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, 2009

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. Please see definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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 11,452,340 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 $70.7 million.

As of March 10, 2010, there were outstanding 15,655,730 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 2010 Annual Meeting of Stockholders to be held on May 20, 2010, which Proxy Statement is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2009, are incorporated by reference in Part III of this Annual Report on Form 10-K.

Sucampo Pharmaceuticals, Inc.

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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. Prostones are a class of compounds occurring naturally in the human body by enzymic, 15-PGDH, transformation of certain fatty acids. 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 promote fluid secretion and enhance cell protection, including the recovery of cellular barrier function. This activity gives prostones wide-ranging therapeutic potential, particularly for age-related diseases. We are focused on developing prostone-based compounds for the treatment of gastrointestinal, ocular, vascular, and respiratory diseases and disorders for which there are unmet medical needs, underserved patients and significant commercial potential.

The therapeutic potential of prostones was first identified by one of our founders, Dr. Ryuji Ueno. To date, two prostone products received marketing approval. Amitiza® (lubiprostone) is a FDA-approved treatment for chronic idiopathic constipation, or CIC, in adults of both genders and all ages and irritable bowel syndrome with constipation, or IBS-C, in adult women. Rescula® (unoprostone isopropyl) is FDA-approved for the treatment of open-angle glaucoma and ocular hypertension.

Amitiza in the U.S. and Canada

Amitiza (lubiprostone) is the only FDA-approved prescription product for the treatment of CIC in adults of both genders and all ages with demonstrated safety and effectiveness for use beyond 12 weeks. Amitiza is also the only FDA-approved prescription product for the treatment of IBS—C in adult women of 18 years and older.

According to IMS Health, a total of between 13 million and 14 million diagnoses of CIC and IBS-C are made in the U.S. on an annual basis. Studies published in The American Journal of Gastroenterology estimate that approximately 42 million people in the U.S. suffer from constipation. Based on these studies, we estimate that approximately 12 million people can be characterized as suffering from chronic idiopathic constipation. According to the American College of Gastroenterology, irritable bowel syndrome affects approximately 58 million people in the U.S. and IBS-C accounts for approximately one-third of these cases. Similar rates of incidence of these disorders are assumed to occur in the rest of the world.

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 CIC and IBS-C and other gastrointestinal indications in the U.S. and Canada. At the same time, we entered into a supply and a manufacturing agreement with Takeda and R-Tech Ueno, Ltd, or R-Tech, a Japanese manufacturing and research and development company that is majority owned by our founders. Following FDA approval, commercial sales of Amitiza were initiated in April 2006 for the treatment of CIC and in May 2008 for the treatment of IBS-C. We are currently planning to file for marketing authorization for Amitiza for CIC in Canada in 2010. We retain, among other rights, the right to develop and commercialize Amitiza in the U.S. and Canada for gastrointestinal indications under the terms of the collaboration and license agreement with Takeda, as well as the exclusive right to develop and commercialize Amitiza in the U.S. and Canada for all indications other than gastrointestinal indications. In early 2006, in response to a notice of material breach sent to Takeda in 2005, we entered into a supplemental agreement which resolved certain disputes with Takeda and further defined certain rights and responsibilities of the parties.

Takeda sells Amitiza mainly to office-based specialty and primary care physicians. Takeda reimburses the Company for a significant portion of our research and development activities as well as a part of our co-promotion expenses. Takeda records all sales of Amitiza within the U.S. and we receive a tiered royalty based on net sales. We are primarily responsible for Amitiza research and development efforts and hold the new drug application, or NDA. Takeda is primarily responsible for the sales and marketing of Amitiza in the U.S. and Canada. We have the right to co-promote Amitiza in the U.S. and Canada through a specialty sales force focused on the institutional marketplace, including specialist physicians based in academic medical centers and long-term care and veteran's affairs facilities.

We are currently pursuing development of a third gastrointestinal indication of Amitiza, for the treatment of opioid-induced bowel dysfunction, or OBD, in patients with non-malignant pain, a constipation-related gastrointestinal indication. In July 2009, we reported top-line results from two identically-designed phase 3 clinical trials of Amitiza. In one trial, the primary endpoint of a statistically significant change from baseline in the frequency of spontaneous bowel movements, or SBMs, was met when Amitiza was compared to placebo. The other trial did not achieve statistical significance for the same primary endpoint. In both trials, a post-hoc sub-population analysis showed that subjects on methadone treatment regimens who were randomized to receive Amitiza showed a lower SBM response when compared to Amitiza subjects treated with other opioid medications. The fully-enrolled, long-term, follow-on, open-label safety study of Amitiza in OBD subjects continues and data from this study together with the data from the two efficacy trials are anticipated to be submitted to the FDA in 2010.

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. Prevalence studies estimate that more than 4.3 million adult patients take opioids regularly and 10.0 million adults take them in any given week. Recent studies in the use of opioids for the treatment of non-cancer pain suggest the rate of constipation of patients might be 40% or higher.

We are disappointed with the level of U.S. sales of Amitiza being generated by Takeda and other failures of performance by Takeda under our agreements. In April 2009, we sent Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. a notice of material breach. The notice stated that Takeda materially breached our agreement, without limitation, by their continuing failure to exercise their best efforts to commercialize Amitiza and maximize net sales revenue, and their ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We subsequently sent a letter that advised Takeda that they had failed to cure said breaches within the 90 day cure period provided under the agreement. Since then, we have spent significant resources in our dispute with Takeda. We also attempted to conduct a review of Takeda's performance but Takeda refused to provide us with certain information necessary to complete that review.

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between us and Takeda Pharmaceuticals Company Limited dated October 29, 2004. In addition to the claims set forth in the notice of material breach, we also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only us and the Amitiza brand, but also consumers. We are seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. We may spend additional significant resources and these legal proceedings may require the continuing attention of our senior management.

Amitiza in Japan

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

To date, we have received a total of $17.5 million in payments from Abbott, consisting of an upfront payment of $10.0 million and $7.5 million upon enrolling the first patient into a pivotal phase 3 trial of Amitiza for CIC in Japanese patients. We could receive additional milestone payments based on achieving other specified development and commercialization goals. We completed enrollments into the phase 3 safety trial and the phase 3 efficacy trial in 2009. We anticipate announcing data from these trials in 2010. If these trials are successful, we anticipate filing a registration application with the Japanese regulatory authorities in 2010.

We are preparing a development plan which will be presented to and discussed with Abbott in 2010. The agreement provides a dispute resolution mechanism for certain disputes including the development plan. 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 and development and commercialization rights to all other therapeutic areas.

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.

In September 2009, we withdrew our marketing authorization application, or MAA, for lubiprostone in multiple countries in the European Union, or E.U. The withdrawal was a strategic decision based upon lubiprostone's projected commercial position in the global market. We continue to evaluate the opportunities to obtain an appropriate label in the E.U. consistent with the fact that lubiprostone is the only product approved by the FDA in the U.S. for chronic therapy for either CIC or IBS-C.

In November 2009, we announced that Swissmedic, the Swiss Agency for Therapeutic Products, has granted a marketing authorization for lubiprostone for the long-term treatment of adult patients with CIC. This is the first European regulatory approval for us. Amitiza is the first prescription medicine to be approved in Switzerland for the long-term treatment of CIC.

Rescula

In April 2009, we entered into agreements with R-Tech, to acquire for $3.5 million the rights to Rescula in the U.S. and Canada. Under these agreements, we hold the exclusive rights to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension and any new indication developed by us. We also have the right of first refusal to commercialize Rescula in the U.S. and Canada for any additional indications for which unoprostone is developed by R-Tech. Currently, we may develop Rescula for treating an array of ophthalmic diseases including retinitis pigmentosa, an orphan indication, dry age-related macular degeneration , or dry AMD, and diabetic retinopathy. R-Tech is conducting a phase 2 clinical trial of Rescula to evaluate its potential as a treatment for retinitis pigmentosa. Although Rescula eye drops were approved by the FDA for the treatment of open-angle glaucoma and ocular hypertension in 2000 and Rescula was initially commercialized under an agreement of R-Tech with a third party, it is not currently marketed in the U.S. or Canada.

R-Tech received first marketing approval for Rescula in Japan in 1994 for the treatment of glaucoma and ocular hypertension. In 1998, R-Tech licensed the rights to develop and commercialize Rescula in the U.S. and Europe to Novartis. Subsequently, Novartis elected to pursue only very limited commercialization in these territories. In 2005, the U.S. license rights were repurchased by R-Tech and Novartis continued to hold the rights to Rescula in Europe. In 2009, we entered into an agency agreement with R-Tech to facilitate the return of the European rights from Novartis to R-Tech.

We continue to pursue intellectual property and development potential of Rescula. We are solely responsible for the development, regulatory and commercialization activities and expenses for Rescula in the U.S. and Canada and R-Tech is exclusively responsible for the supply of Rescula to us within those countries.

Other product candidates

We are developing additional prostones for the treatment of a broad range of diseases. The most advanced of these programs are:

- Cobiprostone: In July 2009, we reported top-line results from our phase 2a clinical trial of orally administered cobiprostone for the prevention of gastric ulcers and other gastrointentinal injuries in patients treated with non-steroidal anti-inflammatory drugs, or NSAIDs. Cobiprostone patients experienced an overall statistically significant reduction in the number of gastric erosions through the treatment period of 12 weeks as compared to placebo patients. In addition, the high dose cobiprostone group experienced a 50.0% reduction in the overall incidence of gastric ulcers when compared to patients taking placebo. We are designing a phase 2b study to complement the findings of earlier studies. We also are designing a preclinical study of cobiprostone for use as a treatment for chronic obstructive pulmonary disease, or COPD, and as a potential treatment for wound healing.
- SPI-017 is currently in preclinical and clinical testing in peripheral arterial and vascular diseases as well as central nervous system disorders. In December 2008, we commenced a phase 1 clinical trial of the intravenous formulation of SPI-017 for peripheral arterial disease, or PAD, in Japan. This phase 1 program has advanced to the administration of multiple doses at different dose levels to patients, and we anticipate having these results in 2010.

- SPI-3608: A novel prostone, SPI-3608 will continue to undergo preclinical testing. Based on preclinical results seen to date, this molecule may have potential as a treatment for spinal stenosis.

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 U.S., Canada and Japan, which is covered by our collaboration and license agreements with Takeda and Abbott, and for Rescula, for which we hold the U.S. and Canadian rights.

Product Pipeline

The table below summarizes the development status of Amitiza, Rescula and our key prostone-based product candidates.

Product/Product Candidate	Target Indication	Development Phase	Next Milestone
Amitiza ® (lubiprostone)	Chronic idiopathic constipation (CIC) (adults of all ages)	Marketed in the U.S.	New drug submission (NDS) in Canada
		Approved in Switzerland	Pricing negotiations with Swiss government health agency
		Phase 3 efficacy and safety trials in Japanese patients	Data expected in 2010
	Irritable bowel syndrome with constipation (adult women) (IBS-C)	Marketed in the U.S.	——
	Chronic idiopathic constipation (CIC) (pediatric, patients with renal impairment and patients with hepatic impairment)	Phase 4 pediatric, renal impairment and hepatic impairment trials completed and submitted to the FDA	——
	Opioid-induced bowel dysfunction (OBD)	Two phase 3 efficacy trials completed, analysis of results ongoing	Phase 3 safety trial to complete in 2010 and data from all 3 trials to be filed with FDA
Rescula ® (unoprostone)	Dry age-related macular degeneration (dry AMD)	Preclinical	Phase 2a trial
	Glaucoma and ocular hypertension	Approved in the U.S.	Limited commercialization
Cobiprostone	*Gastrointestinal*		
	Prevention of non-steroidal anti-inflammatory drug (NSAID)-induced ulcers	Phase 2a trial results reported	Phase 2b trial
	Pulmonary		
	Chronic obstructive pulmonary disease (COPD)	Preclinical	Finalize inhaled formulation
	Dermatology		
	Wound healing	Preclinical	Phase 1 trial
SPI-017	Peripheral arterial disease (PAD)	Phase 1 human clinical safety studies in Japan	Phase 1 program to complete in 2010
SPI-3608	Spinal stenosis	Preclinical	Phase 1 trial

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, or SAG, an affiliated Swiss-based patent-holding company. We are obligated to assign to SAG all patentable improvements that we make in the field of prostones, which SAG 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 SAG. 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, then the commercial rights to that compound will revert to SAG. The specified period ends on the later of June 30, 2011, or the date upon which Drs. Ryuji Ueno and Sachiko Kuno are no longer controlling shareholders, and is subject to a 15-month extension period in the case of any compound that we designate in good faith as planned for development within that extension period.

We also hold an exclusive U.S. and Canada license to develop and commercialize rights to Rescula (unoprostone isopropyl) covered by patents and patent applications from R-Tech. R-Tech will be the exclusive supplier of the finished product to us. Under the terms of the agreement, we have the right to develop Rescula for additional ophthalmic indications other than for the treatment of glaucoma and ocular hypertension. We have the right of first refusal to commercialize in the U.S. and Canada these additional indications whether they are developed by us or R-Tech, including all associated patents and other intellectual property.

We are party to exclusive supply arrangements with R-Tech to provide us with clinical and commercial supplies of Amitiza and Rescula 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 approvals for these compounds world-wide, including assistance with regulatory compliance for chemistry, manufacturing and controls.

Drs. Ueno and Kuno, together, directly or indirectly, own all of the stock of SAG and a majority of the stock of R-Tech. Drs. Ueno and Kuno also are controlling stockholders of this Company and are married to each other. Dr. Ueno is our chief executive officer and chairman of our Board of Directors. Dr. Kuno is a member of our Board of Directors, our advisor on international business development and is Chair of the Board of Directors of R-Tech.

Scientific Background of Prostones

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, lubiprostone, cobiprostone and SPI-017 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 regulates 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 lubiprostone 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. For example, Amitiza promotes fluid secretion into the small intestine by activating the ClC-2 channel in the cell lining of the small intestine thereby enhancing intestinal motility. Likewise, Rescula is a potassium channel activator that works to treat glaucoma by increasing aqueous humor outflow in ocular cells in the eyes thereby lowering intraocular pressure.

- *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. ClC-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.

Amitiza® (lubiprostone)

Overview

Amitiza is the only prescription product that has been approved by the FDA for the chronic treatment of CIC in adults of both genders and all ages or IBS-C in adult women and is being further developed for the treatment of OBD. 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 (CIC)

On January 31, 2006, the FDA approved our NDA for Amitiza for the treatment of CIC 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 U.S. for the treatment of CIC in April 2006. When used for this indication, patients take one Amitiza 24 mcg gelatin capsule twice daily.

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 CIC include straining, hard stools, bloating and abdominal pain or discomfort.

Current Treatment. Some patients suffering from occasional constipation may be treated with lifestyle modification, dietary changes and increased fluid and fiber intake. 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 and are not indicated for long-term use by patients. Though somewhat effective in treating occasional 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 CIC. Also, 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-HT_4 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. Zelnorm has subsequently been withdrawn from most international markets as well. As noted before, Amitiza is the only FDA-approved therapy for CIC and there are no over-the-counter therapies for CIC. Acute use laxatives have never been demonstrated as either safe or effective in chronic use and some trials of osmotic laxatives have demonstrated the risk and inappropriateness of their use in CIC.

Market Opportunity. Studies published in The American Journal of Gastroenterology estimate that approximately 42 million people in the U.S. 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 there are approximately 8.2 million diagnoses of CIC in the U.S.

We believe that Amitiza, as the only FDA approved prescription medication for CIC, has a number of advantages that should allow it to capture a significant portion of, and potentially expand, the existing market for CIC therapies. These advantages include:

- 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;
- 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; and
- There are no existing over-the-counter treatment options for CIC.

Clinical Trial Results. To obtain FDA marketing approval of Amitiza, we conducted a comprehensive program of clinical trials of this drug for use in treating CIC. 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 CIC. In each of these trials, we enrolled approximately 240 participants aged 18 or older with a history of CIC. The primary efficacy endpoint in these trials was the frequency of SBMs during the first week of treatment. Secondary efficacy endpoints included the frequency of SBMs during the second, third and fourth weeks of treatment, the percentage of participants with a SBM within 24 hours after administration, the time to first SBM 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 SBMs 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 during the last two weeks of treatment with Amitiza compared to placebo. The results of these trials were consistent in sub-population 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 CIC. 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 the chronic use of Amitiza when administered to participants in twice-daily doses of 24 mcg each. A secondary objective was to provide further evidence of the long-term efficacy of Amitiza in treating the symptoms of CIC. 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 mcg each in 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 CIC in adults of both genders and all ages, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in pediatric patients, in patients with renal impairment and in patients with hepatic impairment. We completed these studies in 2008 and 2009 and subsequently filed the results with the FDA.

Japanese Patients Studies.

In May 2009, we initiated a pivotal phase 3 double-blinded, placebo-controlled clinical program designed to evaluate the efficacy and safety of lubiprostone in Japanese patients with CIC over a 28-day treatment period. In the phase 3 efficacy trial, patients receive one lubiprostone 24 mcg capsule or a placebo capsule twice a day. This trial enrolled 124 patients, each of whom have a history of fewer than three SBMs per week for at least six months, as confirmed during a 14-day screening period. The primary efficacy endpoint is the change in SBMs at the end of the first week of treatment.

We also initiated enrollment and initial dosing of Japanese CIC patients for up to 48 weeks of treatment in an open-label phase 3 safety trial of lubiprostone. This is an open-label, multi-center trial in which patients receive one 24 mcg lubiprostone capsule twice a day. This trial enrolled 209 patients, each of whom has a history of fewer than three SBMs per week for at least six months, as confirmed during a 14-day screening period. Efficacy parameters being measured in this long-term safety trial include the frequency of SBMs at every week and the changes in SBMs at every week.

We expect to announce the results of these phase 3 trials in 2010.

Irritable Bowel Syndrome with Constipation (IBS-C)

On April 29, 2008, the FDA approved our supplemental NDA, or sNDA, for Amitiza for the treatment of IBS-C in adult women. In collaboration with Takeda, we initiated commercial sales of Amitiza in the U.S. for this indication in May 2008. When used for this indication, patients should take one Amitiza 8 mcg gelatin capsule twice daily.

Disease Overview. Irritable bowel syndrome is a disorder of the intestines with symptoms that include severe cramping, pain, bloating and changes of bowel habits, such as diarrhea or constipation. Patients diagnosed with irritable bowel syndrome are commonly classified as having one of four forms: IBS-C, irritable bowel syndrome with diarrhea, mixed-pattern irritable bowel syndrome alternating between constipation and diarrhea and unspecified irritable bowel syndrome. 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 IBS-C focus on addressing separate symptoms, such as pain or infrequent bowel movements. Some patients suffering from IBS-C may 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 IBS-C before it was withdrawn in March 2007. In December 2005, the European Medicines Agency denied marketing approval for Zelnorm for the treatment of IBS-C in women, citing the inconclusiveness of clinical studies in demonstrating its effectiveness. As noted above, Amitiza is now the only FDA-approved therapy for the treatment of IBS-C in adult women.

Market Opportunity. According to the American College of Gastroenterology, irritable bowel syndrome affects approximately 58 million people in the U.S. IBS-C accounts for approximately one-third of these cases and approximately two-thirds of these cases are females. Amitiza is currently the only approved prescription product for the treatment of IBS-C in the U.S.

Clinical Trial Results.

To obtain FDA marketing approval of Amitiza for IBS-C, we conducted two pivotal phase 3 clinical trials of Amitiza in men and women for IBS-C in 2006 and 2007, each involving 570 or more participants meeting the Rome II criteria for IBS-C at 65 investigative study sites in the U.S. 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 IBS-C using twice daily doses of 8 mcg each, or 16 mcgs total. The primary efficacy endpoint for these trials utilized at the request of the FDA was a subjective assessment of the participant's overall relief from the symptoms of IBS-C 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 mcg twice daily were 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 were nearly twice as likely to experience overall relief from symptoms 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 mcg 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 (OBD)

Disease Overview. OBD 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, and includes other indications such as opioid-induced constipation. 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. These include inhibition of large intestine motility, decreased gastric emptying and hard stools.

Current Treatment. Current treatment options for OBD 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 OBD 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 experiencing 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 4.5 million people in the U.S. currently suffer from OBD.

