering in 2007, or pre-IPO patents, a royalty of 2.2% of net sales in the case of sales of Amitiza in North, Central and South America, including the Caribbean, and Asia, Australia and New Zealand; and 4.5% of net sales in the case of sales of Amitiza in other territories or sales of other compounds. These royalties are payable until the last pre-IPO patent covering each relevant compound in the relevant country has expired.
- After the expiration of all pre-IPO patents, in the case of products covered by new patents or improvement patents that were granted after our initial public offering, or post-IPO patents, a royalty of 1.1% of net sales in the case of sales of Amitiza in North, Central and South America, including the Caribbean, and Asia, Australia and New Zealand; and 2.25% of net sales in the case of sales of Amitiza in other territories or sales of other compounds. These royalties are payable until the last post-IPO patent covering each relevant compound has expired.

In addition, the Company is required to pay Sucampo AG, on a country-by-country basis, a know-how royalty of 1% of net sales in the case of sales of Amitiza in North, Central and South America, including the Caribbean, and Asia, Australia and New Zealand; and 2% of net sales in the case of sales of Amitiza in other territories or sales of other compounds, until the fifteenth anniversary of the first sale of the respective compound.

The product royalties that the Company pays to SAG are based on total product net sales, whether by the Company or a sublicensee, and not on amounts actually received by the Company. The Company expensed $6.0 million, $4.9 million and $1.2 million in product royalties to SAG during the years ended December 31, 2008, 2007 and 2006, respectively, reflecting 3.2% of Amitiza net sales during each of these years, which was recorded as product royalties — related parties in the consolidated statements of operations and comprehensive income.

During the year ended December 31, 2006 the Company paid SAG $1.1 million of non-refundable upfront payments for the initial SPI-017 license which was recorded as a research and development expense.

During the year ended December 31, 2006, the Company paid SAG milestone royalty payments of $1.0 million and $250,000 upon receiving a $20.0 million development milestone payment from Takeda for the FDA approval of Amitiza for chronic idiopathic constipation. During the year ended December 31, 2007, the Company paid SAG $1.5 million upon receiving a $30.0 million development milestone payment from Takeda for the supplemental NDA (sNDA) for irritable bowel syndrome with constipation and $500,000 upon the initiation of the first phase 2b dose-ranging study in Japan. During the year ended December 31, 2008, the Company paid SAG $2.5 million upon

receiving a $50.0 million development milestone payment from Takeda as a result of FDA's approval of the sNDA for irritable bowel syndrome with constipation in women 18 years of age and older and $1.0 million upon the submission of the Marketing Authorization Application for lubiprostone, 24 micrograms, for the indication of chronic idiopathic constipation in adults in Europe. These milestone royalty payments to SAG were expensed in the respective period as milestone royalties — related parties in the consolidated statements of operations and comprehensive income.

Founders' Stock-Based Awards

On June 19, 2007, the Compensation Committee of the Company's Board of Directors authorized a one-time stock and cash award to each of the Company's founders. These awards were granted and fully vested on June 29, 2007 when the founders agreed to their terms, but were not to be settled until the earlier of the completion of the initial public offering or December 31, 2007. In August 2007, the awards were settled upon the completion of the initial public offering. The Compensation Committee intended for these awards to compensate the founders for the lost value of stock options that had been granted to them in 2001 and 2002 and had been understood by them to have ten-year terms, but which had expired in 2006 and early 2007 as a result of the terms of the 2001 Stock Incentive Plan. The expired options would have entitled the founders to purchase an aggregate of 578,000 shares of class A common stock at a price of $0.21 per share and 136,000 shares at a price of $2.95 per share.

Upon their settlement at the completion of the initial public offering, these stock and cash awards had an aggregate value equal to the difference between the value of the shares that could have been purchased under each of the expired options, determined on the basis of the public offering price per share of $11.50, and the respective aggregate exercise prices for such shares as provided in the option agreements.

These awards consisted of a combination of cash and shares of class A common stock. Of the aggregate value of each award, 40% was payable in cash and 60% in stock. For purposes of determining the number of shares of class A common stock to be issued in connection with each award, the stock was valued on the basis of the $11.50 public offering price per share in the initial public offering.

The estimated fair value of these awards, totaling $10.2 million on the grant date, was determined using the Black-Scholes-Merton Option Pricing Formula, as allowed under SFAS 123R. For the six months ended June 30, 2007, the Company recorded $10.2 million of general and administrative expense for these awards, of which $4.1 million was recorded as other liabilities — related parties for the cash settlement portion and $6.1 million as additional paid-in capital for the stock settlement portion. The liability portion of the awards was adjusted based upon the final cash settlement amount, but the equity portion was fixed upon the grant date.

When the initial public offering was completed in August 2007, the awards were settled and 401,133 shares of class A common stock were issued to the founders. In addition, as a result of the lower public offering price compared to the estimated public offering price at June 30, 2007, the Company recorded an adjustment of $1.0 million to reduce the amount of expense and related liability for the cash portion of the awards, which was paid to the founders, resulting in a net expense of $9.2 million for the year ended December 31, 2007.

10. Collaboration and License Agreements

The following table summarizes the cash streams and related collaboration and research and development revenue recognized under the Takeda Agreement and the Supplemental Agreement, which are described in more detail below:

(In thousands)	Cash Received through December 31, 2008	Revenue Recognized for the Year Ended December 31,					Accounts Receivable at December 31, 2008*	Amount Deferred at December 31, 2008
		2004	2005	2006	2007	2008		
Collaboration revenue:								
Up-front payment associated with our obligation to participate in joint committees with Takeda	$ 2,375	$ 23	$ 147	$ 147	$ 147	$ 147	$ —	$ 1,764
Research and development revenue:								
Up-front payment — remainder	$ 17,624	$ 1,356	$ 8,134	$ 6,157	$ 1,977	$ —	$ —	$ —
Development milestones	130,000	—	16,154	28,237	35,609	50,000	—	—
Reimbursement of research and development expenses	82,577	1,482	14,672	11,988	21,793	22,293	4,406	14,755
Total	$ 230,201	$ 2,838	$ 38,960	$ 46,382	$ 59,379	$ 72,293	$ 4,406	$ 14,755

* Includes billed and unbilled accounts receivable.

Upon execution of the Takeda Agreement, the Company was required to complete several deliverables, which Takeda was responsible to fund. The following are the required deliverables of the Company, along with the related contractual cash flows from Takeda and the associated obligations and performance period of the Company relating to research and development revenue:

- Upon receipt of the $20.0 million up-front payment, the Company deferred approximately $2.4 million to be recognized using the time-based model over the performance period of the participation in various joint committee meetings. The Company expects its participation on all committees to continue throughout the term of the Takeda Agreement, except for the Joint Development Committee, which continued until June 2007 when the development work was completed. During each of the years ended December 31, 2008, 2007 and 2006, the Company recognized approximately $147,000 of this deferred amount as collaboration revenue on the consolidated statements of operations and comprehensive income. The related deferred revenue as of December 31, 2008 and 2007 was approximately $1.8 million and $1.9 million, respectively.
- The Company granted Takeda an exclusive license of lubiprostone to co-develop, commercialize, and sell products for gastroenterology indications in the United States and Canada. There are no defined contractual cash flows within the Takeda Agreement for the grant of this license, but the Company did receive a non-refundable up-front payment of $20.0 million upon executing the Takeda Agreement. The license was granted to Takeda on October 29, 2004 and will expire when the Takeda Agreement expires or is terminated. After the commercial launch in 2006, Takeda has paid the Company pre-determined royalties on net revenues on a quarterly basis for the products sold by Takeda during the term of the Takeda Agreement. The level of royalties is tiered based on the net sales recognized by Takeda. The Company has recorded product

royalty revenue of approximately $34.4 million, $27.5 million and $6.6 million for the years ended December 31, 2008, 2007 and 2006, respectively. This revenue is recorded as product royalty revenue in the consolidated statements of operations and comprehensive income.

- The Company has provided development work necessary for an NDA submission to the FDA for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation indications. Takeda funded the initial $30.0 million of development costs, the Company was obligated to fund the first $20.0 million in excess of the initial $30.0 million funded by Takeda and the two parties are to equally share any required development costs in excess of $50.0 million. Although there was no defined performance period for this development work, the period to perform the work would not exceed the term of the Takeda Agreement. In January 2006, the Company received approval for its NDA for Amitiza to treat chronic idiopathic constipation and completed and submitted the supplemental NDA for irritable bowel syndrome with constipation to the FDA in June 2007.

The Company initially deferred the residual amount of the $20.0 million up-front payment totaling approximately $17.6 million, development milestone payments received totaling $50.0 million, and reimbursement of the initial $30.0 million of research and development costs for the development of Amitiza for chronic idiopathic constipation and irritable bowel syndrome with constipation indications. These deferred amounts were applied towards the unit of accounting that combines the participation in the Joint Development Committee and the development of chronic idiopathic constipation and irritable bowel syndrome with constipation and was recognized over the performance period of developing the chronic idiopathic constipation and irritable bowel syndrome with constipation NDA submissions. The Company completed the development of the chronic idiopathic constipation and irritable bowel syndrome with constipation in June 2007 and filed a supplemental NDA (sNDA) for irritable bowel syndrome with constipation. This was the culmination of the performance period. In June 2007, the Company also recognized as revenue, in full, $30.0 million from Takeda upon the filing of the sNDA for Amitiza to treat irritable bowel syndrome with constipation. The Company received a $50.0 million development milestone from Takeda as a result of the FDA's approval on April 29, 2008 of the sNDA for irritable bowel syndrome with constipation in adult women and recognized the payment as research and development revenue during the year ended December 31, 2008.

During the quarter ended June 30, 2006, the Joint Commercialization Committee granted approval for the Company and Takeda to begin three new studies related to funding arrangements discussed in both the Takeda Agreement and the Supplemental Agreement. The following are the three additional deliverables of the Company, along with the related contractual cash flows from Takeda and the associated obligations and performance period of the Company, when the three studies were agreed upon:

- The Company is obligated to perform studies in connection with changes to labeling for chronic idiopathic constipation. Takeda is obligated to fund 70% of the labeling studies and the Company is obligated to fund the remaining 30%. There is no defined performance period, but the performance period will not exceed the term of the Takeda Agreement. The Company initiated the first labeling study for chronic idiopathic constipation in August 2006.
- The Company is obligated to perform studies for the development of an additional indication for opioid-induced bowel dysfunction. Takeda is obligated to fund all development work up to a maximum aggregate of $50.0 million for each additional indication and $20.0 million for each new formulation. If development costs exceed these amounts, Takeda and the Company shall equally share such excess costs. There is no defined performance period, but the performance period will not exceed the term of the Takeda Agreement. The Company initiated work on the first additional indication for Amitiza in July 2006 and expects the development costs to exceed $50.0 million.
- The Company is obligated to perform all development work necessary for phase IV studies, for which Takeda is obligated to fund all development work. There is no defined performance period, but the

performance period will not exceed the term of the Supplemental Agreement. The Company began work on a phase IV study for chronic idiopathic constipation in August 2006.

The Company has assessed these required deliverables under the guidance of EITF 00-21 to determine which deliverables are considered separate units of accounting. As a result of the Company and Takeda agreeing to perform and fund these studies simultaneously, the Company determined that there is no objective and reliable evidence to determine the fair value for each of the studies. Accordingly, the Company has combined these three required deliverables as a single unit of accounting. All cash payments from Takeda related to these three deliverables are deferred upon receipt and recognized over the estimated performance period to complete the three studies using the time-based model. The estimated completion date is December 2009. During the years ended December 31, 2008, 2007 and 2006, the Company recognized approximately $22.3 million, $18.3 million and $1.1 million related to these three deliverables as research and development revenue in the consolidated statements of operations and comprehensive income, respectively.

On February 1, 2006, the Company entered into the Supplemental Agreement with Takeda, which amended the responsibilities of both the Company and Takeda for the co-promotion of Amitiza and clarified the responsibilities and funding arrangements for other marketing services to be performed by both parties.

Upon execution of the Supplemental Agreement, the Company was required to complete several deliverables, which Takeda was responsible to fund. The following are the required deliverables of the Company, along with the related contractual cash flows from Takeda and the associated obligations and performance period of the Company, under the Supplemental Agreement:

- The Company is obligated to co-promote Amitiza with Takeda by employing a sales force of approximately 38 representatives to supplement Takeda's sales activities. Takeda is obligated to reimburse the Company a specified amount per day per sales force representative, but such reimbursements shall not exceed certain pre-defined amounts. The term of this reimbursement arrangement ceases five years following the first date that the Company deployed sales representatives, which was in April 2006. The Company has recognized approximately $4.8 million, $4.3 million and $3.4 million of revenues for the years ended December 31, 2008, 2007 and 2006, respectively, reflecting these co-promotion reimbursements, which is recorded as co-promotion revenue in the consolidated statements of operations and comprehensive income.
- The Company was obligated to perform miscellaneous marketing activities for Amitiza, the majority of which would be reimbursed by Takeda. The miscellaneous marketing activities were completed in the first quarter of 2007. The Company has recorded $1,000, $158,000 and $779,000 of reimbursements of miscellaneous costs for the years ended December 31, 2008, 2007 and 2006, respectively. These amounts are recorded as co-promotion revenue in the consolidated statements of operations and comprehensive income.

The Company views the deliverables under the Supplemental Agreement as economically independent of those in the original Takeda Agreement.

The Company has assessed these required deliverables under the guidance of EITF 00-21 to determine which deliverables are considered separate units of accounting. The Company was able to determine that its sales force and miscellaneous marketing activities are treated as separate units of accounting. The Company is recognizing the cost reimbursements received for these deliverables as co-promotion revenues when services are performed and the reimbursement payments are due under the Supplemental Agreement.

11. Stockholders' Equity

Capital Structure

The class A common stock is entitled to one vote per share and, with respect to the election of directors, votes as a separate class and is entitled to elect that number of directors which constitutes ten percent of the total

membership of the Board of Directors. The class B common stock is entitled to 10 votes per share and votes as a separate class on the remaining percentage of Board of Directors not voted on by the class A common stockholders. Each holder of record of class B common stock may, in such holder's sole discretion and at such holder's option, convert any whole number or all of such holder's shares of class B common stock into fully paid and non-assessable shares of class A common stock for each share of class B common stock surrendered for conversion. The class B common stock is not transferable, except upon conversion. All of the shares of class B common stock are indirectly owned by the Company's founders.

During the year ended December 31, 2006, the Company sold 2,398,758 shares of class A common stock in a private transaction. As a result, the Company received net proceeds of $23.9 million.

In August 2007, the Company completed its initial public offering, consisting of 3,125,000 shares of class A common stock at a public offering price of $11.50 per share. After deducting underwriters' discounts, commissions, and expenses of the offering, including costs of $3.1 million incurred in 2006, the Company raised net proceeds of $28.2 million. Upon completion of the initial public offering, all shares of the Company's series A convertible preferred stock were converted into an aggregate of 3,213,000 shares of class A common stock.

Stock Repurchase

On December 9, 2008, the Company's Board of Directors authorized and approved a stock repurchase program, under which the Company may use up to $10 million to purchase shares of its Class A common stock from time to time in open-market transactions, depending on market conditions and other factors. As of December 31, 2008, the Company had not made any repurchases of stock.

Stock Option Plan

On February 15, 2001, the Company adopted the 2001 Stock Incentive Plan (the 2001 Incentive Plan) in order to provide common stock incentives to certain eligible employees, officers and directors, consultants and advisors of the Company. The Board of Directors administers the 2001 Incentive Plan and has sole discretion to grant options. Prior to the Company's initial public offering, the exercise price of each option granted under the 2001 Incentive Plan was determined by the Board of Directors and was to be no less than 100% of the fair market value of the Company's common stock on the date of grant. Determinations of fair market value of the class A common stock under the 2001 Incentive Plan was made in accordance with methods and procedures established by the Board of Directors prior to the Company's initial public offering. On September 1, 2003, the Board of Directors amended the 2001 Incentive Plan to allow for a maximum of 8,500,000 shares of class A common stock to be issued under all awards, including incentive stock options under the 2001 Incentive Plan. In 2006, the board of directors determined no further options would be granted under this plan.

On June 5, 2006, the Company's Board of Directors approved a 2006 Stock Incentive Plan (the 2006 Incentive Plan) and reserved 8,500,000 shares of class A common stock for issuance under that plan. At December 31, 2008, a total of 8,225,000 shares were available for future grants under the 2006 Incentive Plan. Option awards under the 2006 Incentive Plan are generally granted with an exercise price equal to the closing market price of the Company's stock at the date of grant and they generally vest over four years and have ten-year contractual terms.

On October 18, 2007, the Company's Board of Directors approved an amendment to the 2006 Incentive Plan. The 2006 Incentive Plan includes an "evergreen" provision by which the number of shares of the Company's class A common stock available for issuance under the 2006 Incentive Plan increases automatically on the first day of each calendar year by a number equal to 5% of the aggregate number of shares of the Company's class A common stock and class B common stock outstanding on such date, or such lesser number as the Board of Directors may determine. As amended, the 2006 Incentive Plan will provide that the number of shares of class A common stock included in each annual increase will be 500,000, or such lesser number as the Board of Directors may

determine. The Board of Directors also determined that the amount of the increase in the shares available for issuance under the 2006 Incentive Plan as of January 1, 2008, pursuant to the "evergreen" provision, would be zero.

When an option is exercised, the Company issues a new share of class A common stock.

A summary of the employee stock option activity for the year ended December 31, 2008 under the Company's 2001 Incentive Plan is presented below.

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2007	640,900	$ 10.24		
Options exercised	(51,880)	10.00		
Options forfeited	(36,550)	10.00		
Options expired	(96,870)	10.00		
Options outstanding, December 31, 2008	455,600	10.34	5.65	$ —
Options exercisable, December 31, 2008	442,425	10.35	5.60	$ —

A summary of the employee stock option activity for the year ended December 31, 2008 under the Company's 2006 Incentive Plan is presented below:

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2007	267,500	$ 14.44		
Options granted	44,000	10.57		
Options forfeited	(23,250)	14.12		
Options expired	(13,250)	14.12		
Options outstanding, December 31, 2008	275,000	13.86	7.00	$ —
Options exercisable, December 31, 2008	116,500	14.49	7.66	$ —

The weighted average grant date fair value of options granted during the years ended December 31, 2008, 2007 and 2006 were $5.88, $7.19 and $6.41, respectively. The total intrinsic value of options exercised during the years ended December 31, 2008 and 2006 were $95,000 and $83,000, respectively. There was no intrinsic value of options exercised during December 31, 2007. As of December 31, 2008, approximately $1.0 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards are expected to be recognized over a weighted average period of 2.15 years.

The following table summarizes the non-employee stock option activity for the year ended December 31, 2008 under the Company's 2001 Incentive Plan:

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2007	510,000	$ 5.85		
Options exercised	(60,000)	5.85		
Options outstanding, December 31, 2008	450,000	5.85	6.33	$ —
Options exercisable, December 31, 2008	450,000	5.85	6.33	$ —

Employee Stock Purchase Plan

On June 5, 2006, the Company's Board of Directors approved a 2006 Employee Stock Purchase Plan (ESPP) and reserved 4,250,000 shares of class A common stock for issuance under the ESPP. As of year ended December 31, 2008, the Board has approved 500,000 shares of class A common stock for the ESPP, intended to qualify as an "Employee Stock Purchase Plan" as defined in Section 423 of the Internal Revenue Code of 1986. Under this plan, eligible employees may purchase common stock through payroll deductions of up to 10% of compensation during the plan period. In accordance with SFAS No. 123R, this plan is non-compensatory. The purchase price per share is 95% of market price at the end of each plan period which is generally three months. A total of 1,451 shares of common stock were purchased under the ESPP during the year ended December 31, 2008. Cash received upon purchase of shares under the ESPP during 2008 was $7,926. There were no shares issued under the ESPP during the years ended December 31, 2007 and 2006.

12. Income Taxes

The provision (benefit) for income taxes consists of the following for the three years ended December 31:

(In thousands)	Year Ended December 31, 2008	2007	2006
Current tax provision (benefit):			
Federal	$ 9,903	$ 2,900	$ (715)
State	2,661	671	(261)
Total current tax provision (benefit)	12,564	3,571	(976)
Deferred provision (benefit):			
Federal	(3,450)	3,821	(4,182)
State	(951)	441	261
Total deferred provision (benefit)	(4,401)	4,262	(3,921)
Total income tax provision (benefit)	$ 8,163	$ 7,833	$ (4,897)

Deferred tax assets, net, consist of the following as of December 31:

(In thousands)	2008	2007
Deferred tax assets:		
Foreign net operating loss carryforwards	$ 5,304	$ 1,892
Deferred revenue	2,999	3,345
General business credit carryforwards	—	3,086
Accrued expenses	765	1,102
Tax benefits on stock options	1,654	2,069
Other	212	—
Gross deferred tax assets	10,934	11,494
Deferred tax liabilities:		
Property and equipment	(195)	(42)
Other	(51)	—
Gross deferred tax liabilities	(246)	(42)
Less: valuation allowance	(5,699)	(10,813)
Net deferred tax assets	$ 4,989	$ 639

The Company continued to assess its ability to realize certain deferred tax assets in the three years ended December 31, 2008. During 2008, the Company performed an analysis of future projections due to significant milestone and royalty revenues that resulted in increased profitability in 2008 and the expectation of profitability beyond 2008. As a result of this analysis, the Company reversed an additional $8.4 million of valuation allowance on its U.S. deferred tax assets in 2008. The net deferred tax asset as of December 31, 2008 and 2007 represents the amount the Company believes is more likely than not to be utilized.

The provision (benefit) for income taxes vary from the income taxes provided based on the federal statutory rate of 35%, 35% and 34% as follows for the three years ended December 31:

(In thousands)	Year Ended December 31, 2008	2007	2006
Federal tax provision at statutory rate	35.0%	35.0%	34.0%
State taxes, net of federal tax benefit	5.6	4.7	2.3
General business credits	(0.8)	(2.6)	(2.6)
Changes in valuation allowance	(15.6)	4.2	(69.6)
Adjustment to net operating loss carryforward	—	—	(0.1)
Changes in other tax matters	0.5	(4.0)	7.0
Total effective tax rate	24.7%	37.3%	(29.0)%

At December 31, 2008 and 2007, the Company had foreign net operating loss carry forwards (NOLs) of $14.4 million and $5.4 million, respectively. Approximately $9.8 million of the foreign NOLs begin to expire in December 2011, and $4.6 million of the foreign NOLs do not expire. At December 31, 2007, the Company had U.S. general business credits of $3.1 million. There were no U.S. general business credits as of December 31, 2008.

As of December 31, 2008 and 2007, the Company had a valuation allowance on its deferred tax assets of $5.7 million and $10.8 million, respectively. The decrease in the valuation allowance of $5.1 million was due

primarily to a reversal of valuation allowance on the US deferred tax assets offset by an increase in foreign deferred tax assets related to NOLs that are not “more likely than not” to be utilized.

Should the Company determine that it would be able to realize its deferred tax assets in the foreseeable future, an adjustment to the remaining deferred tax assets could cause a material increase to income in the period such determination is made. Significant management judgment is required in determining the period in which the reversal of a valuation allowance should occur. The Company considered all available evidence, both positive and negative, such as historical levels of income and future forecasts of taxable income amongst other items in determining whether a full or partial release of a valuation allowance was required as of December 31, 2008 and 2007. The valuation allowance at December 31, 2008 relates to deferred tax assets in the foreign jurisdictions. The Company will continue to evaluate its valuation allowance position in each jurisdiction on a regular basis. To the extent that the Company determines that all or a portion of its valuation allowance is no longer necessary, the Company will recognize an income tax benefit in the period such determination is made for the reversal of the valuation allowance. Once the valuation allowance is eliminated in whole or in part, it will not be available to offset the Company’s future tax provision.

The Company has recorded a non-current income tax liability of $517,000 for uncertain tax positions as of December 31, 2008. The amount represents the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in our consolidated financial statements, and are reflected in other liabilities in the accompanying consolidated balance sheets. The liability for uncertain tax positions as of December 31, 2008 mainly pertains to the Company’s interpretation of nexus in certain states related to revenue sourcing for state income tax purposes.

The Company is still open to examination from 2005 forward, although research and experimentation tax attributes that were generated prior to 2005 may still be adjusted upon examination by tax authorities. The Company is currently under examination by the tax authorities in the US for the years ended December 31, 2005, 2006 and 2007.

13. Segment Reporting

The Company has determined that it has three reportable geographic segments based on the Company’s method of internal reporting, which disaggregates the business by geographic location. These segments are the United States, Europe and Japan. The Company evaluates performance of these segments based on income (loss) from operations, as well as other factors, including the progress of its research and development activities. The reportable segments have historically derived their revenue from joint collaboration and strategic alliance agreements. Transactions between the segments consist primarily of intercompany loans and the provision of research and development services. Following is a summary of financial information by reportable geographic segment.

(In thousands)	United States	Europe	Japan	Intercompany Eliminations	Consolidated
Year Ended December 31, 2008					
Research and development revenue	$ 72,293	$ —	$ —	$ —	$ 72,293
Product royalty revenue	34,438	—	—	—	34,438
Co-promotion revenue	4,826	—	—	—	4,826
Contract revenue and collaboration revenue	566	—	840	(840)	566
Total revenues	112,123	—	840	(840)	112,123
Depreciation and amortization	437	3	10	—	450
Other operating expenses	71,811	3,496	6,135	(840)	80,602
Income (loss) from operations	39,875	(3,499)	(5,305)	—	31,071
Interest income	2,559	6	5	(128)	2,442
Other non-operating (expense) income, net	(398)	12	(141)	128	(399)
Income (loss) before income taxes	$ 42,036	$ (3,481)	$ (5,441)	$ —	$ 33,114
Capital expenditures	$ 389	$ 42	$ 20	$ —	$ 451
Year Ended December 31, 2007					
Research and development revenue	$ 59,379	$ —	$ —	$ —	$ 59,379
Product royalty revenue	27,536	—	—	—	27,536
Co-promotion revenue	4,411	—	—	—	4,411
Contract revenue and collaboration revenue	565	—	840	(840)	565
Total revenues	91,891	—	840	(840)	91,891
Depreciation and amortization	239	2	10	—	251
Other operating expenses	69,971	1,125	2,985	(848)	73,233
Income (loss) from operations	21,681	(1,127)	(2,155)	8	18,407
Interest income	2,618	1	7	(161)	2,465
Other non-operating (expense) income, net	(72)	254	(184)	153	151
Income (loss) before income taxes	$ 24,227	$ (872)	$ (2,332)	$ —	$ 21,023
Capital expenditures	$ 2,231	$ —	$ —	$ —	$ 2,231
Year Ended December 31, 2006					
Research and development revenue	$ 46,382	$ —	$ —	$ —	$ 46,382
Product royalty revenue	6,590	—	—	—	6,590
Co-promotion revenue	4,243	—	—	—	4,243
Contract revenue and collaboration revenue	461	1,500	161	(71)	2,051
Total revenues	57,676	1,500	161	(71)	59,266
Depreciation and amortization	59	2	8	—	69
Other operating expenses	43,643	518	343	(70)	44,434
Income (loss) from operations	13,974	980	(190)	(1)	14,763
Interest income	2,035	2	4	(65)	1,976
Other non-operating income (expense), net	11	(48)	134	68	165
Income (loss) before income taxes	$ 16,020	$ 934	$ (52)	$ 2	$ 16,904
Capital expenditures	$ 196	$ —	$ 40	$ —	$ 236
As of December 31, 2008					
Property and equipment, net	$ 2,134	$ 39	$ 102	$ —	$ 2,275
Identifiable assets	$ 163,660	$ 568	$ 4,469	$ (17,903)	$ 150,794
As of December 31, 2007					
Property and equipment, net	$ 2,182	$ —	$ 83	$ —	$ 2,265
Identifiable assets	$ 114,490	$ 2,381	$ 1,987	$ (8,831)	$ 110,027

14. Subsequent Events

In February 2009, the Company entered into a license and commercialization agreement with Abbott Japan Co. Ltd. for Amitiza in Japan. Under the terms of the agreement, Abbott received exclusive rights to commercialize lubiprostone in Japan for the treatment of chronic idiopathic constipation (CIC) and received the right of first refusal to any additional indications for which lubiprostone is developed in Japan. Abbott will be responsible for all commercialization expenses and efforts. The Company received an upfront payment of $10 million and could receive additional milestone payments based on achieving specified development and commercialization goals. The Company will continue to lead the development of, and regulatory activity for, lubiprostone in Japan and will continue to be responsible for the costs of lubiprostone development. Following marketing authorization and pricing approval, Abbott would purchase finished product from the Company for distribution in Japan. The Company also will retain the right to co-promote lubiprostone in Japan.

In February 2009, the Company entered into an Exclusive Manufacturing and Supply Agreement with R-Tech under which the Company granted R-Tech the exclusive right to manufacture and supply lubiprostone to meet the Company's commercial and clinical requirements in Asia, Australia and New Zealand. In consideration, R-Tech will make an up-front payment of $250,000 and will be obligated to make milestone payments of $500,000 upon regulatory approval of lubiprostone in Japan and $250,000 upon the commercial launch in Japan. In addition, R-Tech is required to maintain at least a six-month supply of lubiprostone and a three-month supply of the active ingredient used in manufacturing lubiprostone as a backup inventory.

In February 2009, the Company entered into an addendum to the Amended and Restated Patent Access Agreement originally entered into between the Company and Sucampo AG on June 30, 2006. Under the Addendum, the patent and know-how royalties Sucampo Japan is obligated to pay to Sucampo AG are reduced with respect to sales of lubiprostone in Asia, Australia and New Zealand as follows:

- the patent royalty on net sales, due until the expiration of the last patent covering lubiprostone that existed at the time of the Company's initial public offering, is reduced from 4.5% to 2.2%;
- the patent royalty on net sales, due thereafter until all other patents covering lubiprostone have expired in the relevant country, is reduced from 2.25% to 1.1%; and
- the know-how royalty on net sales, due until the fifteenth anniversary of the first commercial sale of lubiprostone, is reduced from 2.0% to 1.0%.

15. Quarterly Financial Data (unaudited)

	2008 Quarters Ended			
(In thousands, except per share data)	**December 31**	**September 30**	**June 30**	**March 31**
Total revenues	$ 16,374	$ 14,481	$ 67,714	$ 13,554
(Loss) income from operations	$ (2,230)	$ (4,811)	$ 43,901	$ (5,789)
Net (loss) income	$ (3,004)	$ (2,426)	$ 29,876	$ 505
Net (loss) income per share:				
Basic	$ (0.07)	$ (0.06)	$ 0.72	$ 0.01
Diluted	$ (0.07)	$ (0.06)	$ 0.71	$ 0.01

	2007 Quarters Ended			
	December 31	September 30	June 30	March 31
Total revenues	$ 17,145	$ 12,852	$ 48,934	$ 12,960
Loss (income) from operations	$ (2,115)	$ (875)	$ 20,859	$ 538
Net (loss) income	$ (735)	$ (474)	$ 13,883	$ 516
Net (loss) income per share:				
Basic	$ (0.02)	$ (0.01)	$ 0.40	$ 0.01
Diluted	$ (0.02)	$ (0.01)	$ 0.39	$ 0.01

Net (loss) income per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net (loss) income per share information may not equal annual net income (loss) per share.

Schedule II — Valuation and Qualifying Accounts

(In thousands)	Balance at Beginning of Year	Additions Charged to Costs and Expenses	Deductions	Other	Balance at End of Year
Valuation allowance for deferred tax assets:					
2006	$ 21,459	$ —	$ (11,608)(a)	$ —	$ 9,851
2007	9,851	1,166(b)	(204)(c)	—	10,813
2008	10,813	3,262(b)	(8,376)(d)	—	5,699

(a) The 2006 decrease in valuation allowance for deferred tax assets reflects primarily the Company's utilization of the deferred tax assets of $6.7 million and a decrease in valuation allowance for deferred tax assets of $4.9 million resulting from a change in management's judgment related to estimated future taxable income in the United States.

(b) In 2008 and 2007, the increase in valuation allowance is primarily associated with certain foreign net operating losses. This increase in the valuation allowance was based on management's assessment that, due to changing business conditions and the limitation of tax planning strategies, the Company was not likely to fully realize these deferred tax assets.

(c) In 2007, the decrease in valuation allowance for deferred tax assets reflects the change in management's judgment related to estimated future taxable income in the United States.

(d) In 2008, the decrease in the valuation allowance is primarily associated with release of allowance largely due to the receipt of a $50.0 million development milestone and the increase in projected revenues.

Sucampo Pharmaceuticals, Inc.

Exhibit Index

Exhibit Number	Description	Reference
2.1	Agreement and Plan of Reorganization	Exhibit 2.1 to the Company's Current Report on Form 8-K (filed December 29, 2009)
3.1	Certificate of Incorporation	Exhibit 3.1 to the Company's Current Report on Form 8-K (filed December 29, 2009)
3.2	Certificate of Amendment	Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2009)
3.3	Restated Bylaws	Exhibit 3.3 to the Company's Current Report on Form 8-K (filed December 29, 2009)
4.1	Specimen Stock Certificate evidencing the shares of class A common stock	Exhibit 4.1 to Registration Statement No. 333-135133, Amendment No. 5 (filed February 1, 2007)
10.1^	Amended and Restated 2001 Stock Incentive Plan	Exhibit 10.1 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.2^	Amended and Restated 2006 Stock Incentive Plan	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (filed November 14, 2007)
10.3^	2006 Employee Stock Purchase Plan	Exhibit 10.3 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.4^	Form of Incentive Stock Option Agreement for 2006 Stock Incentive Plan	Exhibit 10.4 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.5^	Form of Nonstatutory Stock Option Agreement for 2006 Stock Incentive Plan	Exhibit 10.5 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.6^	Form of Restricted Stock Agreement for 2006 Stock Incentive Plan	Exhibit 10.6 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.7^	Non-employee Director Compensation Summary	Exhibit 10.7 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.8^	Employment Agreement, dated June 16, 2006, between the Company and Ryuji Ueno	Exhibit 10.9 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.9^	Form of Executive Employment Agreement	Exhibit 10.10 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.10	Indemnification Agreement, dated May 26, 2004, between the Company and Sachiko Kuno	Exhibit 10.11 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.11	Indemnification Agreement, dated May 26, 2004, between the Company and Ryuji Ueno	Exhibit 10.12 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.12	Indemnification Agreement, dated May 26, 2004, between the Company and Michael Jeffries	Exhibit 10.13 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.13	Indemnification Agreement, dated May 26, 2004, between the Company and Hidetoshi Mine	Exhibit 10.14 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.14	Form of Investor Rights Agreement	Exhibit 10.16 to Registration Statement No. 333-135133, (filed June 19, 2006)

Exhibit Number	Description	Reference
10.15	Lease Agreement, dated September 16, 1998, between the Company and Plaza West Limited Partnership, successor in interest to Trizechahn Plaza West Limited Partnership, as amended	Exhibit 10.17 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.16	Sublease Agreement, dated October 26, 2005, between the Company and First Potomac Realty Investment L.P.	Exhibit 10.18 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.17	Amended and Restated Patent Access Agreement, dated June 30, 2006, among the Company, Sucampo Pharma Europe Ltd., Sucampo Pharma, Ltd. and Sucampo AG	Exhibit 10.19 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.18*	Exclusive Manufacturing and Supply Agreement, dated June 23, 2004, between the Company and R-Tech Ueno, Ltd., as amended on October 2, 2006	Exhibit 10.20 to Registration Statement No. 333-135133, Amendment No. 3 (filed October 25, 2006)
10.19*	Collaboration and License Agreement, dated October 29, 2004, between the Company and Takeda Pharmaceutical Company Limited	Exhibit 10.21 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.20*	Agreement, dated October 29, 2004, among the Company, Takeda Pharmaceutical Company Limited and Sucampo AG	Exhibit 10.22 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.21*	Supply Agreement, dated October 29, 2004, among the Company, Takeda Pharmaceutical Company Limited and R-Tech Ueno, Ltd.	Exhibit 10.23 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.22*	Supply and Purchase Agreement, dated January 25, 2006, among the Company, Takeda Pharmaceutical Company Limited and R-Tech Ueno, Ltd.	Exhibit 10.24 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.23*	Supplemental Agreement, dated February 1, 2006, between the Company and Takeda Pharmaceutical Company Limited	Exhibit 10.25 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.24*	Services Agreement, dated February 9, 2006, between the Company and Ventiv Commercial Services, LLC	Exhibit 10.26 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.25	Indemnification Agreement, dated September 7, 2006, between the Company and Timothy Maudlin	Exhibit 10.27 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.26	Indemnification Agreement, dated September 7, 2006, between the Company and Sue Molina	Exhibit 10.28 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.27*	Exclusive Manufacturing and Supply Agreement, dated June 24, 2005, between Sucampo Pharma Europe Ltd. and R-Tech Ueno, Ltd., as amended on October 2, 2006	Exhibit 10.29 to Registration Statement No. 333-135133, Amendment No. 3 (filed October 25, 2006)
10.28*	SPI-8811 and SPI-017 Exclusive Clinical Manufacturing and Supply Agreement, dated October 4, 2006, between the Company and R-Tech Ueno, Ltd.	Exhibit 10.31 to Registration Statement No. 333-135133, Amendment No. 3 (filed October 25, 2006)

Exhibit Number	Description	Reference
10.29	Lease Agreement, dated December 18, 2006, between the Company and EW Bethesda Office Investors, LLC	Exhibit 1.29 to the Company's Annual Report on Form 10-K (filed March 27, 2008)
10.30^	Amendment to Employment Agreement, dated November 20, 2006, between the Company and Ryuji Ueno	Exhibit 10.35 to Registration Statement No. 333-135133, Amendment No. 5 (filed February 1, 2007)
10.31	Letter agreement, dated January 29, 2007, between the Company and Takeda Pharmaceutical Company Limited	Exhibit 10.36 to Registration Statement No. 333-135133, Amendment No. 6 (filed May 14, 2007)
10.32^	Employment Agreement, effective June 1, 2007, between the Company and Sachiko Kuno	Exhibit 10.37 to Registration Statement No. 333-135133, Amendment No. 8 (filed July 17, 2007)
10.33^	Amended Employment Agreement, dated May 12, 2007, between the Company and Mariam E. Morris	Exhibit 10.38 to Registration Statement No. 333-135133, Amendment No. 7 (filed June 25, 2007)
10.34	Indemnification Agreement, dated October 18, 2007, between the Company and Anthony C. Celeste	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (filed November 14, 2007)
10.38^	Amendment, dated December 6, 2007, to Employment Agreement between the Company and Gayle Dolecek	Exhibit 10.4 to the Company's Current Report on Form 8-K (filed December 14, 2007)
10.40^	Amendment, dated November 26, 2007, to Employment Agreement between the Company and Ryuji Ueno	Exhibit 10.6 to the Company's Current Report on Form 8-K (filed December 14, 2007)
10.41	Credit Line Agreement, dated March 5, 2008, between the Company and UBS Bank USA	Exhibit 10.41 to the Company's Annual Report on Form 10-K (filed March 27, 2008)
10.42	Amended and Restated Patent Access Agreement, dated February 18, 2009, among the Company, Sucampo Pharma Europe, Ltd., Sucampo Pharma, Ltd. and Sucampo AG	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed February 19, 2009)
10.43*	Supply Agreement, dated February 19, 2009, between Sucampo Pharma Ltd and Abbott Japan Co. Ltd.	Included herewith
10.44*	Exclusive Manufacturing and Supply Agreement, dated February 23, 2009, between Sucampo Pharma, Ltd and R-Tech Ueno, Ltd.	Included herewith
10.45	Indemnification Agreement by and between the Company and Andrew J. Ferrara	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed July 22, 2008)
10.46	Separation Agreement and General Release by and between the Company and Mariam E. Morris	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed July 28, 2008)
10.47	Consulting Agreement by and between the Company and Mariam E. Morris	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed July 28, 2008)
21	Subsidiaries of the Company	Included herewith
23.1	Consent of PricewaterhouseCoopers LLC, Independent Registered Public Accounting Firm	Included herewith
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith

Exhibit Number	Description	Reference
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith

^ Compensatory plan, contract or arrangement.

* Confidential treatment has been requested for portions of this exhibit.

Exhibit 10.43

LICENSE, COMMERCIALIZATION AND SUPPLY AGREEMENT FOR LUBIPROSTONE FOR JAPAN

by and between

ABBOTT JAPAN CO. LTD

and

SUCAMPO PHARMA, LTD.

Dated as of February 19, 2009

LICENSE, COMMERCIALIZATION AND SUPPLY AGREEMENT
FOR LUBIPROSTONE FOR JAPAN

This LICENSE, COMMERCIALIZATION, AND SUPPLY AGREEMENT FOR LUBIPROSTONE FOR JAPAN ("Agreement") is entered into as of February 19, 2009, by and between Sucampo Pharma, Ltd., a corporation organized under the laws of Japan with principal offices at 2-2-2 Uchisaiwai-cho, Chiyoda-ku, Tokyo, 100-0011, Japan ("Sucampo") and Abbott Japan Co. Ltd., a corporation organized under the laws of Japan with principal offices at 3-5-27 Mita, Minato-ku, Tokyo 108-6303, Japan ("Abbott"). Each of Abbott and Sucampo is sometimes referred to individually herein as a "Party" and collectively as the "Parties".

BACKGROUND

WHEREAS, Sucampo Controls the Sucampo Patents Rights and the Sucampo Background Technology related to the Product and is in the process of Developing the Product in the Field in the Territory (as such terms are hereinafter defined);

WHEREAS, Abbott is a healthcare company with research, development and marketing activities throughout the world; and

WHEREAS, Abbott desires to obtain a non-exclusive license to Develop the Product in the Field in the Territory and an exclusive license to Commercialize the Product in the Field in the Territory (as such terms are hereinafter defined).

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this ARTICLE 1 shall have the meanings specified below:

"Abbott" means Abbott Japan Co. Ltd., as identified in the preamble to this Agreement.

"Abbott Indemnitee(s)" has the meaning set forth in Section 14.2.

"Additional Materials" means all raw materials, resins, chemical intermediates, components, excipients, and other ingredients and packaging materials and supplies, including Product Labels and Inserts, needed to manufacture the Product for use in the Field, including costs for relevant in-bound freight.

"Adverse Event" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

"Affiliate" means, with respect to either Party, any Person that, directly or through one or more Affiliates, controls, or is controlled by, or is under common control with, such Party. For purposes of this definition, "control" means (a) ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than fifty percent (50%) of the equity interests in the case of any other type of legal entity, (b) status as a general partner in any partnership, or (c) any other arrangement whereby a Person controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity.

"Agreement" means this License, Commercialization and Supply Agreement for Lubiprostone for Japan, including all Exhibits hereto, as identified in the preamble, as may be amended from time to time in accordance with its terms.

"Annual Net Sales" means the cumulative Net Sales during any given Calendar Year.

"Applicable Law" means all federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations, or requirements of Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity hereunder.

"Audited Party" has the meaning set forth in Section 8.7.

"Auditing Party" has the meaning set forth in Section 8.7.

"Business Day" means a day, other than a Saturday or Sunday, on which banking institutions in Tokyo, Japan are open for business.

"Calendar Year" means each successive period of twelve (12) consecutive calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December

31, 2009, and the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which the Term ends and end on the last day of the Term.

"cGMP" means the quality systems and current good manufacturing practices applicable to the manufacture, labeling, packaging, handling, storage, and transport of the Compound, the Additional Materials and the Product, as set forth in the Pharmaceutical Affairs Law of Japan (Law No. 145 of 1960, as amended), and its related Ordinances including the MHLW Ordinance No. 179, December 24, 2004, any update thereto and any other laws, regulations, policies, or guidelines applicable to the manufacture, labeling, packaging, handling, storage, and transport of pharmaceutical products in the Territory, and/or any applicable foreign equivalents thereof, and any updates of any of the foregoing.

"CIC" means chronic idiopathic constipation.

"CIC Indication" means the prophylactic or therapeutic use in the prevention and/or treatment of CIC.

"Clinical Data" means all data with respect to a product containing the Compound for use in the CIC Indication that is made, collected or otherwise generated anywhere in the world under or in connection with the Clinical Studies for a product containing the Compound for use in the CIC Indication (as opposed to Pre-Clinical Data or non-clinical data derived from laboratory studies, disease models and animal studies). Clinical Data includes, but is not limited to, validated clinical databases.

"Clinical Study(ies)" means Phase I Study, Phase II Study, Phase III Study, Phase IV Study conducted anywhere in the world, or such other tests or studies in humans conducted anywhere in the world, that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for the Product in the Field in the Territory, but excluding Post-Approval Marketing Studies.

"CMC Data" means the data contained in the chemistry, manufacturing and controls section of a submission for Regulatory Approval of the Product in the Field in the Territory.

"Commercialization" or "Commercialize" means any and all activities (whether before or after Regulatory Approval) directed to the commercialization of the Product in the Field in the Territory, including pre-launch and post-launch marketing, Promoting, distributing, offering to sell and selling the Product in the Field in the Territory. When used as a verb, "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

"Commercialization Plan" means a written one (1) year plan prepared by Abbott for the Commercialization of the Product in the Field in the Territory, including, without

limitation, a budget for such activities, as such plan may be amended or updated from time to time in accordance with Section 7.1.

"Commercially Reasonable Efforts" means, with respect to activities of each Party contemplated by this Agreement, the level of effort commonly used in the research-based pharmaceutical industry to conduct development, promotion or commercialization activities for a product that is at a similar stage in its lifecycle and is of comparable market potential, profit potential and strategic value, taking into account relevant considerations, including issues of safety (including Adverse Events) and efficacy, product profile, the proprietary position, the then-current competitive environment for such product, the likely timing of the product's entry into the market, the then-current market penetration, the return on investment potential of such product, the regulatory environment and status of the product, and other relevant scientific, technical and commercial factors, in each case in a manner consistent with the level of effort and expenditure contemplated for such activities by the Development Plan or the Commercialization Plan, as the case may be, and as measured by the facts and circumstances at the time such efforts are due.

"Committee(s)" has the meaning set forth in Section 3.1.1. Each of the JDC and the JCSC is sometimes referred to individually herein as a "Committee" and collectively as the "Committees."

"Competing Product" has the meaning set forth in Section 7.8.

"Compound" means lubiprostone (also known by the tradename AMITIZA®) as further described in Exhibit A, and its salts, metabolites, as well as any active pro-drugs, isomers, tautomers, hydrates and polymorphs.

"Confidential Information" means any and all proprietary information or material, whether oral, visual, in writing or in any other form, that, at any time since September 5, 2007 or after the Effective Date, has been or is provided, communicated or otherwise made known to the Receiving Party or any of its Affiliates by or on behalf of the Disclosing Party or any of its Affiliates pursuant to this Agreement or in connection with the transactions contemplated hereby or any discussions or negotiations with respect thereto, including pursuant to the Confidentiality Agreement.

"Confidentiality Agreement" means the Confidentiality Agreement by and between Abbott Laboratories, an Illinois corporation, and Sucampo Pharmaceuticals, Inc., a Delaware corporation, effective as of September 5, 2007, as amended.

"Control" or "Controlled" means, with respect to any Technology, Patent Right or Regulatory Filing, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense, a right of reference or other right to or under, such Technology, Patent Right or Regulatory Filing, as

provided for herein, without violating the terms of any agreement or other arrangement with any Third Party.

"Core Data Sheets" means a document prepared by the Regulatory Approval holder containing, in addition to the Company Core Safety Information (CCSI), material relating to the CIC Indication, dosing, pharmacokinetics, and other information on the Product for use in the Field in the Territory based on scientific data that are positioned on appropriate prescribing information for safe and effective use of the Product in the Field in the Territory.

"Corporate Names" means (a) in the case of Abbott, the Trademark Abbott and the Abbott corporate logo or such other names and logos used generally by Abbott and its Affiliates in their business (and not relating to a specific product or technology) as Abbott may designate in writing from time to time, and (b) in the case of Sucampo, the Trademark Sucampo and the Sucampo corporate logo or such other names and logos used generally by Sucampo and its Affiliates in its business (and not relating to a specific product or technology) as the JCSC may designate in writing from time to time, in each case ((a) and (b)), together with any variations and derivatives thereof.

"CTN" means an application filed with a Regulatory Authority for authorization to commence human clinical trials of the Compound, including (a) Clinical Trial Notifications as defined in IYAKUSHINHATSU No. 908, August 1, 2000 or any update thereto or any successor application or procedure filed with the Minister of Labour, Health and Welfare of Japan, and (b) all supplements and amendments that may be filed with respect to the foregoing.

"Data Exclusivity" means any data or market exclusivity granted to the Product in the Field in the Territory by any Regulatory Authority as of the Effective Date or at any time during the Term. *

"Development" or "Develop" means, with respect to the Product in the Field in the Territory, all research, all pre-clinical and clinical activities conducted relating to the Product for the CIC Indication, including without limitation, test method development and stability testing, toxicology, animal studies, formulation, process development, manufacturing scale-up, quality assurance/quality control development for Clinical Studies, statistical analysis and report writing, and Clinical Studies, including clinical trial design, operations, data collection and analysis and report writing, publication planning and support, risk assessment mitigation strategies, health economics outcomes research planning and support, clinical laboratory work, disposal of drugs and regulatory activities in connection therewith, the transfer of information, materials, Product regulatory documentation and other technology with respect to the foregoing, the preparation of Regulatory Filings, and obtaining and/ or maintaining Regulatory Approvals for the Product in the Field in the Territory (including regulatory affairs activities and preparation of meetings with Regulatory Authorities in the Territory). When used as a verb,

"Developing" means to engage in Development and "Developed" has a corresponding meaning.

"Development Plan" means a written rolling four (4) year plan for the Development of the Product in the Field in the Territory, as such plan may be amended or updated from time to time in accordance with Section 4.1.2.

"Disclosing Party" means the Party disclosing Confidential Information; provided a Party owning certain property as provided hereunder shall be considered the Disclosing Party and the other Party shall be considered the Receiving Party regardless of which Party discloses such information.

"Disputed Matter" has the meaning set forth in Section 3.1.5.

"Distributor" means any Third Party appointed by Abbott, its Affiliates or Sublicensees to distribute and sell in the Field in the Territory Product purchased from Abbott, its Affiliates or Sublicensees (regardless of whether such Third Party has the right or obligation to provide packaging or labeling services with respect to such Product) that: (i) is not required to make royalty or other similar payment to Abbott, its Affiliates or Sublicensees with respect to any Sucampo Patent Rights or Sucampo Background Technology related to the Product in the Field in the Territory; and (ii) has no right to distribute and sell such Product under its own Trademark.

"Drug Approval Application" means an application submitted to a Regulatory Authority for Regulatory Approval for the Product in the Field in the Territory, and all supplements and amendments that may be filed with respect to the foregoing.

"Effective Date" means the date first set forth in the preamble to this Agreement.

"Field" means the use of the Product for all prophylactic and therapeutic uses in animals and humans, in any formulation, dosage form, strength or delivery mode for the CIC Indication.

"First Commercial Sale" means the first bona fide commercial sale of the Product for use in the Field by Abbott, its Affiliates or Sublicensees to a Third Party in the Territory after all required applicable Regulatory Approvals have been granted.

"Five Year Cumulative Sales Target" means [*] JPY (JPY [*]) in cumulative Net Sales of Product in the Field in the Territory within the first sixty (60) months following the First Commercial Sale of the first Product, based on the assumptions listed in Exhibit I. The Five Year Cumulative Sales Target shall be adjusted upward or downward, as the case may be, by the Parties in the event any of the facts differ from the assumptions listed in Exhibit I.

"Floor Transfer Price" has the meaning set forth in Section 8.3.2.

"Force Majeure" has the meaning set forth in Section 15.10.

"GAAP" means generally accepted accounting principles recognized in the United States.

"Generic Product" means, with respect to a Product, a pharmaceutical product, other than a product that is developed, marketed or sold by a Party or its Affiliates or a Third Party authorized or licensed by such Party to Develop or Commercialize the Product, that contains the Compound.

"Indemnification Claim Notice" has the meaning set forth in Section 14.2.3.

"Initial Period" means the period commencing on the date of the First Commercial Sale and ending seventy-two (72) months later.

"Infringement" has the meaning set forth in Section 11.5.1.

"Infringement Notice" has the meaning set forth in Section 11.5.1.

"Invoice Price" means (i) for as long as Abbott pays the Transfer Price for Product, [*] percent ([*]%) of the NHI Price, and (ii) for as long as Abbott pays the Floor Transfer Price for Product, [*] percent ([*]%) of the NHI Price.

"JCSC" has the meaning set forth in Section 3.1.1(a).

"JDC" has the meaning set forth in Section 3.1.1(b).

"JPY" means Japanese yen.

"Latent Defect" means Product not conforming to Sucampo's warranty for Product set forth in Section 9.1.2 and pursuant to Exhibit B such that (i) the related non-conformance of Product is not readily discoverable based on Abbott's, its Affiliates' or Sublicensees' normal incoming-goods inspections, as the case may be and (ii) the related non-conformance was not caused by Abbott or Abbott's Affiliates, Sublicensees or Distributors after receipt of such Product.

"Losses" has the meaning set forth in Section 14.1.

"Market Withdrawal" means a "market withdrawal" as such term is defined in the Notification of YAKUSHOKUSHINSAHATSU No. 0324002, March 24, 2006 (as amended from time to time, or such successor Applicable Law as may take effect in the Territory) of the Product.

"Net Sales" means, for any period, the total amount billed or invoiced on sales of Product in the Field in the Territory by Abbott, its Affiliates or Sublicensees to independent, unrelated Third Parties such as wholesalers, Distributors or end-users in bona fide arm's length transactions, less the following deductions (specifically excluding any royalty payments made by Abbott or its Affiliates or Sublicensees to Sucampo), in each case related specifically to the Product and actually allowed and taken by such Third Parties and not otherwise recovered by or reimbursed to Abbott, its Affiliates or Sublicensees:

(i) trade, cash and quantity discounts (other than price discounts granted at the time of invoicing and already included in the gross amount invoiced);

(ii) price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to governmental authorities;

(iii) taxes on sales (such as Japanese consumption tax ("JCT"), value added taxes, sales or use taxes), but not including taxes assessed against the income derived from such sales;

(iv) freight, insurance and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced, as well as any fees for services provided by wholesalers and warehousing chains related to the distribution of the Product that are treated as sales allowances under GAAP, provided that such fees are consistent with those charged across Abbott's product line;

(v) amounts repaid or credited by reason of rejections, defects, one percent (1%) return credits, recalls or returns or because of retroactive price reductions, including, but not limited to, rebates or wholesaler charge backs; and

(vi) the portion of management fees paid during the relevant time period to group purchasing organizations and/or pharmaceutical benefit managers relating specifically to the finished Product that are treated as sales allowances under GAAP, provided that such fees are consistent with those charged across Abbott's product line.

Where any reduction in the invoice price or deduction therefrom is based on sales of a bundle of products in which the Product for use in the Field in the Territory is included, the reduction in price or deduction therefrom would be allocated as actually credited unless such Product receives a higher than pro rata share of any reduction or deduction that the bundled set of products receives. In such case, the reduction or deduction therefrom shall be allocated to such Product on a no greater than a pro rata basis based on the sales value (i.e., the unit average selling price multiplied by the number of units) of such Product

relative to the sales value contributed by the other products in the bundle with respect to such sale.

Subject to the above, Net Sales shall be calculated in accordance with Abbott's standard internal policies and procedures, which must be in accordance with GAAP. If consideration in addition to or in lieu of money is received for the sale of the Product in the Field in the Territory on an arm's-length transaction, the fair market value of such consideration must be included in the determination of Net Sales for such a sale. Net Sales shall not include (i) sales, transfers or dispositions between or among Abbott, its Affiliates or Sublicensees, (ii) sampling for preclinical, clinical or regulatory purposes conducted by or on behalf of Abbott, its Affiliates or Sublicensees in connection with the Product in the Field in the Territory, (iii) destruction of the Product and (iv) sales, transfers or dispositions for legitimate charitable purposes at no charge.