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 initiated two pivotal phase 3 clinical trials, OBD0631 and OBD0632, of orally administered Amitiza for the treatment of OBD in September 2007. A total of 873 participants were enrolled at 187 participating sites in the U.S. and Canada. 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 OBD in adults using twice daily doses of 24 mcg each. The primary efficacy endpoint for these trials was the change from baseline in SBM frequency at week 8. In addition, several secondary endpoints include the 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, 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 of 440 participants to assess the long-term safety and efficacy profile of Amitiza in subjects with OBD.

Top-line results for the efficacy studies, reported in July 2009, show that in study OBD0631 Amitiza met the primary endpoint by demonstrating a statistically significant change from baseline in the frequency of SBMs at Week 8 of treatment when compared to placebo. Additionally, statistical significance was achieved for eight of the twelve secondary endpoints, including key symptoms associated with OBD. Study OBD0632 did not achieve statistical significance for the same primary endpoint. Statistically significant improvements with lubiprostone were achieved for two of the secondary endpoints and positive trends were observed in four of the other secondary endpoints. Subjects treated with lubiprostone showed a statistically significant increase in the frequency of SBMs at Week 8 from their baseline, from 1.42 to 4.54 SBMs in the OBD0631 trial and from 1.60 to 4.10 SBMs in the OBD0632 trial. The increase in SBMs for placebo over their baseline was from 1.46 to 3.81 for the OBD0631 trial and 1.60 to 3.95 SBMs for the OBD0632 trial.

In both trials, a post-hoc sub-population analysis showed that subjects on methadone treatment regimens who were randomized to receive lubiprostone showed a lower SBM response when compared to lubiprostone patients treated with other opioid medications. Additionally, in both trials, methadone patients treated with lubiprostone did not show improvement in OBD symptomatic endpoints while lubiprostone patients treated with other opioids showed statistically significant improvement in abdominal discomfort/pain, constipation severity, stool consistency and straining over the placebo.

The overall adverse event rate for the combined trials was 54.9% for lubiprostone and 51.6% for placebo. The most common adverse events were nausea, 15% for lubiprostone compared to 7.5% for placebo, and diarrhea, 8.5% for lubiprostone compared to 3.7% for placebo.

Rescula (unoprostone)

Overview

In April 2009, we licensed from R-Tech the development and commercialization rights to Rescula (unoprostone isopropyl) for the U.S. and Canada, including all associated patents and other intellectual property. In addition, R-Tech will be the exclusive supplier of finished product to us. Under the agreement, we hold the exclusive rights to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension. We also will have the right to develop Rescula for additional indications and we will have the right of first refusal to commercialize in the U.S. and Canada any additional indications for which Rescula is developed by R-Tech.

Rescula was approved by the FDA for the treatment of open-angle glaucoma and ocular hypertension in 2000, but is not currently marketed in the United States or Canada.

Rescula is a synthetic docosanoid that is administered topically as a liquid eye drop. It activates the BK channel in cells within the retina. Clinical studies show that activating the BK channels lowers intraocular pressure, or IOP, by increasing the outflow of aqueous humor. Clinical studies have shown that in patients with a mean baseline IOP of 23 mm Hg unoprostone isopropyl lowers IOP by approximately 3 to 4 mm Hg through the day.

In clinical and preclinical studies, Rescula has increased ocular blood flow to the optic nerve and in the choroid; maintained visual field; delayed retinal degeneration induced by rhodoposin by inhibiting apoptosis; inhibited topographic and blood changes in an ischemic optic nerve head; and lowered intraocular pressure. We believe that these clinical effects suggest that Rescula could potentially be effective in the treatment of other ocular diseases such as dry AMD.

Potential Indication

Dry Age-related Macular Degeneration. According to the National Eye Institute, or NEI, more than 8 million people in the U.S. currently have age-related macular degeneration, or AMD, a disease which causes damage to the retina resulting in loss of vision. AMD is the leading cause of irreversible blindness in adults, worldwide. The prevalence of AMD in the U.S. is expected to increase by more than 50%, to approximately 12 million by 2020, as the population ages according to a report published by visiongain Ltd. More than 85% of all people with intermediate and advanced AMD have the dry form based on information developed by the NEI.

AMD is a disease associated with aging that gradually destroys sharp, central vision. Central vision is needed for seeing objects clearly and for common daily tasks such as reading and driving. AMD affects the macula, the part of the eye that allows the seeing of fine detail. The macula is located in the center of the retina, the light sensitive tissue at the back of the eye. The retina instantly converts light, or an image, into electrical impulses or nerve signals, which are sent to the brain. Dry AMD occurs when the light-sensitive cells in the macula slowly break down, gradually blurring central vision in the affected eye. The most common symptom of dry AMD is slightly blurred vision and a need for more light to read and do other tasks. Dry AMD affects both eyes, but vision can be lost in one eye while the other eye seems unaffected. Currently no drugs have been approved by the FDA for the treatment of dry AMD. Based on the mechanism of action of unoprostone, we believe that Rescula has the potential to be a treatment for dry AMD. As a result, we plan to initiate a phase 2 clinical trial with Rescula for dry AMD in 2010.

Cobiprostone

Overview

We are developing the prostone compound cobiprostone for oral administration to treat various gastrointestinal and liver disorders, including NSAID-induced ulcers. 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 treatment of skin ulcers and wounds based on preclinical results from coetaneous tissue blood flow studies and incision wound healing studies.

Non-Steroidal Anti-Inflammatory Drug-Induced Ulcers (NSAIDs)

In May 2009, we completed and announced results of our phase 2a clinical trial of cobiprostone designed to evaluate the compound's efficacy and safety for the prevention of ulcers and other gastrointestinal injuries in arthritis patients treated with NSAIDs.

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. 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 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 U.S. are regular users of NSAIDs. According to the Arthrisis Foundation, up to 60% of patients consuming NSAIDs regularly will have GI side effects. Additionally, *The Journal of Grastroenterology* states that recent studies show more than 50% of patients taking NSAIDs have some mucosal damage to the small intestine. We believe that many patients treated with NSAIDs are not prescribed preventive 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 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 of 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 was designed to assess the efficacy and safety of cobiprostone in preventing NSAID gastroduodenal injury in non-cancer patients taking Naproxen 500mg twice daily. Study patients were randomized to one of three daily doses of cobiprostone, 18, 36 or 54 mcg, or placebo. The efficacy endpoints for the trial included 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.

The study was completed in May 2009 and a top-line analysis of data, reported in July 2009, indicates that patients receiving cobiprostone experienced a lower overall incidence of ulcers: at week 12, patients receiving a 54 mcg dose experienced a 50.0% reduction in the overall incidence of gastric ulcers when compared to patients taking placebo. Cobiprostone patients experienced an overall statistically significant reduction in the number of gastric erosions through the treatment period of 12 weeks compared to placebo patients. The reduction of gastric erosions through Week 12 was dose dependent, with the 36 mcg and 54 mcg doses demonstrating statistical significance. The time-to-onset of all ulcer or erosion development was delayed in the cobiprostone cohorts with overall statistical significance across the 12-week treatment period.

The retention rates of patients taking naproxen with cobiprostone at Week 12 were statistically significant when compared to patients taking naproxen with placebo and increased in a dose-dependent manner. The rates were 40% for placebo vs. 47%, 52% and 77% for cobiprostone 18 mcg, 36 mcg, and 54 mcg, respectively. The median number of days in the treatment period was 55 days for patients taking placebo compared to 60, 82 and 83 days for cobiprostone 18 mcg, 36 mcg and 54 mcg, respectively.

Overall, the data showed cobiprostone was well tolerated in patients receiving NSAID therapy. The related overall adverse event rates were 66.7% for placebo, compared to 60.0%, 71.0% and 67.7% for cobiprostone 18 mcg, 36 mcg and 53 mcg, respectively. The most common related adverse events were: diarrhea, at 13.3% for placebo compared to 13.3%, 32.3% and 35.5% for cobiprostone 18 mcg, 26 mcg and 54mcg, respectively; nausea at 10.0% for placebo compared to. 10.0%, 16.1% and 16.1% for cobiprostone 18 mcg, 36 mcg and 54 mcg, respectively; and gastritis, at 13.3% for placebo compared to 13.3%, 6.5% and 9.7% for cobiprostone 18 mcg, 36 mcg and 54 mcg, respectively. The drug-related gastrointestinal adverse event rates were 66.7% for placebo compared to 60.0%, 67.7% and 67.7% for cobiprostone 18 mcg, 36 mcg and 54 m cg, respectively, which suggest that gastrointestinal adverse events other than diarrhea and nausea may be related to the naproxen therapy. Withdrawal rates from the trial due to an adverse event were: 21.9% for placebo compared to 13.3%, 16.1% and 16.1% for cobiprostone 18 mcg, 36mcg and 54 mcg respectively.

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.

SPI-017

In December 2008, we announced the initiation of dosing in a first-in-human clinical safety study of a proprietary prostone, SPI-017, as a potential treatment for PAD.

Disease Overview Peripheral Arterial and Vascular Disease. PAD, 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. PAD 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.

Current Treatment. 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 U.S. 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.

Market Opportunity. The American Heart Association estimates that PAD affects as many as 8 million to 12 million people in the U.S. Additionally, PAD affects 12% to 20% of Americans age 65 and older with only 20% to 30% undergoing treatment.

Development Status. In 2009, we completed a phase 1 study of SPI-017 as a potential treatment for PAD. The randomized, double-blind, placebo-controlled, single-center, single ascending dose study was designed to evaluate its safety and pharmacokinetic profile. A total of 74 healthy adult male subjects were enrolled in eight dose groups, receiving intravenous doses of SPI-017 ranging from 3 mcg to 120 mcg. Enrollment into the multiple dose study has been initiated and we expect to announce the results in 2010.

Amitiza

Marketing and Sales

In 2006, we exercised the co-promotion rights under our collaboration and license agreement and supplemental agreement with Takeda to begin developing a specialty sales force focused on the institutional marketplace in the U.S. 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 territories covered by a Sucampo representative. Our specialty sales force promotes Amitiza 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.

The co-promotion rights allow our sales force to market additional products and we intend to evaluate strategic acquisitions, in-licensing or co-promotion opportunities to supplement our existing product pipeline, especially those that would add products that are 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 U.S. and Canada. This agreement provides Takeda with exclusive limited license within these two countries to develop and commercialize Amitiza for these indications. Takeda does not have the right to manufacture Amitiza. We also entered into ancillary agreements: a supply and manufacturing agreement with Takeda and R-Tech, under which R-Tech manufactures and Takeda purchases all supplies of the product from R-Tech; and an intellectual property agreement with Takeda and SAG.

In August 2005, we sent Takeda correspondence and a notice of material breach which stated, among other things, that Takeda had materially breached the license agreement by failing to use its best efforts to promote, market and sell the Amitiza for CIC; engaging in commercialization activities without approval of the joint commercialization committee or in accordance with a commercialization plan approved by that committee; and disclosing confidential information to third parties. In early 2006, we entered into a settlement agreement and supplemental agreement which resolved certain disputes with Takeda and further defined certain rights and responsibilities of the parties, including the right of Sucampo to employ a specialty sales force focused on the institutional marketplace and specialist physicians based in academic medical centers and long-term care and veteran's affairs facilities. Through the supplemental agreement, Takeda was responsible for, among other things, the medical marketing activities; reimbursement of publications, abstracts, and manuscripts directed primarily to the scientific community; developing publications on general disease states or quality-of-life issues; retaining or employing a dedicated sales force in both the primary and secondary positions for promotion of Amitiza for CIC; and reimbursement of certain stated amounts for our limited sales force deployed in the primary position to institutional customers.

We are disappointed with the level of U.S. sales of Amitiza being generated by Takeda and other failures of performance by Takeda under our agreements. In April 2009, we sent Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. a notice of material breach. The notice stated that Takeda materially breached our agreement, without limitation, by their continuing failure to exercise their best efforts to commercialize Amitiza and maximize net sales revenue, and their ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We subsequently sent a letter that advised Takeda that they had failed to cure said breaches within the 90 day cure period provided under the agreement. Since then, we have spent significant resources in our dispute with Takeda. We also attempted to conduct a review of Takeda's performance but Takeda refused to provide us with certain information necessary to complete that review.

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between us and Takeda Pharmaceuticals Company Limited dated October 29, 2004. In addition to the claims set forth in the notice of material breach, we also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only us and the Amitiza brand, but also consumers. We are seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. We may spend additional significant resources and these legal proceedings may require the continuing attention of our senior management.

Development Costs. Our agreement provides for cost-sharing arrangements in which Takeda funds all development costs for Amitiza as a treatment for CIC and IBS-C up to $30.0 million. We have received this full amount. 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 development of any additional indications beyond CIC and IBS-C and for development of 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 CIC or IBS-C, Takeda has agreed to fund 70% of the costs of such studies and we have agreed to fund the remainder. The development costs for Amitiza for the treatment of CIC in pediatric patients will be funded entirely by Takeda. From inception of the Takeda agreement to December 31, 2009, Takeda paid an aggregate of $88.8 million in research and development reimbursement payments.

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 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 IBS-C indication.

Promotion and Marketing. Takeda is required to provide the sales force necessary to fulfill its best effort obligations under the agreement. 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 license agreement, we retain the right to co-promote Amitiza for gastrointestinal indications under the terms of the collaboration and license agreement with Takeda, as well as the exclusive right to develop and commercialize Amitiza in the U.S. and Canada for all indications other than gastrointestinal indications. In connection with our exercise of co-promotion rights, we established 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 until April 2011. 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.

Licensing Fees, Milestone Payments and Royalties. Takeda made an upfront payment of $20.0 million in 2004 and has paid total development milestone payments of $130.0 million through December 31, 2009. Subject to reaching future development and commercial milestones, we are entitled to receive an additional $10.0 million development milestone payment and up to $50.0 million in commercial milestone payments. Takeda records all sales of Amitiza and pays us a tiered royalty based on net sales of Amitiza in the U.S. and Canada.

Governance. Our collaboration with Takeda is governed by four 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. Under the agreement, Takeda has a right of first refusal to obtain a license to develop and commercialize Amitiza in the U.S. and Canada for any new gastrointestinal indications that we may develop, such as OBD. We retain the rights to Amitiza for all other therapeutic areas.

Under the agreement, if we wish to use data or information developed under the collaboration with Takeda outside the U.S. 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.

Term. The Takeda agreement continues until 2020 unless terminated earlier. 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 material breach of the agreement by the other party that is not cured within 90 days of notice thereof, 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 SAG and R-Tech, 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 SAG to develop and commercialize Amitiza and other prostone compounds covered by patents and patent applications held by SAG. As of December 31, 2009, we had licensed from SAG rights to a total of 48 U.S. patents, 29 U.S. patent applications, 22 European patents, 22 European patent applications, 25 Japanese patents and 29 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, or manufacturing method 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 ten issued U.S. patents and five issued European patents, and three 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, 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 2011 and 2027.

The patent rights relating to cobiprostone licensed by us consist of 15 issued U.S. patents, nine issued European patents, and 11 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 2027.

The patent rights relating to SPI-017 licensed by us consist of eleven issued U.S. patents, six issued European patents and eight 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.

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 U.S. 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

Under this license agreement, SAG has granted to us a royalty-bearing, exclusive, worldwide license, with the right to sublicense, develop and commercialize Amitiza, cobiprostone and SPI-017 and any other prostone compounds, other than Rescula, subject to SAG's patents. We are obligated to assign to SAG 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 SAG any patentable improvements derived or discovered by us relating to other licensed prostone compounds. All compounds and patentable improvements assigned to SAG under this agreement are immediately licensed back to us on an exclusive basis.

In consideration of the license, we are 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.

We are also 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, or IPO, 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.

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 SAG, 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.

The license from SAG is perpetual as to Amitiza, cobiprostone and SPI-017 and cannot be terminated unless we default in our payment obligations to SAG. 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. 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, SAG can terminate our license with respect to any compounds 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, SAG may terminate our license 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. Although Dr. Ueno is instrumental in making these decisions, we have formed a selection committee consisting of members of management other than Drs. Ueno and Kuno to make this determination.

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 be controlling shareholders of our company, SAG may not develop or commercialize:

- any products with a primary mode of action substantially the same as that of any Sucampo-licensed compound; or

- any products licensed or approved for an indication for which a Sucampo-licensed compound is approved or under development.

Thereafter, SAG 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 SAG will allocate costs to defend patent infringement litigation brought by third parties and costs to enforce patents against third parties. As of December 31, 2009, we have not incurred any significant 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, Rescula, 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 multiple exclusive supply arrangements with R-Tech and we have granted to R-Tech the exclusive right to manufacture and supply Amitiza and other products and compounds to us to meet our commercial and clinical requirements. 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, including assistance with regulatory compliance for chemistry, manufacturing and controls. In consideration of these exclusive rights, R-Tech has paid to us $8.3 million in upfront and milestone payments as of December 31, 2009. Either we or R-Tech may terminate the supply arrangement with respect to us in the event of the other party's uncured breach or insolvency. R-Tech is obligated to make additional payment upon regulatory or commercial milestones.

Under the supply agreement we have with Takeda and R-Tech, which covers the period of our Takeda license agreement, R-Tech agreed to sell to Takeda all commercial supplies, including product samples, for Amitiza in the U.S. 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. 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.

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 passed cGMP inspection from the FDA in October 2005 and from the United Kingdom's Medicines and Healthcare Products Regulatory Agency, or MHRA, in October 2008 to manufacture Amitiza at this facility. In addition, R-Tech manufactures Rescula at this facility and has been the sole supplier of this product to the marketplace since 1994 without interruption.

In 2009, we have entered into an exclusive manufacturing and supply agreement with R-Tech for ten years to provide us with Rescula for the U.S. and Canada. In addition 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 compounds we may designate, and to assist us in connection with applications for clinical trials and marketing approval for these, 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.

Many patients are treated for CIC with competing over-the-counter or prescription products that are sold for occasional or infrequent use or for recurring use.

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:

- Two drugs targeting serotonin receptors for the treatment of IBS-C were Renzapride, being developed by Alizyme plc. and DDP733, being developed by Dynogen Pharmaceuticals, Inc. Based on the limited clinical efficacy in phase 3 clinical trials, Alizyme discontinued further clinical development for Renzapride and in the light of a bankruptcy filing by Dynogen, future clinical trials for DDP733 are unclear.
- Oral opioid antagonists such as methylnaltrexone, are being developed by Progenics Pharmaceuticals, Inc., for the treatment of opioid-induced bowel dysfunction. Progenics received FDA approval of methylaltrexone in 2008 for the subcutaneous formulation of this drug in treating OBD in patients receiving palliative care. Progenics continues to move forward with an oral form of methylaltrexone. Clinical trials are moving into phase 3 for the indications of OBD or opioid induced constipation, or OIC. Another oral opiod antagonist is NKTR-118, being developed by Nektar Therapeutics/Astra Zeneca. This product has also completed phase 2 studies and is an oral product being studied for an OIC indication.
- TD-5108, being developed by Theravance, Inc. for the treatment of chronic constipation, and linaclotide, being developed by Ironwood Inc. for the treatment of IBS-C and CIC, have both completed phase 2 clinical trials. Ironwood has completed its phase 3 efficacy trials for Linaclotide for both CIC and IBS-C and is now conducting long term safety trials.
- Resolor (prucalopride) is being developed and marketed by Movetis N.V. for the treatment of chronic constipation in adults. In October 2009, Resolor received marketing approval in the E.U., Iceland, Liechtenstein and Norway for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief and launched in Germany in January 2010.

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.

Government Regulation

Government authorities in the U.S., at the federal, state and local level, and in other countries extensively regulate, 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.

U.S. Government Regulation

In the U.S., 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, post-marketing study, and pharmacovigilance 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 following Good Clinical Practices, or GCP, guidelines:

- Phase 1 consists of safety tests with human clinical evaluations, generally in normal, healthy volunteers;
- Phase 2 programs expand safety tests and measure efficacy along with dose finding evalutions and are conducted in people with a 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 clinical tests are 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 following 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 practice, or 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 application 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 obligated to comply with a number of post-approval requirements. For example, the FDA may require post marketing, or phase 4 trials to assess additional elements of the product's 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 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 drug products. 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 U.S.