All Net Sales will be calculated in JPY.

If Abbott, its Affiliates or Sublicensees appoint Distributors for the Product in the Field in the Territory, Net Sales will include the Net Sales invoiced by Abbott, its Affiliates or Sublicensees to such Distributors, but it will not include any sales of the Product in the Field in the Territory made by any such Distributors.

"NHI" means the Japan National Health Insurance Plan.

"NHI Price" means the NHI-approved price for the Product in the Field in the Territory.

"Other Indication(s)" means any indication for use of the Compound in the Territory other than the CIC Indication. Other Indication(s) shall include, but not be limited to, indications for constipation-predominant irritable bowel syndrome and opioid-induced bowel dysfunction.

"Party" means each of Abbott or Sucampo individually; Abbott and Sucampo are collectively referred to herein as "Parties", as identified in the preamble to this Agreement.

"Patent Defect" means Product not conforming to Sucampo's warranty for Product set forth in Section 9.1.2 and pursuant to Exhibit B such that the related non-conformance of Product may be readily discovered based on Abbott's, its Affiliates' or Sublicensees' normal incoming-goods inspections procedures, as the case may be.

"Patent Rights" means the rights and interests in and to all Japanese patents and patent applications, including provisional applications, divisional applications, continuation applications, continuation-in-part applications, converted provisional applications, continued prosecution applications, utility models, petty patents design patents, certificate of inventions, extensions or restorations, including adjustments,

revalidations, reissues, re-examinations, patent term extensions, supplementary protection certificates, any similar rights, including so-called pipeline protection rights, introduction patents, registration patents and patents of addition of any foregoing patents and patent applications.

"Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture, or other entity or organization, in any case whether for-profit or not-for profit, and including, without limiting the generality of any of the foregoing, a government or political subdivision, department or agency of a government.

"Pharmacovigilance Agreement" has the meaning set forth in Section 6.4.

"Phase I Study" means a human clinical trial of a product containing the Compound, the principal purpose of which is a preliminary determination of safety or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise.

"Phase II Study" means, collectively, a Phase IIa Study and a Phase IIb Study.

"Phase IIa Study" means a human clinical trial of a product containing the Compound, the principal purpose of which is a demonstration of proof of concept in the target patient population or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise.

"Phase IIb Study" means a human clinical trial of a product containing the Compound, the principal purpose of which is to find the dose range in the target patient population or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise.

"Phase III Study" means a human clinical trial of a product containing the Compound on a sufficient number of subjects that is designated to establish that such product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support marketing of such product, including all tests, studies, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise.

"Phase IV Study" means a human clinical trial of a product containing the Compound that is not included in the original Drug Approval Application submission for the Product for an indication, including studies conducted to fulfill commitments made as a condition of the Regulatory Approval of the Drug Approval Application or any subsequent

human clinical trials requested, required or recommended by the Regulatory Authority(ies) in the Territory as a condition of maintaining such Regulatory Approval.

"Post-Approval Marketing Studies" means a human clinical trial or other test or study with respect to the Product for use in the Field, which test or study is conducted on a voluntary basis by a Party (rather than under a mandate from a Regulatory Authority in order to obtain or maintain Regulatory Approval for the Product in the Field) after the Drug Approval Application for the Product in the Field in the Territory has been approved by the Regulatory Authority in the Territory. Any human clinical study that is intended to expand the label for the Product for use in the Field in the Territory shall be a Clinical Study. Subject to the foregoing, Post-Approval Marketing Studies may include clinical studies conducted in support of pricing or reimbursement for the Product in the Field in the Territory, epidemiological studies, modeling and pharmacoeconomic studies, post-marketing studies, investigator sponsored studies, and health economic studies.

"Pre-Clinical Data" means data derived from a study to test the Compound for use in the Field, including, but not limited to, laboratory studies, toxicology, safety pharmacology, disease models and animal models.

"Pricing Approval" means any and all pricing or reimbursement approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary to Commercialize, Promote, distribute, sell or market the Product in the Field in the Territory.

"Product" means any product (including any form or dosage form of a pharmaceutical composition or preparation) in finished form labeled and packaged for (i) sale, (ii) distribution, (iii) samples, or (iv) use in Clinical Studies, comprising the Compound (whether as sole active ingredient or in combination with one or more other active ingredients) for use in the Field in the Territory, including all future formulations, dosage forms and delivery modes. The term "Product" or "the Product" as used herein may be used to reference one or more than one Product(s).

"Product Labels and Inserts" means (a) any display of written, printed or graphic matter upon the immediate container, outside container, wrapper or other packaging of the Product for use in the Field in the Territory or (b) any written, printed or graphic material on or within the package from which the Product for use in the Field in the Territory is to be dispensed.

"Product Trademark" means (i) the Trademark AMITIZA as well as derivatives thereof, (ii) the Trademarks listed on Exhibit C, (iii) in the event the Trademark AMITIZA or any other trademarks listed in Exhibit C have not been granted to Sucampo at least one (1) year prior to the date of the estimated launch of the Product in the Field in the Territory or the Regulatory Authorities in the Territory do not approve that the Product uses the Trademark AMITIZA or any other Trademarks listed in Exhibit C, then any other Trademarks relating to the Product for use in the Field in the Territory designated by JCSC

with Sucampo's written consent, which shall not be unreasonably withheld, conditioned or denied and (iv) any current or future modifications or variances of the foregoing Trademarks, but excluding the Corporate Names.

"Promote" or "Promotion" means those activities normally undertaken by a pharmaceutical company's sales force and marketing team to implement marketing plans and strategies aimed at encouraging the appropriate use of a particular prescription or other pharmaceutical product, including detailing. When used as a verb, "Promote" means to engage in such activities.

"Promotional Materials" means all written, printed or graphic material, other than Product Labels and Inserts, intended for use by representatives in Promoting the Product for use in the Field in the Territory, including visual aids, file cards, premium items, clinical study reports, reprints, drug information updates, and any other promotional support items.

"Publication Policies" has the meaning set forth in Section 10.3.2.

"Quality Agreement" means the agreement to be entered into between Abbott and Sucampo, under which the Parties shall address Product quality issues to assure the Product is manufactured and packaged according to all Applicable Laws in the Territory.

"Quarterly Reconciliation" has the meaning set forth in Section 8.3.4.

"Recall" means a "recall" as such term is defined in the Notification of YAKUSHOKUHATSU No. 0331021, March 31, 2005 (as amended from time to time, or such successor Applicable Law as may take effect in the Territory) of the Product for use in the Field.

"Receiving Party" means the Party receiving Confidential Information; provided that a Party owning certain property as provided hereunder shall be considered the Disclosing Party and the other Party shall be considered the Receiving Party regardless of which Party discloses such information.

"Regulatory Approval" means any and all approvals, licenses (including product and establishment licenses), registrations, or authorizations of any Regulatory Authority necessary to Develop, manufacture, Commercialize, Promote, distribute, transport, store, use, sell or market the Product for use in the Field in the Territory, including all CTNs, Drug Approval Applications and the manufacturing license and marketing registration required under the Drug Approval and Licensing Procedures in Japan 2008, or any update thereto, and Pricing Approvals, or pre- and Post-Approval Marketing Studies, labeling approvals, technical, medical and scientific licenses.

"Regulatory Authority" means any national, supra-national, regional, federal, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity (including, without limitation, the Minister of Health, Labour and Welfare of Japan, the National Health Insurance Plan, and any prefecture having jurisdiction over the manufacture of the Product in the Field in the Territory) regulating or otherwise exercising authority over the distribution, manufacture, use, storage, transport, clinical testing or sale of the Product.

"Regulatory Filings" means, with respect to the Product in the Field in the Territory, all applications, registrations, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from the Regulatory Authorities (including minutes and official contract reports relating to any communications with any Regulatory Authority) and all supporting documents and all Pre-Clinical Data, Clinical Data and CMC Data (including all Clinical Studies and Post-Approval Marketing Studies, and all data contained in any of the foregoing, including all CTNs, Drug Approval Applications, Adverse Event files and complaint files.

"Remaining Period" means the period commencing on the day immediately following the last day of the Initial Period and ending on the last day of the Term.

"Rolling Forecast" has the meaning set forth in Section 9.1.5(a).

"SKU(s)" means Stock Keeping Unit(s) and are the smallest unit of measure to identify manufacturing and distribution of the Product.

"Specifications" means the processes, methods, formulae, analyses, instructions, standards, know-how, testing and control procedures, information and specifications relating to the manufacture of the Product in the Field in the Territory as reflected in the relevant formulae edition and Regulatory Approvals.

"Sublicensee" means any Person (other than an Abbott Affiliate) to whom Abbott sublicenses any rights as permitted by Section 2.1.2.

"Sucampo" means Sucampo Pharma, Ltd., as identified in the preamble to this Agreement.

"Sucampo Background Technology" means any Technology Controlled by Sucampo or its Affiliates, as of the Effective Date or at any time during the Term, that is useful or necessary for Developing, Promoting or Commercializing the Product in the Field in the Territory.

"Sucampo Indemnitee(s)" has the meaning set forth in Section 14.1.

"Sucampo Patent Rights" means any Patent Rights that are Controlled by Sucampo or its Affiliates, as of the Effective Date or at any time during the Term, including patents applied for and issued after the Effective Date, and that would otherwise be infringed, absent a license, by the Development, Promotion or Commercialization of the Product in the Field in the Territory. Sucampo Patent Rights include the patents and patent applications set forth in Exhibit D, which may be amended from time-to-time by Sucampo to add additional patents and patent applications.

"Technology" means, collectively, proprietary information, know-how and data, technical or non-technical, trade secrets, materials (including tangible chemical, biological or other physical materials) or inventions, discoveries, improvements, processes, methods of use, methods of manufacturing and analysis, compositions of matter, or designs, whether or not patentable.

"Term" has the meaning set forth in Section 12.1.

"Territory" means Japan.

"Third Party" means any Person other than Abbott and Sucampo and their respective Affiliates or Sublicensees.

"Third Party Claim(s)" has the meaning set forth in Section 14.1.

"Third Party Royalties" means all fees, milestones, royalties and other payments payable to a Third Party in consideration for intellectual property rights necessary or useful for the Development, manufacturing, Commercialization or Promotion of a Compound or a Product.

"Trademark" means (a) any trademark, trade dress, brand mark, service mark, brand name, logo or business symbol, Internet domain name and e-mail address, whether or not registered, or any application, renewal, extension or modification thereto, and (b) all goodwill associated therewith.

"Transfer Price" has the meaning set forth in Section 8.3.1.

ARTICLE 2
LICENSE GRANTS; EXCLUSIVITY

2.1 Development and Commercialization Licenses

2.1.1 Sucampo Grants. Subject to the terms and conditions of this Agreement, during the Term, Sucampo hereby grants to Abbott and its Affiliates, and

Abbott hereby accepts, on behalf of itself and its Affiliates, under the Sucampo Patent Rights, the Sucampo Background Technology and the Data Exclusivity:

(a) a non-exclusive right and license, with the right to grant sublicenses to multiple tiers of Sublicensees subject to Section 2.1.2, to Develop, to the extent expressly agreed to by the Parties in the JDC, the Product anywhere in the world in support of obtaining Regulatory Approval for the Product in the Field in the Territory;

(b) an exclusive, even as to Sucampo and its Affiliates (except as otherwise provided in ARTICLE 7 with respect to Promotion of the Product in the Field in the Territory by Sucampo and its Affiliates), right and license, with the right to grant sublicenses to multiple tiers of Sublicensees subject to Section 2.1.2, to Promote and Commercialize the Product in the Field in the Territory; and

(c) an exclusive, except as to Sucampo and its Affiliates, license and right of reference under the Regulatory Filings, with the right to grant sublicenses and further rights of reference to multiple tiers of Sublicensees subject to Section 2.1.2, to use and reference in Regulatory Filings in the Territory any data Controlled by Sucampo or its Affiliates necessary to support Regulatory Filings for Regulatory Approval of the Product in the Field in the Territory, including, but not limited to, all Pre-Clinical Data, Clinical Data and CMC Data regarding the Product Controlled by Sucampo or its Affiliates generated at any time inside or outside the Territory, without any additional compensation from Abbott to Sucampo.

2.1.2 Right to Sublicense. Subject to and in accordance with the terms and conditions of this Agreement, Abbott and its Affiliates shall have the right to grant sublicenses or further rights of reference under the licenses and rights of reference granted by Sucampo under Section 2.1.1 to any Person (each, a "Sublicensee") provided that (a) Abbott or its Affiliates enter into a written sublicense agreement with each such Sublicensee that is consistent in all material terms with this Agreement, (b) Abbott and its Affiliates shall not be relieved of its obligations pursuant to this Agreement as a result of such sublicense, except to the extent they are satisfactorily performed by the Sublicensee, (c) the Sublicensee shall expressly agree in writing to be bound by the terms of this Agreement, to the extent applicable, and (d) Sucampo shall have the right to approve any such Sublicensee, such approval not to be unreasonably withheld, conditioned or delayed. If Sucampo fails to respond to Abbott or one of its Affiliates' request for approval within fifteen (15) Business Days, then it shall be deemed to have consented to the sublicense.

2.1.3 License to Product Trademarks. Subject to and in accordance with the terms and conditions of this Agreement, during the Term (except to the extent extended pursuant to Section 11.4), Sucampo, on behalf of itself or its Affiliates, hereby grants to Abbott and its Affiliates, and Abbott hereby accepts, an exclusive, except as to Sucampo and its Affiliates, royalty-free license, with the right to sublicense to multiple tiers of Sublicensees, to use the Product Trademarks in the Territory in connection with the performance by Abbott of its Development and Commercialization obligations with

respect to the Product in the Territory. In furtherance of the foregoing license, Sucampo hereby covenants and agrees that, during the Term, without Abbott's prior written consent, Sucampo shall not use, and shall cause its Affiliates and sublicensees not to use the Product Trademarks or any other Trademarks confusingly similar to the Product Trademarks in connection with the Other Indications in the Territory.

2.1.4 Covenant Not to Sue. In the event the using, offering for sale or selling by Abbott, its Affiliates or Sublicensees of Product in the Field, would infringe in the Territory, during the Term, a claim of an issued patent which is Controlled by Sucampo or its Affiliates and which issued patent is not covered by the grant in Section 2.1.1, Sucampo hereby covenants not to sue Abbott, its Affiliates, Sublicensees or Distributors under such patent solely for Abbott, its Affiliates, Sublicensees or Distributors to develop, use, sell, offer for sale or import Product in the Territory, to the extent that Sucampo has the authority to grant such a covenant not to sue as to any such patent(s). Notwithstanding any other provisions of this Agreement, if Sucampo's authority to grant, or cause its Affiliates to grant, such a covenant not to sue on any such issued patents is subject to any Third Party restrictions and: (a) if a Third Party Royalty would be owed to a Third Party for any grant of rights to such issued patent that would otherwise be covered under this Section, and (b) Sucampo or its Affiliates have the ability to grant a sublicense to such issued patent then: (i) Sucampo or its Affiliates shall not grant Abbott a covenant not to sue such issued patent and (ii) at Abbott's option, Sucampo and Abbott shall enter into a sublicense for such issued patent and (iii) Sucampo shall be responsible for all payments and other obligations to such Third Party that are required under the sublicense for such issued patent.

2.1.5 Development of Intellectual Property. In the event that a Party or its Affiliates develop any intellectual property covering the Product, such Party or its Affiliates shall own such intellectual property, shall be free to use such intellectual property without regard to, or accounting to, the other Party except as otherwise provided herein, and the other Party and its Affiliates shall have a royalty-free, perpetual license to use such intellectual property solely with respect to the Product for use in the Field in the Territory. Publication or presentation of a manuscript related to intellectual property developed under this Section 2.1.5 shall be governed by Section 3.1.3(b)(viii) and Section 10.3.2. In the case that Abbott, Sucampo or their respective Affiliates develop any intellectual property covering the Product, Abbott or Sucampo, as applicable, for itself and its Affiliates, shall notify the other Party of its intent to use such intellectual property.

2.1.6 Joint Development. In the event that the Parties jointly develop any intellectual property covering the Product, the Parties shall jointly own such jointly developed intellectual property and each Party shall be free to use such jointly developed intellectual property without regard to, or accounting to, the other Party, except as otherwise provided herein. Both Parties shall cooperate with each other in any filings or assignments necessary to give effect to this Section 2.1.6 or to seek protection for the jointly developed intellectual property. Each Party shall submit any proposed manuscript for publication, presentation or securing Patent Rights related to the jointly developed

intellectual property to the JDC at least sixty (60) days before submission, and each Party shall have the right to review and comment on the manuscript. Upon a Party's request, the publication of a manuscript or the presentation will be delayed up to sixty (60) additional days to enable the non-requesting Party to either secure adequate intellectual property protection that would be affected by the publication or presentation or amend any existing manuscript.

2.1.7 Product Diversion. To the extent permitted by Applicable Law, Sucampo shall not, and shall cause its Affiliates and sublicensees not to, knowingly or intentionally sell the Product in the Field into the Territory and should Sucampo become aware of any such Product diversion, it shall use Commercially Reasonable Efforts to stop the diversion. To the extent permitted by Applicable Law, Abbott or its Affiliates shall include in agreements with Sublicensees that sell Product in the Field covenants from such Sublicensees to not knowingly or intentionally sell, the Product outside of the Territory or outside the Field. Should Abbott become aware of any such Product diversion, it shall use Commercially Reasonable Efforts to stop the diversion.

ARTICLE 3
ADMINISTRATION OF THE COLLABORATION

3.1 Committees

3.1.1 Committees' Establishment. Within thirty (30) days of the Effective Date, Sucampo and Abbott shall establish the following committees (the "Committees"):

(a) a Joint Commercialization and Steering Committee ("JCSC") with responsibility for overseeing Commercialization-related activities with respect to the Product in the Field in the Territory, and managing the collaboration and resolving any conflicts and overseeing the JDC.

(b) a Joint Development Committee ("JDC") with responsibility for overseeing Development-related activities with respect to the Product in the Field in the Territory, including, without limitation, the regulatory approach and filing strategy designed to generate the successful submission and approval of the Product in the Field in the Territory.

Within sixty (60) days of the establishment of the foregoing Committees, the Committees shall meet to prepare such procedures and mechanisms as may be reasonably necessary for their operation to assure the most efficient conduct of each Party's obligations under this Agreement.

3.1.2 JCSC

(a) Membership. Sucampo and Abbott shall each designate three (3) of its employees or consultants or its Affiliates' employees or consultants to serve as members of the JCSC (or such other equal number of representatives as the Parties may agree). The initial members of the JCSC are set forth on Exhibit E. Each representative of the JCSC shall have the requisite experience and seniority to make decisions on behalf of the Parties with respect to issues falling within the jurisdiction of the JCSC. The chairperson shall serve for a term of one (1) year, beginning on the Effective Date or an anniversary thereof, as the case may be. The right to name the chairperson of the JCSC shall alternate between the Parties. The initial chairperson shall be selected by Abbott and is set forth on Exhibit E. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JCSC by giving written notice to the other Party; provided such substitute meets the criteria defined herein. Neither Party shall have the right to remove a sitting member of the other Party.

(b) Responsibilities. The JCSC shall have the responsibilities set forth in Section 3.1.1(a), including to:

(i) Review the Commercialization Plan, including any material updates, amendments, modifications, and waivers of provisions thereof;

(ii) Review and evaluate progress under the Commercialization Plan;

(iii) Discuss strategies for Commercialization of the Product in the Field in the Territory;

(iv) Review the activities and monitor the progress of the JDC;

(v) Resolve any issues, including, but not limited to, Disputed Matters referred to the JCSC by the JDC; and

(vi) Perform such other functions as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

3.1.3 JDC

(a) Membership. Sucampo and Abbott shall each designate three (3) of its employees or consultants or its Affiliates' employees or consultants to serve as members of the JDC (or such other equal number of representatives as the Parties may agree). Each Party shall designate to be a member of the JDC at least one (1) representative from its regulatory department and one (1) representative from its clinical development department. The initial members of the JDC are set forth on Exhibit E. Each representative of the JDC shall have the requisite experience and seniority to make

decisions on behalf of the Parties with respect to issues falling within the jurisdiction of the JDC. The chairperson shall serve for a term of one (1) year beginning on the Effective Date or an anniversary thereof, as the case may be. The right to name the chairperson of the JDC shall alternate between the Parties. The initial chairperson shall be selected by Sucampo and is set forth in Exhibit E. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JDC by giving written notice to the other Party; provided such substitute meets the criteria defined herein. Neither Party shall have the right to remove a sitting member of the other Party.

(b) Responsibilities. The JDC shall have the responsibilities set forth in Section 3.1.1(b), including to:

(i) Review the Development Plan, including all material updates, amendments, modifications, and waivers of provisions thereof;

(ii) Review and evaluate progress under the Development Plan;

(iii) Review the statistical analysis plans and protocols for all pre-clinical and Clinical Studies prepared in support of obtaining or maintaining Regulatory Approvals for the Product in the Field in the Territory;

(iv) Unless otherwise agreed by the Parties, review all proposed initial submissions to Regulatory Authorities anywhere in the world;

(v) Unless otherwise agreed by the Parties, review the submission of all draft and final Product Labels and Inserts for the Product in the Field in the Territory and any material changes thereto;

(vi) Monitor the progress of all Clinical Studies and other Development activities in the Field anywhere in the world;

(vii) Assess the potential impact of Clinical Studies conducted anywhere in the world on Product Labels and Inserts for the Product in the Field in the Territory;

(viii) Review all proposed publications or presentations related to the Product pursuant to Clinical Studies that is based on (a) data developed by Sucampo and its Affiliates or any Third Party, or (b) any jointly developed intellectual property under Section 2.1.5 within sixty (60) days of such request being made, except as otherwise provided herein; and

(ix) Perform such other Development functions as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

3.1.4 Committee Meetings. Each Committee shall establish a schedule of times for regular meetings and shall meet at least once per calendar quarter. Meetings may be held in person, by telephone or videoconference, provided that at least one meeting per Calendar Year shall be held in person. Such in-person meeting shall alternate between the respective offices of Abbott and Sucampo or such other locations mutually agreed upon by the Committees. The chairperson of each Committee shall prepare and circulate to each Committee member an agenda for each Committee meeting reasonably in advance of each meeting. At each Committee meeting, the presence of at least one (1) member designated by each Party shall constitute a quorum. The Committees shall keep minutes of their meetings that record all decisions and all actions recommended or taken in reasonable detail. The chairperson of each Committee shall circulate a draft of the minutes no later than five (5) Business Days after each meeting and each member of the Committee shall have the opportunity to comment on the draft minutes. The minutes shall be approved, disapproved or revised as necessary within thirty (30) days of each meeting; provided, however, that if the Parties cannot agree as to the content of the minutes, such minutes will be finalized to reflect such disagreement. The chairperson of each Committee shall circulate final minutes of each meeting to each Committee member.

3.1.5 Decision-Making. Except as otherwise provided herein, decisions of each Committee shall be made by consensus. Each Committee shall use reasonable efforts to reach agreement on any and all matters for which it is responsible. In the event that, despite such reasonable efforts, agreement on a particular matter cannot be reached by a Committee within fifteen (15) Business Days after the Committee first meets to consider such matter (each such matter, a "Disputed Matter"), then the following procedure shall apply:

(a) JDC Disputed Matters. Disputed Matters arising from the JDC shall be referred for resolution to the JCSC. The JCSC shall initiate discussions in good faith to resolve each Disputed Matter within ten (10) Business Days of receipt of the notice of such Disputed Matter. In the event that the JCSC does not reach agreement on such Disputed Matter within fifteen (15) Business Days from the date of initiation of such discussions, such Disputed Matter shall be referred to senior management for resolution in accordance with Section 3.1.5(c).

(b) JCSC Disputed Matters. Disputed Matters first arising in the JCSC shall be referred to senior management for resolution in accordance with Section 3.1.5(c).

(c) Management Negotiations. In the event that the JCSC cannot resolve a Disputed Matter, either Party may, by written notice to the other, refer such Disputed Matter to the Parties' respective senior management for good faith

negotiations. In the event that, despite good faith efforts, resolution of such Disputed Matter cannot be reached by senior management of the Parties within fifteen (15) Business Days of its referral:

(i) with respect to any Disputed Matter that relates to the Commercialization of the Product in the Field in the Territory, Abbott shall have final decision-making authority; and

(ii) with respect to any Disputed Matter that relates to Development of the Product, the final decision-making authority shall rest with Sucampo, unless the Disputed Matter relates to the conduct of Post-Approval Marketing Studies by Abbott under Section 4.3.1, in which case Abbott shall have final decision-making authority.

3.2 Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement, or the Parties expressly so agree in writing. Neither Committee shall have the authority to make any determination that a Party is in breach of this Agreement, or that a Party has engaged or not engaged in acts related to breach. Neither Committee shall have the power to amend, modify or waive compliance with this Agreement, which may only be amended or modified, or compliance with which may only be waived, as provided in Section 15.5.

3.3 Interactions Between a Committee and Internal Teams. The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. Nothing contained in this Article shall prevent a Party from making routine day-to-day decisions relating to the conduct of those activities for which it has a performance or other obligation hereunder, provided that such decisions are consistent with the then-current Commercialization Plan or Development Plan, as applicable, and the terms and conditions of this Agreement.

3.4 Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, a Committee.

3.5 Purpose of the Committees. The Parties acknowledge and agree that the Committees are strictly for the purposes of decision-making and governance of the Agreement.

3.6 Communication. With regard to the Parties' entire relationship, the Parties shall cooperate and provide support in connection with each other's reasonable requests and shall promptly respond to each other's communications.

ARTICLE 4
DEVELOPMENT

4.1 Development Plan

4.1.1 Initial Plan. The Development of the Product for use in the Field in the Territory shall be governed by a comprehensive, multi-year plan detailing (i) the Development program (including pharmacokinetics studies) to be conducted by Sucampo on an activity-by-activity basis, and (ii) the regulatory strategy for obtaining Regulatory Approval for the Product in the Field in the Territory, which Development program is designed to generate all the Clinical Data and regulatory information required to obtain the Regulatory Approval required for Abbott to be able to Commercialize the Product in the Field in the Territory (the "Development Plan"). Within thirty (30) days following the Effective Date, Sucampo shall prepare and provide to the JDC a proposed Development Plan for its review in accordance with the provisions of ARTICLE 3.

4.1.2 Amendments. Commencing in the first full Calendar Year after the Effective Date and continuing for so long as Development activities are being performed by or on behalf of Sucampo, Sucampo shall prepare and submit no later than January 31st of each Calendar Year for review by the JDC appropriate amendments and updates to the Development Plan.

4.2 Responsibilities. Sucampo shall be solely responsible for conducting all Development activities set forth in the Development Plan.

4.3 Development Activities

4.3.1 Sucampo Responsibilities. Sucampo shall use Commercially Reasonable Efforts to Develop the Product in the Field in the Territory, including the activities in the Development Plan and in this Section 4.3.1. Sucampo shall be solely responsible for funding and completing all Clinical Studies required to obtain and maintain Regulatory Approval in the Territory in the Field. Sucampo shall be responsible for all the other Development activities contemplated by the Development Plan and shall bear all Development costs required for registration for the CIC Indication of the Product in the Territory. If the Ministry of Health, Labor and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA) or any other Regulatory Authority in the Territory requires or recommends any Phase IV Clinical Studies as a condition to obtaining the Regulatory Approval for the Product in the Field in the Territory or maintaining such Regulatory Approval, Sucampo shall fund, conduct and direct all such Phase IV Clinical Studies.

4.3.2 Other Post-Approval Marketing Studies. Abbott shall fund, conduct and direct any Post-Approval Marketing Studies determined by the JCSC provided that such Post-Approval Marketing Studies shall not negatively impact Sucampo's marketing of the Product outside of the Territory.