In addition to regulations in the U.S., we are subject to a variety of regulations in other jurisdictions most notably by the European Medicines Agency in the E.U. and the Ministry of Health, Labor and Welfare in Japan. Whether or not we obtain FDA approval for a product, we must obtain permission or approval by the comparable regulatory authorities of countries outside the U.S. 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 is country dependent and may be longer or shorter than that required by the FDA.

Europe

In Europe medicinal products are governed by a framework of E.U. regulations which apply across all E.U. member states. To obtain regulatory approval of a drug under the E.U. regulatory system, we may submit a MAA, either under a centralized, decentralized, or mutual recognition 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 E.U. member states. The decentralized procedure provides for a member state, known as the reference member state, to assess an application, with one or more concerned, member states subsequently approving that assessment. The mutual recognition procedure provides approval in one country and then allows for a request from subsequent countries to mutually recognize the original country's approval. The E.U. 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 E.U. 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.

Japan

In Japan, pre-marketing approval and clinical studies are required for all pharmaceutical products. The regulatory requirements 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 pivotal 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 U.S. or E.U. 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 prohibit 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 U.S. 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, pharmacy benefit managers, 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 products 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 U.S. continue to work towards significant legislation aimed to limit the growth of healthcare costs, including the cost of prescription drugs. Currently, both the chambers of Congress have separately passed versions of a healthcare reform bill. Recently, the President released a proposed bill which was a confirmation of various features of both chambers' bills. These bills 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 U.S. Proposed legislation would allow the re-importation of approved drugs originally manufactured in the U.S. back into the U.S. 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.

Further, both the U.S. House of Representatives and U.S. Senate are considering patent reform legislation that may impact the intellectual property protections of the products we are developing.

Different pricing and reimbursement schemes exist in other countries. In Europe, 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 some cases, pharmacoeconomic analyses from clinical studies and other available resources are used to establish pricing using risk-benefit comparisons with currently available products.

In Japan, pricing is established utilizing various information including reference prices from other international markets. However, the Ministry of Health, Labor and Welfare 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 10, 2010.

Name	Age	Position
Ryuji Ueno, M.D., Ph.D., Ph.D.	56	Chief Executive Officer, Chief Scientific Officer and Director, Chairman of the Board of Directors
James J. Egan	59	Chief Operating Officer
Jan Smilek	43	Chief Financial Officer and Treasurer
Stanley G. Miele	45	President, Sucampo Pharma Americas, Inc. and Senior Vice President of Sales and Marketing
Gayle R. Dolecek	67	Senior Vice President of Research and Development and member of the Board of Directors
Thomas J. Knapp	57	Senior Vice President, General Counsel and Corporate Secretary

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 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 SAG 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 medicinal 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.

James J. Egan. Mr. Egan joined us September 2009 as Chief Operating Officer. Prior to joining our company, he was Chief Business Officer at ESBATech AG, a privately held biotech company in Zurich, Switzerland, until ESBATech's acquisition by Alcon S.A. in September 2009. From June 2001 to January 2006, he was Senior Vice President, Licensing & Corporate Development at Idenix Pharmaceuticals, Inc., a Cambridge, Massachusetts-based biotech company. From June 2000 to June 2001, Mr. Egan was the CEO of Neuronz Limited, a privately held company based in Auckland, New Zealand. From September 1993 to June 2000, he served as the Senior Director, Global Licensing, Business Development, Mergers and Acquisitions at G.D. Searle & Co. and from April 1984 to September 1993 as Division Counsel, International Operations at Abbott Laboratories. He also served as a Trial Attorney, Foreign Commerce Section, Antitrust Division of the U.S. Department of Justice and a Foreign Services Officer at the U.S. Embassy in Tokyo, Japan. Mr. Egan earned a B.S. in Foreign Service at Georgetown University, in Washington, D.C. and a J.D. at University of Santa Clara School of Law, in Santa Clara, California.

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 and Treasurer 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 graduate of the School of Economics, Bratislava, Slovakia and holds an International Executive M.B.A. degree from Georgetown University, McDonough School of Business.

Stanley G. Miele. Mr. Miele was our Senior Vice President of Sales and Marketing since October 2008 until he was promoted to President of Sucampo Pharma Americas, Inc. in September 2009. He had been our Vice President of Sales and National Director of Sales since February 2006. Prior to joining Sucampo as a Sales Director, Mr. Miele 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 in 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.

Gayle R. Dolecek. Dr. Dolecek has been our Senior Vice President of Research and Development since May 2006 and a member of our Board of Directors since August 2008. 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.

Thomas J. Knapp. Mr. Knapp joined us February 2010 as Vice President General Counsel and Corporate Secretary. Prior to joining our company, he was Of Counsel at Exemplar Law Partners, LLC and a Partner and member at Knapp Law Firm beginning September 2008. From March 2003 to August 2008, he was Deputy General Counsel and then Vice President, General Counsel and Corporate Secretary at NorthWestern Corporation. From January 2001 to December 2002, Mr. Knapp served as Of Counsel of Paul, Hastings, Janofsky & Walker, LLP, in Washington, D.C. and from May 1998 to December 2000 as Assistant General Counsel at The Boeing Company in Seattle, Washington. Mr. Knapp also served as Of Counsel of Paul, Hastings, Janofsky & Walker, LLP, in Washington, D.C. from May 1996 to April 1998 and he served in various in-house positions culminating with Labor Counsel at The Burlington Northern & Santa Fe Railway Company, in Chicago, Illinois and Fort Worth, Texas from September 1980 to December 1995. Mr. Knapp earned a B.A in Political Science at University of Illinois-Urbana and a J.D. at Loyola University of Chicago School of Law.

Employees

As of March 10, 2010, we had 93 full-time employees, including 37 with doctoral or other advanced degrees. Of our workforce, 25 employees are engaged in research and development, 41 are engaged in sales and marketing and 27 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 10, 2010, we had outstanding 15,655,730 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 are 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 wholly owned subsidiaries of the new holding company.

The current 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 and Oceania 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., 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.

Risks Related to Our Ongoing Dispute with Takeda

We sent Takeda a notice of material breach and recently filed an arbitration demand and if our dispute with Takeda continues or escalates, we could be required to commit significant financial resources and management time and could ultimately face termination of our Takeda contract and the need to market Amitiza through other means.

We are disappointed with the level of U.S. sales of Amitiza being generated by Takeda and other failures of performance by Takeda under our agreements. In April 2009, we sent Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. a notice of material breach. The notice stated that Takeda materially breached our agreement, without limitation, by their continuing failure to exercise their best efforts to commercialize Amitiza and maximize net sales revenue, and their ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We subsequently sent a letter that advised Takeda that they had failed to cure said breaches within the 90 day cure period provided under the agreement. Since then, we have spent significant resources in our dispute with Takeda. We also attempted to conduct a review of Takeda's performance but Takeda refused to provide us with certain information necessary to complete that review.

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between us and Takeda Pharmaceuticals Company Limited dated October 29, 2004. In addition to the claims set forth in the notice of material breach, we also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only us and the Amitiza brand, but also consumers. We are seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs.

We will likely spend additional significant resources in connection with our dispute with Takeda and these legal proceedings will likely require significant continuing attention from our senior management. If our request in the arbitration that the contractual relationship with Takeda be terminated were to be granted, we would be required to market the product by ourselves or to find another commercial partner. In either case, our efforts to market Amitiza through other means may not be successful and we may lose significant Amitiza revenues, and at a minimum there would likely be a transition period during which Amitiza sales might be expected to decline.

Risks 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.

Risks Related to Our Limited Commercial Operations

Although we have reported profits in the last few years, we recorded a net loss in 2009 and we may not regain or maintain operating profitability in the future.

We initiated commercial sales of our first product, Amitiza, for the treatment of CIC in adults of both genders and all ages in April 2006 and for the treatment of IBS-C in May 2008 and we first generated product royalty revenue in the quarter ended June 30, 2006. Although we have reported net income for the past few years, this was primarily attributable to our development milestones under our agreements with Takeda. We recorded a net loss of $760,000 in 2009. 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 commercialization of Amitiza outside with U.S. and Canada, 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 CIC in adults of both genders and all ages and IBS-C in adult women 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 efforts of Takeda to commercialize and maximize net sales revenue;
- our ability to complete clinical trials and secure regulatory approval of lubiprostone in Japan, our ability to successfully develop lubiprostone and the ability of Abbott to successfully commercialize it;
- 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 CIC and IBS-C, 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 regulatory approval processes 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 rely on Takeda and Abbott to perform many of these sales and marketing functions with respect to the sale of Amitiza in the respective territories, 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 U.S., it could be difficult for us to obtain and devote the resources necessary to successfully manage our commercialization efforts.

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. 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 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. Due to our limited resources, we may not be able to effectively manage any expansion of our operations. 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 international operations. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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.

If we identify material weaknesses in our internal controls over financial reporting and we 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 to SAG in the future unless we devote sufficient development resources to those compounds during the next several years; if any of the compounds that revert to SAG 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.

SAG has granted to us an exclusive worldwide license to develop and commercialize products based upon SAG'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, SAG 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, SAG 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 SAG.

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. Although Dr. Ueno is instrumental in making these decisions, we have formed a selection committee consisting of members of management other than Drs. Ueno and Kuno to make this determination. 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 to SAG. After the reversion of these rights to SAG, we will have no ability to develop or commercialize the compound. Although SAG 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 SAG will be prohibited from marketing products that compete with our products for 24 months after the end of the specified period, after that date SAG 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;
- 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 U.S. 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 CIC in adults of both genders and all ages, 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 U.S., 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 U.S. 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.

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.

Many patients are treated for CIC with competing over-the-counter or prescription products that are sold for occasional or infrequent use or for recurring use, such as the osmotic laxatives MiraLax, which is marketed by Braintree Laboratories, Inc. and lactulose, which is produced by Solvay S.A.

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:

- Two drugs targeting serotonin receptors for the treatment of IBS-C were Renzapride, being developed by Alizyme plc. and DDP733, being developed by Dynogen Pharmaceuticals, Inc. Based on the limited clinical efficacy in phase 3 clinical trials, Alizyme discontinued further clinical development for Renzapride and in the light of a bankruptcy filing by Dynogen, future clinical trials for DDP733 are unclear.
- Oral opioid antagonists such as methylnaltrexone, are being developed by Progenics Pharmaceuticals, Inc., for the treatment of opioid-induced bowel dysfunction. Progenics received FDA approval of methylaltrexone in 2008 for the subcutaneous formulation of this drug in treating OBD in patients receiving palliative care. Progenics continues to move forward with an oral form of methylaltrexone. Clinical trials are moving into phase 3 for the indications of OBD or opioid induced constipation, or OIC. Another oral opiod antagonist is NKTR-118, being developed by Nektar Therapeutics/Astra Zeneca. This product has also completed phase 2 studies and is an oral product being studied for an OIC indication.
- TD-5108, being developed by Theravance, Inc. for the treatment of chronic constipation, and linaclotide, being developed by Ironwood Inc. for the treatment of IBS-C and CIC, have both completed phase 2 clinical trials. Ironwood has completed its phase 3 efficacy trials for Linaclotide for both CIC and IBS-C and is now conducting long term safety trials.
- Resolor (prucalopride) is being developed and marketed by Movetis N.V. for the treatment of chronic constipation in adults. In October 2009, Resolor received marketing approval in the E.U., Iceland, Liechtenstein and Norway for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief and launched in Germany in January 2010.

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 CIC 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.

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 U.S. 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 U.S. 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 U.S. 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 U.S., including foreign countries where the drugs are sold at lower prices than in the U.S., 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 U.S. This could include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. 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 E.U., 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 and any awards exceed our applicable insurance coverages, 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 appropriate 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 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 agreements with Takeda and Abbott and milestone and other payments from 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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.

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.

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 IBS-C. 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 SAG 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 SAG 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 SAG, 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 SAG 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 to SAG at the end of the specified period;
- a decision whether to renegotiate the terms of our existing agreements with R-Tech or SAG; 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 SAG 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 or future subsidiaries on an ongoing basis. As a result of these transactions, we will be subject to complex transfer pricing regulations in both the U.S. 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 U.S. 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, 2009, 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 SAG, 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 SAG, 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 SAG and R-Tech 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 U.S. and other countries may diminish the value of SAG or R-Tech'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 SAG and R-Tech also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. 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, SAG, nor R-Tech 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 SAG and by us. We and SAG 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 SAG 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 SAG 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 SAG, 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 U.S. 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 U.S. 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 fails 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 U.S. and could adversely affect our reputation and our product marketing activities within the U.S.

We intend to market our products both domestically and outside the U.S. In order to market our products in the E.U., 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 U.S., 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 U.S., 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 U.S. 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.

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, 2009, we continued to have $10.0 million invested in a non-mortgage auction rate security, 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. The ongoing uncertainties in the credit markets have prevented us from liquidating our last remaining ARS.

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 this security 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 at offices in two locations in Bethesda, Maryland. We have sublet the 1,600 square feet at one location under a lease that expires in December 2010 and remain obligated to make rent payments under the lease. The lease and sublease for the 11,166 square feet at the other location expired in November 2009.

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

ITEM 3. LEGAL PROCEEDINGS

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between us and Takeda Pharmaceuticals Company Limited dated October 29, 2004. In addition to the claims set forth in the notice of material breach, we also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only us and the Amitiza brand, but also consumers. We are seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. We may spend additional significant resources and these legal proceedings may require the continuing attention of our senior management.

ITEM 4. RESERVED

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
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
March 31, 2009	$ 8.22	$ 3.88
June 30, 2009	$ 8.62	$ 5.21
September 30, 2009	$ 7.71	$ 4.58
December 31, 2009	$ 5.65	$ 3.28

As of March 10, 2010, we had 15,655,730 shares of class A common stock outstanding held by 10 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 10, 2010, the closing price of our class A common stock was $3.62. As of March 10, 2010, 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.

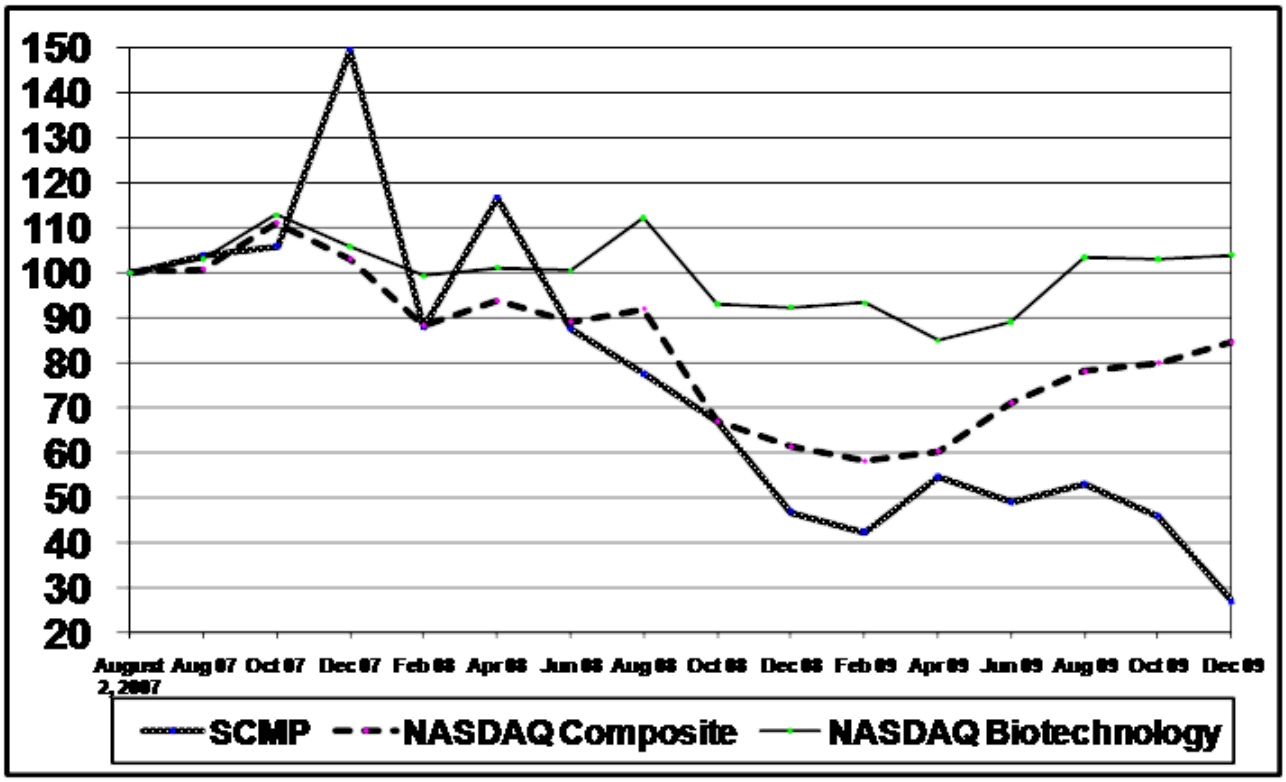
On December 9, 2008, our Board of Directors authorized and approved a stock repurchase program, under which we may use up to $10 million to purchase shares of our class A common stock from time to time in open-market transactions, depending on market conditions and other factors. We did not repurchase any of our equity securities in 2009 or 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, 2009.

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, 2008 and 2009 and for the years then ended from our audited consolidated financial statements. Consolidated balance sheets as of December 31, 2008 and 2009 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, 2007, 2008 and 2009 and notes thereto appear elsewhere in this Annual Report. We have derived the following consolidated financial data as of December 31, 2005, 2006 and 2007 and for the two years ended December 31, 2006, 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)	**2005**	**2006**	**2007**	**2008**	**2009**
Statement of operations data					
Revenues	$ 40,205	$ 59,266	$ 91,891	$ 112,123	$ 67,351
Operating expenses:					
Research and development	31,167	19,204	31,697	46,181	32,904
General and administrative	7,760	11,699	21,423	14,400	14,504
Selling and marketing	295	11,179	13,474	10,895	10,030
Milestone royalties — related parties	1,500	1,250	2,000	3,531	875
Product royalties — related parties	—	1,171	4,890	6,045	6,693
Total operating expenses	40,722	44,503	73,484	81,052	65,006
Income (loss) from operations	(517)	14,763	18,407	31,071	2,345
Total non-operating income, net	990	2,141	2,616	2,043	1,186
Income before income taxes	473	16,904	21,023	33,114	3,531
Income tax benefit (provision)	(789)	4,897	(7,833)	(8,163)	(4,291)
Net income (loss)	$ (316)	$ 21,801	$ 13,190	$ 24,951	$ (760)
Basic net income (loss) per share	$ (0.01)	$ 0.63	$ 0.35	$ 0.60	$ (0.02)
Diluted net income (loss) per share	$ (0.01)	$ 0.63	$ 0.35	$ 0.59	$ (0.02)
Weighted average common shares outstanding — basic	32,601	34,383	37,778	41,787	41,844
Weighted average common shares outstanding — diluted	32,601	34,690	38,226	41,973	41,844

	Year Ended December 31,				
(In thousands)	**2005**	**2006**	**2007**	**2008**	**2009**
Balance sheet data:					
Cash and cash equivalents	$ 17,436	$ 22,481	$ 25,559	$ 62,562	$ 26,714
Short-term investments	28,435	29,399	51,552	42,750	72,434
Working capital	10,051	40,623	84,313	98,229	94,125
Total assets	47,985	67,084	110,027	150,794	144,971
Notes payable — related parties, current	848	—	—	—	—
Notes payable — related parties, net of current portion	2,546	—	—	—	—
Total liabilities	58,225	28,551	23,499	37,004	31,418
Convertible preferred stock	20,228	20,288	—	—	—
Retained earnings (deficit)	(45,167)	(23,366)	(10,176)	14,775	14,015
Total stockholders' equity (deficit)	(10,240)	38,533	86,528	113,790	113,553

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 are an international biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds occurring naturally in the human body by enzymic (15-PGDH) transformation of certain fatty acids. In January 2006, we received marketing approval from the U.S. Food and Drug Administration, or FDA, for our first product, Amitiza® (lubiprostone), for the treatment of chronic idiopathic constipation, or CIC, in adults of all ages. In April 2008, the FDA approved Amitiza for its second indication for the treatment of irritable bowel syndrome with constipation, or IBS-C, in adult women. We are currently developing Amitiza for the treatment of opioid-induced bowel dysfunction, or OBD.

In the U.S. and Canada, Amitiza is being marketed and developed under a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, for gastrointestinal indications. Under the agreement with Takeda, we are primarily responsible for the research and development of Amitiza, while Takeda is primarily responsible for the commercialization and marketing activities. Additionally, Takeda funds the majority of our research and development activities in the U.S. and part of the co-promotion activities of our own sales force. Takeda records all product revenue and we receive a royalty on such product sales.

We are disappointed with the level of U.S. sales of Amitiza being generated by Takeda and other failures of performance by Takeda under our agreements. In April 2009, we sent Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. a notice of material breach. The notice stated that Takeda materially breached our agreement, without limitation, by their continuing failure to exercise their best efforts to commercialize Amitiza and maximize net sales revenue, and their ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We subsequently sent a letter that advised Takeda that they had failed to cure said breaches within the 90 day cure period provided under the agreement. Since then, we have spent significant resources in our dispute with Takeda. We also attempted to conduct a review of Takeda's performance but Takeda refused to provide us with certain information necessary to complete that review.

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between us and Takeda Pharmaceuticals Company Limited dated October 29, 2004. In addition to the claims set forth in the notice of material breach, we also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only us and the Amitiza brand, but also consumers. We are seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. We may spend additional significant resources and these legal proceedings may require the continuing attention of our senior management.

In February 2009, we entered into a license, commercialization and supply agreement with Abbott Japan Co. Ltd., or Abbott, for lubiprostone in Japan. Under the terms of the agreement, Abbott received exclusive rights to commercialize lubiprostone in Japan for the treatment of CIC 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. We are responsible for the research and development activities under the agreement. We have retained the right to co-promote lubiprostone in Japan and we are responsible for such costs of co-promotion. Based on the terms of the agreement, we received an upfront payment of $10.0 million upon execution of the agreement in February 2009 and in May 2009 we received a development milestone payment of $7.5 million upon the initiation of phase 3 clinical trials of lubiprostone for CIC in Japanese patients. We are preparing a development plan which will be presented to and discussed with Abbott in 2010. The agreement provides a dispute resolution mechanism for certain disputes including the development plan.

In April 2009, we entered into two agreements with R-Tech Ueno Ltd., or R-Tech, a Japanese manufacturing and research and development company, to license Rescula® (unoprostone isopropyl) in the U.S. and Canada.

We generate revenue mainly from product royalties, development milestone payments, and research and development activities. We expect to continue to incur significant expenses for the next several years as we continue our research and development activities, seek regulatory approvals for additional indications for Amitiza and for other compounds in the U.S. and other countries and expand our international operations. We hold an exclusive worldwide royalty-bearing license from Sucampo AG, or SAG, a Swiss patent-holding company, to develop and commercialize Amitiza and all other prostone compounds covered by patents and patent applications held by SAG. We are obligated to assign to SAG all patentable improvements that we make in the field of prostones, which in turn SAG is obligated to license back to us on an exclusive basis.

Drs. Ryuji Ueno and Sachiko Kuno, our founders, are married to each other and directly or indirectly own the majority of our common stock, a majority of the stock of R-Tech and all of the stock of SAG. Dr. Ueno serves as the chairman of our Board of Directors and is our chief executive officer and chief scientific officer. Dr. Kuno is a member of our Board of Directors and executive advisor of international business development. Dr. Kuno also serves as the chair of the Board of Directors of R-Tech.

We conduct our business through our subsidiaries based in the U.S., the United Kingdom and Japan. These subsidiaries represent our reportable geographic segments and we evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors that depend on the development status of these subsidiaries. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other factors.

Our Clinical Development Programs

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

Amitiza (lubiprostone) in the U.S. and Canada. We currently are developing Amitiza to treat OBD. In July 2009, we reported top line results from the two identically designed phase 3 placebo-controlled pivotal clinical trials of Amitiza, 24 mcg, twice daily, for the treatment of OBD in patients with chronic, non-cancer pain.

The initial results of the completed phase 3 clinical trials of Amitiza for the treatment of OBD are as follows:

- The first study met the primary endpoint of a statistically significant change from baseline in the frequency of spontaneous bowel movements, or SBMs, at week 8 of treatment when lubiprostone was compared to placebo. Additionally, statistical significance was achieved for eight of the twelve secondary endpoints, including key symptoms associated with OBD. The second study did not achieve statistical significance for the same primary endpoint. Statistically significant improvements with lubiprostone were achieved for two of the secondary endpoints and positive trends were observed in four of the other secondary endpoints in the second trial. Subjects treated with lubiprostone in both trials showed a statistically significant increase in the frequency of SBMs at week 8 from their baseline, from 1.42 to 4.54 SBMs in the first trial and from 1.60 to 4.10 SBMs in the second trial. The increase for placebo over their baseline was from 1.46 to 3.81 SBMs for the first trial and 1.60 to 3.95 SBMs for the second trial.

- There was a high rate of response in the placebo arm of the second trial. Approximately 58% of subjects treated with placebo in the second trial experienced more than three SBMs per week during each week of the trial.

- In both trials, a post-hoc sub-analysis showed that subjects on methadone treatment regimens who were randomized to receive lubiprostone showed a lower SBM response when compared to lubiprostone patients treated with other opioid medications. Additionally, in both trials, methadone subjects treated with lubiprostone did not show improvement in OBD symptomatic endpoints while lubiprostone subjects treated with other opioids showed statistically significant improvement in both studies in abdominal discomfort and pain, constipation severity, stool consistency and straining over the placebo.

- The overall adverse event rate for the combined trials was 54.9% for lubiprostone and 51.6% for placebo. The most common adverse events were nausea, 15% for lubiprostone compared to 7.5% for placebo, and diarrhea, 8.5% for lubiprostone compared 3.7% for placebo.

We continue to analyze the results of these trials. The outcome of this process and the results of the fully-enrolled, long-term, follow-on open-label safety extension trial will determine the next steps in this development program. Currently, we plan to submit the data from these trials to the FDA in 2010.

In connection with our marketing approval of Amitiza for the treatment of CIC in adults of both genders and all ages, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in pediatric patients, in adult patients with renal impairment and in adult patients with hepatic impairment, which were initiated in January 2007. We filed results from these three post-marketing studies with the FDA in May 2009. In connection with our marketing approval for Amitiza for the treatment of IBS-C in adult women, we committed to the FDA to conduct a post-marketing study to evaluate the safety and efficacy for the treatment of irritable bowel syndrome in pediatric patients ages 6 to 17 years. In addition, we committed to conduct a post-marketing study in male and female patients with IBS-C utilizing a higher dose than currently recommended for this indication. In accordance with the collaboration and co-promotion arrangement, Takeda funds the majority of Amitiza's development program in the U.S.

Amitiza (lubiprostone) in other countries. In August 2009, we completed enrollment into the open-label phase 3 safety trial and in October 2009, we completed enrollment of the pivotal phase 3 efficacy trial of lubiprostone for CIC in Japan. In September 2009, we announced the withdrawal of our European marketing authorization applications, or MAAs, for lubiprostone, 24 mcg, for the indication of CIC in adults of both genders and all ages filed in nine European countries using the decentralized procedure. Our decision to withdraw the MAAs was strategic, based upon lubiprostone's projected commercial position in the global market. We continue to evaluate our opportunities to obtain an appropriate label in the E.U. based on the fact that lubiprostone is the only product approved by the FDA for chronic therapy for either CIC or IBS-C in the U.S.

In November 2009, we received a marketing authorization for Amitiza in Switzerland for the treatment of CIC.

Rescula. In April 2009, we licensed from R-Tech the development and commercialization rights to Rescula (unoprostone isopropyl) in the U.S. and Canada, including all associated patents and other intellectual property. Although Rescula has been approved for marketing in the U.S. for the treatment of open-angle glaucoma and ocular hypertension since 2000, it was marketed only to a limited extent by a previous licensee shortly after the approval and is not currently commercialized in the U.S. or Canada. We plan to relaunch Rescula in the U.S. for the treatment of open-angle glaucoma and ocular hypertension in 2010. We also intend to initiate a phase 2 clinical trial of unoprostone isopropyl to treat dry age-related macular degeneration in 2010.

Under the terms of the R-Tech agreements, we made an upfront payment of $3.0 million and may be required to pay up to $5.5 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of $500,000 is payable upon the re-launch of Rescula for the treatment of glaucoma.

Cobiprostone. We are developing cobiprostone as a potential treatment for various gastrointestinal and liver disorders, including the prevention of non-steroidal anti-inflammatory drug, or NSAID, induced ulcers. We also are evaluating it as a potential treatment for chronic obstructive pulmonary disease and a topical formulation for the treatment of skin ulcers and wounds.

Our near-term focus is on the development of cobiprostone for the prevention of NSAID-induced ulcers. In July 2009, we announced top-line results of our phase 2 clinical trial of cobiprostone for this indication. A total of 124 patients with osteoarthritis and/or rheumatoid arthritis were enrolled at 12 sites in the U.S. in this 12-week, double-blinded, randomized, dose-ranging and placebo-controlled phase 2 trial. All patients in the trial received 500 mg of naproxen twice a day. There were four treatment cohorts. One cohort received placebo while the other three cohorts received 18 mcg of cobiprostone either once, twice or three times a day (daily totals of 18, 36 or 54 mcg, respectively).

Efficacy endpoints that we evaluated included: the overall incidence of gastric ulcers during the 12-week treatment period, overall incidence of duodenal ulcers, change in the number of ulcers and erosions (gastric and duodenal) by patient, time-to-onset analysis of ulcer and erosion development, and the severity of overall gastrointestinal injury measured on a standardized grading scale.

A top-line analysis of data from the trial indicates that patients receiving cobiprostone experienced a lower overall incidence of ulcers. At week 12, the 54 mcg dose cohort experienced a 50.0% reduction in the overall incidence of gastric ulcers when compared to the placebo cohort placebo. Cobiprostone cohorts experienced an overall statistically significant reduction in the number of gastric erosions through the treatment period of 12 weeks compared to placebo cohort. The reduction of gastric erosions through week 12 was dose dependent, with 36 mcg and 54 mcg cohorts demonstrating statistical significance. The time-to-onset of all ulcer or erosion development was delayed in the cobiprostone cohorts with overall statistical significance across the 12-week treatment period. Overall, the data showed cobiprostone was well tolerated in patients receiving NSAID therapy.

SPI-017. We are currently developing SPI-017 to treat vascular disease and central nervous system disorders. We are initially focused on developing an intravenous formulation of this product candidate for the treatment of peripheral arterial disease, or PAD. We commenced phase 1 clinical trials of the intravenous formulation of SPI-017 for this indication in December 2008 in Japanese patients. That program continues, and we expect to have data from it in 2010.

Financial Terms of our License and Commercialization and Supply Agreement with Abbott

In February 2009, we entered into a 19-year license, commercialization and supply agreement with Abbott in February 2009 to develop and commercialize lubiprostone for the treatment of CIC in Japan. The agreement also grants Abbott the right of first refusal to any additional indications for which lubiprostone is developed in Japan under all relevant patents, know-how and trademarks. We have retained all other rights to Amitiza in Japan.

Our collaboration efforts under the Abbott agreement are governed by two committees consisting of an equal number of representatives from both parties. The joint commercialization and steering committee oversees commercialization-related activities and resolves any conflicts arising from a joint development committee, which oversees the development-related activities in Japan. The dispute mechanism under the Abbott agreement provides Abbott with final decision regarding disputes over commercialization of the products, while we have the same rights in respect to the disputes over the development agreement.

We are required to fund and complete all the development work including additional clinical studies required to obtain regulatory approval for the treatment of CIC in Japan. We own all the rights covered under the regulatory filings.

Abbott is required to fund and undertake all commercialization efforts including pre-launch and post-launch marketing, promotion and distribution. Abbott is required to maintain the number of sales staff and the estimated level of annual net sales based on the commercialization plan to be developed and approved by the joint commercialization and steering committee described above. We have retained the right to co-promote the product in Japan and the development and commercialization rights to all other therapeutic areas and are responsible for the cost of co-promotion.

Upfront Payment

Upon signing the original license, commercialization and supply agreement with Abbott, we received a non-refundable upfront payment of $10.0 million.

Product Development Milestone Payments

In May 2009, Abbott paid us a $7.5 million non-refundable development milestone upon the initiation of the phase 3 clinical trial for lubiprostone for the treatment of CIC in Japanese patients. There can be no assurances that we will receive additional development or commercial milestone payments under our agreement with Abbott.

Product Revenue

Once Amitiza is commercialized in Japan, the Company will purchase and assume title to inventories of Amitiza and recognize revenues from the sales of such product when earned.

Abbott Cash Flows and Revenue

The following table summarizes the cash streams and related revenue recognized or deferred under the license, commercialization and supply agreement with Abbott:

(In thousands)	Amount Deferred at December 31, 2008	Cash Received for Year Ended December 31, 2009	Revenue Recognized for the Year Ended December 31, 2009	Foreign Currency Effects for the Year Ended December 31, 2009	Amount Deferred at December 31, 2009
Collaboration revenue:					
Up-front payment associated with the Company's obligation to participate in joint committees	$ —	$ 846	$ 38	$ (4)	$ 812
Research and development revenue:					
Up-front payment	$ —	$ 9,154	$ 5,112	$ 51	$ 3,991
Development milestone payment	—	7,500	4,314	(180)	$ 3,366
Total	$ —	$ 16,654	$ 9,426	$ (129)	$ 7,357

Financial Terms of our License and Collaboration Agreement with Takeda

In October 2004, we entered into a 16-year collaboration agreement with Takeda to jointly develop and commercialize Amitiza for gastrointestinal indications in the U.S. 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.

Upfront Payment

Upon signing the 2004 agreement with Takeda, we received a non-refundable upfront payment of $20.0 million.

Product Development Milestone Payments

We have received the following non-refundable payments from Takeda reflecting our achievement of specific product development milestones:

- $10.0 million upon the filing of the NDA for Amitiza to treat CIC in March 2005;
- $20.0 million upon the initiation of our phase 3 clinical trial related to Amitiza for the treatment of IBS-C in May 2005;
- $20.0 million upon the receipt of approval from the FDA for Amitiza for the treatment of CIC in adults of both genders and all ages 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 IBS-C in June 2007; and
- $50.0 million upon the receipt of approval from the FDA for Amitiza for the treatment of IBS-C in women 18 years and older in May 2008.

Subject to our achieving further product development milestones, we are 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 U.S. and Canada as follows:

Research and development expense related to Amitiza for the treatment of CIC and IBS-C:

- Pursuant to the agreement, Takeda is responsible for first $30.0 million in research and development expenses incurred after October 2004 related to Amitiza for the treatment of CIC and IBS-C. We received reimbursements from Takeda of $28.5 million in 2005 and $1.5 million in 2004. 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. No expenses were incurred in 2009 for the CIC and IBS-C indications.

- For research and development expenses relating to changing or expanding the labeling of Amitiza to treat CIC and IBS-C, 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 CIC in adults of both genders and all ages, 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, 2009, we had incurred $2.3 million of these expenses, of which we were reimbursed approximately $1.6 million by Takeda.

- The expense of phase 4 clinical programs of Amitiza for the treatment of CIC in pediatric patients that we initiated in January 2007 will be borne by Takeda in full. As of December 31, 2009, we had incurred $7.9 million of these expenses, all of which have been or are to be reimbursed by Takeda.

- For expenses in connection with additional clinical trials required by regulatory authorities relating to Amitiza to treat CIC or IBS-C, 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 CIC and IBS-C:

- 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 CIC and IBS-C 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 OBD in September 2007 and we began incurring expenses for these trials in the third quarter of 2007. As of December 31, 2009 we had incurred $48.6 million of these expenses, all of which have been or are to 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 the February 2006 Takeda agreements, Takeda agreed to reimburse a portion of our expenses related to our specialty sales force. We recognized $4.5 million, $4.8 million and $4.4 million of co-promotion revenue reflecting these reimbursements for the years ended December 31, 2009, 2008 and 2007, 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.

Product Royalty Revenue

Takeda is obligated to pay us a sliding royalty rate based on a percentage of the net sales revenue from the sale of Amitiza in the U.S. and Canada. The actual percentage depends on the level of net sales revenue attained each calendar year. All sales of Amitiza in the U.S. and Canada, including those arranged by our specialty sales force, are made through Takeda. Amitiza is currently marketed only in the U.S. and during the years ended December 31, 2009, 2008 and 2007, we recognized a total of $38.3 million, $34.4 million and $27.5 million, respectively, as product royalty revenue.

Commercialization Milestone Payments

Our agreements also require Takeda to pay us up to an additional aggregate of $50.0 million upon the achievement of specified targets for annual net sales revenue from Amitiza in the U.S. and Canada. Sales of Amitiza have not met these targets as of December 31, 2009.

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, 2009	Revenue Recognized for the Year Ended December 31, Through 2006	2007	2008	2009	Accounts Receivable for the Year Ended December 31, 2009 (1)	Amount Deferred at December 31, 2009
Collaboration revenue:							
Up-front payment associated with our obligation to participate in joint committees	$ 2,375	$ 317	$ 147	$ 147	$ 147	$ —	$ 1,617
Research and development revenue:							
Up-front payment — remainder	$ 17,624	$ 15,647	$ 1,977	$ —	$ —	$ —	$ —
Development milestones	130,000	44,391	35,609	50,000	—	—	—
Reimbursement of research and development expenses	88,847	28,141	21,793	22,293	14,530	644	2,734
Total	$ 236,471	$ 88,179	$ 59,379	$ 72,293	$ 14,530	$ 644	$ 2,734
Product royalty revenue	$ 95,791	$ 6,590	$ 27,536	$ 34,438	$ 38,250	$ 11,023	$ —
Co-promotion revenue	$ 17,657	$ 4,243	$ 4,411	$ 4,826	$ 4,541	$ 364	$ —

(1) Includes billed and unbilled accounts receivable.

Financial Terms of our License Agreement with SAG

Under our license agreement with our affiliate, we are required to pay SAG 5% of every milestone payment we receive from a sublicensee, such as Takeda or Abbott. We also are obligated to make the following milestone payments to SAG:

- $500,000 upon initiation of the first Phase II 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
- $1.0 million for the first NDA filing or comparable foreign regulatory filing for each compound in each of these three territories.

In addition, we are required to pay SAG, on a country-by-country basis, royalty payments of 6.5% of net sales for every product covered by existing patents and, if applicable, thereafter 4.25% of net sales for every product candidate covered by new or improvement patents assigned by us to SAG. With respect to sales of Amitiza in North, Central and South America, including the Caribbean, the rates for these royalty payments are set at 3.2% and 2.1% of net sales, respectively. The product royalties that we pay to SAG are based on total product net sales, whether by us or a sublicensee, and not on amounts actually received by us. We expensed $6.7 million, $6.0 million and $4.9 million in product royalties to SAG during the years ended December 31, 2009, 2008 and 2007, 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 (loss).

In February 2009, we entered into an addendum to the 2006 agreement originally entered between us and SAG. Under the addendum, the patent and know-how royalties we are obligated to pay to SAG were 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, was 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, was 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, was reduced from 2.0% to 1.0%.

We paid SAG the following milestone royalty payments that were expensed as incurred and recorded as milestone royalties — related parties during the years ended December 31, 2009, 2008 and 2007.

- In June 2007, a $1.5 million payment, reflecting 5% of a $30.0 million milestone payment received from Takeda as a result of our submission to the FDA of the supplement to our existing NDA for Amitiza seeking marketing approval for Amitiza for the treatment of IBS-C;
- In 2007, a $500,000 payment upon the initiation of the first phase 2b dose-ranging study in Japan;
- In May 2008, a $2.5 million payment, reflecting 5% of a $50.0 million development milestone payment that we received from Takeda as a result of our submission to the FDA of the supplement to our existing NDA for Amitiza seeking marketing approval for Amitiza for the treatment of IBS-C;
- In February 2008, a $1.0 million milestone royalty payment in connection with our MAA filed in the United Kingdom, representing the first such filing for the rest-of-the-world territory;
- In February 2009, a $500,000 payment, reflecting 5% of a $10.0 million upfront payment that we received from Abbott as a result upon signing the original license, commercialization and supply agreement; and
- In May 2009, a $375,000 payment, reflecting 5% of a $7.5 million development milestone payment that we received from Abbott as a result of initiating the phase 3 clinical trial for lubiprostone for the treatment of CIC in Japan.