4.3.3 Other Development Activities. In the event the JDC identifies an opportunity to expand and optimize the Compound in the Field in the Territory such as expanding the label for the Product for use in the Field in the Territory, Sucampo shall be responsible for the related Development costs (including any Clinical Studies required to expand the label of the Product for use in the Field in the Territory) of pursing any such opportunities for the first six (6) years following Regulatory Approval. Thereafter, in the event JDC identifies an opportunity to expand and optimize the Compound in the Field in the Territory and the Parties decide to pursue such opportunity, the Parties shall then agree on an allocation of the Development costs and activities between Sucampo and Abbott.

4.4 Conduct of Development

4.4.1 Compliance. Sucampo shall perform its obligations under the Development Plan and all other Development activities required for registration for the CIC Indication of the Product in the Territory in good scientific manner and in material compliance with Applicable Law.

4.4.2 Cooperation. The Parties shall reasonably cooperate through the JDC in the performance of the Development Plan.

4.4.3 Phase III Study Results. Sucampo shall provide Abbott with a copy of the Phase III Study report within ten (10) Business Days after such Phase III Study report has been completed. Within thirty (30) days after Abbott's receipt of such Phase III Study report and any reasonable documentation in support of such Phase III Study report, that Abbott may request, Abbott shall notify in writing Sucampo whether or not the Phase III Study results are acceptable to Abbott and until Sucampo has received such notification, Sucampo shall restrain from filing the Drug Approval Application. In the event the Phase III Study results do not have a favorable outcome for both Parties, both Parties shall discuss in good faith the results. If the outcome of the discussion is not acceptable to Abbott, Abbott shall have the right to terminate this Agreement and the provisions of Section 12.3 shall apply.

4.5 Records. Sucampo shall maintain records of its Development activities under the Development Plan in sufficient detail, in good scientific manner and otherwise in a manner that reflects all work done and results achieved in the performance of the Development Plan. Sucampo shall retain such records for at least five (5) years after the expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law or agreed to in writing by the Parties. Subject to ARTICLE 10, Sucampo shall provide Abbott, upon reasonable request, a copy of such records to the extent reasonably required for the performance of the requesting Party's obligations and exercise of its rights under this Agreement. Each Party agrees to maintain a policy that requires its employees and consultants to record and maintain Technology developed during the Development Plan in accordance with generally accepted practice in the industry.

ARTICLE 5
DEVELOPMENT AND COMMERCIALIZATION OF OTHER INDICATIONS

5.1 Reporting. From time to time during the Term, Sucampo and its Affiliates may seek to develop Other Indication(s). Sucampo shall provide Abbott with notice of such Other Indication(s) within [*] ([*]) Business Days after the [*]. The notice shall include such information with regard to such Other Indication(s) as Sucampo and its Affiliates reasonably determines is necessary to permit Abbott and its Affiliates to evaluate the Other Indication(s) and its/their potential marketability for purposes of determining whether to exercise the option described in Section 5.2. Sucampo shall promptly provide any additional information requested by Abbott.

5.2 Abbott Right of First Refusal for Other Indications. Abbott shall have [*] ([*]) days from the date of the notice referred to in Section 5.1 to provide a written response as to whether it wishes to participate in negotiations with Sucampo with respect to such Other Indication(s) opportunity, provided that Abbott agrees that, if it determines not to participate in such negotiations prior to the end of such period, it shall in good faith provide written notice to Sucampo promptly upon such determination. If Abbott's response indicating whether or not it wishes to participate in negotiations with respect to such Other Indication(s) opportunity is not delivered to Sucampo within the [*] ([*]) day response period, Abbott shall no longer have the right to exercise such Other Indication(s) opportunity. If Abbott indicates in its response delivered within such [*] ([*]) day period that it wishes to participate in negotiations with Sucampo with respect to such Other Indication(s) opportunity, the Parties shall then negotiate in good faith for a period of [*] ([*]) days after Abbott's receipt of such notice. If basic terms and conditions of such license agreement have not been agreed upon by the Parties within the foregoing period, Sucampo shall be entitled to negotiate with Third Parties for the development and commercialization of such Other Indication(s) from any Third Party. If Sucampo receives a bona fide offer to develop and/or commercialize any such Other Indication(s) from any Third Party, Sucampo shall present the material terms of such offer to Abbott in writing. Abbott shall have [*] ([*]) days after receipt of the offer to meet the offer's material terms on consideration and if Abbott does so, Abbott shall then have the right to develop and commercialize the Product for such Other Indication(s). Sucampo hereby covenants and agrees that in the event Sucampo grants a license to develop and/or commercialize Other Indication(s) in the Territory to a Third Party, Sucampo shall coordinate and consult with Abbott and such Third Party with respect to all regulatory matters related to the Other Indication(s) in the Territory.

ARTICLE 6
REGULATORY

6.1 Regulatory Filings; Regulatory Approvals

6.1.1 Ownership. Unless prohibited by Applicable Law, Sucampo shall own all Regulatory Filings.

6.1.2 Regulatory Strategy; Preparation of Regulatory Filings; Communications.

(a) Development of Regulatory Strategy. The Parties shall reasonably cooperate and consult with each other, through the JDC, in good faith, to develop strategies for all Regulatory Filings in the Field in the Territory for the Compounds and the Product, and from time to time update the Development Plan as appropriate to reflect such developed strategies.

(b) Preparation of Regulatory Filings; Review of Regulatory Filings. Sucampo shall be responsible for, and possess all rights with respect to: (i) implementing the regulatory strategy for Clinical Studies (other than Post-Approval Marketing Studies) (including interactions with Regulatory Authorities); (ii) preparing and submitting all Regulatory Filings in the Territory in the Field (provided that the Parties shall reasonably cooperate with each other regarding such preparation and submission); and (iii) other public disclosure and confidentiality provisions in this Agreement notwithstanding, obtaining, referencing and using all Regulatory Filings, Pre-clinical Data, Clinical Data and CMC Data for the Product (including but not limited to countries outside the Territory) for use in the Territory in connection with the Regulatory Filings, without any additional compensation from Abbott to Sucampo. At Abbott's request, Sucampo shall provide Abbott with (a) copies of such Regulatory Filings in the Territory in the Field, Pre-clinical Data, Clinical Data and CMC Data within thirty (30) days, and (b) with other related information as soon as practicable.

(c) Communications; Regulatory Meetings. After the Regulatory Authorities in the Territory have approved the Drug Approval Application, Abbott shall cooperate, at Abbott's expense, with Sucampo's reasonable requests relating to, and provide support in responding to, communications from Regulatory Authorities in the Territory related to the Product in the Field, including providing comments on Sucampo's submissions' and responses within ten (10) Business Days from the time of receipt or sooner if required by such Regulatory Authorities.

(d) Occurrences or Information Arising out of Sucampo Manufacturing Activities. During the Term, Sucampo will advise Abbott, without undue delay following, and in any event within a period not to exceed seven (7) Business Days of, any occurrences or information arising out of Sucampo's manufacturing activities that have or could reasonably be expected to have adverse regulatory compliance and/or reporting consequences concerning the Product in the Field in the Territory, including actual or threatened Regulatory Authorization withdrawals or labeling changes in the Field in the Territory.

(e) Regulatory Authority Inspections. During the Term, Sucampo will be responsible for handling and responding to any Regulatory Authority inspections with respect to Sucampo's manufacture of the Product. Sucampo will provide to Abbott any information reasonably requested by Abbott and all significant information requested by any Regulatory Authority in the Territory concerning any governmental inspection related to the Product, and will allow Regulatory Authorities in the Territory to conduct reasonable inspections upon the request of such Regulatory Authority.

(f) Violations or Deficiencies Relating to the Product. In the event Sucampo is inspected by any Regulatory Authority in the Territory, Sucampo will notify Abbott without undue delay, and in any event within a period not to exceed seven (7) Business Days, of any written alleged violations or deficiencies relating to the Product, and any proposed corrective actions to be taken. Sucampo will as expeditiously as practicable take any such corrective action required to comply with the provisions of this Agreement and Applicable Law. Prior to submission of any written response submitted to any applicable Regulatory Authority in the Territory, to the extent reasonably practicable, Abbott may review and comment on any portion of the response regarding written alleged violations or deficiencies relating to the Product; provided that Sucampo shall have final say regarding and the content of any submission to a such Regulatory Authority.

(g) NHI Price Decisions. For the initial approval of the NHI Price of the Product, Abbott shall have sole approval authority as between the Parties, provided that the initial price proposed by the NHI is equal to or above [*] JPY (JPY [*]) per capsule. In the event the initial NHI Price is below [*] JPY (JPY [*]) per capsule or becomes below [*] JPY (JPY [*]) per capsule by revision of NHI price and not commercially viable for Sucampo or Abbott, then the Parties shall meet and hold good faith discussions to determine an appropriate NHI Price strategy or alternative commercial terms for the Agreement.

6.2 Product Labels and Inserts; Core Data Sheets. Sucampo shall own and be responsible for the manufacturing of all Product Labels and Inserts and Core Data Sheets for the Product in the Field in the Territory. Abbott shall provide the artwork for the Product Labels and Inserts, subject to Sucampo's written consent, which shall not be unreasonably withheld, conditioned or denied.

6.3 Pharmacovigilance Administration. For so long as Sucampo holds the Regulatory Approvals for the Product in the Field in the Territory, Sucampo shall be solely responsible and shall bear all costs of pharmacovigilance administration of Product in the Territory in accordance with the Development Plan and the Pharmacovigilance Agreement, including without limitation, any post-marketing Clinical Studies obligations (PMS) and any obligations to submit periodic safety updated reports (PSUR) to the Regulatory Authorities in the Territory. Sucampo shall ensure that it, its Affiliates, or its licensees provide Abbott with all information and data required to allow Abbott to comply with its regulatory obligations.

6.4 Adverse Event Reports. Sucampo shall be responsible for investigating Adverse Events and other required safety information associated with the use of the Product in the Field in the Territory. Sucampo shall be responsible for the collection, review, assessment, tracking and filing of information related to Adverse Events, and Sucampo will cooperate and provide or cause Third Parties, as appropriate, to provide such information to Abbott with respect thereto. Within ninety (90) days after the Effective Date, the Parties shall enter into an agreement to initiate a process for the exchange of Adverse Event safety data in a mutually agreed format, including, but not limited to, post-marketing spontaneous reports received by a Party or its Affiliates, sublicensees or Distributors in order to monitor the safety of the Product, and to meet reporting requirements with any applicable Regulatory Authority ("Pharmacovigilance Agreement").

6.5 Recalls and Market Withdrawals

6.5.1 Notification. Each Party shall make every reasonable effort to notify the other Party promptly (but in no event later than forty-eight (48) hours) upon its determination that any event, incident or circumstance has occurred that may result in the need for a Recall or Market Withdrawal of the Product in the Territory, and include in such notice the reasoning behind such determination and any supporting facts.

6.5.2 Initiation. Both Parties shall jointly determine whether to voluntarily implement any Recall and upon what terms and conditions the Product shall be subject to a Recall in the Territory. Both Parties shall jointly determine whether to voluntarily implement a Market Withdrawal in the Territory and upon what terms and conditions the Product shall be subject to a Market Withdrawal or otherwise temporarily or on a limited basis withdrawn from sale in the Territory. In the event Sucampo and Abbott are unable to agree whether or not to voluntary implement a Recall or Market Withdrawal of the Product in the Territory, notwithstanding anything herein to the contrary, Sucampo shall make the final determination but Abbott shall have the right to immediately terminate this Agreement if it disagrees with Sucampo's determination. If a Recall is mandated by a Regulatory Authority, Sucampo shall initiate such a Recall to be in compliance with Applicable Law. In the event of any voluntary Recall, Market Withdrawal or other withdrawal of the Product in the Territory, Abbott shall provide, and cause its Affiliates and Sublicensees to provide as necessary, any and all assistance and support reasonably required by Applicable Law, or reasonably requested by Sucampo.

6.5.3 Responsibility. In the event of a Recall or Market Withdrawal of the Product or any lot(s) thereof, Sucampo shall bear all costs and expenses of such Recall or Market Withdrawal, including expenses and other costs or obligations of Third Parties, the cost and expense of notifying customers and the costs and expenses associated with the Market Withdrawal or Recall of the Product and the cost and expenses of destroying the Product recalled from the market, if necessary, unless such Recall or Market Withdrawal was caused by the Commercialization of the Product by Abbott in the Field in the

Territory, in which case Abbott shall pay for all costs and expenses of such Market Withdrawal to the extent the Recall or Market Withdrawal was caused by Abbott.

6.6 Complaints. Each Party shall refer to the other Party complaints that it receives concerning the Product in the Territory within forty-eight (48) hours of its receipt of the same; provided that all complaints concerning suspected or actual Product tampering, contamination or mix-up (e.g. wrong ingredients) shall be delivered within twenty-four (24) hours of receipt of the same. Although Sucampo shall be responsible for investigating complaints and taking corrective action as necessary, Abbott shall provide all reasonable efforts and collaboration with Sucampo in the resolution of complaints. Abbott shall train its employees on the proper handling and resolution of complaints concerning the Product.

ARTICLE 7
PROMOTION OF PRODUCTS

7.1 Commercialization Plan

7.1.1 Initial Plan and Updates. Approximately six (6) months prior to the estimated date for the filing of the Drug Approval Application, Abbott shall prepare and submit to the JCSC the initial Commercialization Plan, which will include the number of full time representative equivalents to be deployed. The Commercialization Plan shall be revised annually by Abbott and submitted to the JCSC on or before November 30 of each year.

7.1.2 Contents of Plan. The Commercialization Plan shall, among other things, specify Abbott's responsibilities for Promotion and Commercialization, including the estimated number of FTEs to be used to Promote the Product in the Field in the Territory and the estimated levels of Annual Net Sales in the Territory in the next Calendar Year.

7.2 Responsibility. Subject to the terms and conditions of this Agreement, Abbott shall be responsible for all aspects of Commercializing the Product in the Field in the Territory in accordance with the Commercialization Plan, including, but not limited to, the utilization of Third Parties (including Distributors) to Commercialize the Product.

7.3 Sales Efforts by Abbott. Abbott shall use Commercially Reasonable Efforts (a) to Commercialize the Product in the Territory throughout the Term, and (b) to accomplish the objectives set forth in the Commercialization Plan.

7.4 Sales Target. In the event Abbott fails to achieve, in the aggregate, the Five Year Cumulative Sales Target during the first sixty (60) months after the First Commercial Sale of the first Product, then Abbott shall have the option to pay to Sucampo the difference in Transfer Price or Floor Transfer Price resulting from the difference between

the Five Year Cumulative Sales Target and the cumulative Net Sales achieved during such first sixty (60) months. In the event Abbott does not pay such difference, each Party's sole remedy under this Section 7.4 shall be to terminate this Agreement upon sixty (60) days prior written notice to the other Party. In no event shall either Party's termination of the Agreement under this Section 7.4 prevent that Party from pursuing any other remedies for breach of any other provision of this Agreement, including Section 7.3.

7.5 Costs. Abbott will be responsible for all costs of Commercialization in the Territory, including the costs of developing all Promotional Materials, scientific meetings, CME-related educational symposia, promotional marketing programs, sales training, distribution, salaries and similar expenses, as appropriate.

7.6 Promotional Materials

7.6.1 Materials. During the Term, Abbott shall be solely responsible for creating and developing all Promotional Materials to be used in connection with the Promotion of the Product in the Field in the Territory. Abbott shall ensure that all Promotional Materials comply with all Applicable Laws in the Territory and do not infringe or otherwise violate the intellectual property or other rights of any Third Party. To the extent any Promotional Materials are required by Applicable Law to be submitted to the Regulatory Authority in the Territory, Abbott shall make such submissions, and Abbott shall be the Regulatory Authority liaison on all marketing, advertising and Promotional matters. Sucampo, if and to the extent permitted under any agreement with other parties, shall provide Abbott with copies of Promotional Materials used by Sucampo, its Affiliates, its licensees and distributors. In the event Sucampo elects to co-promote the Product in the Field in the Territory in accordance with the provisions of Section 7.6, Abbott shall provide to Sucampo and its Affiliates, at Sucampo's cost, the same quantities of Promotional Materials per sales representative as it provides to its own sales representative. Sucampo and its Affiliates shall use such Promotional Materials solely to Promote the Product in the Field in the Territory.

7.6.2 Presentation and Promotion of the Product. The Commercialization Plan shall describe the manner in which the Product will be presented and described to the medical community in any Promotional Materials or other materials and the placement of the Corporate Names of the Parties, in each case as permitted by Applicable Law in the Territory and with the labeling for the Product approved by the applicable Regulatory Authority in the Territory.

7.7 Co-Promotion of the Product by Sucampo. Sucampo and its Affiliates shall have the right, with [*] ([*]) months prior written notice (unless a shorter time period is approved by Abbott through the JCSC), to elect to participate with Abbott in detailing the Product in the Field in the Territory on the terms and conditions set forth in this Section 7.7, provided, however, that (i) Sucampo and its Affiliates shall be responsible for all costs and shall not be entitled to receive any compensation from Abbott as a result of Sucampo's and its Affiliates' co-promotion of the Product and (ii) all Net Sales generated by

promotional activities by either Party shall be recognized by Abbott. The level and nature of any such activities shall be determined in good faith by the JCSC. Sucampo or its Affiliates may terminate the co-promotion of the Product in the Territory upon not less than [*] ([*]) months prior written notice to Abbott. In the event Sucampo terminates its co-promotion activities, Abbott, Sucampo and Sucampo's Affiliates shall reasonably cooperate to transition to Abbott Sucampo's and its Affiliates' co-promotion activities with respect to the Product so as to minimize disruption to sales activity of the Product, and Sucampo and its Affiliates shall withdraw its sales representatives from such co-promotion activities in a professional manner. Sucampo shall have the right to sublicense the co-promotion rights set out in this Section 7.7 only upon prior written consent by Abbott, which consent is within Abbott's full and unfettered discretion.

7.8 Non Compete.

7.8.1 During the Term, Abbott and Sucampo shall refrain, and shall cause their respective Affiliates, to refrain from Promoting, marketing, selling or offering to sell any [*] (a "Competing Product"), without the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed.

7.8.2 Notwithstanding the foregoing covenant not to compete, it is understood and agreed by the Parties that:

(a) neither Abbott nor its Affiliates shall be deemed to be in default with respect to the foregoing covenant not to compete as a result of any investment in any other Person that they currently hold;

(b) the present covenant not to compete shall not be construed to prohibit or limit Abbott, Sucampo, or any of their Affiliates from hereinafter (1) acquiring and continuing to own less than fifty percent (50%) of the outstanding equity of any Person which Promotes, markets, sells or offers to sell any Competing Product in the Territory so long as such Person is not an Affiliate of Abbott or Sucampo or (2) acquiring (i) more than fifty percent (50%) of the outstanding equity of any Person that Promotes, markets sells or offers to sell a Competing Product or (ii) acquiring a Competing Product, provided that Abbott, Sucampo, their Affiliates or such Person divests such Competing Product with respect to the Territory or, at Abbott's or Sucampo's election, otherwise ceases to Promote, market, sell or offer to sell such Competing Product in the Territory within twelve (12) months following the consummation of such acquisition;

(c) [*]; and

(d) [*].

The Parties further agree and acknowledge that in the event: (1) Sucampo and/or its Affiliates breach this Section 7.8, Abbott shall have all remedies in accordance with

Section 12.2.1, including lost profit damages; (2) Abbott breaches this Section 7.8, Sucampo's sole remedy shall be termination in accordance with the provisions of Section 12.2.1, except in the event of Abbott acquiring a Competing Product in Section 7.8.2(b)(2), where Abbott shall have the right to terminate this Agreement if it does not divest the Competing Product and Sucampo shall be entitled to no further remedies.

ARTICLE 8
CONSIDERATION

8.1 Upfront Payment. Abbott or its Affiliates shall make a nonrefundable payment to Sucampo in the amount of Ten Million United States Dollars (US$10,000,000), within fifteen (15) days of the Effective Date.

8.2 Milestone Payments. Abbott or its Affiliates shall make each of the following non-refundable payments to Sucampo, in the amounts set forth below, each on a one (1) time basis within the time period specified below:

Milestone Event	Milestone Payment
Initiation of the first Phase III Study for the CIC Indication in the Territory (first patient dose)	US$[*] within fifteen (15) days after the occurrence of the milestone event
Filing of Drug Approval Application for the CIC Indication with Regulatory Authorities in the Territory	US$[*] within fifteen (15) days after the occurrence of the milestone event
Regulatory Approval (including Pricing Approval of the initial NHI Price) of the CIC Indication in the Territory for efficacy and First Commercial Sale	US$[*] within fifteen (15) days after the occurrence of the milestone event
1st occurrence of Annual Net Sales of JPY[*] or more in the Territory	US$[*] within forty-five (45) days after the end of the month during which the milestone event occurs
1st occurrence of Annual Net Sales of JPY[*] or more in the Territory	US$[*] within forty-five (45) days after the end of the month during which the milestone event occurs
1st occurrence of Annual Net Sales of JPY[*] or more in the Territory	US$[*] within forty-five (45) days after the end of the month during which the milestone event occurs
1st occurrence of Annual Net Sales of JPY[*] or more in the Territory	US$[*] within forty-five (45) days after the end of the month during which the milestone event occurs
1st occurrence of Annual Net Sales of JPY[*] or more in the Territory	US$[*] within forty-five (45) days after the end of the month during which the milestone event occurs
1st occurrence of Annual Net Sales of JPY[*] or more in the Territory	US$[*] within forty-five (45) days after the end of the month during which the milestone event occurs

Milestone Event	Milestone Payment
1st occurrence of Annual Net Sales of JPY[*] or more in the Territory	US$[*] within forty-five (45) days after the end of the month during which the milestone event occurs
1st occurrence of Annual Net Sales of JPY[*] or more in the Territory	US$[*] within forty-five (45) days after the end of the month during which the milestone event occurs

8.3 Transfer Price and Floor Transfer Price Payments

8.3.1 Subject to Sections 8.3.2, 8.3.3 and 8.3.4, Abbott shall pay, or cause its Affiliates to pay to, Sucampo, in JPY, the transfer price (the "Transfer Price") for finished Product ready for commercial sale at the rate of [*] percent ([*]%) of:

(a) During the Initial Period, the greater of (i) the Net Sales of the Product in the Field in the Territory during the relevant calendar quarter or (ii) [*] percent ([*]%) of the following amount: (a) the NHI Price for such Product, as it may be changed from time to time, multiplied by (b) the number of units of Product sold to Third Parties (based on the unit used for such price) during the relevant calendar quarter by Abbott, its Affiliates or Sublicensees in the Territory to independent, unrelated Third Parties such as wholesalers, Distributors or end-users in bona fide arm's length transaction; and

(b) During the Remaining Period, the Net Sales of the Product in the Field in the Territory during the relevant calendar quarter.

8.3.2 Floor Transfer Price. Upon the first occurrence of a Generic Product reaching, in any consecutive two (2) month period during the Term, more than [*] percent ([*]%) of the total unit market share (based upon mutually agreed Third Party data), Abbott or its Affiliates or Sublicensees shall thereafter pay to Sucampo, in JPY, the transfer price for finished Product sold to Third Parties at the rate of [*] percent ([*]%) of:

(a) During the Initial Period, the greater of (i) the Net Sales of the Product in the Field in the Territory during the relevant calendar quarter or (ii) [*] percent ([*]%) of the following amount: (a) the NHI Price for such Product, as it may be changed from time to time, multiplied by (b) the number of units of Product sold to Third Parties (based on the unit used for such price) during the relevant calendar quarter by Abbott, its Affiliates or Sublicensees in the Territory to independent, unrelated Third Parties such as wholesalers, Distributors or end-users in bona fide arm's length transaction.

(b) During the Remaining Period, the Net Sales of the Product in the Territory during the relevant calendar quarter ((a) or (b), the "Floor Transfer Price").

For the purposes of this Section 8.3.2, the market shall be defined as all products containing the Compound in the Field in the Territory. The example in Exhibit G sets forth the calculation of the payment of the Transfer Price and Floor Transfer Price by Abbott.

8.3.3 Invoice Price. Promptly after shipment of Product to Abbott, its Affiliates or its Sublicensees, Sucampo shall invoice Abbott, its Affiliates or Sublicensees, as the case may be, at the Invoice Price for such Product shipped to Abbott, its Affiliates or its Sublicensees. Abbott shall pay, or cause its Affiliates to pay, for such Product within forty-five (45) days after such invoice is received by Abbott, its Affiliates, or Sublicensees, as the case may be, provided that if Abbott or its Affiliates reject such Product pursuant to Section 9.7 due to a Patent Defect , a Latent Defect or because the delivery of such Product is not in compliance with the quantities and delivery date set forth on the relevant purchase order or does not meet the minimum shelf life set forth in Section 9.1.2(d), then payment shall be due within forty-five (45) days after receipt by Abbott or its Affiliates of notice from the laboratory or other expert that the invoiced Product does not contain a Patent Defect, Latent Defect or the delivery of Product is in compliance with the quantities and delivery date set forth on the relevant purchase order or meets the minimum shelf life set forth in Section 9.1.2(d).

8.3.4 Quarterly Reconciliation. Within forty-five (45) days following the last day of each calendar quarter, Abbott will provide to Sucampo a reconciliation of amounts invoiced by Sucampo in accordance with Section 8.3.3 and paid by Abbott for Product shipped to Abbott during such calendar quarter and a calculation of actual Transfer Price or Floor Transfer Price owed to Sucampo based on aggregate Net Sales during such calendar quarter (the "Quarterly Reconciliation") together with payment or credit representing the difference between the total amount invoiced by Sucampo and paid by Abbott for Product shipped to Abbott during such calendar quarter and the actual Transfer Price or Floor Transfer Price owed to Sucampo as calculated by the Quarterly Reconciliation.

8.4 Product for Post-Approval Marketing Studies. After Regulatory Approval, the Parties shall meet to discuss in good faith the cost of Product for Post-Approval Marketing Studies. Such cost shall not exceed [*] JPY (JPY [*]) per capsule.

8.5 Third Party Royalties. If the Development or Commercialization of the Product by Abbott, its Affiliates or Sublicensees in the Field in the Territory infringes or misappropriates any intellectual property rights of a Third Party or Sucampo Affiliate in the Field in the Territory such that Abbott or its Affiliates or Sublicensees cannot Develop or Commercialize the Product in the Field in the Territory as provided for herein without infringing the intellectual property rights of such Third Party and/or Sucampo Affiliate, Sucampo shall obtain such licenses and rights as are necessary for Abbott, its Affiliates or Sublicensees to Develop or Commercialize the Product in the Field in the Territory as provided for herein. Sucampo shall be solely responsible for the payment of all such Third Party Royalties.

8.6 Payment Dates and Reports. Upon making the payments under Section 8.2 and Section 8.3, Abbott or its Affiliates shall also provide a report showing: (a) a statement identifying the amount of Net Sales during the relevant calendar quarter and, if applicable, the calculation of the Transfer Price or Floor Transfer Price, as applicable, which shall have accrued based upon such amount of Net Sales; and (b) the withholding taxes, if any, required by Applicable Law to be deducted with respect to such sales. Starting with the month following the month in which the First Commercial Sale occurs and continuing thereafter during each month of the Term, within five (5) days following the end of month, Abbott shall provide to Sucampo a monthly report that includes the estimated Net Sales for the previous month solely for revenue recognition purposes.