In February 2009, we entered into a Technology Assignment and License Agreement with R-Tech and SAG, under which the parties agreed that R-Tech and SAG would share joint ownership of eight U.S. patents and patent applications, and several related international patents and patent applications, which had previously been filed by R-Tech. These patents relate to specific prostone compounds and formulations and to methods for producing prostone compounds. The parties also agreed that R-Tech and SAG would share joint ownership of know-how and other inventions previously created by R-Tech relating to prostones. R-Tech and SAG cross-licensed to each other, on a worldwide, royalty-free, perpetual, exclusive basis, their respective rights in these patents, patent applications, know-how and other inventions. R-Tech's right to utilize the licensed intellectual property is limited to uses in connection with research, development and commercialization of Rescula, and three other prostone compounds it is currently developing. SAG's right to utilize the licensed intellectual property is limited to uses in connection with research, development and commercialization of all other prostone compounds. SAG's rights under this agreement are in turn licensed to us under the existing patent license arrangements. None of the parties made any monetary payments to the other parties under this agreement.

Financial Terms of our Supply Agreement with R-Tech

On March 7, 2003, we entered into an exclusive supply agreement with R-Tech. This agreement grants R-Tech the exclusive right to manufacture and supply lubiprostone in the U.S. and Canada, and in consideration for such rights R-Tech agreed to pay us as follows: $1.0 million upon execution of the agreement, $2.0 million upon commencement of a first phase 2 lubiprostone trial. Upon execution of the agreement, we had already commenced phase 2 clinical trials lubiprostone, which resulted in an immediate payment of $3.0 million — $1.0 million for the agreement execution and $2.0 million for the commencement of the first phase 2 lubiprostone trial. We evaluated the cash receipts from R-Tech and determined the payments were made for the exclusive right to supply inventory to us and determined that the amounts should be deferred until commercialization of the drug begins since this is the point at which the underlying services would commence. Management determined that the full deferred amount would be amortized over the contractual life of the relationship which was equivalent to the estimated commercialization period of lubiprostone (estimated to be through December 2020).

As previously reported, we ceased development of another prostone, RUG-015, in 2005. This changed the amortization period of the $6.0 million deferred revenue to the commercialization period of Amitiza, which began in April 2006. We recognized revenue of $419,000 for the years ended December 31, 2009 and 2008, respectively, which is recorded as contract revenue. During the years ended December 31, 2009, 2008 and 2007, we purchased clinical supplies from R-Tech of $205,000, $58,000 and $1.6 million, respectively, under the terms of this agreement.

On June 24, 2005, we 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 us $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. During the year ended December 31, 2007, we purchased from R-Tech $336,000 of clinical supplies under the terms of this agreement. There were no such clinical supply purchases in 2009 or 2008. During the year ended December 31, 2009, we purchased $692,000 of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch in Europe. Subsequent to the purchase, we withdrew our European MAA and recorded a write down of $658,000 to reflect the fair value of this inventory.

On October 4, 2006, we 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 is 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 is automatically renewed for an additional two years. During the years ended December 31, 2009, 2008 and 2007, we purchased from R-Tech $1.1 million, $1.9 million and $1.8 million, respectively, of clinical supplies under the terms of this agreement.

In February 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 its commercial and clinical requirements in Asia, Australia and New Zealand. In consideration, R-Tech made an upfront 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.

On April 23, 2009, we entered into two agreements with R-Tech to acquire rights to Rescula in the U.S. and Canada. Under the terms of the agreements, we hold the exclusive rights to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension and any new indication developed by the Company, and has the right of first refusal to commercialize in the U.S. and Canada any additional indications for which unoprostone isopropyl is developed by R-Tech. We are solely responsible for the development, as well as regulatory and commercialization activities and expenses, for Rescula in the U.S. and Canada and R-Tech is exclusively responsible for the supply of Rescula to the Company within the U.S. and Canada.

Under the terms of the 2009 agreements, we made an upfront payment of $3.0 million and may be required to pay up to $5.5 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of $500,000 is payable upon the U.S. re-launch of Rescula for the treatment of glaucoma. This event is considered as being probable of occurring.

We recorded the following expenses under all of our agreements with R-Tech:

	Year Ended December 31,		
(In thousands)	**2009**	**2008**	**2007**
Clinical supplies	$ 2,525	$ 1,917	$ 3,380
Other research and development services	100	118	563
	$ 2,625	$ 2,035	$ 3,943

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 U.S. 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 estimate 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.

Revenue Recognition

Collaboration and License Agreements

Our revenues are derived primarily from collaboration and license agreements and include upfront payments, development milestone payments, reimbursements of development and co-promotion costs and product royalties.

We evaluated the multiple deliverables within our joint collaboration and license agreements to determine whether the delivered elements that are our obligation have value to other parties to the agreement 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.

We apply a time-based model of revenue recognition for cash flows associated with research and development deliverables under the Takeda collaboration and license agreement. 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, such as development milestones, revenue is recognized to the extent the accumulated service time 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. In cases where milestone payments are received after the completion of the associated development period, we recognize revenue upon completion of the performance obligation. Revenue is limited to amounts that are nonrefundable and that the other party to the agreement is contractually obligated to pay to us. We recognize reimbursable research and development costs under the Takeda agreement as research and development revenue using a 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 can be reasonably determined.

We apply a proportional-performance model using the percentage-of-completion method of revenue recognition for cash flows associated with research and development deliverables under the Abbott license, commercialization and supply agreement. Since we have previous research and development experience and the expected cost to complete the development can be reasonably estimated, we believe a proportional-performance methodology of revenue recognition is appropriate. Under this method, revenue in any period is recognized as a percentage of the total actual cost expended relative to the total estimated costs required to satisfy the performance obligations under the arrangement. Revenue recognized is limited to the amounts that are non-refundable and that the other party to the agreement is contractually obligated to pay us. A change in the period of time expected to complete the deliverable is accounted for as a change in estimate on a prospective basis. Research and development costs are not reimbursable under the Abbott agreement.

Under the Takeda agreement, royalties are based on net 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. Under the Abbott agreement, if Amitiza is commercialized in Japan, we will purchase and assume title to inventories of Amitiza and recognize revenues from the sales of such product when earned.

Takeda reimbursements of co-promotion costs under the supplemental agreement, 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.

We recognize contract revenue related to development and commercialization activities under the time-based method over the applicable period.

We consider our participation in the joint committees under the Takeda and Abbott collaboration agreements as separate deliverables under the contracts and recognize the fair value of such participation as revenue over the period of the participation per the terms of the contracts.

We have determined that we are acting as a principal under both the Takeda and Abbott agreements and, as such, record revenue on a gross basis in the consolidated statements of operations and comprehensive income (loss), except in regards to selling product under the Takeda agreement where we recorded product royalty revenue.

Current and Non-Current Investments

Current and non-current investments consist primarily of U.S. Treasury bills and notes, U.S. government agencies securities, municipal and corporate bonds and auction rate securities, or ARS. We classify our investments into current and non-current based on their maturities and management's reasonable expectation to realize these investments in cash. We classify all of our investments, except ARS, as available for sale securities and report unrealized gains or losses, net of related tax effects, in other comprehensive income. Pursuant to our acceptance of settlement rights for our investments in ARS in October 2008, we classify our investments in ARS as trading securities and record gains or losses resulting from the changes in fair values of our ARS and related settlement rights in other income (expense), net. The fair value of the settlement rights related to ARS is recorded as non-current other assets. The fair value of the settlement rights has been derived from the par value of our investment in ARS and the fair value of ARS as of the recognition date, since the settlement rights obligate the broker to redeem the ARS at par value.

Auction rate securities

As of December 31, 2009, we continue to hold one non-mortgage related ARS in the amount of $10.0 million. Although the ARS have variable interest rates which typically reset every seven to 49 days through a competitive bidding process they have long-term contractual maturities usually exceeding ten years, and therefore are not classified as cash equivalents. As a result of ongoing liquidity issues in the global credit and capital markets, the ARS market has been significantly disrupted and it has been difficult to sell the ARS in the open market.

On October 16, 2008, we accepted a settlement rights offer from the broker, UBS AG, that 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, 2009, we have recorded an asset of $1.1 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 unrealized gains or losses on our ARS and the related settlement rights as other income in the consolidated statement of operations and comprehensive income. 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.

Fair Value Estimates

Effective January 1, 2008, we adopted FASB's guidance of fair value measurements for our financial assets and liabilities. Our financial assets and liabilities subject to the disclosure requirements of fair value measurements include investments and ARS related settlement rights asset. We determined the fair market value of other financial assets and liabilities approximate their carrying values as of year end.

Fair value estimate for auction rate securities

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.

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.

The fair value model calculated market-required rates of return that included a risk-free interest rate and a credit spread. 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, 2009 and 2008.

Reflecting the settlement rights offer from UBS, we assumed the remaining life of our investment in ARS to be one year as of December 31, 2009. We identify 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 one year to three years would result in a $1.7 million decrease in fair value of ARS outstanding as on December 31, 2009. We measured sensitivity for a range of one to three 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 FASB's guidance for the fair value option for financial assets and financial liabilities, 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 $1.1 million within other assets in the consolidated balance sheet as of December 31, 2009 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.

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, or CRO's, 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

We estimate the fair value of share-based payment awards on the date of the grant using an option-pricing model and recognize the expense over the required service periods.

For recording our stock-based compensation expense, we have chosen to use:

- the straight-line method of allocating compensation cost;
- 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 the SEC's guidance for share-based payments; and
- an estimate of expected volatility based on the historical volatility of similar entities whose share prices are publicly available.

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.

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 FASB's guidance for accounting for income taxes which 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 $8.5 million and $5.7 million as of December 31, 2009 and 2008, respectively, which resulted in a net deferred tax asset of $4.3 million and $5.0 million as of December 31, 2009 and 2008, respectively. Significant future events, not under our control, including continued success in commercialization of products in U.S. markets or regulatory approvals for products in international markets, could affect our future earnings potential and consequently the amount of deferred tax assets that will be utilized.

As of December 31, 2009 and 2008, we had foreign net operating loss carry forwards of $10.9 million and $14.4 million, respectively. Approximately $1.9 million of the foreign NOLs begin to expire in December 2015, and $9.0 million of the foreign NOLs do not expire.

On January 1, 2007, we adopted FASB guidance for uncertainty in income taxes that 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, this guidance 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 approximately $765,000 including interest for uncertain tax positions as of December 31, 2009. 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, 2009 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 was $36,000 of interest recorded in 2009 related to uncertain tax positions. 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 the U.S. tax authorities from 2008 forward. Our examination for 2005, 2006, and 2007 by U.S. tax authorities was completed in 2009 and resulted in no change.

Related Party Transactions

As part of our operations, we enter into transactions with our affiliates. At the time of each 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 affiliates, we have evaluated the terms of transactions to be 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. 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 completion of the initial public offering. These awards consisted of a combination of cash and shares of class A common stock, with 40% payable in cash and 60% in stock. 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.

The estimated fair value of these awards was determined using the Black-Scholes-Merton Option Pricing Formula resulting in an expense of $9.2 million for the year ended December 31, 2007, of which the $3.1 million was paid in cash and $6.1 million was settled by issuance of 401,133 shares of class A common stock.

Results of Operations

Comparison of years ended December 31, 2009 and December 31, 2008

Revenues

The following table summarizes our revenues for the years ended December 31, 2009 and 2008:

	Year Ended December 31,	
(In thousands)	**2009**	**2008**
Research and development revenue	$ 23,957	$ 72,293
Product royalty revenue	38,250	34,438
Co-promotion revenue	4,541	4,826
Contract and collaboration revenue	603	566
Total	$ 67,351	$ 112,123

Total revenues were $67.4 million in 2009 compared to $112.1 million in 2008, a decrease of $44.7 million or 39.9%.

Research and development revenue

Research and development revenue was $24.0 million in 2009 compared to $72.3 million in 2008, a decrease of $48.3 million or 66.9%. This decrease was primarily due to the $50.0 million development milestone received from Takeda in May 2008 upon FDA approval of Amitiza for the treatment of the IBS-C in adult women that was immediately recognized as research and development revenue. The decrease also reflects reduced activity and related revenue recognized for the pediatric, renal, hepatic and OBD trials for Amitiza reimbursed by Takeda. The 2009 research and development revenue includes the $9.4 million in revenue recognized from the initial $10.0 million upfront payment and the $7.5 million development milestone payment received under the agreement with Abbott.

Product royalty revenue

Product royalty revenue is earned from Takeda on net sales of Amitiza in the U.S. In 2009, we recognized $38.2 million of product royalty revenue compared to $34.4 million in 2008, an increase of $3.8 million or 11.1%, reflecting mainly a higher price per pill.

Co-promotion revenue

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force. In 2009, we recognized $4.5 million of co-promotion revenues compared to $4.8 million in 2008. The co-promotion reimbursement is capped at $4.5 million annually for 12-month periods ending March 31. The reduced co-promotion revenue during the year ended December 31, 2009 reflects the annual limit that was reached earlier in 2009 than in 2008.

Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2009 and 2008:

	Year Ended December 31,	
(In thousands)	**2009**	**2008**
Direct costs:		
Amitiza	$ 25,017	$ 33,303
Cobiprostone	2,294	4,648
SPI-017	2,752	4,377
Rescula	235	—
Other	530	1,625
Total	$ 30,828	$ 43,953
Indirect costs	2,076	2,228
Total	$ 32,904	$ 46,181

Total research and development expenses in 2009 were $32.9 million compared to $46.2 million in 2008, a decrease of $13.3 million or 28.7%. In 2008, we incurred filing and data purchase costs of approximately $2.5 million, which supported our European regulatory filings for Amitiza. No such expenditure was recorded during 2009. The decrease was also due to the completion in July 2009 of the two phase 3 pivotal clinical trials for the treatment of OBD, the completion in 2008 of the pediatric constipation trial for Amitiza and the completion in July 2009 of the phase 2 trial of cobiprostone for the prevention of NSAID-induced ulcers. This reduction in expenses was offset in part by ongoing costs in 2009 of the phase 3 efficacy and safety trials of lubiprostone for CIC in Japan.

General and Administrative Expenses

The following summarizes our general and administrative expenses for years ended December 31, 2009 and 2008:

(In thousands)	Year Ended December 31, 2009	2008
Salaries, benefits and related costs	$ 3,808	$ 4,315
Legal, consulting and other professional expenses	5,608	2,900
Other expenses	5,088	7,185
Total	$ 14,504	$ 14,400

General and administrative expenses were $14.5 million in 2009 compared to $14.4 million in 2008, an increase of $104,000 or 0.7%. The decrease in salaries, benefits and related costs was primarily attributable to a reduction in force in January 2009 and an overall reduction in incentive compensation for 2009. The increase in legal, consulting and other professional expenses was primarily a result of $2.6 million in costs incurred in connection with our dispute with Takeda and to a one-time business development effort that we elected not to pursue.

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 $10.0 million in 2009 compared to $10.9 million in 2008, a decrease of $865,000 million or 7.9%. The decrease was primarily due to streamlined commercial operations and a reduction in market research expenses offset in part by the approximately $658,000 of one-time expenses in 2009 resulting from the withdrawal of our European MAAs for lubiprostone.

Milestone Royalties — Related Parties

Milestone royalties — related parties expense was $875,000 in 2009 compared to $3.5 million in 2008, a decrease of $2.7 million, or 75.2%. The milestone royalties of $875,000 reflect the 5% royalty payments to SAG as a result of the $10.0 million upfront payment and the $7.5 million development milestone payment we received from Abbott in 2009. In 2008, we paid SAG a $1.0 million milestone in connection with our European MAAs filed in February 2008. As a result of our sNDA approval for Amitiza to treat IBS-C, we paid SAG $2.5 million, reflecting 5% of the $50.0 million development milestone payment that we received from Takeda in May 2008.

Product Royalties — Related Parties

Product royalties — related parties expense represent royalty payments of 3.2% to our affiliate SAG based on net sales of Amitiza. In 2009, our product royalty expense was $6.7 million compared to $6.0 million in 2008, an increase of $648,000, or 10.7%, which was consistent with the increase of product royalty revenue.

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the years ended December 31, 2009 and 2008:

(In thousands)	Year Ended December 31, 2009	2008
Interest income	$ 957	$ 2,442
Other income (expense), net	229	(399)
Total	$ 1,186	$ 2,043

Interest income was $957,000 in 2009 compared to $2.4 million in 2008, a decrease of $1.5 million, or 60.8%. The decrease was primarily due to lower prevailing interest rates earned by our investments and a shift in the composition of our portfolio from ARS, which bear higher interest rates, to other types of investments.

Other expenses primarily include an unrealized gain or loss on trading securities offset by unrealized loss on settlement rights on our investments in auction rate securities and unrealized loss on foreign currency.

Income Taxes

For the years ended December 31, 2009 and 2008, our consolidated effective tax rate was 120.5% and 24.7%, respectively. For the years ended December 31, 2009 and 2008, we recorded a tax provision of $4.3 million and $8.2 million, respectively. The increase in the effective tax rate in 2009 from 2008 was attributable to the release of a valuation allowance in 2008 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 the continuation of foreign losses that are not benefited due to full valuation allowances. As of December 31, 2009, our remaining valuation allowance against our deferred tax assets was $8.5 million solely relating to foreign jurisdictions.

Cost Reduction Initiatives

To conserve cash and more closely align our spending towards our strategic objectives, we implemented cost reduction initiatives in January 2009, which included a workforce reduction and refocused research and development plans. These initiatives resulted in reduced costs of approximately $3.4 million during 2009. Additionally, during the second quarter of 2009, we decided to initiate most of our future preclinical and early clinical research and development through our Japanese subsidiary as a further effort to control costs.

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 IBS-C 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 relates to reimbursement from Takeda for the following three activities: post-marketing studies to evaluate the safety of Amitiza in patients with renal and hepatic impairment, phase 4 clinical trial of Amitiza for the treatment of CIC in pediatric patients and clinical trials of Amitiza for the treatment of OBD. The research and development revenue in 2007 includes $21.7 million reimbursed research and development expenses from Takeda and $7.7 million revenue from 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 CIC in adults of both genders and all ages and sales of Amitiza 8 mcg for IBS-C 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
Rescula	—	—
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 OBD and CIC 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 mcg, for the indication of CIC in adults of both genders and all ages .

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, consulting and other professional expenses	2,900	2,967
Founders' stock-based awards	—	9,188
Other expenses	7,185	5,176
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 U.S. 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.

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 SAG a $1.0 million milestone in connection with our European MAAs filed in February 2008. As a result of our sNDA approval for Amitiza to treat IBS-C, 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 SAG $1.5 million reflecting the 5% of $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.

Product Royalties — Related Parties

Product royalties — related parties expense represent royalty payments to our affiliate SAG 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.

Non-Operating Income and Expense

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

	Year Ended December 31,	
(In thousands)	**2008**	**2007**
Interest income	$ 2,442	$ 2,465
Other income (expense), net	(399)	151
Total	$ 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 U.S. As of December 31, 2008, our remaining valuation allowance against our deferred tax assets was $5.7 million solely relating to foreign jurisdictions.

Reportable Geographic Segments

We have determined that we have three reportable segments based on our method of internal reporting, which disaggregates the business by geographic location. These segments are the Americas, Europe and Asia. We evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors, including the progress of research and development activities.

The financial results of our segments reflect their varying stages of development. Our Americas segment recorded income before taxes of $11.5 million in 2009 compared to income before taxes of $42.0 million in 2008, primarily reflecting the $50.0 million milestone payment from Takeda.

Our segment in Europe recorded a loss before taxes of $3.4 million in 2009. This compared to a loss before taxes of $3.5 million in 2008, reflecting the withdrawal of our MAA for lubiprostone in multiple countries in the E.U.