8.7 Audit Rights. Each Party shall keep and maintain for at least three (3) years complete and accurate records in sufficient detail to allow confirmation of any payment calculations or components thereof and made hereunder. Upon the written request of a Party ("Auditing Party") and not more than once in each Calendar Year, the other Party ("Audited Party") shall permit an independent certified public accounting firm of internationally-recognized standing, selected by the Auditing Party (provided that the Auditing Party shall not without the Audited Party's prior written consent select the same public accounting firm that conducts the Auditing Party's annual financial statement audit) and reasonably acceptable to the Audited Party, at the Auditing Party's expense, to have access, with not less than thirty (30) days notice, during normal business hours, to the records of the Audited Party and its Affiliates as may be reasonably necessary to verify the accuracy of the payments hereunder for any year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm will be instructed to provide its audit report first to the Audited Party, and will be further instructed to redact any proprietary information of the Audited Party not relevant to verifying the accuracy of payments prior to providing that audit report to the Auditing Party. The accounting firm's audit report shall state whether the applicable report(s) is/are correct or not, and, if applicable, the specific details concerning any discrepancies. No other information shall be shared. If such accounting firm concludes that additional monies were owed by the Audited Party to the other, the Audited Party shall have the option to invoke the arbitration proceedings of Section 15.2 or pay the additional monies within thirty (30) days of the date the Audited Party receives such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by the Auditing Party; provided if an error in favor of the Auditing Party of more than ten percent (10%) is discovered, then the Audited Party shall pay the reasonable fees and expenses charged by such accounting firm. Any audit reports provided hereunder shall be the Confidential Information of the Audited Party.

8.8 Withholding Taxes. All payments made under this Agreement shall be free and clear (exclusive of) of any and all taxes, duties, levies, fees or other charges including, without limitation, any JCT, except for withholding taxes. Where any sum due to be paid to a Party hereunder is subject to any withholding tax, the Parties shall use Commercially Reasonable Efforts to do all such acts and things and to sign all such documents as will

enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the paying Party shall deduct any withholding taxes from payment and pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to the receiving Party and secure and send to the receiving Party the best available evidence of such payment.

8.9 Payments. All Transfer Price, Floor Transfer Price and Quarterly Reconciliation payments due under this Agreement shall be payable in JPY. The upfront payment set forth in Section 8.1 and all the milestone payments set forth in Section 8.2 shall be payable in US Dollars. Unless specified otherwise herein, all payments under this Agreement shall be by appropriate electronic funds transfer in immediately available funds to the following bank account of Sucampo:

Bank information

For US dollar
Bank: [*]
Address: [*]
Swift Code: [*]
Account: [*]
Contact Person: [*]
Telephone: [*]

For JPY
Bank: [*]
Address: [*]
Swift Code: [*]
Account: [*]
Contact Person: [*]
Telephone: [*]

Each payment shall reference this Agreement and identify the obligation under this Agreement that the payment satisfies. If at any time legal restrictions prevent the remittance of part or all of payments owed by a Party hereunder in the Territory, payments due hereunder shall continue to accrue until such time payment shall be made through any lawful means or methods that may be available as the Parties shall reasonably determine.

8.10 No Other Compensation. Unless otherwise agreed to by the Parties and set forth in writing, Sucampo and Abbott hereby agree that the terms of this Agreement and all ancillary agreements hereto fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by each Party to the other in

connection with the transactions contemplated herein. Neither Party has previously paid or entered into any other commitment to pay, whether orally or in writing, any employee of the other Party, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transactions contemplated herein.

ARTICLE 9
SUPPLY

9.1 General

9.1.1 Strategy. The JCSC shall determine the supply strategy for the Compound and the Product in the Territory. The Parties, through the JCSC, shall provide regular updates on the supply of Product in the Territory, and issues related thereto. The Parties will review the supply strategy on an ongoing basis to ensure adequate risk mitigation for supply of the Compound and the Product in the Territory. Sucampo shall keep Abbott promptly informed of inventory or production issues that may affect the availability of Product in the Territory.

9.1.2 Manufacturing by Sucampo. Subject to the terms and conditions of this Agreement, Sucampo shall manufacture (or have manufactured), in compliance with the Specifications and test and deliver to Abbott and/or its Affiliates or Sublicensees Product, in the quantities and at times as provided herein, for the Development and Commercialization thereof. All such Product manufactured and supplied by or on behalf of Sucampo shall:

(a) be manufactured in accordance and in compliance with Applicable Law, including cGMP;

(b) be manufactured in accordance with the applicable Regulatory Filings and Regulatory Approvals;

(c) upon delivery, not be adulterated or misbranded as defined by Applicable Law;

(d) upon delivery, have a minimal shelf life of the longer of [*] ([*]) months or [*] percent ([*]%) of the shelf life registered in the underlying Regulatory Approval;

(e) be free from defects in materials and workmanship; and

(f) be in compliance with all Specifications for the Product.

9.1.3 Supply of Additional Materials. Sucampo shall purchase or have purchased all Additional Materials (as referred to in the relevant Regulatory Approvals)

which are needed for the manufacture of the Product as per the current regulatory files, under its own liability and costs. If Sucampo wishes to change suppliers of such Additional Materials and the change will have an impact on a Regulatory Filing, such change shall be subject to Abbott's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed.

9.1.4 Sufficient Inventories. For the Term, and subject to the timely supply of the Rolling Forecast pursuant to Section 9.1.5, Sucampo shall cause its supplier to maintain sufficient inventories of Additional Materials required to manufacture the Product in order to ensure timely delivery of the Product. If only one site is used for manufacturing the Compound, Sucampo shall cause its supplier to maintain a safety stock of active Compound equal to six (6) months of forecast demand based on Abbott's most recent Rolling Forecast. Sucampo shall cause its supplier to maintain a safety stock of Additional Materials to support the Product manufacture and packaging equal to three (3) months of forecast demand based on Abbott's most recent Rolling Forecast.

9.1.5 Forecasts and Orders.

(a) No later than the last Business Day of each calendar month during the Term, Abbott will provide Sucampo with an updated twenty-four (24) month rolling forecast of the Product to be manufactured and supplied by or on behalf of Sucampo (each a "Rolling Forecast") for the twenty-four (24) month period commencing at the beginning of the following month with the first three (3) months considered a purchase order period. Each Rolling Forecast will be broken down for each month of such period into the quantity (by SKU, packaging and size of Product) and shipping dates. The first two (2) months of each new Rolling Forecast will restate the balance of the purchase order period of the prior Rolling Forecast, and the third month of the Rolling Forecast will constitute the new purchase order for which Abbott will be obligated to purchase and take delivery of the Product.

(b) Except as set forth herein, all months of the Rolling Forecast other than the first three (3) months will set forth Abbott's best estimate of its requirements for the supply of Product, and the Rolling Forecast for the months four (4) through twenty-four (24) of each Rolling Forecast will not be binding.

(c) The Rolling Forecast for each of the months four (4) through twenty-four (24) of each Rolling Forecast shall not increase or decrease by more than [*] ([*]%) on a month-to-month basis.

(d) Increases or decreases in the Rolling Forecast beyond those set out in Section 9.1.5(c) shall be at Sucampo's discretion.

9.1.6 Purchase Order. All purchases of Product shall be pursuant to written purchase orders consistent with Section 9.1.5(a), which shall be placed by Abbott and/or its Affiliates or Sublicensees at least sixty (60) days prior to the date of which

Product shall be delivered to Abbott or the applicable Affiliate or Sublicensee. Each such purchase order will be consistent with the purchase order period of the most recent Rolling Forecast. If a purchase order for any month is not submitted by the above deadline, Abbott will be deemed to have submitted a purchase order in that month for the amount of Product set forth in the most recent Rolling Forecast for such month. Each purchase order hereunder shall specify the desired quantities of each of the Product, in finished forms and samples, and the delivery dates therefore.

9.1.7 Acceptance of Orders. Orders and delivery dates will be deemed accepted unless Abbott and/or its Affiliate or Sublicensee receives written notice of rejection within ten (10) Business Days. Sucampo may only reject an order that (a) lists products that are not covered by this Agreement, or (b) that is inconsistent with the amounts permitted by Section 9.1.5 and Section 9.1.6.

9.1.8 Subcontracting. Abbott hereby authorizes that Sucampo may subcontract the manufacturing of the Compound and the Product with R-Tech Ueno Ltd., provided that no such permitted subcontracting shall relieve Sucampo of any liability or obligation hereunder except to the extent that they are satisfactorily performed by R-Tech Ueno Ltd. Sucampo may subcontract with a Third Party to perform its manufacturing and supply obligations hereunder only to the extent approved in advance by Abbott in writing, which approval shall not be unreasonably withheld, conditioned or delayed; provided that no such permitted subcontracting shall relieve Sucampo of any liability or obligation hereunder except to the extent they are satisfactorily performed by such contractor; provided further that Sucampo may not subcontract any of its manufacturing and supply obligations hereunder unless the agreement pursuant to which it engages any Third Party subcontractor (a) is consistent in all material respects with this Agreement and the Quality Agreement, (b) contains terms obligating such subcontractor to comply with the confidentiality, intellectual property, and all other relevant provisions of this Agreement, and (c) contains terms obligating such subcontractor to permit Abbott's rights of inspection, access and audit provided in this Agreement and the Quality Agreement.

9.2 Delivery. The Products hereunder shall be delivered FCA the packaging site in the Territory designated from time to time by Sucampo (Incoterms 2000) for the relevant Product on or up to three (3) days before the delivery date specified in the order accepted by Sucampo, subject to the release of the relevant Products as per Section 9.3. Abbott shall designate to Sucampo the carrier which will take delivery of the Product. Sucampo shall contact such carrier when the Product is ready for shipping and shall arrange for collection, and transportation of the Product. Sucampo shall inform Abbott two (2) Business Days prior to pick-up by the carrier. Abbott shall bear the costs for transport of the Product and will be invoiced directly by the carrier. The quantity of each Product actually delivered by Sucampo with respect to each accepted order shall not exceed a range of minus [*] percent ([*]%) up to plus [*] percent ([*]%) of the quantity of the relevant Product specified in the order, unless agreed differently by Abbott or its Affiliates. Delivery documents shall include PO number, quantity, copy of the certificate of analysis,

items codes and description, lot number, expiry date of Product, number of shippers, weight, number of pallets.

9.2.1 Limited Supply. In the event that Product is in short supply, Sucampo shall notify Abbott of such shortage as soon as possible. In the event there is a short supply of Product and Sucampo cannot supply Product to Abbott in an amount equal to Abbott's firm order, then Sucampo (i) shall indemnify Abbott for any loss, including but not limited to loss of profit, arising from such shortage of Product and (ii) shall allocate available Product and cause its Third Party manufacturer to allocate sufficient manufacturing capacity to provide to Abbott in each month that such a shortfall exists (and in each month thereafter until the shortfall to Abbott is remedied) in an amount equal to the product of (a) the amount of available lubiprostone product and/or related manufacturing capacity, multiplied by (b) a fraction the numerator of which is (i) the aggregate of firm orders made by Abbott over the subsequent twelve (12) month period including the shortfall month and the denominator of which is (ii) the sum of (x) the aggregate quantity of firm orders made by Abbott over the subsequent twelve (12) month period including the shortfall months and (y) the aggregate quantity of lubiprostone product over the same twelve (12) month period required by other licensees outside the Territory by reference to firm orders placed with Sucampo for such licensees' requirements outside the Territory.

9.2.2 Specifications. Sucampo shall manufacture and package the Products in compliance with (a) the Specifications, (b) GMP, and (c) any other requirements set forth in the Regulatory Approval for the relevant Product. Unless agreed otherwise by Abbott in writing, all Products supplied by Sucampo shall have a minimal shelf life of the longer of [*] ([*]) months or [*] percent ([*]%) of the shelf life registered in the underlying Regulatory Approval.

9.3 Testing and Release. Testing and release of the Product shall be made in accordance with Exhibit B, which is subject to Regulatory Approval, any amendments thereto and/or any changes to the Japanese pharmacopoeia. During the Term, Sucampo will conduct the commercial stability program with respect to the Product pursuant to Applicable Law, at its own expense.

9.4 Records. At its own cost, Sucampo shall keep and maintain documentation and records with respect to manufacturing, testing and delivery of Product in accordance with Applicable Law.

9.5 Manufacturing Changes. Sucampo assumes any and all responsibility for any changes made to the manufacturing processes and test methods for the Product, and for any other changes made relating to the manufacture of Products at the manufacturing location, that are not specific to the Product, and will solely bear all expenses related thereto. For manufacturing changes relating to the manufacture of the Product that are not required by a Regulatory Authority, including but not limited to reformulations of the Product, addition of new strengths to the Product, new presentations and formats of the Product and changes to Product Label and Inserts, that negatively impact Abbott's

Commercialization of the Product in the Field in the Territory, then Sucampo shall indemnify Abbott for any loss, including but not limited to loss of profit, arising from such manufacturing changes.

9.6 Quality Agreement. A Quality Agreement shall be executed between Sucampo and Abbott within one hundred twenty (120) days of the Effective Date with respect to the Product.

9.7 Non-Conforming Shipment. Abbott will have a period of thirty (30) Business Days from the date of its receipt of a shipment of Product to inspect and reject such shipment for Patent Defects based on Abbott's normal incoming-goods inspections procedures. In the event Abbott wishes to reject any such shipment for a Patent Defect, Abbott shall provide Sucampo with written notice of such rejection for any Patent Defect within such period of thirty (30) Business Days together with samples of the non-conforming Products in the relevant shipment for testing. In the case of Product with Latent Defects, Abbott will promptly, and in no event more than thirty (30) Business Days of Abbott knowing of any such Latent Defect, notify Sucampo in writing of such Latent Defect; provided however, that any Latent Defect must be notified no later than one (1) month following the expiry date of the applicable Product, together with samples of the non-conforming Products in the relevant shipment for testing. If Sucampo disagrees with Abbott regarding Abbott's rejection of a shipment or portion thereof based on a Patent Defect or a Latent Defect , the Parties will submit samples of such shipment to a mutually acceptable independent laboratory for testing. If such independent laboratory determines that the shipment did not contain a Patent Defect or a Latent Defect, Abbott will bear all expenses of shipping Product to and from and the testing by such independent laboratory for such shipment. If Sucampo or such independent laboratory confirms that such shipment did contain a Patent Defect or a Latent Defect, Sucampo will (i) as soon as practicable, give Abbott a credit for any amount paid with respect to that portion of the Product which had a Patent Defect or Latent Defect, (ii) bear all of Abbott's expenses of returning such Product to Sucampo or its designee, and (iii) all expenses of shipping Product to and from and the testing by such independent laboratory for such shipment. Sucampo or Abbott, as directed by Sucampo, will dispose of any non-conforming portion of any shipment, at Sucampo's expense.

9.8 Audits & Inspections. Sucampo shall use commercially reasonable efforts to make available facilities being used to manufacture Products and relevant manufacturing records for inspection by Abbott for regulatory or quality assurance purposes upon reasonable notice and at reasonable times during normal business hours; provided, however, that the inspection by Abbott hereunder shall be within the scope of inspection that is allowed under the relevant statutes and regulations.

ARTICLE 10
CONFIDENTIALITY AND NON-DISCLOSURE

10.1 Confidentiality

10.1.1 Nondisclosure Obligations. Except to the extent expressly permitted by this Agreement, at all times during the Term and for a period of five (5) years following the expiration or termination hereof, the Receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than the purpose of this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party shall treat Confidential Information as it would its own proprietary information which in no event shall be with less than a reasonable standard of care, and take reasonable precautions to prevent the disclosure of Confidential Information to a Third Party, except as explicitly set forth herein, without written consent of the Disclosing Party.

10.1.2 Exceptions to Confidentiality. The Receiving Party's obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party that:

(a) is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like or is made generally available by a Third Party, in each case, other than through a wrongful act, fault or negligence on the part of the Receiving Party, or a breach of this Agreement or the Confidentiality Agreement;

(b) is received from a Third Party without restriction and with the right to disclose such Confidential Information;

(c) the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party;

(d) the Receiving Party can demonstrate by competent evidence was independently developed by or for the Receiving Party without reference to, use of or disclosure of the Disclosing Party's Confidential Information; or

(e) is released from the restrictions set forth in this Agreement by the express prior written consent of the Disclosing Party.

Notwithstanding the foregoing, specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the

combination and its principles are in the public domain or in the possession of the Receiving Party.

10.1.3 Authorized Disclosures. The Receiving Party may disclose Confidential Information to the extent that such disclosure is:

(a) made in response to an order of a court of competent jurisdiction or other Regulatory Authority or any political subdivision or regulatory body thereof of competent jurisdiction; provided that the Receiving Party shall first have, if reasonably possible, given notice to the Disclosing Party and given the Disclosing Party, at such Disclosing Party's own expense, a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order be held in confidence by such court or Regulatory Authority or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such order shall be limited to that information which is legally required, in the reasonable opinion of legal counsel to the Receiving Party, to be disclosed in such response to such court or governmental order;

(b) otherwise required by Applicable Law or the requirements of a major national securities exchange (*e.g.*, U.S. Securities and Exchange Commission), in the reasonable opinion of legal counsel to the Receiving Party, provided that the Party disclosing such Confidential Information shall exercise its commercially reasonable efforts to obtain a protective order or other reliable assurance that confidential treatment will be accorded and if possible give the other Party a reasonable opportunity to review and comment on any such disclosure in advance thereof (but not less than five (5) Business Days, if possible, prior to the date of such disclosure);

(c) made to an applicable Regulatory Authority as useful or required in connection with any filing, application or request for Regulatory Approval; provided that reasonable measures shall be taken to assure confidential treatment of such information;

(d) (i) reasonably necessary in filing or prosecuting of Sucampo Patent Rights directed to the Compound or the Product or (ii) reasonably necessary in defending litigation related to Sucampo Patent Rights if such litigation relates to this Agreement; and

(e) to the extent necessary, and subject to subcontracting provisions set forth in this Agreement, to its Affiliates, directors, officers, employees, consultants, sublicensees of Abbott or Sucampo (or bona fide potential sublicensees of Abbott or Sucampo), vendors and clinicians, under written agreements of confidentiality substantially similar or at least as restrictive as those set forth in this Agreement, who have a need to know such information in connection with a Party performing its obligations or exercising its rights under this Agreement; provided, that either Party may enter into such

written agreements that provide for shorter timeframes for maintaining confidentiality than those set forth in this Agreement with the written consent of the other Party.

10.2 Patient Information. The Parties shall abide (and cause their respective Affiliates and sublicensees to abide), and take (and cause their respective Affiliates and sublicensees to take) all reasonable and appropriate actions to ensure that all Third Parties conducting or assisting with any clinical development activities hereunder in accordance with, and subject to the terms of, this Agreement, shall abide, to the extent applicable, by all Applicable Law concerning the confidentiality or protection of patient identifiable information and other patient protected health information.

10.3 Press Releases; Publications; Use of Name and Disclosure of Terms.

10.3.1 Press Release. The Parties have agreed upon the content of a press release which shall be issued substantially in the form attached hereto as Exhibit H as soon as practicable after the execution and delivery of this Agreement. Except for the press release set forth on Exhibit H, each Party shall maintain the confidentiality of all provisions of this Agreement and this Agreement itself and, without the prior written consent of both Parties, no Party shall make any press release or other public announcement of or otherwise disclose to any Third Party this Agreement or any of its provisions , except for: (a) disclosure to those of its directors, officers, employees, accountants, attorneys, advisers and agents whose duties reasonably require them to have access to the Agreement, provided that such directors, officers, employees, accountants, attorneys, advisers, and agents are required to maintain the confidentiality of the Agreement to the same extent as if they were Parties hereto, (b) such disclosures as may be required by Applicable Law, in which case the disclosing Party shall provide the nondisclosing Party with at least five (5) Business Days prior written notice of such disclosure (to the extent permitted by Applicable Law) so that the nondisclosing Party shall have the opportunity if it so desires to seek a protective order or other appropriate remedy and, in connection with any such required disclosure, the disclosing Party shall use reasonable efforts to obtain confidential treatment for such disclosure or to prevent or modify such disclosure as may be requested by the nondisclosing Party (to the extent permitted by applicable law), and (c) either Party may disclose the terms of this Agreement to its existing or potential investors, lenders, collaborative partners or, in the case of a change of control, acquires as part of their due diligence investigations, provided, however, that such existing investors, lenders, collaborative partners or acquirers have agreed to maintain the confidentiality of the terms of this Agreement and to use such information solely for the purpose of such due diligence investigation.

10.3.2 Publications. The Parties, through the JDC, shall develop policies and procedures (the "Publication Policies") for any publication with respect to the results of Clinical Studies and Post-Approval Marketing Studies for a Product in the Territory, including disclosure applicable to clinical trial registries, which policies and procedures shall be consistent with the Parties' respective policies and procedures for publication and

disclosure of the results of human clinical trials, with disputes to be resolved in favor of the polity that provides for the broadest disclosure of such results. All abstracts, manuscripts and presentations (including information to be presented verbally) that disclose results of Clinical Studies or Post-Approval Marketing Studies for a Product shall be reviewed and approved by the JDC in accordance with the Publication Policies. Notwithstanding the foregoing, each Party shall provide to the other Party (through the JDC) the opportunity to review each of the submitting Party's proposed abstracts, manuscripts or presentations (including information to be presented verbally) that relate to any Development activities or otherwise with respect to the Product, at least thirty (30) days prior to its intended presentation or submission for publication, and such submitting Party agrees, upon written request from the other Party given within such thirty (30)-day period, not to submit such abstract or manuscript for publication or to make such presentation until the other Party is given up to sixty (60) days from the date of such written request to seek appropriate Patent protection for any material in such publication or presentation that it reasonably believes may be patentable. Once an abstract, manuscript or presentation has been reviewed and approved by the JDC, the same abstract, manuscript or presentation does not have to be provided again to the other Party for review for a later submission for publication. Each Party also shall have the right to require that any of its Confidential Information (but not the results of the Clinical Studies or Post-Approval Marketing Studies for a Product that have been approved for disclosure pursuant to the Publication Policies) that is disclosed in any such proposed publication or presentation be deleted prior to such publication or presentation. In any permitted publication or presentation by a party, the other Party's contribution shall be duly recognized, and co-authorship shall be determined in accordance with customary standards.

ARTICLE 11
INTELLECTUAL PROPERTY RIGHTS

11.1 Sucampo Intellectual Property Rights. As between the Parties, Sucampo and its Affiliates shall have sole and exclusive ownership of all right, title and interest (subject to the licenses granted in this Agreement) in and to any and all Sucampo Patent Rights, Sucampo Background Technology and Product Trademarks in the Territory.

11.2 Patent Filing, Prosecution and Maintenance. Sucampo and its Affiliates, acting through patent counsel of its choice, and in consultation with Abbott, shall be responsible for the preparation, filing, prosecution and maintenance of the Sucampo Patent Rights in the Field in the Territory. Sucampo will notify Abbott and its Affiliates within thirty (30) days in the event that Sucampo and its Affiliates decide not to prepare, file, prosecute and/or maintain the Sucampo Patent Rights in the Field in the Territory, and shall assign to Abbott its rights into the applicable Sucampo Patent Rights in the Field in the Territory. Abbott or its Affiliates shall then have the right and option to do so at its own expense and shall own any resulting patent applicable or patent. Such rights of Abbott

would be in addition to, and not replace, any other rights and remedies of Abbott's available by Applicable Law and/or this Agreement.

11.3 Information and Cooperation. Sucampo shall (a) provide Abbott with copies of all patent applications filed with respect to the Sucampo Patent Rights that cover the Product in the Field in the Territory and other material submissions and correspondence with the Japan Patent Office relating thereto, in sufficient time to allow for review and comment by Abbott, (b) provide Abbott and its patent counsel with an opportunity to consult with Sucampo and its patent counsel regarding the filing and contents of any such application, amendment, submission or response with respect to the Sucampo Patent Rights that cover the Product in the Field in the Territory and (c) provide notice of filing of new Sucampo Patent Rights that cover the Product in the Field in the Territory to Abbott within ten (10) Business Days of such filing. Sucampo hereby agrees that the advice and suggestions of Abbott and its patent counsel shall be taken into reasonable consideration by Sucampo and its patent counsel in connection with each filing.

11.4 Product Trademarks. As between the Parties, Sucampo and its Affiliates shall own all Product Trademarks and all goodwill associated therewith. Sucampo shall be responsible for the filing, prosecution, defense and maintenance before all Trademark offices of all Product Trademarks and using Commercially Reasonable Efforts to ensure Product Trademarks exist in the Territory, and are kept in good standing during the Term and any period thereafter that Abbott has a license to such Product Trademarks under Section 2.1.3. If, at the expiration of the Term (but not in the event of early termination of the Agreement), Abbott wishes to continue to sell the Product under the Product Trademark, the license granted to Abbott and its Affiliates in Section 2.1.3 to the Product Trademark shall continue for an additional ten (10) years with the option for Abbott to renew such license for two (2) additional terms of ten (10) years each. If Sucampo chooses not to prepare, file, prosecute, maintain or defend any Product Trademarks in the Territory, then Abbott or its Affiliates shall have the right and option to do so at its own expense. At Abbott's request, Sucampo shall register domain names containing all or any of the Product Trademarks, including without limitation, the Amitiza Trademark.

11.5 Intellectual Property Legal Actions

11.5.1 Notice of Third Party Infringement and Third Party Litigation. In the event (a) either Party becomes aware of any possible infringement of any Sucampo Patent Rights or Sucampo Background Technology relating to the Product or any Product Trademark in the Field in the Territory, (b) either Party becomes aware of the submission by any Third Party of regulatory filing in the Territory for a product that seeks approval to sell the Compound in Field, or the regulatory approval granted upon such regulatory filing, (c) either Party becomes aware of any interference, opposition, or a nullity action being filed in the Territory against any Sucampo Patent Right that relates to the making, use or sale by a Third Party of a Product in the Field, or (d) either Party becomes aware of the institution or threatened institution of any suit by a Third Party against such Party for

patent infringement involving the sale, distribution or marketing of any Product in the Field in the Territory (each, an "Infringement"), that Party shall promptly notify the other Party and provide it with all details of such Infringement of which it is aware (each, an "Infringement Notice").

11.5.2 Sucampo's Right to Enforce and Defend. In the event of an Infringement, Sucampo and its Affiliates shall have the right and option to initiate legal proceedings, through counsel of its choosing, or take other commercially reasonable steps regarding such Infringement. If Sucampo and its Affiliates do not take or initiate commercially reasonable steps to initiate legal proceedings or take other actions regarding the Infringement within thirty (30) days from any Infringement Notice, then Abbott and its Affiliates shall have the right and option to do so at its own expense.

11.5.3 No Settlement and Allocation of Damages. Neither Party shall settle any Infringement claim or proceeding under this Section 11.5 that would limit the rights of a Party hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. If either Abbott and/or Sucampo collects any settlement or judgment from any Third Party infringers, the Parties shall first allocate any such amounts to each Party equal to their respective attorneys' fees, litigation costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of the attorneys' fees, litigation costs and expenses of both Parties). To the extent that any such award of damages represents lost Net Sales, any additional amounts collected shall be payable to Abbott with a deduction equal to the Transfer Price percent in Section 8.3 payable to Sucampo. To the extent that any such award of damages does not represent lost Net Sales, Sucampo shall retain all of any additional amounts collected after the allocation for costs described above.

11.5.4 Right to Representation. Abbott and its Affiliates shall have the right, at their own expense, to participate and be represented by counsel that it selects, in any legal proceedings or other action instituted under this Section 11.5 by Sucampo.

11.5.5 Cooperation. In any action, suit or proceeding instituted under this Section 11.5, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such action, suit or proceeding, the other Party shall join therein and shall be represented using counsel of its own choice, at the requesting Party's expense.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Agreement, shall expire upon the latest of (a) eighteen (18) years after the Effective Date, (b) a period of fifteen (15) years after the

First Commercial Sale, or (c) the loss of Data Exclusivity with respect to the Product (the "Term"). If the Term of this Agreement expires or this Agreement is terminated earlier pursuant to Section 4.4.3, Section 7.4, Section 12.2.1(b), Section 12.2.2 or Section 12.2.3, then, at Abbott's request, the Parties shall negotiate in good faith the terms by which Abbott could continue to promote or co-promote and distribute the Product in the Field in the Territory or Abbott will sell back to Sucampo, and Sucampo will repurchase from Abbott, at Abbott's actual cost, any remaining inventory of Product with greater than twelve (12) months remaining shelf life.

12.2 Termination

12.2.1 Termination for Material Breach. In the event of an alleged material breach of this Agreement by a Party, the other Party must give the Party that is allegedly in default notice thereof if such non-breaching party intends to terminate the Agreement pursuant to this Section 12.2.1. Any dispute regarding an alleged material breach of this Agreement shall be resolved in accordance with this Section. It is the Parties' express intent that consideration shall first and foremost be given to remedying any breach of this Agreement through the payment of monetary damages or such other legal or equitable remedies as shall be appropriate under the circumstances, as decided, in each case, according to the provisions of Section 15.2, and that there shall only be a limited right to terminate this Agreement as a matter of last resort, except as otherwise set forth in this Agreement. If, however, a Party receives a notice of material breach that relates solely to the payment of amounts due hereunder, and (a) there is no dispute as to the amounts owed and (b) such breach for non-payment is not cured within ninety (90) days after receipt of such notice, the notifying Party shall be entitled to terminate this Agreement by giving written notice to the defaulting Party. In the event that the neutral (as defined in Exhibit F), in accordance with the procedures set forth in Section 15.2, has rendered a ruling that a Party has materially breached this Agreement, which ruling specified the remedies imposed on such breaching Party for such breach, and the breaching Party has failed to comply with the terms of such adverse ruling within the time period specified therein for compliance, or if such compliance cannot be fully achieved by such date, the breaching Party has failed to commence compliance and/or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible, or in the event the material breach cannot be remedied, then in each case the non-breaching Party shall then in each case the non-breaching Party shall have the following rights:

(a) if Abbott is the breaching Party that failed to cure such breach or, if applicable comply with an adverse ruling and if the basis for such breach is Abbott's failure to abide by a material obligation under this Agreement, Sucampo may terminate this Agreement by delivering written notice to Abbott after the expiration of the period during which Abbott was to comply as set forth in the adverse ruling (if applicable); and

(b) if Sucampo is the breaching Party that failed to cure such breach or, if applicable, comply with an adverse ruling and if the basis for such breach is Sucampo's failure to abide by a material obligation under this Agreement, Abbott may terminate this Agreement by delivering written notice to Sucampo after the expiration of the period during which Sucampo was to comply as set forth in the adverse ruling (if applicable).

12.2.2 Termination for Insolvency. In the event a Party files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

12.2.3 Termination for Product Withdrawal or Material Adverse Event. In the event the Product or another product containing the Compound for use in the CIC Indication is withdrawn from the market by a Regulatory Authority in the Territory, in the United States or Europe or Abbott has a reasonable safety concern with respect to the Product, then Abbott may terminate this Agreement effective immediately upon written notice to Sucampo.

12.3 Consequences of Termination of Agreement. Upon any termination of this Agreement by a Party pursuant to Sections 4.4.3, 7.4, 12.2.1, 12.2.2 or 12.2.3:

(a) the licenses granted by Sucampo to Abbott under this Agreement shall terminate, and all rights granted by Sucampo to Abbott shall be returned to Sucampo free of charge, except for any licenses granted pursuant to Section 2.1.5 or rights acquired pursuant to Section 2.1.6;

(b) all Development, Commercialization and Promotion activities under this Agreement shall promptly cease; and

(c) each Party, at the request of the other Party, shall return or destroy, and thereafter provide to the other Party written certification evidencing such destruction, all data, files, records and other materials in its possession or control relating to the other Party's Technology, or containing or comprising the other Party's Confidential Information.

12.4 Surviving Provisions. 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 in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of Sections 2.1.3 (to the extent provided in Section 11.4), 2.1.5, 2.1.6, 4.5, 8.7, 11.4 (to the extent set forth therein), 12.3, 12.4 and 13.10 and those of ARTICLE 10, ARTICLE 14 and ARTICLE 15 and, to the extent

applicable, all other Sections or Articles referenced in any such Section or Article and including ARTICLE 1, shall survive such termination.

12.5 Continued Obligations. Upon expiration or termination of this Agreement, in whole or in part, for any reason, nothing herein shall be construed to release either Party from any accrued rights or obligations that matured prior to the effective date of such expiration or termination, nor preclude either Party from pursuing any right or remedy it may have hereunder or at law or in equity with respect to any breach of this Agreement.

ARTICLE 13
REPRESENTATIONS AND WARRANTIES

13.1 Mutual Representations and Warranties. Sucampo and Abbott each represents and warrants to the other, as of the Effective Date, as follows:

13.1.1 Corporate Power. Such Party is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to perform its obligations hereunder.

13.1.2 Due Authorization. Such Party has taken all necessary corporate action required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

13.1.3 Binding Agreement. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with the terms hereof subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

13.1.4 Conflicts. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) does not conflict with or violate any provision of the articles of incorporation, bylaws or any similar instrument of such Party, as applicable, in any material way and (b) does not conflict with, violate or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

13.2 Compliance with Applicable Law. Sucampo and Abbott each represents, warrants and covenants to the other that it shall comply, in all material respects, with Applicable Law relating to such Party's rights, duties, responsibilities and obligations set forth in this Agreement.

13.3 Intellectual Property — Sucampo Representations and Warranties

13.3.1 Right to Grant Licenses. Sucampo is the sole and exclusive licensee in the Territory of all right, title and interest in and to, and is entitled to grant the sublicenses granted to Abbott, with respect to the Patent Rights listed in Exhibit D. The Patent Rights listed on Exhibit D constitute all Patent Rights Controlled by Sucampo and its Affiliates that would be infringed by the Development and Commercialization of the Product in the Field in the Territory. Sucampo represents and warrants to Abbott that it has the right to grant to Abbott the rights and licenses set forth in this Agreement, free and clear of any licenses, sublicenses and all encumbrances. Sucampo represents and warrants that no agreements exist with Third Parties that limit or restrict use of the Sucampo Patent Rights or Sucampo Background Technology in the Field in the Territory. Sucampo represents, warrants and covenants that it will not enter into an agreement that is inconsistent with the rights and licenses granted to Abbott in this Agreement.

13.3.2 No Existing Claims. Sucampo represents, warrants and covenants that, to its knowledge, as of the Effective Date, Sucampo Patent Rights and Product Trademarks are valid and in good standing, all assignments for patents and patent applications have been appropriately obtained and recorded, all inventors have been correctly and appropriately listed, and no inventorship disputes exist. There is, to Sucampo's knowledge, as of the Effective Date, no claim or demand of any Person pertaining to, or any proceeding which is pending or threatened that challenges Sucampo's interest in the Sucampo Patent Rights or Product Trademarks or makes any adverse claim of ownership thereof. To Sucampo's knowledge, as of the Effective Date, none of the relevant Patent Rights and Trademarks in the Sucampo Patent Rights and Product Trademarks are the subject of any pending or threatened, adverse claim, judgment, injunction, order, decree or agreement restricting its use in connection with the Product in the Field in the Territory.

13.3.3 Disclosure and Delivery. Sucampo represents, warrants and covenants that Sucampo shall, to its knowledge, have the full right and legal capacity to disclose and deliver the Sucampo Patent Rights and Product Trademark without violating the rights of Third Parties.

13.3.4 Maintaining Existing Licenses and Rights. Sucampo represents, warrants and covenants that Sucampo and its Affiliates shall maintain all rights and licenses executed by Sucampo and its Affiliates that materially affect Abbott's rights set forth in this Agreement. In the event Sucampo receives written notice that it is in breach of any such rights or license, Sucampo represents and warrants that it shall give prompt written notice to Abbott and take all commercially reasonable actions to cure such breach. Sucampo represents, warrants and covenants that Sucampo shall use Commercially Reasonable Efforts to ensure Product Trademarks exist in each country in the Territory and are kept in good standing during the Term.

13.3.5 Future Authorizations. Sucampo shall obtain and maintain during the Term all authorizations, consents and approvals, governmental or otherwise, necessary for Sucampo to grant the rights and licenses granted by Sucampo under this Agreement.

13.3.6 Non-Infringement. As of the Effective Date, Sucampo is not aware of any intellectual property owned or controlled by a Third Party that would be infringed or misappropriated by the Development, manufacture and Commercialization of the Product in the Field in the Territory, and Sucampo has received no written claims relating to any such infringement or misappropriation.

13.4 No Debarment. Each Party certifies as of the Effective Date that neither Party has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by any Regulatory Authority. Each Party further certifies as of the Effective Date that it has not used prior to the Effective Date and shall not use during the Term, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by any Regulatory Authority. Each Party further represents, warrants and covenants that its not sanctioned, suspended, excluded or otherwise declared ineligible from any Regulatory Authority healthcare program, including, but not limited to any United States healthcare program, such as Medicare or Medicaid or comparable foreign healthcare program. In the event that during the Term, such Party (i) becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible; (ii) received notice of an action or threat of an action with respect to any such debarment, suspension, exclusion, sanction or ineligibility, such Party shall immediately notify the other Party. In the event a Party becomes debarred by a Regulatory Authority during the Term, the other Party shall have a right to terminate this Agreement upon thirty (30) days written notice to the debarred Party.

13.5 No Litigation. As of the Effective Date, Sucampo represents and warrants that there is no pending, settled or, to its knowledge, threatened litigation with respect to the Compound or the Product or that may materially affect Sucampo's ability to grant the rights and licenses granted by Sucampo under this Agreement.

13.6 Manufacturing of the Compound and the Product. Sucampo represents, warrants and covenants that during the Term Sucampo and any permitted subcontractor of Sucampo shall manufacture the Compound and the Product supplied to Abbott, its Affiliates or Sublicensees in the Territory.

13.7 No Additional Material Information. Sucampo represents and warrants that, to its knowledge, there is no material information that has not been provided to Abbott that may be relevant to the transaction contemplated by this Agreement.

13.8 Affiliate Compliance. Abbott represents and warrants that each of Abbott's Affiliates who obtain a license as permitted under Section 2.1.1 will comply with the terms

of this Agreement, and that Abbott shall remain responsible for and be a guarantor of the compliance of all such Affiliates.

13.9 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE MANUFACTURE OF PRODUCT, ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY SPECIFICALLY DISCLAIMS ALL WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

13.10 Limited Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, EXCEPT IN CIRCUMSTANCES OF INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES, OR WITH RESPECT TO INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS SET FORTH IN ARTICLE 14 AND BREACHES OF A PARTY'S CONFIDENTIALITY OBLIGATIONS HEREUNDER AND SUCAMPO'S INDEMNIFICATION IN SECTIONS 9.2.1 AND SUCAMPO'S LIABILITY IN SECTION 7.8, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS OR LOST REVENUES, OR COST/EXPENSE OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY.

ARTICLE 14
INDEMNIFICATION; INSURANCE

14.1 Indemnification by Abbott. Abbott agrees to indemnify, defend and hold harmless Sucampo and its Affiliates and their respective employees, agents, officers, directors and permitted assigns ("Sucampo Indemnitees") from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' fees and other expenses of litigation and/or arbitration) (collectively, "Losses") resulting from a claim, suit or proceeding made or brought by a Third Party (collectively, a "Third Party Claim") arising out of or resulting from the following:

(a) improper storage or handling of the Product by Abbott or its Affiliates, Sublicensees or Distributors;

(b) Abbott's or its Sublicensees' or Distributors' negligence or willful misconduct in regard to its performance, or non-performance, under this Agreement; or

(c) Abbott's breach of or failure to perform under this Agreement, including a breach of any of Abbott's representations or warranties hereunder;

In all cases, (a) through (c), except for Losses for which Sucampo has an obligation to indemnify Abbott Indemnitees pursuant to Section 14.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for Losses.

14.2 Indemnification by Sucampo.

14.2.1 General Indemnity. Sucampo agrees to indemnify, defend and hold harmless Abbott and its Affiliates and their respective employees, agents, officers, directors and permitted assigns ("Abbott Indemnitees") from and against any and all Losses resulting from a Third Party Claim arising out of or resulting from the following:

(a) improper storage, handling, manufacturing, formulation or contamination of the Compound or the Product by Sucampo or its Affiliates or Third Party subcontractors;

(b) Infringement of Third Party intellectual property rights by the Product or any Product Trademark;

(c) failure by Sucampo or any Affiliate or subcontractor of Sucampo to supply Product in accordance with the Specifications and Applicable Law;

(d) any personal injury or death caused by the Product for use in the Field in the Territory due to a design defect;

(e) any other product liability claim;

(f) Sucampo's and/or its subcontractors' negligence or willful misconduct in regard to its performance, or non-performance, under this Agreement; or

(g) Sucampo's breach of or failure to perform under this Agreement, including a breach of any of Sucampo's representations or warranties hereunder;

In all cases (a) through (h), except for Losses for which Abbott has an obligation to indemnify the Sucampo Indemnitees pursuant to Section 14.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

14.2.2 Procedures for Indemnification. The obligations of an indemnifying Party under Section 14.1 and Section 14.2 shall be governed by and contingent upon the following:

14.2.3 Notice of Claim. Each Party shall give the other Party prompt written notice of any Third Party Claim (an "Indemnification Claim Notice"). Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of the loss claimed (to the extent that the nature and amount of such loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any such Third Party Claim. The indemnifying Party shall not be required to provide indemnification with respect to a Third Party Claim to the extent that the defense of such Third Party Claim is materially prejudiced by the failure to give timely notice by the indemnified Party.

14.2.4 Assumption of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the indemnified Party within fourteen (14) days after the indemnifying Party's receipt of an Indemnification Claim Notice or sooner if necessary. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgement that the indemnifying Party is liable to indemnify any Abbott Indemnitees or Sucampo Indemnitees (as applicable) in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any indemnified Party's claim for indemnification.

14.2.5 Control of the Defense. Upon the assumption of the defense of a Third Party Claim by the indemnifying Party:

(a) the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party, which shall be reasonably acceptable to the indemnified Party;

(b) the indemnified Party shall promptly deliver to the indemnifying Party all original notices and documents (including court papers) received by the indemnified Party in connection with the Third Party Claim; and

(c) except as expressly provided in Section 14.2.4, the indemnifying Party shall not be liable to the indemnified Party for any legal expenses subsequently incurred by such indemnified Party or any Abbott Indemnitee or Sucampo Indemnitee (as applicable) in connection with the analysis, defense or settlement of the Third Party Claim. To the extent that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless an Indemnitee from and against the Third Party Claim, the indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including reasonable attorneys' fees and costs of

suit) and any loss incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such indemnified Party or Indemnitee.

14.2.6 Right to Participate in the Defense. Without limiting Section 14.2.4 or Section 14.2.5, any Abbott Indemnitee or Sucampo Indemnitee (as applicable) shall be entitled to participate in, but not control, the defense of a Third Party Claim and to retain counsel of its choice for such purpose; provided that such retention shall be at its own expense unless, (a) the indemnifying Party has failed to assume the defense and retain counsel in accordance with Section 14.2.4 (in which case the indemnified Party shall control the defense), or (b) the interests of the Indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under Applicable Law, ethical rules or equitable principles.

14.2.7 Settlement

(a) The indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of any Third Party Claim, on such terms as the indemnifying Party, in its reasonable discretion, shall deem appropriate; provided that:

(i) the sole relief provided is the payment of money damages;

(ii) the consent, settlement or other disposition does not, and will not, result in a finding or admission of any violation of any Applicable Law or any violation of the rights of any person and does not materially affect any other claims that may be made against the indemnified Party;

(iii) the consent, settlement or other disposition does not, and will not, result in the indemnified Party's rights under this Agreement being adversely affected; and

(iv) the consent, settlement or other disposition does not, and will not, result in the indemnified Party becoming subject to injunctive or other relief or otherwise will adversely affect the business of the indemnified Party in any manner.

(b) With respect to all other Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with ARTICLE 14, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Third Party Claim with the prior written consent of the indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Third Party Claim by an indemnified Party that is

reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

14.2.8 Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the indemnified Party shall, and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the indemnified Party for any out-of-pocket expenses in connection therewith.

14.3 Insurance. Each Party shall obtain and carry in full force and effect the minimum insurance requirements set forth herein, which shall protect Indemnitees with respect to events covered by Section 14.1 and Section 14.2. Such insurance (a) shall be primary insurance with respect to each Party's own participation under this Agreement, (b) shall be issued by a recognized insurer rated by A.M. Best "A-VII" (or its equivalent) or better, or an insurer pre-approved in writing by the other Party, (c) shall list the other Party as an additional named insured thereunder, and (d) shall require thirty (30) days written notice to be given to the other Party prior to any cancellation, non-renewal or material change thereof. The types of insurance, and minimum limits shall be General liability insurance with a minimum limit of [*] JPY (JPY [*]) per occurrence and [*] JPY (JPY [*]) in aggregate. General liability insurance shall include, at a minimum, Professional Liability, Clinical Trial Insurance and, beginning at least thirty (30) days prior to First Commercial Sale of the Product, product liability insurance. Upon request by a Party, the other Party shall provide Certificates of Insurance evidencing compliance with this Section. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement during any period in which such Party continues to make, to have made, to use, to offer for sale or to sell a product that was the Product under this Agreement, and thereafter for a period of five (5) years. Notwithstanding the foregoing, either Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies . For purposes of determining whether Sucampo has obtained and maintained the required amounts of insurance pursuant to this Section, insurance obtained and maintained by R-Tech Ueno, Ltd. shall be included as if such insurance was obtained and maintained by Sucampo.

ARTICLE 15
MISCELLANEOUS

15.1 Governing Law. This Agreement and all disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the substantive laws of New York, United States of America, without regard to conflict of laws principles, except that (a) questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent, shall have been granted and (b) matters related to Regulatory Filings and Regulatory Approval, shall governed by the Pharmaceutical Affairs Law of Japan (Law No. 145 of 1960, as amended) and (c) any matters to be exclusively resolved pursuant to the Applicable Laws in the Territory, shall be resolved by the Applicable Laws in the Territory. The Parties hereby exclude the United Nations Convention on Contracts for the International Sale of Goods from this Agreement.

15.2 Arbitration. In the event of any dispute, difference or question arising between the Parties in connection with this Agreement, the construction thereof, or the rights, duties or liabilities of either Party hereunder, other than any Disputed Matter that is submitted for resolution as provided in Section 3.1.5 and non-conformity of Product under Section 9.7, the Parties shall initiate an arbitration proceeding to be conducted in accordance with the procedures set forth in Exhibit F.

15.3 Notices

15.3.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing and in English, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or by internationally recognized overnight delivery service that maintains records of delivery, or transmitted by facsimile (with transmission confirmed), addressed to the Parties at their respective addresses specified in Section 15.3.2, or to such other address as the Party to whom notice is to be given may have provided in writing to the other Party, in accordance with this Section 15.3. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or upon receipt (at the place of delivery) if sent by an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

15.3.2 Addresses for Notice

For Abbott:	For Sucampo:
Abbott Japan Co. Ltd. [*]	Sucampo Pharma, Ltd. [*]
With a copy to:	With a copy to:
Abbott Laboratories [*]	Sucampo Pharma, Ltd. [*]
With a copy to:	With a copy to:
Abbott Laboratories [*]	Sucampo Pharmaceuticals, Inc. 4520 East West Highway 3rd Floor Bethesda, MD 20814 Fax: [*] Attention: CEO office

15.4 Equitable Relief. The Parties acknowledge and agree that the restrictions set forth in ARTICLE 10 are reasonable and necessary to protect the legitimate interests of the Parties and that neither Party would have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of ARTICLE 10 may result in irreparable injury to the other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of ARTICLE 10 by a Party, the other Party shall be entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. Nothing in this Section 15.4 is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

15.5 Amendment; Waiver. This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a written instrument signed by duly authorized representatives of both Parties or, in the case of waiver, signed by duly authorized representatives of the Party waiving compliance. The delay or failure of a Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by a Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

15.6 No Third Party Beneficiaries. Except as set forth in Section 14.1 and Section 14.2, the provisions of this Agreement are for the sole benefit of the Parties and their permitted successors and permitted assigns and none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, without limitation, any employee or creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

15.7 Relationship of the Parties. Nothing in this Agreement shall be construed (a) to create or imply a partnership, association, joint venture or fiduciary duty between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, or (d) to give either Party the right to bind the other or to create any duties or obligations between the Parties, except as expressly set forth herein. All Persons employed by a Party shall be employees of such Party and not of the other Party and all costs/expenses and obligations incurred by reason of such employment shall be for the account and expense of such Party. The Parties agree that the rights and obligations under this Agreement are not intended to constitute a partnership or similar arrangement that will require separate reporting for tax purposes in the Territory.

15.8 Assignment and Successors. This Agreement is personal to both Parties and neither Party shall sell, transfer, assign, delegate, pledge or otherwise dispose — other than Abbott's right to sublicense under ARTICLE 2 of its rights or delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, except that (a) each Party may, on providing written notice to the other Party, assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, without the written consent of the other Party to any of its Affiliates or to any purchaser of all or substantially all of its assets and/or all or substantially all of its assets to which this Agreement relates or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation, (b) Sucampo may, without the prior written consent of Abbott, subcontract its manufacturing obligations under this Agreement to R-Tech Ueno, Ltd. and (c) Abbott may perform any or all of its obligations and exercise any and all of its rights under this Agreement through any of its Affiliates. Any permitted assignee of all of a Party's rights under this Agreement shall be deemed to be a party to this Agreement as though named herein; provided with respect to an assignment to an Affiliate, such assigning Party shall remain responsible for the performance of all of its obligations under this Agreement and the performance by such Affiliate of the rights and obligations assigned to such Affiliate, (ii) shall cause such Affiliate to act in a manner consistent with this Agreement. Any attempted assignment or delegation in violation of this Section shall be void.

15.9 Binding Effect. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party, provided that such Party, if it survives, shall remain jointly and severally liable for the performance of such delegated obligations under this Agreement.

15.10 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties under this Agreement which is not within the reasonable control of the Party affected, not due to malfeasance, and which, with the exercise of due diligence could not have been avoided ("Force Majeure"), including, without limitation, fire, explosion, flood, earthquake, war, accident, strike, riot, terrorist attacks, civil commotion, acts of God, or the like, will not excuse such Party from the performance of its obligations or duties under this Agreement, but will suspend such performance during the continuation of Force Majeure. The Party prevented from performing its obligations or duties because of Force Majeure shall be required to, as soon as reasonably possible, notify the other Party hereto of the occurrence and particulars of such Force Majeure and shall be required to provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure and with notice of the termination thereof. The Party so affected shall use reasonable efforts to avoid or remove such causes of nonperformance. Upon termination of Force Majeure, the obligation to perform any previously suspended obligation or duty shall promptly recommence.

15.11 Headings; References. Article, Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Exhibit shall mean references to such Article, Section or Exhibit of this Agreement, (b) references in any section to any clause are references to such clause of such section, and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or as amended if expressly stated in this Agreement.

15.12 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties acknowledge and agree that: (a) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (b) the terms and provisions of this Agreement shall be construed fairly as to all Parties and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

15.13 Severability. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions or parts thereof of this

Agreement, or the application hereof to any circumstances, to be illegal, invalid or to be unenforceable in a final non-appealable order, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, in each case provided that the basic purpose and structure of this Agreement is not altered.

15.14 Entire Agreement. This Agreement and the Quality Agreement constitute the entire agreement between the Parties with respect to the subject matter of the Agreement. This Agreement supersedes all prior agreements and understandings, whether written or oral, with respect to the subject matter of the Agreement, including all confidentiality agreements entered in to between the Parties with respect to the subject matters hereof. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement. All Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Exhibits and this Agreement, the terms of this Agreement shall govern.

15.15 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original and both of which, taken together shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile transmission, by electronic mail in “portable document format” (“.pdf”) form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signature.

15.16 Expenses. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective attorneys and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

15.17 Further Assurance. Each Party shall perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to give effect to this Agreement.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

SUCAMPO PHARMA, LTD.	**ABBOTT JAPAN CO. LTD.**
By: /s/ Ryuji Ueno, MD, PhD, PhD (Signature)	By: /s/ [*] (Signature)
Ryuji Ueno, MD, PhD, PhD (Printed Name) Ryuji Ueno, MD, PhD, PhD	[*] (Printed Name) [*]
(Title) President & Representative Director	(Title) President and Representative Director

EXHIBIT A
COMPOUND, INSOMERS AND TAUTOMERS

Chemical Name: [*]

Code Name: SPI-0211, SPL-0211, RU-0211
CAS Number: 333963-40-9
Monocyclic Tautomer
CAS Number: 136790-76-6

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT B
TESTING AND RELEASE

[*]

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[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT C
PRODUCT TRADEMARKS

Trade Mark	Country	Class	Appl. No.	Appl. Date	Regist. No.	Regist. Date	Status	Next renewal
AMITIZA	JAPAN	5	2006-086199	2006/9/14	5039486	2007/4/6	Registration	2017/4/6
アミティザ	JAPAN	5	2008-090429	2008/11/7			pending	
アミティーザ	JAPAN	5	2008-090430	2008/11/7			pending	

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT D
SUCAMPO PATENT RIGHTS

Title	Country	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date
[*]	JAPAN	**[*]**	**[*]**	**[*]**	**[*]**		
[*]	JAPAN	**[*]**	**[*]**	**[*]**	**[*]**		
[*]	JAPAN	**[*]**	**[*]**	**[*]**	**[*]**		
[*]	JAPAN	**[*]**	**[*]**	**[*]**	**[*]**		
[*]	JAPAN	**[*]**	**[*]**	**[*]**	**[*]**		
[*]	JAPAN	**[*]**	**[*]**	**[*]**			

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EXHIBIT E
JCSC AND JDC INITIAL MEMBERS

ABBOTT

JCSC Initial members: [*]
JDC Initial members: [*]

SUCAMPO

JCSC Initial members: Ryuji Ueno, Sachiko Kuno, Takashi Sekida

JDC Initial members: Ryuji Ueno, Gayle Dolecek, Nobuaki Sato

EXHIBIT F
ALTERNATIVE DISPUTE RESOLUTION

The Parties recognize that from time to time a dispute may arise relating to either Party's rights or obligations under this Agreement. The Parties agree that any such dispute shall be resolved by the Alternative Dispute Resolution ("ADR") provisions set forth in this Exhibit, the result of which shall be binding, upon the Parties.

To begin the ADR process, a Party first must send written notice of the dispute to the other Party for attempted resolution by good faith negotiations between their respective presidents (or their designees) of the affected subsidiaries, divisions, or business units within twenty-eight (28) days after such notice is received (all references to "days" in this ADR provision are to calendar days). If the matter has not been resolved within twenty-eight (28) days of the notice of dispute, or if the Parties fail to meet within such twenty-eight (28) days, either Party may initiate an ADR proceeding as provided herein. The Parties shall have the right to be represented by counsel in such a proceeding.

1. To begin an ADR proceeding, a Party shall provide written notice to the other Party of the issues to be resolved by ADR. Within fourteen (14) days after its receipt of such notice, the other Party may, by written notice to the Party initiating the ADR, add additional issues to be resolved within the same ADR.

2. Within twenty-one (21) days following the initiation of the ADR proceeding, the Parties shall select a mutually acceptable independent, impartial and conflicts-free neutral to preside in the resolution of any disputes in this ADR proceeding. If the Parties are unable to agree on a mutually acceptable neutral within such period, each Party will select one independent, impartial and conflicts-free neutral and those two neutrals will select a third independent, impartial and conflicts-free neutral within ten (10) days thereafter. None of the neutrals selected may be current or former employees, officers or directors of either Party, its subsidiaries or Affiliates.

3. No earlier than forty-five (45) days or later than seventy (70) days after selection, the neutral(s) shall hold a hearing to resolve each of the issues identified by the Parties. The ADR proceeding shall take place in New York, New York. If the Parties cannot agree, the neutral(s) shall designate a location other than the principal place of business of either Party or any of their subsidiaries or Affiliates.

4. At least seven (7) days prior to the hearing, each Party shall submit the following to the other Party and the neutral(s):

(a) a copy of all exhibits on which such Party intends to rely in any oral or written presentation to the neutral;

(b) a list of any witnesses such Party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;

(c) a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed rulings and remedies shall not contain any recitation of the facts or any legal arguments and shall not exceed one (1) page per issue. The Parties agree that neither side shall seek as part of its remedy any punitive damages.

(d) a brief in support of such Party's proposed rulings and remedies, provided that the brief shall not exceed fifty (50) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

Except as expressly set forth in subparagraphs 4(a) — 4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.