Our segment in Asia recorded a loss before taxes of $4.5 million in 2009 compared to a loss before taxes of $5.4 million in 2008. These results reflect the revenue recognized from the upfront and milestone payments received from Abbott in 2009 offset by the ongoing investment in the clinical program for lubiprostone and SPI-017 and the ongoing preclinical programs for other prostone-based compounds.

(In thousands)	Americas	Europe	Asia	Intercompany Eliminations	Consolidated
Year Ended December 31, 2009					
Total revenues	$ 57,887	$ —	$ 10,431	$ (967)	$ 67,351
Income (loss) before taxes	11,485	(3,447)	(4,507)	—	3,531
Identifiable assets	134,714	864	11,294	(1,901)	144,971
Year Ended December 31, 2008					
Total revenues	$ 112,123	$ —	$ 840	$ (840)	$ 112,123
Income (loss) before taxes	42,036	(3,481)	(5,441)	—	33,114
Identifiable assets	146,074	568	4,469	(317)	150,794
Year Ended December 31, 2007					
Total revenues	$ 91,891	$ —	$ 840	$ (840)	$ 91,891
Income (loss) before taxes	24,227	(872)	(2,332)	—	21,023
Identifiable assets	105,772	2,381	1,987	(113)	110,027

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 upfront payments, milestone and royalty payments and research and development expense reimbursements received from Takeda, Abbott and other parties, private placements of equity securities and our initial public offering.

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

	Year Ended December 31,	
(In thousands)	2009	2008
Cash and cash equivalents	$ 26,714	$ 62,562
Investments, current	72,434	42,750
Investments, non-current	19,167	16,222
Total	$ 118,315	$ 121,534

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, 2009, our short-term investments consisted of corporate bonds, U.S. government securities, U.S. Treasury notes and bills, municipal securities, certificates of deposits and money market funds which have short-term maturities of one year or less. Our non-current investments consisted of corporate bonds, U.S. government securities, investments in ARS, municipal securities and certificates of deposits. Pursuant to a settlement rights agreement from our ARS broker, we can require the broker 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 June 30, 2010.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2009, 2008 and 2007:

	Year Ended December 31,		
(In thousands)	**2009**	**2008**	**2007**
Cash provided by (used in):			
Operating activities	$ (800)	$ 37,192	$ 5,649
Investing activities	(35,455)	(1,520)	(33,784)
Financing activities	19	878	31,341
Effect of exchange rates	388	453	(128)
Net increase (decrease) in cash and cash equivalents	$ (35,848)	$ 37,003	$ 3,078

Year ended December 31, 2009

Net cash used in operating activities was $800,000 for the year ended December 31, 2009. This reflected a net loss of $760,000, which included a decrease in deferred revenue of $4.6 million and in accrued expenses of $3.3 million, offset by a decrease in unbilled revenue of $3.7 million, an increase in accounts payable of $1.7 million and changes in other operating assets and liabilities.

Net cash used in investing activities of $35.5 million for the year ended December 31, 2009 primarily reflected net purchases of investments and the Rescula license, offset in part by proceeds from the sales and maturities of investments.

Net cash provided by financing activities of $19,000 for the year ended December 31, 2009 resulted from the proceeds received under our employee stock purchase plan.

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 related to the prepayments received from Takeda towards research and development expense reimbursement and $3.9 million of additional deferral of revenue due to a change in the estimated development period of Amitiza for OBD.

Net cash used in investing activities of $1.5 million for the year ended December 31, 2008 reflects purchases of investments less sales and maturities of investments.

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 that 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 U.S. 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.

Commitments and Contingencies

As of December 31, 2009, our principal outstanding contractual obligations related to our office leases in the U.S., England and Japan. The following table summarizes these significant contractual obligations at December 31 for the indicated year:

(In thousands)		
2010	$	1,395
2011		1,068
2012		966
2013		994
2014		1,023
2015 and thereafter		2,275
Total minimum lease payments	$	7,721

The above table does not include:

- Contingent milestone and royalty obligations under our license agreement with SAG 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 3.2% of net sales of products covered by patents licensed to us by SAG.
- Our share of research and development costs for Amitiza for the treatment of OBD, which will not be reimbursed by Takeda. We share equally with Takeda research and development expenses in excess of $50.0 million.
- Expenses under agreements with CRO's 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, 2009, our current commitments to CRO's will be $9.4 million during 2010 and 2011.

Off-Balance Sheet Arrangements

As of December 31, 2009, we did not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4) of Regulation S-K under the Securities Act of 1933, as amended.

Funding Requirements

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

- fund our share of the ongoing development program of Amitiza in the U.S.;
- fund development and regulatory efforts in Europe and Asia for lubiprostone;
- fund development and regulatory activities for Rescula in the U.S. and Canada;
- fund research and development activities for other prostone compounds, including cobiprostone and SPI-017;
- fund the expansion of our commercialization activities in the U.S. and the initiation of commercialization efforts in non-U.S. markets;
- fund capital expenditures to support the growth of our business; and
- fund the purchase of shares of our 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 preclinical and clinical 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 and Rescula;
- the future expenditures we may incur to increase revenue from Amitiza or in our disputes with Takeda;
- 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. At December 31, 2009, we have sufficient liquidity for the next 12 months.

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, the results of our 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.

Accounting Pronouncements

Recent accounting pronouncements applicable to our financial statements are described in Note 2 to the accompanying consolidated financial statements.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

Foreign Exchange Risk

We are subject to foreign exchange risk for revenues and expenses denominated in foreign currencies. Foreign currency risk arises from the fluctuation of foreign exchange rates and the degree of volatility of these rates relative to the U.S. dollar. We do not believe that we have any material risk due to foreign currency exchange. We do not currently hedge our foreign currency transactions.

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, 2009.

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, cash equivalents and restricted cash with what we believe to be highly rated financial institutions and invest the excess cash in highly rated investments. As of December 31, 2009 and 2008, 51.2% and 51.1%, respectively, of our cash, cash equivalents, restricted cash and investments was issued or insured by the federal government or government agencies. We have not experienced any losses on these accounts related to amounts in excess of insured limits.

As of December 31, 2009, we had $8.9 million at fair value invested in one non-mortgage related ARS. Pursuant to the $10.0 million settlement rights offered by our ARS broker, we have the right to require the broker to purchase this ARS at par value of $10.0 million at any time during the two-year period beginning June 30, 2010. We recorded the fair value of the ARS settlement right of approximately $1.1 million in other non-current assets in the accompanying consolidated balance sheet.

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, 2009. 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 have concluded that, as of December 31, 2009, 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, 2009 that have materially affected, or are 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, 2009. 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, 2009.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2009 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 Directors
(Principal Executive Officer)

Jan Smilek
Vice President, Finance and Chief Financial Officer
(Principal Financial and 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, 2009, 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 ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the information provided under the heading “Principal Accountant 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-38. 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)

Exhibit Number	Description	Reference
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)
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)

Exhibit Number	Description	Reference
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)
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.	Exhibit 10.43 to the Company's Current Report on Form 10-K (filed March 16, 2009)

Exhibit Number	Description	Reference
10.44*	Exclusive Manufacturing and Supply Agreement, dated February 23, 2009, between Sucampo Pharma, Ltd and R-Tech Ueno, Ltd.	Exhibit 10.44 to the Company's Current Report on Form 10-K (filed March 16, 2009)
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)
10.48*	Form of Nonstatutory Stock Option Agreement for Non-Employee Directors	Exhibit 10.1 to the Company's Current Report on Form 10-Q (filed November 6, 2009)
21	Subsidiaries of the Company	Exhibit 21 to the Company's Current Report on Form 10-K (filed March 16, 2009)
23.1	Consent of PricewaterhouseCoopers LLP, 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
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.

March 15, 2010

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
(Principal Executive Officer)

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 15, 2010
/s/ JAN SMILEK Jan Smilek	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2010
/s/ WILLIAM L. ASHTON William L. Ashton	Director	March 15, 2010
/s/ ANTHONY C. CELESTE Anthony C. Celeste	Director	March 15, 2010
/s/ GAYLE R. DOLECEK Gayle R. Dolecek Ph.D.	Director	March 15, 2010
/s/ ANDREW J. FERRARA Andrew J. Ferrara	Director	March 15, 2010
/s/ SACHIKO KUNO Sachiko Kuno Ph.D.	Director	March 15, 2010
/s/ TIMOTHY I. MAUDLIN Timothy I. Maudlin	Director	March 15, 2010

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 index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Sucampo Pharmaceuticals, Inc. and its subsidiaries at December 31, 2009 and December 31, 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 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, 2009, 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 were integrated audits in 2009 and 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 audit 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 15, 2010

SUCAMPO PHARMACEUTICALS, INC.
Consolidated Balance Sheets
(In thousands, except share data)

	December 31, 2009	December 31, 2008
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 26,714	$ 62,562
Investments, current	72,434	42,750
Product royalties receivable	11,023	9,725
Unbilled accounts receivable	644	4,373
Accounts receivable, net	512	538
Prepaid and income taxes receivable	—	133
Deferred tax assets, net	315	963
Prepaid expenses and other current assets	3,137	3,981
Total current assets	114,779	125,025
Investments, non-current	19,167	16,222
Property and equipment, net	2,242	2,275
Deferred tax assets, non-current	3,995	4,026
Other assets	4,788	3,246
Total assets	$ 144,971	$ 150,794
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 3,195	$ 1,433
Accrued expenses	6,545	9,764
Deferred revenue, current	10,565	15,599
Income taxes payable	349	—
Total current liabilities	20,654	26,796
Deferred revenue, non-current	8,643	8,061
Other liabilities	2,121	2,147
Total liabilities	31,418	37,004
Commitments (Note 8)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 5,000,000 shares authorized at December 31, 2009 and 2008; no shares issued and outstanding at December 31, 2009 and 2008	—	—
Class A common stock, $0.01 par value; 270,000,000 shares authorized at December 31, 2009 and 2008; 15,655,730 and 15,651,849 shares issued and outstanding at December 31, 2009 and 2008, respectively	156	156
Class B common stock, $0.01 par value; 75,000,000 shares authorized at December 31, 2009 and 2008; 26,191,050 shares issued and outstanding at December 31, 2009 and 2008	262	262
Additional paid-in capital	98,636	98,243
Accumulated other comprehensive income	484	354
Retained earnings	14,015	14,775
Total stockholders' equity	113,553	113,790
Total liabilities and stockholders' equity	$ 144,971	$ 150,794

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

SUCAMPO PHARMACEUTICALS, INC.
Consolidated Statements of Operations and Comprehensive Income (Loss)
(In thousands, except per share data)

	Year Ended December 31,		
	2009	**2008**	**2007**
Revenues:			
Research and development revenue	$ 23,957	$ 72,293	$ 59,379
Product royalty revenue	38,250	34,438	27,536
Co-promotion revenue	4,541	4,826	4,411
Contract and collaboration revenue	603	566	565
Total revenues	67,351	112,123	91,891
Operating expenses:			
Research and development	32,904	46,181	31,697
General and administrative	14,504	14,400	21,423
Selling and marketing	10,030	10,895	13,474
Milestone royalties — related parties	875	3,531	2,000
Product royalties — related parties	6,693	6,045	4,890
Total operating expenses	65,006	81,052	73,484
Income from operations	2,345	31,071	18,407
Non-operating income (expense):			
Interest income	957	2,442	2,465
Other income (expense), net	229	(399)	151
Total non-operating income, net	1,186	2,043	2,616
Income before income taxes	3,531	33,114	21,023
Income tax provision	(4,291)	(8,163)	(7,833)
Net income (loss)	$ (760)	$ 24,951	$ 13,190
Net income (loss) per share:			
Basic net income (loss) per share	$ (0.02)	$ 0.60	$ 0.35
Diluted net income (loss) per share	$ (0.02)	$ 0.59	$ 0.35
Weighted average common shares outstanding — basic	41,844	41,787	37,778
Weighted average common shares outstanding — diluted	41,844	41,973	38,226
Comprehensive income (loss):			
Net income (loss)	$ (760)	$ 24,951	$ 13,190
Other comprehensive income gain (loss):			
Unrealized gain (loss) on investments, net of tax effect	(55)	79	—
Foreign currency translation	185	668	(99)
Comprehensive income (loss)	$ (630)	$ 25,698	$ 13,091

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 Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
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 the initial public offering	—	—	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	—	—	—
Employee stock option expense	—	—	401,133	4	—	—	6,678	—	—	6,682
Foreign currency translation	—	—	—	—	—	—	—	(99)	—	(99)
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
Employee stock option expense	—	—	—	—	—	—	374	—	—	374
Stock issued under employee stock purchase plan	—	—	3,881	—	—	—	19	—	—	19
Foreign currency translation	—	—	—	—	—	—	—	185	—	185
Unrealized loss on investments, net of tax effect	—	—	—	—	—	—	—	(55)	—	(55)
Net loss	—	—	—	—	—	—	—	—	(760)	(760)
Balance at December 31, 2009	—	$ —	15,655,730	$ 156	26,191,050	$ 262	$ 98,636	$ 484	$ 14,015	$ 113,553

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,		
	2009	**2008**	**2007**
Cash flows from operating activities:			
Net income (loss)	$ (760)	$ 24,951	$ 13,190
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	758	450	251
Loss on disposal of property and equipment	—	—	63
Deferred tax provision (benefit)	715	(4,401)	4,262
Stock-based compensation	374	686	6,682
Amortization of premiums on investments	1,415	—	—
Unrealized (gain) loss on trading securities	(2,092)	3,178	—
Unrealized (gain) loss on settlement rights on auction rate securities	1,732	(2,818)	—
Changes in operating assets and liabilities:			
Accounts receivable	32	1,016	(23)
Unbilled accounts receivable	3,729	1,510	(5,883)
Product royalties receivable	(1,298)	(1,058)	(6,638)
Prepaid and income taxes receivable and payable, net	483	1,789	431
Accounts payable	1,733	(2,018)	924
Accrued expenses	(3,255)	1,074	3,341
Deferred revenue	(4,564)	13,972	(11,028)
Other assets and liabilities, net	198	(1,139)	77
Net cash provided by (used in) operating activities	$ (800)	$ 37,192	$ 5,649
Cash flows from investing activities:			
Purchases of investments	(150,712)	(116,679)	(88,647)
Proceeds from the sales of investments	9,504	46,610	57,094
Maturities of investments	109,163	69,000	—
Purchases of property and equipment	(495)	(451)	(2,231)
Purchases of intangible assets	(2,915)	—	—
Net cash used in investing activities	(35,455)	(1,520)	(33,784)
Cash flows from financing activities:			
Issuance of common stock, net of offering costs	—	—	31,341
Proceeds from exercise of stock options	—	870	—
Proceeds from employee stock purchase plan	19	8	—
Net cash provided by financing activities	19	878	31,341
Effect of exchange rates on cash and cash equivalents	388	453	(128)
Net increase (decrease) in cash and cash equivalents	(35,848)	37,003	3,078
Cash and cash equivalents at beginning of period	62,562	25,559	22,481
Cash and cash equivalents at end of period	$ 26,714	$ 62,562	$ 25,559
Supplemental cash flow disclosures:			
Tax refunds received	$ —	$ 1,957	$ 1,361
Tax payments made	$ 1,069	$ 11,370	$ 4,500
Supplemental disclosure of non-cash investing and financing activities:			
Purchase of intangible assets included in accrued expenses	$ 500	$ —	$ —

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

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements

1. Business Organization and Basis of Presentation

Description of the Business

Sucampo Pharmaceuticals, Inc., or the Company, is 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. The Company is focused on developing prostones for the treatment of gastrointestinal, respiratory, vascular and central nervous system diseases and other disorders for which there are unmet or underserved medical needs and significant commercial potential.

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, or CIC in adults of both genders and all ages. In April 2008, the Company received a second marketing approval from the FDA for Amitiza to treat irritable bowel syndrome with constipation, or IBS-C in adult women. Amitiza is being marketed and developed in the U.S. for gastrointestinal indications under a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda. The Company is primarily responsible for development activities under the agreement. The Company and Takeda initiated commercial sales of Amitiza in the U.S. for the treatment of CIC in April 2006 and for the treatment of IBS-C in May 2008 and they are currently developing Amitiza for the treatment of opioid-induced bowel dysfunction, or OBD.

The Company is disappointed with the level of U.S. sales of Amitiza being generated by Takeda and other failures of performance by Takeda under the agreements. In April 2009, the Company sent Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. a notice of material breach. The notice stated that Takeda materially breached its agreement, without limitation, by its continuing failure to exercise its best efforts to commercialize Amitiza and maximize net sales revenue, and its ongoing refusal to collaborate and provide the Company with information to which the Company is entitled under the agreement. The Company subsequently sent a letter that advised Takeda that it had failed to cure said breaches within the 90 day cure period provided under the agreement. Since then, the Company has spent significant resources in the dispute with Takeda. The Company also attempted to conduct a review of Takeda's performance but Takeda refused to provide the Company with certain information necessary to complete that review.

On March 12, 2010, the Company submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between the Company and Takeda Pharmaceuticals Company Limited dated October 29, 2004. In addition to the claims set forth in the notice of material breach, the Company also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only the Company and the Amitiza brand, but also consumers. The Company is seeking all appropriate relief, including production by Takeda of all information to which the Company is entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. The Company may spend additional significant resources and these legal proceedings may require the continuing attention of the Company's senior management.

In February 2009, the Company 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 CIC 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 and the Company is responsible for the development effort and expenses. The Company is preparing a development plan which will be presented to Abbott in 2010. Any disputes over the development plan are to be resolved under the terms of the agreement. 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 the Company for distribution in Japan. The Company has retained the right to co-promote lubiprostone in Japan. In August 2009, the Company completed enrollment into the open-label phase 3 safety trial and in October 2009, the Company completed enrollment of the pivotal phase 3 efficacy trial of lubiprostone for CIC in Japan.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

In April 2009, the Company entered into two agreements with R-Tech Ueno Ltd., or R-Tech, a Japanese manufacturing and research and development company, to acquire all patents and other intellectual property rights related to Rescula® (unoprostone isopropyl) in the U.S. and Canada (Note 10). R-Tech is majority owned by the Company's founders and one of the founders serves as the chair of R-Tech's Board of Directors. Although Rescula eye drops were approved by the FDA for the treatment of open-angle glaucoma and ocular hypertension in 2000, Rescula is not currently marketed in the U.S. or Canada. The Company plans to re-launch Rescula in the U.S. for the treatment of open-angle glaucoma and ocular hypertension and to initiate clinical trials of Rescula for the treatment of dry age-related macular degeneration, or dry AMD, in 2010.

In September 2009, the Company withdrew its European MMAs for lubiprostone in multiple countries in the European Union, or E.U. The withdrawal was a strategic decision based upon lubiprostone's projected commercial position in the global market. The Company continues to evaluate the opportunities to obtain an appropriate label in the E.U. consistent with the fact that lubiprostone is the only product approved by the FDA in the U.S. for chronic therapy for either CIC or IBS-C.

In November 2009, the Company announced that Swissmedic, the Swiss Agency for Therapeutic Products, has granted a marketing authorization for lubiprostone for the long-term treatment of adult patients with CIC. This is the first European regulatory approval for the Company. Amitiza is the first prescription medicine to be approved in Switzerland for the long-term treatment of CIC.

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, wound healing, non-alcoholic fatty liver disease, disorders associated with cystic fibrosis and chronic obstructive pulmonary disease. In July 2009, the Company reported top-line results from our phase 2a clinical trial of orally administered cobiprostone for the prevention of gastric ulcers and other gastrointentinal injuries in patients treated with NSAIDs. The Company is designing a phase 2b study to complement the findings of earlier studies and a preclinical study of cobiprostone for use as a treatment for chronic obstructive pulmonary disease, or COPD, and as a potential treatment for wound healing.

- SPI-017 for the treatment of peripheral arterial and vascular disease and central nervous system disorders. In December 2008, the Company commenced a phase 1 clinical trial of the intravenous formulation of SPI-017 for peripheral arterial disease, or PAD, in Japan. This phase 1 program has advanced to the administration of multiple doses at different dose levels to patients, and the Company anticipates having these results in 2010.

- SPI-3608 for the potential treatment for spinal stenosis. SPI-3608 is a novel prostone and will continue to undergo preclinical testing.