5. The hearing shall be conducted on two (2) consecutive days and shall be governed by the following rules:

(a) Each Party shall be entitled to five (5) hours of hearing time to present its case. The neutral shall determine whether each Party has had the five (5) hours to which it is entitled.

(b) Each Party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the Party conducting the cross-examination.

(c) The Party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address not only issues it raised but also any issues raised by the responding Party. The responding Party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.

(d) Except when testifying, witnesses shall be excluded from the hearing until closing arguments.

(e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the neutral(s) shall have sole discretion regarding the admissibility of any evidence.

6. Within seven (7) days following completion of the hearing, each Party may submit to the other Party and the neutral(s) a post-hearing brief in support of its proposed rulings and remedies, provided that such brief shall not contain or discuss any new evidence and shall not exceed thirty (30) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

7. The neutral(s) shall rule on each disputed issue within fourteen (14) days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one of the Parties on each disputed issue but may adopt one Party's proposed rulings and remedies on some issues and the other Party's proposed rulings and remedies on other issues. The neutral(s) shall not issue any written opinion or otherwise explain the basis of the ruling.

8. The neutral(s) shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the Parties(including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:

(a) If the neutral(s) rule(s) in favor of one Party on all disputed issues in the ADR, the losing Party shall pay one hundred percent (100%) of such fees and expenses.

(b) If the neutral(s) rule(s) in favor of one Party on some issues and the other Party on other issues, the neutral(s) shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The neutral(s) shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.

9. The rulings of the neutral(s) shall be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction.

10. Except as provided in paragraph 9 or as required by law, the existence of the dispute, any settlement negotiations, the ADR hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed Confidential Information. The neutral(s) shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.

11. All ADR hearings shall be conducted in the English language.

EXHIBIT G
TRANSFER PRICE AND TRANSFER FLOOR EXAMPLE

Assumptions			
NHI Price		¥	[*] per capsule
Actual Net Price			[*]% of NHI Price
Scenario 1 - Transfer Price — Per Section 8.3.1			
Purchases from Sucampo During Quarter			
Total Inventory Purchase for Quarter		[*]	capsules
Invoice Price per capsule	¥	[*]	NHI Price x [*]%
Sucampo Invoice at Invoice Price	¥	[*]	Number of capsules x Invoice Price
Quarterly Reconciliation			
Abbott Sales in Japan			
Product capsules sold		[*]	capsules
Sales at NHI Price	¥	[*]	
Net Sales	¥	[*]	Assumes [*]% of NHI Price
Calculation			
Amounts Invoiced by Sucampo for units sold			
Sucampo Invoice	¥	[*]	Number of capsules sold x Invoice Price
Transfer Price due to Sucampo	¥	[*]	Net Sales x [*]%
Balance due to Sucampo	¥	[*]	

Scenario 2 — Floor Transfer Price — Per Section 8.3.2			
Purchases from Sucampo During Quarter			
Total Inventory Purchase for Quarter		[*]	capsules
Invoice Price per capsule	¥	[*]	NHI Price x [*]%
Sucampo Invoice at Invoice Price	¥	[*]	Number of capsules x Invoice Price
Quarterly Reconciliation			
Abbott Sales in Japan			
Product capsules sold		[*]	capsules
Sales at NHI Price	¥	[*]	
Net Sales	¥	[*]	Assumes [*]% of NHI Price
Calculation			
Amounts Invoiced by Sucampo for units sold			
Sucampo Invoice	¥	[*]	Number of capsules sold x Invoice Price
Transfer Price due to Sucampo	¥	[*]	Net Sales x [*]%
Balance due to Sucampo	¥	[*]	

EXHIBIT H
PRESS RELEASE

Contact:
Kate de Santis
Sucampo Pharmaceuticals, Inc.
240-223-3834
kdesantis@sucampo.com
And
John Woolford
Westwicke Partners
410-213-0506
john.woolford@westwicke.com

Sucampo Licenses Lubiprostone in Japan to Abbott

Bethesda, Maryland, February xx, 2009 - Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP) today announced that its subsidiary, Sucampo Pharma, Ltd., has entered into a license and commercialization agreement with Abbott Japan Co. Ltd. for Sucampo's lubiprostone (trade name Amitiza®) in Japan.

Lubiprostone is the only FDA-approved treatment for chronic idiopathic constipation (CIC) in adults and for the treatment of irritable bowel syndrome with constipation (IBS-C) in adult women. In September 2008, Sucampo reported results from a phase 2b dose-ranging study of lubiprostone for CIC in Japanese patients. Based on these results, Sucampo plans to initiate phase 3 clinical testing of lubiprostone for CIC in Japan in the second quarter of 2009.

Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman and Chief Executive Officer of Sucampo, said, "We are very excited to enter into this agreement with Abbott because of their strong international presence and infrastructure. Entering the Japanese market represents a key element of Sucampo's overall growth strategy of bringing our proprietary products to the global-market place while also continuing to develop and commercialize other prostone-based portfolio product candidates."

Terms of the Agreement

Under the terms of the agreement, Abbott will receive exclusive rights to commercialize lubiprostone in Japan for the treatment of chronic idiopathic constipation (CIC) and will receive the right of first refusal to any additional indications for which lubiprostone is developed in Japan. Abbott will be responsible for all commercialization expenses and efforts.

Sucampo will receive an upfront payment of $10 million and could receive additional milestone payments based on achieving specified development and commercialization goals. Sucampo will continue to lead the development of and regulatory activity for lubiprostone in Japan and will continue to be responsible for the costs of lubiprostone

development. Following marketing authorization and pricing approval, Abbott will purchase finished product from Sucampo for distribution in Japan. Sucampo also will retain the right to co-promote lubiprostone in Japan.

In addition, Sucampo and Abbott have agreed to begin negotiating a license, commercialization and supply agreement with respect to other available territories.

About lubiprostone

Lubiprostone is a selective activator of type-2 chloride channels through which negatively charged chloride ions flow out of the cells lining the small intestine and into the intestinal cavity. As these negatively charged chloride ions enter the intestine, positively charged sodium ions move through spaces between the cells into the intestine to balance the negative charge of the chloride ions. As these sodium ions move into the intestine, water is also allowed to pass into the intestine through these spaces between the cells. This movement of water into the small intestine promotes fluid content, which in turn softens the stool and facilitates its movement, or motility, through the intestine. Amitiza is a registered trademark of Sucampo Pharmaceuticals, Inc.

About chronic idiopathic constipation

Constipation is characterized by infrequent and difficult passage of stool and becomes chronic when a patient suffers specified symptoms for over 12 non-consecutive weeks within a 12-month period. Chronic constipation is idiopathic if it is not caused by other diseases or by use of medications. Symptoms of chronic idiopathic constipation include straining, hard stools, bloating and abdominal pain or discomfort. Factors contributing to the development of chronic idiopathic constipation include a diet low in soluble and insoluble fiber, inadequate exercise, bowel disorders and poor abdominal pressure and muscular weakness.

About Sucampo Pharmaceuticals

Sucampo Pharmaceuticals, Inc., a biopharmaceutical company based in Bethesda, Maryland, focuses on the development and commercialization of medicines based on prostones. The therapeutic potential of prostones, which are bio-lipids that occur naturally in the human body, was first identified by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo Pharmaceuticals' Chairman and Chief Executive Officer. Dr. Ueno founded Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, Ph.D., founding Chief Executive Officer and currently Advisor, International Business Development.

Sucampo markets Amitiza® (lubiprostone) 24 mcg in the U.S. for chronic idiopathic constipation in adults and Amitiza 8 mcg in the U.S. to treat irritable bowel syndrome with constipation in adult women. Sucampo also is developing the drug for additional gastrointestinal disorders with large potential markets. In addition, Sucampo has a robust pipeline of compounds with the potential to target underserved diseases affecting millions of patients worldwide. Sucampo Pharmaceuticals, Inc. has three wholly owned subsidiaries: Sucampo Pharma Europe, Ltd., located in the UK; Sucampo Pharma, Ltd., located in Japan; and, Sucampo Pharma Americas, Inc., located in Maryland. To learn more about Sucampo Pharmaceuticals and its products, visit www.sucampo.com.

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Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Sucampo Pharmaceuticals are forward-looking statements made under the provisions of The Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words “project,” “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “should,” “would,” “could,” “will,” “may” or other similar expressions. Forward-looking statements include statements about potential trial results, the potential utility of Amitiza to treat particular indications and expected trial initiation. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those described in Sucampo Pharmaceuticals’ filings with the Securities and Exchange Commission (SEC), including the annual report on Form 10-K for the year ended December 31, 2007 and other periodic reports filed with the SEC. Any forward-looking statements in this press release represent Sucampo Pharmaceuticals’ views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Sucampo Pharmaceuticals anticipates that subsequent events and developments will cause its views to change. However, while Sucampo Pharmaceuticals may elect to update these forward-looking statements publicly at some point in the future, Sucampo Pharmaceuticals specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

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EXHIBIT I
FIVE YEAR CUMULATIVE SALES TARGET ASSUMPTIONS

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Exhibit 10.44

LUBIPROSTONE EXCLUSIVE MANUFACTURING AND SUPPLY AGREEMENT

THIS LUBIPROSTONE EXCLUSIVE MANUFACTURING AND SUPPLY AGREEMENT ("Agreement") is made this 23th day of February, 2009 (the "Effective Date"), by and among Sucampo Pharma, Ltd., a corporation organized and existing under the laws of Japan and a wholly-owned subsidiary of Sucampo Pharmaceuticals, Inc., a corporation organized and existing under the laws of the state of Delaware, U.S.A., and having its principal office at Sakurabashi Toyo Building, Fourth Floor, 2-2-16 Sonezakishinchi, Kita-ku, Osaka 530-0002 ("SPL"), R-Tech Ueno, Ltd., a corporation organized and existing under the laws of Japan and having its registered office at 1-1-7 Uchisaiwaicho, Chiyoda-ku, Tokyo 100-0011 ("RTU") (each referred to herein as a "Party" and collectively as the "Parties").

WHEREAS, RTU has expertise in the manufacture of drug substances and drugs for preclinical, clinical and commercial use;

WHEREAS, SPL is a Japan-based pharmaceutical company that seeks a supply source for Drug Substance and Drug Product (defined below) for SPL clinical evaluation and commercial sale in the SPL Territory (defined below);

WHEREAS, SPL may, from time-to-time, and in accordance with this Agreement, enter into Third Party (as defined below) agreements with Persons (as defined below) for joint clinical evaluation and joint commercial sale of Drug Substance and Drug Product in the SPL Territory;

WHEREAS, RTU has in the past supplied to SPL LUBIPROSTONE (also known as RU-0211, SPI-0211, and AMITIZA®) for preclinical and clinical development, and as such RTU has developed a substantial level of expertise in the manufacture of Drug Substance and Drug Product;

WHEREAS, RTU desires to be the exclusive clinical and commercial supplier of Drug Substance and Drug Product; and

WHEREAS, SPL seeks to have RTU supply Drug Substance and Drug Product as further defined herein for use in SPL clinical development and for future commercial sale in the SPL Territory and desires to have RTU be SPL's exclusive supplier of Drug Substance and Drug Product.

NOW, THEREFORE, in consideration of the mutual promises herein, the Parties agree as follows:

ARTICLE 1. DEFINITIONS

Article 1.1. "Additional Materials" means all raw materials, resins, chemical intermediates, components, excipients, and other ingredients and packaging materials and supplies, needed to manufacture the Drug Substance and Drug Product for use in SPL Territory, including costs for relevant in-bound freight.

Article 1.2 "Applicable Law" mean all federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations, or requirements of Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity hereunder.

Article 1.3 "Certificate of Analysis" means a certificate provided by RTU to SPL with each shipment of the Drug Substance and the Drug Product, which sets forth: (a) the results of any quality assurance testing; and (b) the manufacturing date.

Article 1.4. "Confidential Information" means all information, whether in tangible form or not, provided by either party hereunder to the other, including but not limited to: financial information, including but not limited to current and projected financials and funding needs; information on research and development compounds, products, and processes; trade secrets; technical know-how; formulas; studies; regulatory submissions and records; research data and information; sales and marketing information (including, without limitation, customer lists); inventions; patent information and all other information pertaining to a party's intellectual property; in any form (including but not limited to information provided orally, electronically, or in writing). It shall further include the existence and nature and terms of this Agreement, and any and all attachments or exhibits thereto.

Article 1.5. "Drug Substance" means the LUBIPROSTONE active ingredient, prior to formulation as a final drug product.

Article 1.6. "Drug Product" means a finally formulated LUBIPROSTONE drug product PRIOR to packaging for clinical use or commercial sale, as appropriate.

Article 1.7 "Good Manufacturing Practices" or **"GMP"** means quality systems and current good manufacturing practices applicable to the manufacture, labeling, packaging, handling, storage, and transport of active pharmaceutical ingredients, bulk dosage forms and packaged dosage forms, as set forth in the Pharmaceutical Affairs Law and its related Ordinances including the MHLW Ordinance No. 179, December 24, 2004, any update thereto and any other laws, regulations, policies, or guidelines applicable to the manufacture, labeling, packaging, handling, storage, and transport of pharmaceutical products in the Territory, and/or any applicable foreign equivalents thereof, and any updates of any of the foregoing.

Article 1.8 "Latent Defect" means Drug Substance or Drug Product not conforming to RTU's obligation for Drug Product pursuant to Article 2.1 and pursuant to batch testing and release such that the related non-conformance of Drug Product is not readily discoverable based on SPL's or SPL designee's normal incoming-goods inspections, as the case may be.

Article 1.9 "LUBIPROSTONE" means the compound known as RU-0211, SPL-0211, or SPI-0211 or Amitiza® as described in more detail in Appendix A.

Article 1.10 "NDA" refers to a New Drug Application, as defined by laws for such

application within the SPL Territories (as defined below) and applicable regulations promulgated in the countries or territories there under, or other appropriate marketing authorization in Japan, or any counterpart application or marketing authorization in any country of the SPL Territory.

Article 1.11 "Order" means, with respect to clinical or commercial supply of Drug Product, a written communication from SPL to RTU of SPL's need for a particular supply period, issued in accordance with Articles 2.4 and 2.5.

Article 1. 12 "Person" means any individual, trust (or any of its beneficiaries), estate, partnership, limited partnership, association, limited liability company, corporation, any other enterprise engaged in the conduct of business or operating as a non-profit entity, however formed or wherever organized, or any governmental body, agency or unit.

Article 1.13 "Product Defect" means Drug Product not conforming to RTU's obligations for Drug Product pursuant to Article 2.1 and pursuant to batch testing and release such that the related non-conformance of Drug Product may be readily discovered based on SPL's or its designee's normal incoming-goods inspections procedures, as the case may be.

Article 1.14 "Regulatory Approval" means any and all approvals, licenses (including product and establishment licenses), registrations, or authorizations of any Regulatory Authority necessary to develop, manufacture, commercialize, promote, distribute, transport, store, use, sell or market the Drug Substance or Drug Product for use in the SPL Territory.

Article 1.15 "Regulatory Authority" means any national, supra-national, regional, federal, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity (including, without limitation, the Minister of Health, Labour and Welfare of Japan, the National Health Insurance Plan, and any prefecture having jurisdiction over the manufacture of the Product in the Territory) regulating or otherwise exercising authority over the distribution, importation, exportation, manufacture, use, storage, transport, clinical testing or sale of the Drug Substance or Drug Product.

Article 1.16 "Regulatory Filings" means, with respect to the Product in the Territory, all applications, registrations, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from the Regulatory Authorities (including minutes and official contract reports relating to any communications with any Regulatory Authority) and all supporting documents, and all data contained in any of the foregoing.

Article 1.17. "SKU(s)" means Stock Keeping Unit(s) and are the smallest unit of measure to identify manufacturing and distribution of the Drug Product.

Article 1.18 "Specifications" mean the manufacturing, quality control, packaging, labeling, shipping and storage specifications as separately set out for Drug Product in Appendix B and as updated from time to time on mutual agreement in writing by the parties.

Article 1.19. "SPL Territory" means all of the countries located in Japan, Asia and Oceania,

and their territories and possessions.

Article 1.20 "Third Parties" means any Person other than SPL and RTU and their respective affiliates and subsidiaries.

ARTICLE 2. GENERAL TERMS OF MANUFACTURING AND SUPPLY

Article 2.1. Supply. Subject to the terms of this Agreement, and to the terms and conditions of agreements related to development and commercialization of Drug Substance and Drug Product with Third Parties, RTU agrees to manufacture and supply the Drug Substance and the Drug Product to SPL and SPL agrees to purchase said Drug Substance and Drug Product in all such quantities as required by SPL for SPL's clinical and commercial purposes. All such Drug Substance and Drug Product manufactured or supplied by RTU in accordance with this Agreement shall:

(a) be manufactured in accordance and in compliance with Applicable Law, including GMP;

(b) be manufactured in accordance with the applicable Regulatory Filings and Regulatory Approvals;

(c) upon delivery, not be adulterated or misbranded as defined by Applicable Law;

(d) upon delivery, have a minimal shelf life of the longer of [*] ([*]) months or [*] percent ([*]%) of the shelf life registered in the underlying Regulatory Approval;

(e) be free from defects in materials and workmanship; and

(f) be in compliance with all Specifications for the Drug Substance and Drug Product.

Article 2.2. Cost to Produce. RTU, at its sole expense, will provide all labor, utilities, equipment, personnel, facilities, raw materials and components necessary for manufacturing, development and implementation of all appropriate quality control measures, shipping, and storage of the Drug Substance and the Drug Product in compliance with the Specifications and the warranties contained in Article 9 and the Regulatory and Legal requirements of Article 7. RTU shall also be responsible for all process development and validation, including manufacturing process improvements, and scale-up. SPL, at its sole expense, will provide all resources necessary to ship, store, and otherwise handle such Drug Substance and Drug Product in a manner necessary to meet applicable Regulatory and Legal requirements, after delivery of the Drug Substance and the Drug Product to SPL as described in Article 2.8. RTU shall purchase all Additional Materials (as referred to in the relevant Regulatory Approvals) which are needed for the manufacture of the Drug Substance and Drug Products as per the current regulatory files, under its own liability and costs. If RTU wishes to change suppliers and the change will have an impact of a Regulatory Filing, such change shall be subject to SPL's prior written approval, such approval not to be unreasonably withheld.

Article 2.3. Quality Assurance. RTU, at its sole expense, will (i) conduct the commercial stability program with respect to the Drug Product pursuant to Applicable Law, and (ii) perform all testing for compliance with the Specifications and the applicable GMPs and will supply a chemical Certificate of Analysis with each batch of Drug Substance and Drug Product and any other documentation required by law or regulation. Complete copies of all test results and/or assays and/or batch records will be submitted to SPL promptly following any reasonable request therefor during the term of this Agreement. RTU shall make available their facilities and relevant records for inspection

by the appropriate government authorities, SPL or its licensee for regulatory or quality assurance purposes upon reasonable notice and at reasonable times during normal business hours; provided, however, that the inspection by SPL or its licensee hereunder shall be within the scope of inspection that is allowed under the relevant statutes and regulations.

Article 2.4. Clinical Supply; Order. During the term of this Agreement, SPL shall grant RTU the exclusive right to manufacture and supply Drug Substance and Drug Product to SPL for clinical development purposes. During the term of this agreement, RTU and SPL shall from time to time confer and agree on SPL's drug supply needs for SPL's ongoing clinical development program. SPL shall inform RTU of its final requirements in advance of needing clinical supply in such timing as RTU shall reasonably need to duly perform its obligations hereunder, which shall constitute SPL's Order to RTU and which, subject to the terms and conditions of this Agreement, RTU agrees to supply.

Article 2.5. Commercial Supply; Exclusivity; Forecasting; Order. During the term of this Agreement, SPL shall grant RTU the exclusive right to manufacture and supply Drug Product to SPL for commercial purposes subject to appropriate marketing authorization in Japan or any counterpart marketing authorization in any country of the SPL Territory in respect of the Drug Product. Commencing from the date of filing of the first NDA for a particular Drug Product, SPL shall provide to RTU in writing a 12 month forecast of its requirements for Drug Product which forecast will be updated quarterly until SPL's first commercial sale. Thereafter, SPL shall provide RTU a forecast in accordance with the following:

(a) No later than the last business day of each calendar month during the Term SPLwill provide RTU with an updated twenty-four (24) month rolling forecast of the Drug Product to be manufactured and supplied by RTU (each a "Rolling Forecast") for the twenty-four (24) month period commencing at the beginning of the following month with the first three (3) months considered an Order. Each Rolling Forecast will be broken down for each month of such period into the quantity (by SKU, packaging and size of Drug Product) and shipping dates. The first two (2) months of each Rolling Forecast will restate the balance of the purchase order period of the prior Rolling Forecast, and the third month of the Rolling Forecast will constitute the new Order for which SPL will be obligated to purchase and take delivery of the Drug Product.

(b) Except as set forth herein, all months of the Rolling Forecast other than the first three (3) months will set forth SPL's best estimate of its requirements for the supply of Drug Product, and the Rolling Forecast for the months four (4) through twenty-four (24) of each Rolling Forecast will not be binding.

(c) The Rolling Forecast for the months four (4) through twenty-four (24) of each Rolling Forecast shall not increase or decrease by more than [*] percent ([*]%) on a month-to-month basis.

(d) Increases or decreases in the Rolling Forecast beyond those set out in Section 2.5(c) shall be at RTU's discretion.

Article 2.6. Promotional Sample Supply. During the term of this agreement, RTU and SPL shall from time to time confer and agree on SPL's Drug Product supply needs for promotional purpose. SPL shall inform RTU of its final requirements in advance of needing promotional sample shall reasonably need to duly perform its obligations hereunder, which shall constitute SPL's Order to RTU and which, subject to the terms and conditions of this Agreement, RTU agrees to supply.

Article 2.7. Placement and Acceptance of an Order.

2.7.2 Placement. All purchases of Drug Products shall be pursuant to written Orders consistent with Article 2.5(a), which shall be placed by SPL and/or its distributors at least sixty (60) days prior to the date of which Drug Products shall be delivered to SPL or the applicable distributor. Each such purchase order will be in agreement with the purchase order period of the most recent Rolling Forecast. If an Order for any month is not submitted by the above deadline, SPL will be deemed to have submitted an Order in that month for the amount of Drug Product set forth in the most recent Rolling Forecast for such month. Each Order hereunder shall specify the desired quantities of each of the Drug Products, in finished forms and samples, and the delivery dates therefore.

2.7.3 Acceptance. RTU shall have ten (10) Business Days from receipt of an Order from SPA to reject or propose to modify an Order. RTU may only reject an Order that (a) lists products that are not covered by this Agreement, or (b) that is in excess of the amount permitted by Article 2.5 and Section 2.7.2.

Article 2.8. Delivery; Risk of Loss. The Drug Products hereunder shall be delivered per SPL specifications for the relevant Drug Product on or up to three (3) days before the delivery date specified in the order accepted by RTU, subject to the release of the relevant Drug Products as per Article 2.3. SPL shall designate to RTU the carrier which will take delivery of the Drug Products. RTU shall contact such carrier when the Drug Products are ready for shipping and shall arrange for collection, and transportation of the Drug Products. RTU shall inform SPL two (2) Business Days prior to pick-up by the carrier. SPL or a designated Third Party shall bear the costs for transport of the Drug Product and will be invoiced directly by the carrier. The quantity of each Drug Product actually delivered by RTU with respect to each accepted Order shall not exceed a range of minus [*] percent ([*]%) up to plus [*] percent ([*]%) of the quantity of the relevant Drug Product specified in the Order, unless agreed differently by SPL or its designated Third Party. Delivery documents shall include Order, quantity, copy of the Certificate of Analysis, items codes and description, lot number, expiry date of Products, number of shippers, weight, number of pallets.

Article 2.9 Inventory; Reports. On a monthly basis, RTU shall provide SPL with a report detailing present inventory of Drug Substance and Drug Product, along with RTU's schedule for production for the succeeding three months. In the event that Drug Product available to SPL is in short supply, RTU shall notify SPL of such shortage as soon as possible. In the event there is a short supply of Drug Product and RTU cannot supply Drug Product to SPL in an amount equal to SPL's firm order, then RTU (i) shall indemnify SPL for any loss, including but not limited to loss of profit, arising from such shortage of Drug Product and (ii) shall allocate available Drug Product to SPL in each month that such a shortfall exists (and in each month thereafter until the shortfall to SPL is remedied) in an amount equal to the Drug Product of (a) the amount of available Drug Product for that month, and (b) a

fraction the numerator of which is (i) the aggregate of firm orders made by SPL over the subsequent twelve (12) month period including the shortfall month and the denominator of which is (ii) the sum of (x) the aggregate quantity of firm orders made by SPL over the subsequent twelve (12) month period including the shortfall months and (y) the aggregate quantity of lubiprostone product over the same twelve (12) month period required by other licensees outside the SPL Territory by reference to firm orders placed with RTU for such licensees' requirements outside the SPL Territory.

Article 2.10. Non-Exclusivity. Nothing in this Agreement shall prohibit RTU, either clinically or commercially, from manufacturing or supplying, either on its behalf or for any third party, drug products containing the Drug Substance, or drug products containing different active ingredients which require the same reagents as the production of LUBIPROSTONE, either in the SPL territory or in other parts of the world, provided, however, that RTU shall be prohibited from supplying the Drug Substance or the Drug Products in the SPL Territory or to those that induce or facilitate sale in the SPL Territory of the Drug Substance or the Drug Products by any party other than SPL.

Article 2.11. Performance Issue. If either party becomes aware of any issue that may materially impact RTU's ability to fulfill its obligations under this Agreement, it shall immediately notify the other party and both parties shall confer in good faith in order to address such issue.

Article 2.12 Manufacturing Changes. RTU assumes any and all responsibility to make changes to the manufacturing processes, test methods, etc. for the manufacture of products at the manufacturing location, not specific to the Drug Substance and Drug Product, and will solely bear all expenses related thereto. For changes that are not required by a Regulatory Authority, including but not limited to reformulations of the Drug Substance or Drug Product, addition of new strengths to the Drug Product, new presentations and formats of the Product that negatively impacts SPL's commercialization of the Product, then RTU shall indemnify SPL or its designee for any loss, including but not limited to loss of profit, arising from such change.

ARTICLE 3. ADDITIONAL SERVICES

Article 3.1 Laboratory and Regulatory Consulting Services. From time-to-time, under this Agreement, SPL may request performance of "Additional Services" by RTU, which may include without limitation (i) the formulation and/or process development of Drug Substance and/or Drug Product, or (ii) regulatory consulting in connection with RTU's supply of such compound and/or product. The resulting work products of Additional Services will be "Deliverables".

Article 3.2 Placement and Acceptance of an Order for Additional Services.

3.2.1 Placement. SPL shall place an Order for Additional Services at least thirty (30) days prior to the date of which Deliverable shall be due to SPL.

3.2.2 Acceptance. RTU shall have ten (10) Business Days from receipt of an Order for Additional Services from SPL to reject or propose to modify such Order. If such Order is not rejected it shall be deemed accepted and RTU shall, subject to the terms and conditions of this Agreement, be obligated to supply it by its terms.

Article 3.3 Performance of Additional Services. RTU shall perform Additional Services in accordance with the terms of this Agreement, the Order, and all Applicable Laws. RTU shall provide, at its own expense, a place of work and all equipment, tools, and other materials necessary to complete the Order. In performing the Additional Services, RTU shall not utilize the intellectual property of a third party or incorporate know-how owned by any third party without first obtaining SPL's prior written approval. RTU shall not initiate any Additional Services prior to execution of the applicable Order by the Parties.

Article 3.4 Change Proposals. Upon receipt of proposal from SPL to change the terms of an Order for Additional Services (a "Change Proposal"), RTU shall promptly provide (i) any information requested in such proposal, and (ii) its written acceptance or rejection of the proposal. RTU may not reject any Change Proposal that does not materially shorten the delivery or performance schedule or materially alter the Additional Services or Deliverables, and may not unreasonably reject any other Change Proposal. The Order shall be revised accordingly and authorized by the parties involved, including any change in fees and costs caused by or resulting from such Change Proposal.

Article 3.5 Acceptance of Additional Services and/or Deliverables. SPL shall have the right to inspect RTU's progress of the Additional Services or preparation of Deliverables in accordance with a schedule set forth in the applicable Order. SPL shall have the right to accept or reject the Service and/or Deliverable, or any portion thereof, in writing, within five (5) Business Days from the date of such inspection or the receipt of the Services and/or Deliverables at the conclusion of the Additional Services, as the case may be. Such acceptance or rejection shall be consistent with the criteria set forth in the Order. If SPL does not reject in writing within five (5) Business Days, the Additional Service and /or Deliverable shall be considered accepted by SPL. Within five (5) Business Days, SPL shall clearly state in writing the reasons for any rejection, and within five (5) Business Days of receipt of rejection, RTU shall present a corrective plan of action to SPL. Upon approval by SPL, RTU, at no additional cost to SPL, shall make corrections, and where applicable RTU shall resubmit the corrected Additional Service or Deliverable to SPL.

ARTICLE 4. PRICING AND PAYMENT

Article 4.1. Up-Front and Milestone Payments. In consideration of the exclusive rights to manufacture and supply granted to RTU under the terms and conditions set forth in this Agreement including but not limited to Article 2.5, RTU shall pay SPL a total of $1 million (within a consumption tax) according to the following schedule.

EVENT	PAYMENT
On Execution of this Agreement	$0.25 million
NDA approval in Japan	$ 0.5 million
At beginning of commercial launch in Japan	$0.25 million

Article 4.2 Clinical Development Schedule and Report. Schedule of the clinical development of LUBIPROSTONE in each Phase shall be outlined, in reasonable details, in Appendix C, which shall be updated from time to time during the term of this Agreement as there arises any material

change in the schedule. SPL shall provide RTU with updates in writing in reasonable details of progress and forecast of the clinical development of LUBIPROSTONE on at least a quarterly basis and as reasonably requested from time to time during the term of this Agreement.

Article 4.3. Clinical Supply Price. Drug Substance and Drug Product for use in clinical development shall be supplied pursuant to an Order issued under Article 2.4 on a batch-by-batch basis and supplied at [*]$ (or JPY equivalent of [*]$) per capsule without the packaging cost.

Article 4.4. Promotional Supply Price. The Promotional samples described in Article 2.6 shall be supplied at [*]JPY (in Japanese Yen) per capsule without the packaging cost.

Article 4.5. Commercial Cost of Goods; Base Price. In consideration for RTU's supply of Drug Product for commercial sale hereunder, SPL shall pay RTU [*] JPY (in Japanese Yen) per capsule (without the packaging cost) in the case of BID (the "Base Price"). Notwithstanding the terms above, in the vent of significant economic changes, including those with regards to the price of AMITIZA®, the Parties shall meet and discuss in good faith about modifications to the Base Price in accordance with Article 13.1 below.

Article 4.6. Terms of Payment. Any payments due hereunder shall be made within thirty (30) days of receipt of an invoice. Payment may be made by wire transfer or other suitable means agreed upon by the parties.

Article 4.7. Non-conforming Shipments. SPL or its designee will have a period of thirty (30) business days from the date of its receipt of a shipment of Drug Product to inspect and reject such shipment for non-conformance with the obligations under this Article 4.7 and the obligations of RTU pursuant to Article 2.1 including the Specifications based on SPL's normal incoming-goods inspections procedures, by providing RTU with written notice of rejection for any Product Defect within such period of thirty (30) business days together with samples of the non-conforming Drug Products in the relevant shipment for testing. In the case of Product with Latent Defects, SPL or its designee will promptly, and in no event more than thirty (30) business days of SPL knowing of any such Latent Defect, notify RTU of such Latent Defect; provided however, that any Latent Defect must be notified no later than one (1) month following the expiry date of the applicable Drug Product, together with samples of the non-conforming Drug Products in the relevant shipment for testing. If RTU determines that such shipment did conform to the warranties of RTU for product pursuant to Article 2.1 including the Specifications and did conform to documented batch testing and release, the Parties will submit samples of such shipment to a mutually acceptable independent laboratory for testing. If such independent laboratory determines that the shipment conformed to the obligations of RTU for Drug Product pursuant to Article 2.1 including the Specifications and conformed to batch testing and release and was not affected by a Product or Latent Defect, SPL or its designee will bear all expenses of shipping and testing by such independent laboratory of such shipment samples. If RTU or such independent laboratory confirms that such shipment did not meet the obligations of RTU for product pursuant to Article 2.1 including the Specifications and did not conform to documented batch testing and release, RTU will, as soon as practicable, give SPL or its designee a credit for any amount paid with respect to that portion of the Product which does not conform and will bear all of SPL's expenses of returning such Drug Product

to RTU or its nominee. RTU or SPL, as directed by RTU, will dispose of any non-conforming portion of any shipment, at RTU's expense. The costs of the activities of any such independent laboratory will be borne by the Party in error.

ARTICLE 5. CONFIDENTIALITY

Article 5.1. General Obligation. In order that each party may provide appropriate products and services, each has, and will continue to provide the other with, certain Confidential Information prepared by or on behalf of and belonging to the "Disclosing Party." The "Receiving Party" shall maintain Confidential Information in confidence and shall not, without Disclosing Party's written authorization, disclose to any Person any Confidential Information. Receiving Party shall not use Confidential Information for any purpose except for the purposes delineated in this Agreement and for the Disclosing Party's benefit.

Article 5.2. Exceptions. Article 5.1 shall not apply to any information (1) that was in Receiving Party's possession prior to receipt from Disclosing Party, (2) that was in the public domain at the time of receipt from Disclosing Party, (3) that becomes part of the public domain without breach of any obligation of confidentiality to Disclosing Party, (4) that is lawfully received by Receiving Party from a third party independent of Disclosing Party that has no obligation of confidentiality to Disclosing Party, or (5) that is required by law to be disclosed.

Article 5.3. Notice; Return of Confidential Information. Receiving Party shall provide immediate notice to Disclosing Party of any request or demand for Disclosing Party's Confidential Information, or any request or demand for information pertaining to the subject matter of this Agreement. Upon written request, Receiving Party shall promptly provide to Disclosing Party all Confidential Information provided to Receiving Party or prepared by Receiving Party on Disclosing Party's behalf in connection with this agreement.

Article 5.4. Irreparable Harm. The Parties mutually acknowledge and agree that Confidential Information disclosed under this Agreement is valuable principally because of its confidential nature, and so any improper disclosure of Confidential Information will represent irreparable harm that cannot be adequately compensated monetarily.

Article 5.5. Term. This Article 5 confidentiality provision in all events shall remain in effect for ten (10) years following any disclosure made hereunder. Notwithstanding the foregoing, however, any trade secret disclosed to either Party, shall be held in strict confidence in perpetuity or until said trade secret is publicly disclosed through no fault of the receiving party.

ARTICLE 6. INTELLECTUAL PROPERTY

Article 6.1. Ownership.

6.1.1. Prior to each Order placed hereunder, and in compliance with any existing agreements between the Parties as of the date of each Order, each Party shall retain all right, title and interest in its intellectual property, including without limitation information, improvements,

developments, inventions, patents, trade secrets and know-how, and Confidential Information ("**Intellectual Property**").

6.1.2. RTU shall retain sole rights to any data processes, software (including codes), technology, means and know-how developed by RTU which relate solely to manufacture and supply processes and its refinement/improvement and which do not utilize SPL's Intellectual Property.

6.1.3. SPL shall retain sole rights to any know-how developed for SPL in (i) the production of Drug Substance and Drug Product and/or (ii) Additional Services and/or Deliverables, which are prepared or submitted to SPL by RTU under this Agreement.

6.1.4. RTU will disclose to SPL (in accordance with Article 13.7 (*Notices*) hereunder) within ten (10) business days of occurrence, any and all inventions, discoveries and/or improvements utilizing SPL Intellectual Property ("Inventions"). Ownership of such Inventions shall be negotiated by the Parties in good faith in compliance with each Party's Intellectual Property obligations to any third party at the time of Invention.

Article 6.2. Grant of Limited License. Subject to the terms and conditions of this Agreement, each party hereby grants to the other party a non-exclusive, non-transferable license to the extent, and only to the extent, necessary to perform this Agreement. All rights and licenses not granted herein are reserved to each party, and no other rights or licenses are granted or will be deemed to be granted to the other party (whether by implication, estoppel or otherwise). Without limiting the generality of the foregoing, RTU retains the right to manufacture the Drug Substance and the Drug Product, and to permit third parties to manufacture the Drug Substance and the Drug Product, both in and out of the SPL Territory, subject, however, to the provisions of Sections 2.10 and 6.1.

ARTICLE 7. REGULATORY & LEGAL

Article 7.1. Compliance. RTU shall at all times remain in substantial compliance, with all applicable laws, regulations and guidelines that apply to the manufacturing and supply contemplated hereunder.

Article 7.2. Records. RTU shall keep accurate written records in substantial compliance with all applicable legal and regulatory requirements that apply to the manufacturing and supply contemplated hereunder. Such records will be made available to SPL on reasonable request for inspection, to the same extent that they would be available to an appropriate governmental inspector, during normal business hours. Records shall be maintained for the period of time required by applicable laws or regulations, or if there is no period of time specified by such laws or regulations, for three (3) years following the respective dates of records.

Article 7.3. Authorization of the Manufacturing Facility by MHLW. RTU shall be responsible for providing information that may be used in, or referenced by, an application filed by SPL with the Ministry of Health, Labor and Welfare (the "MHLW") or any other relevant regulatory authority for purposes of ensuring that the RTU manufacturing facility is authorized to manufacture the

Drug Substance and Drug Product to be supplied under this Agreement. SPL shall have no obligation to purchase any Drug Product from RTU if they are produced in a manufacturing facility that is not, in any material respect, in compliance with all applicable legal and regulatory requirements.

Article 7.4. Regulatory Audits; Notice of Audit. RTU shall make its facilities, records and personnel available to the MHLW or any other relevant regulatory authority as may be needed for compliance with the applicable laws, rules and regulations enforced by such authority. RTU shall advise SPL in writing immediately if:

(a) an agent of any regulatory body having jurisdiction over the manufacture or distribution of the Drug Product makes an inquiry about the Drug Product or visits RTU's manufacturing facility for the Drug Product, and shall specify what, if any, inquiry was made; or

(b) any regulatory authority takes action against RTU on any issue related directly or indirectly to the manufacturing or distribution of the Drug Product.

Article 7.5. Drug Master File. RTU shall produce and maintain a drug master file for Drug Substance made under this Agreement, which shall contain all information necessary to comply with MHLW standards with respect to the applicable manufacturing processes and Drug Product.

Article 7.6. Import/Export Issues. RTU shall be responsible for (i) obtaining all governmental permits, consents and approvals which are required in order to export Drug Product from the country of origin, and (ii) making any required notifications or other filings (whether before or after shipment) which are required in connection with the exportation of Drug Product from the country of origin.

ARTICLE 8. REPRESENTATIONS & WARRANTIES OF SPL

Article 8.1. Organization. SPL represents and warrants to RTU that it is a corporation duly organized, validly existing, and, where applicable, in good standing under the laws of the jurisdiction of its incorporation.

Article 8.2. Authority. SPL represents and warrants that it: (a) has the right to enter into this Agreement; (b) has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and (c) has by all necessary corporate action duly and validly authorized the execution and delivery of this Agreement and the performance of its obligations hereunder.

Article 8.3. No Conflicts. SPL represents and warrants to RTU that it has not and will not during the term of this Agreement enter into any agreement which conflicts with or which will result in any breach of, or constitute a default under, any note, security agreement, commitment, contract or other agreement, instrument or undertaking to which it is a party.

Article 8.4. Insurance. SPL represents that it will at all times maintain commercially reasonable levels of insurance, including general liability insurance, in light of their responsibilities hereunder. SPL shall provide RTU with certificates of insurance upon RTU's written request for the same.

Article 8.5. Obligations of Confidentiality. SPL represents and warrants that any employee or other affiliated person, including subcontractors, who will be involved in performing this Agreement is bound, or will be bound prior to performing any work, by a proprietary information and technology agreement in favor of the other party, consistent with the obligations of Article 5, pursuant to which such employee or other person is obligated to confidentiality.

ARTICLE 9. REPRESENTATIONS AND WARRANTEES OF RTU

Article 9.1. Organization. RTU represents and warrants to SPL that it is a corporation duly organized, validly existing, and, where applicable, in good standing under the laws of the jurisdiction of its incorporation.

Article 9.2. Authority. RTU represents and warrants that it: (a) has the right to enter into this Agreement; (b) has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and (c) has by all necessary corporate action duly and validly authorized the execution and delivery of this Agreement and the performance of its obligations hereunder.

Article 9.3. No Conflicts. RTU represents and warrants to SPL that it has not and will not during the term of this Agreement enter into any agreement which conflicts with or which will result in any breach of, or constitute a default under, any note, security agreement, commitment, contract or other agreement, instrument or undertaking to which it is a party.

Article 9.4. Insurance. RTU represents that it will at all times maintain commercially reasonable levels of insurance, including general product liability insurance, in light of their responsibilities hereunder. RTU shall provide SPL with certificates of insurance upon SPL's written request for the same.

Article 9.5. Qualified Personnel. RTU warrants that it will at all time use appropriately qualified personnel, having the appropriate levels of training and skill, to fulfill its obligations arising under this Agreement

Article 9.6. Regulatory and Legal Compliance. RTU hereby warrants that its facilities and processes supplied hereunder substantially comply with, or will substantially comply with at all relevant times, all applicable legal and regulatory requirements necessary to fulfill its obligations under this Agreement, including without limitation, securing and maintaining any necessary certificates or permits.

Article 9.7. Obligations of Confidentiality. RTU represents and warrants that any employee or other affiliated person, including subcontractors, who will be involved in performing this Agreement is bound, or will be bound prior to performing any work, by a proprietary information and technology agreement in favor of the other party, consistent with the obligations of Article 5, pursuant to which such employee or other person is obligated to confidentiality.

Article 9.8. Process and Product Warranties. RTU warrants and represents that:

(a) Drug Product sold by RTU to SPL hereunder shall (i) materially comply with the Specifications for Drug Product, and (ii) materially conform with the information shown on the Certificate of Analysis provided for the particular shipment;

(b) no Drug Product sold by RTU to SPL hereunder shall be adulterated or misbranded within the meaning of the applicable Pharmaceutical Law of Japan, as amended and in effect at the time of shipment to the Drug Product and containing terms with substantially similar meanings as the meaning of adulteration or misbranding under the Act; provided, however, that this paragraph shall not apply to, and RTU shall have no responsibility for, misbranding caused directly by SPL as a result of labels or package texts specified or provided by SPL for the Drug Product; and RTU shall have no responsibility for issues of regulatory and legal compliance that are the responsibility of SPL, including but not limited to (1) maintaining a complete and valid NDA for the product, (2) ensuring that the product specifications are consistent with the NDA, and (3) ensuring that the product is stored and distributed in the SPL Territory in a manner that does not result in its becoming adulterated, misbranded, or otherwise in violation of law.

Article 9.9. Continuity of Supply. The parties acknowledge that continuous supply of Drug Substance and Drug Product are of critical importance to the commercial interests of both parties, and accordingly, RTU shall use commercially reasonable efforts to maintain the continuity of supply, and SPL shall reasonably cooperate with RTU (including but not limited to providing forecasts pursuant to Article 2.5 of this Agreement), so that Drug Substance and Drug Product be supplied continuously during the term of this Agreement. RTU shall maintain a safety stock of active Drug Substance equal to six (6) months of forecast demand based on SPL's most recent Rolling Forecast. RTU shall maintain a safety stock of Additional Materials to support the drug product manufacture and packaging equal to three (3) months of forecast demand based on SPL's most recent Rolling Forecast.

ARTICLE 10. INDEMNIFICATION

Article 10.1. RTU's Obligation. RTU shall defend, indemnify and hold SPL, and the respective officers, directors and employees of each, harmless from and against any and all claims, demands, losses, damages, liabilities (including without limitation product liability), settlement amounts, cost or expenses whatsoever (including reasonable legal fees and costs and court costs) arising from or relating to any claim, action or proceeding made or brought against such person by a third party as a result of RTU's negligence, willful misconduct or breach of this Agreement (including, without limitation, RTU's failure to comply with the Specifications, any breach by RTU of the warranties contained in Article 9, or otherwise any breach of the provisions of this Agreement by RTU). RTU shall have no obligation under this clause to indemnify SPL for claims described in Article 10.2. For the avoidance of doubt with regard to product liability claims relating to Drug Substance and Drug Product, RTU's indemnification of SPL hereunder shall extend only to matters of drug quality.

Article 10.2. SPL's Obligation. SPL shall defend, indemnify and hold RTU and the respective officers, directors and employees of each harmless from and against any and all claims, demands, losses, damages, liabilities (including without limitation product liability), settlement amounts,

cost or expenses whatsoever (including reasonable legal fees and costs and court costs) arising from or relating to any claim, action or proceeding made or brought against such person by a third party as a result of (1) SPL's negligence, willful misconduct or any breach of the terms of this Agreement (including any of its representations and warranties set forth therein), (2) the manufacture and delivery to SPL of Drug Substance and Drug Product done in accordance with the Specifications, warranties and provisions of this Agreement, and/or (3) the investigation, administration, use, sale, marketing, promotion, advertising, storage, distribution, and any other activity with respect to the Drug Substance and the Drug Product that is the responsibility of SPL under this Agreement. SPL shall have no obligation under this clause to indemnify RTU for claims described in Article 10.1. For the avoidance of doubt with regard to product liability claims relating to Drug Product, SPL's indemnification of RTU hereunder shall extend only to matters inherent to the drug substance.

Article 10.3. Notice; Defense of Claims. In the event of any claim, action or proceeding for which a person is entitled to indemnity hereunder, the Person seeking indemnity ("Claimant") shall promptly notify the relevant party ("Indemnitor") in reasonable detail in writing the factual basis for such claim, action or proceeding and the amount of the claim; provided, however, that any delay by the Claimant in giving such notice shall not relieve the Indemnitor of its obligations under this Agreement except and only to the extent that the Indemnitor is materially damaged by such delay. The Indemnitor shall be entitled to assume the defense thereof at its own expense, with counsel satisfactory to such Claimant in its reasonable judgment; provided, however, that any Claimant may, at its own expense, retain separate counsel to participate in such defense. The Claimant shall not settle, compromise, discharge or otherwise admit to any liability for any claim or demand for which it is indemnified without the prior written consent of the Indemnitor (which consent shall not be unreasonably withheld or delayed). The Indemnitor shall not settle, compromise, discharge or otherwise admit to any liability for any claim or demand on a basis that would adversely affect the future activity or conduct of the Claimant without the prior written consent of the Claimant.

ARTICLE 11. TERM AND TERMINATION

Article 11.1. Term. This Agreement shall become effective as of the date hereof and remain in full force and effect for twenty (20) years following the first commercial sale of the Drug Product under this Agreement to be approved by a competent regulatory authority in the SPL Territory, unless otherwise earlier terminated by mutual written agreement or by the provisions set forth below.

Article 11.2. Termination for Cause. In addition to any other rights or remedies a party may have, either party may terminate this Agreement upon the occurrence of any of the following events of default which is not cured within sixty (60) days after written notice thereof is received by the other party:

(a) breach by the other party of any of its material obligations hereunder; or

(b) should the other party become subject of proceedings involving bankruptcy, receivership, administration, insolvency, moratorium of payment reorganization or liquidation, or make any assignment for the benefit of the creditors or any equivalent measures in any relevant jurisdiction.

Article 11.3. Survival of Certain Rights and Obligations. The obligations under Article 5, Article 6, Article 8, Article 9, Article 10, this Article 11.3 and Article 12 shall survive any expiration or other termination of this Agreement in accordance with their terms.

ARTICLE 12. DISPUTE RESOLUTION

Article 12.1. Negotiation. The parties agree to consult and negotiate in good faith to try to resolve any dispute, controversy or claim, of any nature or kind, whether in contract, tort or otherwise, that arises out of or relates to this Agreement. No formal dispute resolution shall be used by either party unless and until the chief executive officers of each party shall have attempted to meet in person to achieve such an amicable resolution.

Article 12.2. Arbitration. Any dispute, controversy or claim that arises out of or relates to this Agreement that is not resolved under Article 12.1 shall be settled by final and binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC") in effect on the Effective Date, as modified by Article 12.3 below. Judgment upon the award rendered by the arbitrators may be entered in any court of competent jurisdiction. The place of arbitration shall be Paris, France unless another location is agreed upon between the parties and arbitrators. The arbitration shall be conducted in the English language by three (3) neutral arbitrators selected by mutual agreement of the parties or, if that is not possible within thirty (30) days of the initial demand for such arbitration, by the ICC. At least one (1) arbitrator shall have knowledge of and experience in the ethical pharmaceutical industry.

Article 12.3. Special Rules. Notwithstanding any provision to the contrary in the ICC's Rules of Arbitration, the parties hereby stipulate that any arbitration hereunder shall be subject to the following special rules:

(a) The arbitrators may not award or assess punitive damages against either party; and

(b) Each party shall bear its own costs and expenses of the arbitration and shall share equally the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing party.

ARTICLE 13. MISCELLANEOUS

Article 13.1. Changed Circumstances. The parties recognize that the obligations of this Agreement may run for many years in the future. In the event of any material change in circumstances, the parties shall meet and confer in good faith in order to try and find a solution that accommodates the interests of both parties. RTU acknowledges that SPL will enter into one or more agreements with third parties for the purpose of commercial sale of LUBIPROSTONE in the SPL Territory, and in the event that such third parties raise concerns or place demands on SPL concerning matters pertaining to this Agreement, RTU shall work with SPL to resolve such concerns or demands, including amending this Agreement, as may be commercially appropriate or necessary. SPL acknowledges that RTU will enter into agreements with third parties for the purpose of procuring various materials necessary for

RTU to manufacture and supply LUBIPROSTONE hereunder, and in the event that such third parties raise concerns or place demands on RTU that will result in increase of manufacturing costs, SPL shall work with RTU to resolve such concerns or demands, including amending this Agreement, as may be commercially appropriate or necessary.

Article 13.2. Subcontracting. RTU may subcontract its obligations hereunder with SPL's prior written consent, which shall not be unreasonably withheld, conditioned or denied.

Article 13.3. Entire Agreement. This Agreement, together with the Appendices attached hereto, constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes the Term Sheet and any and all other previous proposals or agreements, oral or written, and all negotiations, conversations or discussions heretofore between the parties related to the subject matter of this Agreement.

Article 13.4. Independent Contractor; No Agency. This agreement shall not be construed to create an employment or agency relationship between the parties. This Agreement is not intended to create any agency relationship of any kind; the Parties agree not to contract any obligations in the name of the other or to use each other's credit in conducting any activities under this Agreement. Each party is solely responsible for the payroll taxes, workman's compensation insurance, and any other benefits owed to their own employees.

Article 13.5. Assignment. Upon written approval of the other party, which approval shall not unreasonably be withheld and shall be timely given, a party may assign or otherwise transfer its rights and obligations under this Agreement to any successor in interest (by merger, share exchange, combination or consolidation of any type, operation of law, purchase or otherwise), provided that such assignee or successor agrees to be bound by the terms hereof. Notwithstanding anything contained in this Article, this Agreement shall be assigned from SPL to any entity which acquired, or otherwise succeeded in interest in, all or substantially all of the assets in relation to LUBIPROSTONE, and such entity shall be bound by this Agreement. The parties specifically contemplate that this agreement may be assigned to RTU if it becomes an independent company from R-Tech Ueno, Ltd. and retains the proper expertise, equipment and personnel for carrying out the obligations of this Agreement. For the avoidance of doubt, the parties acknowledge that SPL is entering into this Agreement on the basis of RTU's special expertise in manufacturing prostaglandin-related compounds, and so SPL may withhold their approval of a proposed assignment if the proposed successor does not have reasonably comparable expertise.

Article 13.6. Governing Law. This Agreement shall be construed in accordance with Japanese law, excluding its choice of law provisions.

Article 13.7. Notices. All notices or other communications to a party required or permitted hereunder shall be in writing and shall be delivered personally or by telecopy (receipt confirmed) to such party (or, in the case of an entity, to an executive officer of such party) or shall be given by certified mail, postage prepaid with return receipt requested, addressed as follows:

if to SPL:	Sucampo Pharma, Ltd. 2-2-2 Uchisaiwai-cho, Chiyoda-ku Tokyo, 100-0011 Japan Attention: Mr. Takashi Sekida Facsimile number: [*]
and if to RTU:	R-Tech Ueno, Ltd. 4-1, Techno Park Sanda, Hyogo 669-1339 Japan Attention: Mr. Ryu Hirata Facsimile number: [*]

Article 13.8. Severability. If a court of competent jurisdiction holds any provision of this Agreement invalid, the remaining provisions shall nonetheless be enforceable according to their terms. Further, if any provision is held to be overbroad as written, such provision shall be deemed amended to narrow its application to the extent necessary to make the provision enforceable according to applicable law and shall be enforced as amended.

Article 13.9. Waiver, Discharge, etc. This Agreement may not be released, discharged, abandoned, changed or modified in any manner, except by an instrument in writing signed on behalf of each of the parties to this Agreement by their duly authorized representatives. The failure of either party to enforce at any time any of the provisions of this Agreement shall in no way be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part of it or the right of either party after any such failure to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach. No inspection or acceptance, approval, acquiescence, or payment by SPL with respect to non-conforming Drug Product shall relieve RTU from any portion of its warranty obligations hereunder unless expressly agreed by SPL in writing.

Article 13.10. Titles and Headings; Construction. The titles and headings to Articles herein are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the party causing this Agreement to be drafted.

Article 13.11. Benefit. Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the parties to this Agreement or their respective permitted successors or assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

Article 13.12. Execution in Counterparts. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement, and shall become a binding agreement when one or more counterparts have been signed by each party and delivered to the other party.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the parties has caused this Exclusive Supply Agreement to be executed in the manner appropriate to each, effective as of the date first above written.

R-TECH UENO, LTD.

By: /s/ Yukiko Hashitera
Yukiko Hashitera
President

SUCAMPO PHARMA, LTD.

By: /s/ Misako Nakata
Misako Nakata
Representative Director

Appendix A
Description of LUBIPROSTONE

Generic name:	lubiprostone
Chemical names:	[*]
Code name:	LUBIPROSTONE
CAS No.:	333963-40-9 (bicyclic type) or 136790-76-6 (monocyclic type)
Structural Formula:	[*]

Appendix B
Specifications for LUBIPROSTONE
Drug Product

[*]

Appendix C
Clinical Development Schedule

[*]

EXHIBIT 21

SUBSIDIARIES OF COMPANY

Name	Jurisdiction of Formation
Sucampo Pharma Europe Ltd.	England and Wales
Sucampo Pharma, Ltd.	Japan
Sucampo Pharma Americas, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-147420) of Sucampo Pharmaceuticals, Inc. of our report dated March 16, 2009 relating to the financial statements, financial statement schedule, and the effectiveness of internal control over financial reporting, which appears in this Form 10-K**.**

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland
March 16, 2009

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryuji Ueno, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sucampo 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 registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(F)) for the registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrants fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant'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 registrant's internal control over financial reporting.

Date: March 16, 2009

/s/ RYUJI UENO
Ryuji Ueno, M.D., Ph.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jan Smilek, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sucampo 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 registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(F)) for the registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrants fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant'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 registrant's internal control over financial reporting.

Date: March 16, 2009

/s/ JAN SMILEK
Jan Smilek
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Sucampo Pharmaceuticals, Inc. (the "Company") certifies to the best of his knowledge that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2008 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2009

/s/ RYUJI UENO
Ryuji Ueno, M.D., Ph.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Sucampo Pharmaceuticals, Inc. (the "Company") certifies to the best of her knowledge that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2008 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2009

/s/ JAN SMILEK
Jan Smilek
Chief Financial Officer
(Principal Financial and Accounting Officer)