Drs. Ryuji Ueno and Sachiko Kuno, together, directly or indirectly, own all of the stock of Sucampo AG, or SAG, an affiliated Swiss-based patent-holding company, and a majority of the stock of R-Tech. Drs. Ueno and Kuno also are controlling stockholders of the Company and are married to each other. Dr. Ueno is the Company's chief executive officer and chairman of the Board of Directors. Dr. Kuno is a member of the Company's Board of Directors, an advisor on international business development and is Chair of the Board of Directors of R-Tech.

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, an entity wholly-owned by our founders, Drs. Ueno and Kuno.

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the U.S. of America, or GAAP. The consolidated financial statements include the accounts of the Company and its three wholly owned subsidiaries. Sucampo Pharma Ltd., based in Tokyo and Osaka, Japan, in which the Company conducts its 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., in which the Company conducts operations in Europe and the rest of the world. All 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.

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.

Current and Non-Current Investments

Current and non-current investments consist primarily of U.S. Treasury bills and notes, U.S. government agencies securities, municipal and corporate bonds, mutual funds and auction rate securities, or ARS. The Company classifies its investments into current and non-current based on their maturities and management's reasonable expectation to realize these investments in cash. The Company classifies all of its investments, except ARS, as available for sale securities and reports unrealized gains or losses, net of related tax effects, in other comprehensive income. Pursuant to the Company's acceptance of settlement rights for its investments in ARS in October 2008, the Company classifies its investments in ARS as trading securities and records gains or losses resulting from the changes in fair values of its ARS and related settlement rights in other income (expense), net. The fair value of the settlement rights related to ARS is recorded in non-current other assets. The fair value of the settlement rights 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 the broker 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, cash equivalents and restricted cash with highly rated financial institutions and invests its excess cash in highly rated investments. As of December 31, 2009 and 2008, approximately $60.7 million, or 51.2%, and $62.2 million, or 51.1%, respectively, of the Company's cash, cash equivalents, restricted cash and investments was issued or insured by the federal government or government agencies. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

The settlement rights between the Company and UBS AG, or the ARS Broker, obligate the ARS Broker to purchase the remaining ARS at a par value of $10.0 million during a two-year period beginning June 30, 2010 if the Company exercises its related settlement rights. The Company does not anticipate needing to sell the remaining ARS before June 30, 2010.

The Company's products and product candidates under development require approval from the FDA or other international regulatory agencies prior to commercial sales. For those product candidates or indications 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 products, Amitiza and Rescula, compete 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 or timely 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 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 and Rescula, research and development efforts to develop new products or indications, 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 its existing cash and investments as well as with product royalty revenue and cash received from milestones and other revenue related to its joint collaboration, license and supply agreements.

Revenues from one unrelated party, Takeda, accounted for 85%, 100% and 100%, of the Company's total revenues for the years ended December 31, 2009, 2008 and 2007, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 96% and 97% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at December 31, 2009 and 2008, respectively. Revenues from another unrelated party, Abbott, accounted for 14% of the Company's total revenues for the year ended December 31, 2009. There was no corresponding revenue for 2008 and 2007. The Company depends significantly upon the collaborations with Takeda and Abbott and its activities may be impacted if these relationships are disrupted (Note 11).

The Company has an exclusive supply arrangement with R-Tech 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 10).

The Company has previously entered into a restated license agreement with Sucampo AG, or SAG, to grant the Company a royalty-bearing, exclusive, worldwide license to develop prostone compounds, including Amitiza. 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 10).

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 expenses, approximate their fair values based on their short maturities, independent valuations or internal assessments.

Accounts Receivable and Unbilled Accounts Receivable

Accounts receivable represent mainly amounts due under the joint collaboration and licensing agreement with Takeda and the license, commercialization and supply agreement with Abbott (Note 11). 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 recorded an allowance for doubtful accounts at December 31, 2009 of approximately $75,000 related to refundable deposits from its clinical investigators. No allowance was recorded in 2008.

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, 2009, 2008 or 2007 because there have been no indicators of impairment during those years.

Revenue Recognition

The Company's revenues are derived primarily from collaboration and license agreements and include upfront payments, development milestone payments, reimbursements of development and co-promotion costs and product royalties.

The Company evaluated the multiple deliverables within the collaboration and license agreements in accordance with the guidance of multiple deliverables to determine whether the delivered elements that are the obligation of the Company have value to other parties to the agreement 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 and Abbott agreements, including the related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 11.

The Company applies a time-based model of revenue recognition for cash flows associated with research and development deliverables under the Takeda collaboration and license agreement. 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, such as development milestones, revenue is recognized to the extent the accumulated service time 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. In cases where milestone payments are received after the completion of the associated development period, the Company recognizes revenue upon completion of the performance obligation. Revenue is limited to amounts that are nonrefundable and that the other party to the agreement is contractually obligated to pay to the Company. The Company recognizes reimbursable research and development costs under the Takeda agreement as research and development revenue using a 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 can be reasonably determined.

The Company applies a proportional-performance model using the percentage-of-completion method of revenue recognition for cash flows associated with research and development deliverables under the Abbott license, commercialization and supply agreement. Since the Company has previous research and development experience and the expected cost to complete the development can be reasonably estimated, the Company believes a proportional-performance methodology of revenue recognition is appropriate. Under this method, revenue in any period is recognized as a percentage of the total actual cost expended relative to the total estimated costs required to satisfy the performance obligations under the arrangement related to the development. Revenue recognized is limited to the amounts that are non-refundable and that the other party to the agreement is contractually obligated to pay to the Company. A change in the period of time expected to complete the deliverable is accounted for as a change in estimate on a prospective basis. Research and development costs are not reimbursable under the Abbott agreement.

Under the Takeda agreement, royalties are based on net 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. Under the Abbott agreement, should Amitiza be commercialized in Japan, the Company will purchase and assume title to inventories of Amitiza and recognize revenues from the sales of such product when earned.

The Takeda 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, which the Company recognizes as revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

The Company considers its participation in the joint committees under the collaboration and license agreements as separate deliverables under the contracts and recognizes the fair value of such participation as collaboration revenue over the period of the participation per the terms of the contracts.

The Company has determined that it is acting as a principal under both the Takeda and Abbott agreements and, as such, records revenue on a gross basis in the consolidated statements of operations and comprehensive income (loss).

Contract Revenue

Contract revenue relates to development and consulting activities with R-Tech and is accounted for under the time-based model.

Deferred Revenue

Deferred revenue represents payments received or receivable for licensing fees, option fees, consulting, research and development contracts and related cost sharing and supply agreements, mainly with Takeda, Abbott and R-Tech, which 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, 2009 and 2008, deferred revenue that relates to these prepayments was approximately $136,000 and $10.9 million, respectively. At December 31, 2009 and 2008, total deferred revenue was approximately $19.2 million and $23.7 million, respectively.

Total deferred revenue consists of the following as of:

	December 31,	
(In thousands)	**2009**	**2008**
Deferred revenue, current	$ 10,565	$ 15,599
Deferred revenue, non-current	8,643	8,061
	$ 19,208	$ 23,660
Deferred revenue to related parties, included in total deferred revenue:		
Deferred revenue to related parties, current	431	419
Deferred revenue to related parties, non-current	6,256	6,444
Total	$ 6,687	$ 6,863

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, or CROs, are accrued when it is considered 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.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

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

Milestone royalties — related parties expenses 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 when the related milestones become probable. For the years ended December 31, 2009 and 2008, the Company expensed $875,000 and $3.5 million in milestone royalties — related parties, respectively.

Product Royalties — Related Parties

Product royalties — related parties expenses 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, 2009 and 2008, the Company expensed approximately $6.7 million and $6.0 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 accruals 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 contract service organizations. In addition, the Company makes estimates of costs incurred to date but not yet invoiced, in relation to external CRO's 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 accounting guidance for share-based awards that 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. This guidance 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'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.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

The assumptions used to estimate the fair value of stock options granted for the three years ended December 31, 2009 were as follows:

	Year Ended December 31,		
	2009	**2008**	**2007**
Expected volatility	47% - 55%	53% - 56%	39% - 60%
Risk-free interest rate	2.67% - 3.11%	2.78% - 3.45%	2.99% - 3.59%
Expected term (in years)	6.00 - 7.00	6.25	3.25 - 6.25
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 to calculate its expected term of share-based awards. 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 2009 has been reduced for estimated forfeitures as such expense is based upon awards expected to ultimately vest. Accounting's guidance on share-based payments 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, 2009, 2008 and 2007, the estimated forfeiture rate ranged from 8.0% to 17.0%.

Employee stock-based compensation expense recorded in the Company's consolidated statements of operations and comprehensive income (loss) for the three years ended December 31, 2009 was as follows:

	Year Ended December 31,		
(In thousands)	**2009**	**2008**	**2007**
Research and development expense	$ 96	$ 245	$ 190
General and administrative expense	193	199	405
Selling and marketing expense	85	242	333
Founders' stock-based awards (Note 9)	—	—	6,112
Cumulative out-of-period adjustment	—	—	(358)
Total	$ 374	$ 686	$ 6,682
Employee stock-based compensation expense per basic share of common stock	$ 0.01	$ 0.02	$ 0.18
Employee stock-based compensation expense per diluted share of common stock	$ 0.01	$ 0.02	$ 0.17

Income Taxes

The Company accounts for income taxes under the asset and liability method in accordance with the FASB's guidance for accounting for income taxes 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.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

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 $4.3 million and $5.0 million as of December 31, 2009 and December 31, 2008, 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 intercompany transactions, 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

The Company applies the accounting guidance for uncertain tax positions that 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, the Company recognizes a tax benefit measured at the largest amount of the tax benefit that, in its judgment, is more than 50 percent likely to be realized upon settlement.

The Company has recorded non-current income tax liability of approximately $765,000 and $517,000 including interest for uncertain tax positions as of December 31, 2009 and 2008, respectively. 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 is reflected in other liabilities in the accompanying consolidated balance sheets. The liability for uncertain tax positions as of December 31, 2009 and 2008 mainly pertained 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 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 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

Comprehensive income consists of 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 (loss).

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.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

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 U.S., 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 study, the Joint Commercialization Committee approved an increase in funding for patient recruitment. The Company concluded at that time 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.

Additionally, the Company further revised the estimated timeline and costs associated with a separate study and recorded a change in estimate during 2009 related to the amount of research and development revenues.

These changes in estimate had the following impact on revenues, net income (loss) and basic and diluted net income (loss) per share:

	Year Ended December 31,	
(In thousands, except per share data)	**2009**	**2008**
Decrease in revenue and income before income taxes	$(6,543)	$(4,785)
Impact on basic net income (loss) per share	(0.09)	(0.07)
Impact on diluted net income (loss) per share	(0.09)	(0.07)

Reclassifications

Certain amounts in the prior year financial statements have been reclassified to conform to the current year presentation. The Company reclassified money market funds of $51.0 million from current investments to cash and cash equivalents as of December 31, 2008. The Company has adjusted the cash flow statement for the year-ended December 31, 2008 accordingly.

Recent Accounting Pronouncements

In December 2007, the FASB issued authoritative guidance for collaborative arrangements which prohibits the equity method of accounting for collaboration agreements unless a legal entity exists. According to this guidance, payments between the collaborative partners are 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 is effective for periods that begin after December 15, 2008 and applies to arrangements in existence as of the effective date. The effect of the new consensus is accounted for as a change in accounting principle through retrospective application. The Company adopted the provisions of this guidance effective January 1, 2009 and such adoption did not have a material impact on the consolidated financial statements.

In February 2008, the FASB issued authoritative guidance which delayed the effective date of the guidance for fair value measurements for one year for all nonfinancial assets and liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. This statement partially deferred the effective date to fiscal years beginning after November 15, 2008. The Company adopted the provisions of this guidance effective January 1, 2009 and such adoption did not have a material impact on the consolidated financial statements.

In April 2009, the FASB issued authoritative guidance which affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. This guidance addresses estimating fair value when the volume and level of market activity for an asset or liability have significantly decreased and determining whether a transaction was orderly. It became effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. This guidance applies to all fair value measurements when appropriate. The Company adopted the guidance effective April 1, 2009 and such adoption did not have a material impact on the consolidated financial statements.

In June 2009, the FASB issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities, or VIEs. The elimination of the concept of qualifying special-purpose entities, or QSPEs, removes the exception from applying the consolidation guidance within this amendment. This amendment requires an enterprise to perform a qualitative analysis when determining whether or not it must consolidate a VIE. The amendment also requires an enterprise to continuously reassess whether it must consolidate a VIE. Additionally, the amendment requires enhanced disclosures about an enterprise's involvement with VIEs and any significant change in risk exposure due to that involvement, as well as how its involvement with VIEs impacts the enterprise's financial statements. Finally, an enterprise will be required to disclose significant judgments and assumptions used to determine whether or not to consolidate a VIE. This amendment is effective for financial statements issued for fiscal years beginning after November 15, 2009. The Company is continuing to evaluate the impact that this amendment would have on its financial condition and results of operation upon adoption.

In June 2009, the FASB issued the FASB Accounting Standards Codification, or Codification. The Codification has become the single source for all authoritative GAAP recognized by the FASB to be applied for financial statements issued for periods ending after September 15, 2009. The Codification does not change GAAP and has no effect on these consolidated financial statements, other than to modify certain disclosures regarding the accounting policies followed by the Company.

In September 2009, the FASB issued an amendment to the authoritative guidance which addresses how revenues should be allocated among products and services in a singular sales arrangement. The guidance establishes a hierarchy for determining the selling price of each product or service, with vendor-specific objective evidence, or VSOE, at the highest level, third-party evidence of VSOE at the intermediate level, and management's best estimate at the lowest level. It replaces "fair value" with "selling price" in revenue allocation guidance. It also significantly expands the disclosure requirements for multiple-deliverable revenue arrangements. This guidance will be effective prospectively for agreements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is continuing to evaluate the impact that this amendment would have on its financial condition and results of operation upon adoption.

In January 2010, the FASB issued authoritative guidance on improving the disclosures about fair value measurements. This statement requires additional disclosures about fair value measurements including transfers in and out of Levels 1 and 2 and a higher level of disaggregation for the different types of financial instruments. For the reconciliation of Level 3 fair value measurements, information about purchases, sales, issuances and settlements should be presented separately. This statement is effective for annual and interim reporting periods beginning after December 15, 2009 for most of the new disclosures and for periods beginning after December 15, 2010 for the new Level 3 disclosures. The Company is continuing to evaluate the impact that this guidance would have on its financial condition and results of operation upon adoption.

3. Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing net income (loss) 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. Diluted net loss per share, when applicable, is computed by dividing net loss by the weighted average common shares outstanding without the impact of potential dilutive common shares outstanding because they would have an anti-dilutive impact on diluted net loss per share.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

The computation of net income (loss) per share for the three years ended December 31, 2009, is shown below:

	December 31,		
(in thousands, except per share data)	**2009**	**2008**	**2007**
Basic net income (loss) per share:			
Net income (loss)	$ (760)	$ 24,951	$ 13,190
Weighted average class A and B common shares outstanding	41,844	41,787	37,778
Basic net income (loss) per share	$ (0.02)	$ 0.60	$ 0.35
Diluted net income (loss) per share:			
Net income (loss)	$ (760)	$ 24,951	$ 13,190
Weighted average class A and B common shares outstanding for diluted net income per share	41,844	41,787	37,778
Assumed exercise of stock options under the treasury stock method	—	186	448
	41,844	41,973	38,226
Diluted net income (loss) per share	$ (0.02)	$ 0.59	$ 0.35

For the years listed above, the potentially dilutive securities used in the calculations of diluted net income per share as of December 31, 2009, 2008 and 2007 are as follows:

	December 31,		
(In thousands)	**2009**	**2008**	**2007**
Employee stock options	—	5	908
Non-employee stock options	—	470	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, 2009, 2008 and 2007:

	December 31,		
(In thousands)	**2009**	**2008**	**2007**
Employee stock options	912	772	11
Non-employee stock options	450	—	—

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

4. Current and Non-Current Investments

At December 31, 2009 and 2008, current and non-current investments consisted of the following securities:

	December 31, 2009			
(In thousands)	**Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Current:				
U.S. Treasury bills and notes	$ 2,999	$ —	$ —	$ 2,999
U.S. commercial paper	1,000	—	—	1,000
U.S. government securities	26,020	16	(6)	26,030
Municipal securities	25,339	4	(7)	25,336
Certificates of deposits	1,250	—	(1)	1,249
Corporate bonds	15,782	38	—	15,820
Total	$ 72,390	$ 58	$ (14)	$ 72,434
Non-current:				
U.S. government securities	$ 6,065	$ 7	$ (12)	$ 6,060
Municipal securities	1,802	4	—	1,806
Certificates of deposits	500	—	(2)	498
Corporate bonds	1,891	1	(3)	1,889
Auction rate securities	10,000	—	(1,086)	8,914
Total	$ 20,258	$ 12	$ (1,103)	$ 19,167

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

The Company records unrealized gains and losses resulting from changes in the fair value of the auction rate securities and related settlement rights within other income (loss).

The Company's assets measured at fair value on a recurring basis, which are subject to the fair value disclosure requirements, are as follows:

	Fair Value Measurements at Reporting Date Using			
December 31, 2009 (In thousands)	**Quoted Prices in Active Markets for identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
U.S. Treasury bills and notes	$ 2,999	$ —	$ —	$ 2,999
U.S. government securities	32,090	—	—	32,090
U.S. commercial paper	—	1,000	—	1,000
Corporate bonds	17,709	—	—	17,709
Municipal securities	27,142	—	—	27,142
Auction rate securities	—	—	8,914	8,914
Settlement rights for auction rate securities*	—	—	1,086	1,086
Certificates of deposits	—	1,747	—	1,747
Total assets measured at fair value	$ 79,940	$ 2,747	$ 10,000	$ 92,687

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

December 31, 2008 (In thousands)	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
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
Total assets measured at fair value	$ 42,750	$ —	$ 19,040	$ 61,790

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

The following table presents the Company's assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in the fair value measurement statement during the year ended December 31, 2009:

(In thousands)	Auction Rate Securities and Related Settlement Rights
Balance at December 31, 2008	$ 19,040
Total net unrealized gains included in earnings	360
Redemptions	(9,400)
Balance at December 31, 2009	$ 10,000

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. 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 (loss) for the year ended December 31, 2008.

5. Property and Equipment

Property and equipment consists of the following as of:

(In thousands)	December 31, 2009	2008
Computer and office machines	$ 1,858	$ 1,494
Furniture and fixtures	348	348
Leasehold improvements	1,384	1,282
Total cost	3,590	3,124
Less: accumulated depreciation	(1,348)	(849)
Total	$ 2,242	$ 2,275

Depreciation expense for the years ended December 31, 2009, 2008 and 2007 was $530,000, $450,000 and $251,000, respectively.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

The leasehold improvements as of December 31, 2009 are related to tenant improvements to the Company's headquarters in Bethesda, Maryland, to which the Company relocated in July 2007.

6. Intangible Assets

In April 2009, we entered into two agreements with R-Tech Ueno Ltd., or R-Tech, a Japanese manufacturing and research and development company that is majority owned by our founders, to acquire all patents and other intellectual property rights related to Rescula® (unoprostone isopropyl) in the U.S. and Canada. Although Rescula eye drops have been approved by the FDA for the treatment of open-angle glaucoma and ocular hypertension since 2000, Rescula is not currently marketed in the U.S. or Canada. We plan to re-launch Rescula in the U.S. for the treatment of open-angle glaucoma and ocular hypertension and to initiate clinical trials of Rescula for the treatment of dry age-related macular degeneration, or dry AMD, in 2010.

Under the terms of the R-Tech agreements, we made an upfront payment of $3.0 million and may be required to pay up to $5.5 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of $500,000 is payable upon the re-launch of Rescula for the treatment of glaucoma which is considered as being probable; therefore, this amount is recorded as part of the initial cost of the acquired assets. We allocated the acquisition cost between an intangible asset of $3.4 million and a non-current prepaid inventory of $85,000 as of December 31, 2009, both of which are reflected in other non-current assets in the accompanying consolidated balance sheet. We are amortizing the $3.4 million over the 10-year life of the license agreement, which we believe approximates the useful life of the underlying rights and data. Amortization expense was $228,000 for the year ended December 31, 2009. The annual amortization expense will be approximately $342,000 through April 2019.

7. Accrued Expenses

Accrued expenses consist of the following as of:

	December 31,	
(In thousands)	**2009**	**2008**
Research and development costs	$ 3,624	$ 7,086
Employee compensation	879	1,748
Selling and marketing costs	731	346
Other accrued expenses	1,311	584
Total	$ 6,545	$ 9,764

8. Other Liabilities

Other liabilities consist of the following as of:

	December 31,	
(In thousands)	**2009**	**2008**
Deferred leasehold incentive	$ 844	$ 962
Deferred rent expense	508	468
Lease loss liability	—	176
Other liabilities	769	541
Total	$ 2,121	$ 2,147

In July 2007, the Company relocated to new offices (Note 9). 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.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

9. Commitments

Operating Leases

The Company leases office space in the U.S., 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 $60,000, are as follows as of December 31, 2009:

(In thousands)		
2010	$	1,395
2011		1,068
2012		966
2013		994
2014		1,023
2015 and thereafter		2,275
Total minimum lease payments	$	7,721

Rent expense for all operating leases was $1.3 million, $1.2 million and $1.1 million for the years ended December 31, 2009, 2008 and 2007, respectively.

The Company is party to a non-cancelable operating lease agreement for office space in the U.S., which expired in November 2009. The Company vacated these premises in July 2007 to relocate to its new leased facility. According to FASB's guidance for accounting for costs associated with exit or disposal activities, 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 the provisions of this guidance, 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, 2009 were approximately $9.4 million.

10. 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 U.S. 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).

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

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, 2009 and 2008, which is recorded as contract revenue. During the years ended December 31, 2009, 2008 and 2007, the Company purchased from R-Tech $205,000, $58,000 and $1.6 million, respectively, of clinical supplies under the terms of this agreement. Commercial supplies of Amitiza in the U.S. are subject to a three-party agreement among the Company, R-Tech and Takeda and are not reflected in the Company's financial statements (Note 11).

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 yet been approved within Europe, the $2.0 million has been recorded as non-current deferred revenue as of December 31, 2009 and 2008. During the year ended December 31, 2007, the Company purchased from R-Tech $336,000 of clinical supplies under the terms of this agreement. There were no such clinical supply purchases in 2009 or 2008. During the year ended December 31, 2009, Sucampo Europe purchased $692,000 of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch. Subsequent to the purchase, the Company withdrew its European MAA and recorded a write down of $658,000 to reflect the fair value of this inventory.

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. The Company had no clinical supply purchases from a back-up supplier in 2009, 2008 or 2007.

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, 2009, 2008 and 2007, the Company purchased from R-Tech $1.1 million, $1.9 million and $1.8 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 upfront 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.

On April 23, 2009, the Company entered into two agreements with R-Tech to acquire rights to Rescula in the U.S. and Canada. Under the terms of the agreements, the Company holds the exclusive rights to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension and any new indication developed by the Company, and has the right of first refusal to commercialize in the U.S. and Canada any additional indications for which unoprostone isopropyl is developed by R-Tech. The Company is solely responsible for the development, as well as regulatory and commercialization activities and expenses, for Rescula in the U.S. and Canada and R-Tech is exclusively responsible for the supply of Rescula to the Company within the U.S. and Canada. The terms of these agreements are described in Note 6 above.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

The Company recorded the following expenses under all of its agreements with R-Tech:

	Year Ended December 31,		
(In thousands)	**2009**	**2008**	**2007**
Clinical supplies	$ 2,525	$ 1,917	$ 3,380
Other research and development services	100	118	563
	$ 2,625	$ 2,035	$ 3,943

	Year Ended December 31,		
(In thousands)	**2009**	**2008**	**2007**
Deferred revenue, current	$ 431	$ 419	$ 418
Deferred revenue, non-current	6,256	6,444	6,863
	$ 6,687	$ 6,863	$ 7,281

In November 2009, the Company entered into an agent agreement with R-Tech to facilitate an acquisition of possible product rights for R-Tech. No revenue or expenses have been recorded in 2009.

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 February 2009, the Company entered into an addendum to this agreement whereby the patent and know-how royalties Sucampo Japan is obligated to pay to SAG were reduced with respect to sales of lubiprostone in Asia, Australia and New Zealand. 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 SAG, 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 approximately $6.7 million, $6.0 million and $4.9 million in product royalties to SAG during the years ended December 31, 2009, 2008 and 2007, 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 (loss).

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 upfront or milestone payments that are received from sublicensees.

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, or sNDA, for IBS-C 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 IBS-C in adult women and $1.0 million upon the submission of the marketing authorization application, or MAA, for lubiprostone, 24 mcg, for the indication of CIC in adults of both genders and all ages in Europe. During the year ended December 31, 2009, the Company paid SAG $500,000 upon receiving the $10.0 million upfront payment and $375,000 upon receiving a $7.5 million development milestone payment from Abbott upon the initiation of the phase 3 clinical trial for lubiprostone for the treatment of CIC in Japan.

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 (loss).

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 completion of the initial public offering. These awards consisted of a combination of cash and shares of class A common stock with 40% payable in cash and 60% in stock. 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.

The estimated fair value of these awards was determined using the Black-Scholes-Merton Option Pricing Formula resulting in an expense of $9.2 million for the year ended December 31, 2007, of which $3.1 million was paid in cash and $6.1 million was settled by issuance of 401,133 shares of class A common stock.

11. Collaboration and License Agreements

Abbott license and commercialization and supply agreement

In February 2009, the Company entered into an exclusive 15-year license, commercialization and supply agreement with Abbott to develop and commercialize lubiprostone for the treatment of CIC in Japan. Additionally, the agreement grants Abbott the right of first refusal to any additional indications for which lubiprostone is developed in Japan under all relevant patents, know-how and trademarks.

The collaboration efforts under the agreement are governed by two committees consisting of an equal number of representatives from both parties. The joint commercialization and steering committee oversees commercialization-related activities and resolves any conflicts arising from a joint development committee, which oversee the development-related activities in Japan.

The Company is required to fund and complete all the development work including additional clinical studies required to obtain regulatory approval for the treatment of CIC in Japan. The Company owns all the rights covered under the regulatory filings.

Abbott is required to fund and undertake all commercialization efforts including pre-launch and post-launch marketing, promotion and distribution. Abbott is required to maintain the number of sales staff and the estimated level of annual net sales based on the commercialization plan to be developed and approved by the joint commercialization and steering committee described above. The Company has retained the right to co-promote the product in Japan and is responsible for the cost of co-promotion.

Under the terms of the agreement, payments to the Company include a non-refundable upfront payment and non-refundable development and commercial milestone payments based on achieving specified development, regulatory and sales goals. Following marketing authorization and pricing approval, Abbott will purchase the finished product from the Company for distribution in Japan at agreed upon prices. Based on the terms of the agreement, the Company received an upfront payment of $10.0 million upon execution of the agreement in February 2009. In May 2009, the Company achieved the first development milestone when it initiated the phase 3 clinical trial for lubiprostone for the treatment of CIC in Japan and received a $7.5 million milestone payment from Abbott. The Company is recognizing these payments as research and development revenue under a proportional-performance model using the percentage-of-completion method of revenue recognition. There can be no assurances that the Company will receive additional development or commercial milestone payments under this agreement.

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Notes to Consolidated Financial Statements — (Continued)

The following table summarizes the cash streams and related revenue recognized or deferred under the license, commercialization and supply agreement with Abbott for the year ended December 31, 2009:

(In thousands)	Amount Deferred at December 31, 2008	Cash Received for Year Ended December 31, 2009	Revenue Recognized for the Year Ended December 31, 2009	Foreign Currency Effects for the Year Ended December 31, 2009	Amount Deferred at December 31, 2009
Collaboration revenue:					
Up-front payment associated with the Company's obligation to participate in joint committees	$ —	$ 846	$ 38	$ (4)	$ 812
Research and development revenue:					
Up-front payment	$ —	$ 9,154	$ 5,112	$ 51	$ 3,991
Development milestone payment	—	7,500	4,314	(180)	$ 3,366
Total	$ —	$ 16,654	$ 9,426	$ (129)	$ 7,357

Takeda collaboration and license agreement

In October 2004, the Company entered into a 16-year collaboration and license agreement with Takeda to exclusively co-develop, commercialize and sell products that contain lubiprostone for gastroenterology indications in the United States and Canada. On February 1, 2006, the Company entered into a supplemental agreement with Takeda, which supplemented 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. Payments to the Company under these agreements include a non-refundable upfront payment, non-refundable development and commercial milestone payments, reimbursement of certain development and co-promotion costs and product royalties.

The Company has received a total of $150.0 million in upfront and development milestone payments through December 31, 2009 under these agreements. Subject to future development and commercial milestones, the Company is potentially entitled to receive additional development milestone and commercial milestone payments under the collaboration and license agreements with Takeda, although there can be no assurance that the Company will receive any such payments.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

The following table summarizes the cash streams and related revenue recognized or deferred under the collaboration and license agreements with Takeda, which are described in more detail below:

(In thousands)	Cash Received Through December 31, 2009	Revenue Recognized for the Year Ended December 31,				Accounts Receivable for the Year Ended December 31, 2009 (1)	Amount Deferred at December 31, 2009
		Through 2006	2007	2008	2009		
Collaboration revenue:							
Up-front payment associated with the Company's obligation to participate in joint committees	$ 2,375	$ 317	$ 147	$ 147	$ 147	$ —	$ 1,617
Research and development revenue:							
Up-front payment — remainder	$ 17,624	$ 15,647	$ 1,977	$ —	$ —	$ —	$ —
Development milestones	130,000	44,391	35,609	50,000	—	—	—
Reimbursement of research and development expenses	88,847	28,141	21,793	22,293	14,530	644	2,734
Total	$ 236,471	$ 88,179	$ 59,379	$ 72,293	$ 14,530	$ 644	$ 2,734
Product royalty revenue	$ 95,791	$ 6,590	$ 27,536	$ 34,438	$ 38,250	$ 11,023	$ —
Co-promotion revenue	$ 17,657	$ 4,243	$ 4,411	$ 4,826	$ 4,541	$ 364	$ —

(1) 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 upfront 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. During each of the years ended December 31, 2009, 2008 and 2007, the Company recognized approximately $147,000 of this deferred amount as collaboration revenue on the consolidated statements of operations and comprehensive income (loss). The related deferred revenue as of December 31, 2009 and 2008 was approximately $1.6 million and $1.8 million, respectively.

- The Company granted Takeda an exclusive license of lubiprostone to co-develop, commercialize, and sell products for gastroenterology indications in the U.S. 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 upfront 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 $38.3 million, $34.4 million and $27.5 million for the years ended December 31, 2009, 2008 and 2007, respectively. This revenue is recorded as product royalty revenue in the consolidated statements of operations and comprehensive income (loss).

- The Company has provided development work necessary for an NDA submission to the FDA for the treatment of CIC and IBS-C 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 CIC and completed and submitted the supplemental NDA for IBS-C to the FDA in June 2007.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

The Company initially deferred the residual amount of the $20.0 million upfront 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 CIC and IBS-C indications. These deferred amounts were applied towards the unit of accounting that combines the participation in the Joint Development Committee and the development of CIC and IBS-C and was recognized over the performance period of developing the CIC and IBS-C NDA submissions. The Company completed the development of the CIC and IBS-C in June 2007 and filed a sNDA for IBS-C. 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 IBS-C. 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 IBS-C 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 CIC. 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 completed these studies in 2009.

- The Company is obligated to perform studies for the development of an additional indication for OBD. 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 completed and announced mixed results of the two pivotal phase 3 studies in 2009 and continues to conduct an open-label safety study. The results of all three studies are expected to be submitted to the FDA in 2010.

- 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 completed a phase IV study for CIC in 2009.

The Company has assessed these required deliverables to determine which deliverables are considered separate unites 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. During the years ended December 31, 2009, 2008 and 2007, the Company recognized approximately $14.5 million, $22.3 million and $18.3 million related to these three deliverables as research and development revenue in the consolidated statements of operations and comprehensive income (loss), 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 $4.5 million, $4.8 million and $4.3 million of revenues for the years ended December 31, 2009, 2008 and 2007, respectively, reflecting these co-promotion reimbursements, which is recorded as co-promotion revenue in the consolidated statements of operations and comprehensive income (loss).

- 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 and $158,000 of reimbursements of miscellaneous costs for the years ended December 31, 2008 and 2007, respectively. These amounts are recorded as co-promotion revenue in the consolidated statements of operations and comprehensive income. No such amount was recorded for the year ended December 31, 2009.

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 to determine which deliverables are considered separate units of accounting. The Company determined 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.

12. 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.

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 $10.0 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, 2009, 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.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

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, 2009, a total of 7,979,200 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 determined that the amount of the increase in the shares available for issuance under the 2006 Incentive Plan as of January 1, 2008, and 2009 pursuant to the "evergreen" provision, would be zero.

On October 7, 2009, the Board of Directors of the Company adopted a new compensation program under the 2006 Incentive Plan, for its non-employee directors and approved a new form of stock option agreement to be used for future stock option awards to non-employee directors. According to the plan, the independent directors will receive an annual grant of 20,000 stock options on the date of each annual meeting of stockholders. Additionally, the directors received an initial grant of 30,000 stock options upon the adoption of the plan.

A summary of the employee stock option activity for the year ended December 31, 2009 under the Company's 2001 Incentive Plan is presented below.

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2008	455,600	$ 10.34		
Options forfeited	(850)	10.00		
Options expired	(96,050)	10.00		
Options outstanding, December 31, 2009	358,700	10.43	4.20	$ —
Options exercisable, December 31, 2009	358,700	10.43	4.20	$ —

A summary of the employee stock option activity for the year ended December 31, 2009 under the Company's 2006 Incentive Plan is presented below:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2008	275,000	$ 13.86		
Options granted	317,000	5.30		
Options forfeited	(38,950)	13.07		
Options expired	(32,250)	14.12		
Options outstanding, December 31, 2009	520,800	8.70	8.30	$ —
Options exercisable, December 31, 2009	88,000	14.42	6.25	$ —

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Notes to Consolidated Financial Statements — (Continued)

The weighted average grant date fair value of options granted during the years ended December 31, 2009, 2008 and 2007 were $2.73, $5.88 and $7.19, respectively. The total intrinsic value of options exercised during the year ended December 31, 2008 was $95,000. No options were exercised during the year ended December 31, 2009. There was no intrinsic value of options exercised during December 31, 2007. As of December 31, 2009, approximately $1.2 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 2.99 years. When an option is exercised, the Company issues a new share of class A common stock.

The Company granted 510,000 stock options with an exercise price of $5.85 per share to non-employees in August 2005 under the 2001 Incentive Plan. As of December 31, 2009 and 2008, 450,000 options were outstanding and exercisable. These non-employee stock options vested immediately and have a weighted average exercise price per share and remaining contractual life of 5.33 and 5.85 years, respectively, as of both December 31, 2009 and 2008.

Employee Stock Purchase Plan

On June 5, 2006, the Company's Board of Directors approved a 2006 Employee Stock Purchase Plan, or ESPP, and reserved 4,250,000 shares of class A common stock for issuance under the ESPP. As of December 31, 2009, the Board has approved 500,000 shares of class A common stock for the ESPP. The ESPP is non-compensatory and is 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. 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 3,881 and 1,451 shares of common stock were purchased under the ESPP during the years ended December 31, 2009 and 2008, respectively. The Company received $19,450 and $7,926 upon purchase of shares under the ESPP for the years ended December 31, 2009 and 2008, respectively. There were no shares issued under the ESPP during the year ended December 31, 2007.

13. Income Taxes

The provision (benefit) for income taxes consists of the following for the three years ended December 31:

	Year Ended December 31,		
(In thousands)	**2009**	**2008**	**2007**
Current tax provision:			
Federal	$ 2,764	$ 9,903	$ 2,900
State	785	2,661	671
Foreign	27	—	—
Total current tax provision	3,576	12,564	3,571
Deferred provision (benefit):			
Federal	644	(3,450)	3,821
State	71	(951)	441
Total deferred provision (benefit)	715	(4,401)	4,262
Total income tax provision	$ 4,291	$ 8,163	$ 7,833

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

Deferred tax assets, net, consist of the following as of December 31:

(In thousands)	December 31, 2009	2008
Deferred tax assets:		
Foreign net operating loss carryforwards	$ 3,309	$ 5,304
Deferred revenue	5,930	2,999
Allowance for doubtful accounts	30	—
Accrued expenses	2,331	765
Tax benefits on stock options	1,561	1,654
Other	336	212
Gross deferred tax assets	13,497	10,934
Deferred tax liabilities:		
Property and equipment	(642)	(195)
Other	(30)	(51)
Gross deferred tax liabilities	(672)	(246)
Less: valuation allowance	(8,515)	(5,699)
Net deferred tax assets	$ 4,310	$ 4,989

The net deferred tax asset as of December 31, 2009 and 2008 represents the amount the Company believes is more likely than not to be utilized. 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 $8.4 million of valuation allowance on its U.S. deferred tax assets in 2008.

The provision (benefit) for income taxes vary from the income taxes provided based on the federal statutory rate of 34%, 35% and 35% as follows for the three years ended December 31:

(In thousands)	Year Ended December 31, 2009	2008	2007
Federal tax provision	34.0%	35.0%	35.0%
State taxes, net of federal tax benefit	17.4%	5.6%	4.7%
General business credits	-3.9%	-0.8%	-2.6%
Changes in valuation allowance	75.7%	-15.6%	4.2%
Adjustment to net operating loss carryforward	0.0%	0.0%	0.0%
Changes in other tax matters	-2.7%	0.5%	-4.0%
	120.5%	24.7%	37.3%

At December 31, 2009 and 2008, the Company had foreign net operating loss carry forwards, or NOLs, of $10.9 million and $14.4 million, respectively. Approximately $1.9 million of the foreign NOLs begin to expire in December 2015, and $9.0 million of the foreign NOLs do not expire. There were no U.S. general business credits as of December 31, 2009 and 2008.

As of December 31, 2009 and 2008, the Company had a valuation allowance on its deferred tax assets of $8.5 million and $5.7 million, respectively. The increase in the valuation allowance of $2.8 million was due to 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 considers 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 is warranted. The valuation allowance at December 31, 2009 and 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 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 approximately $765,000 and $517,000 including interest for uncertain tax positions as of December 31, 2009 and 2008, respectively. 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, 2009 and 2008 mainly pertains to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes.

A reconciliation of the beginning and ending amount of unrecognized tax benefits, including interest and penalties, is as follows:

	Year Ended December 31,		
	2009	2008	2007
Balance at January 1	$ 517,000	$ —	$ —
Increases for tax positions taken during prior period	83,000	—	—
Increases for tax positions taken during current period	165,000	517,000	—
Balance at December 31	$ 765,000	$ 517,000	$ —

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision. During 2009, the Company recorded $36,000 of interest related to uncertain tax positions. 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 the next 12 months, except for recurring accruals on existing uncertain tax positions. In addition, future changes in the unrecognized tax benefits described above would not have a significant impact on the effective tax rate.

In 2009, the Company was currently under examination by the U.S. tax authorities for the years ended December 31, 2005, 2006 and 2007. In January 2010, the Company received official notice indicating that the examination of tax returns for 2005, 2006 and 2007 has closed and resulted in no change to the reported tax.

14. Segment Reporting

The Company has determined that it has three reportable segments based on the Company's method of internal reporting, which disaggregates business by geographic location. These segments are the Americas, Europe and Asia. The Company evaluates the 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 loans and the provision of research and development services. Following is a summary of financial information by reportable geographic segment.

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

(In thousands)	Americas	Europe	Asia	Intercompany Eliminations	Consolidated
Year Ended December 31, 2009					
Research and development revenue	$ 14,531	$ —	$ 9,426	$ —	$ 23,957
Product royalty revenue	38,250	—	—	—	38,250
Co-promotion revenue	4,541	—	—	—	4,541
Contract and collaboration revenue	565	—	1,005	(967)	603
Total revenues	57,887	—	10,431	(967)	67,351
Research and development expenses	19,829	1,091	12,951	(967)	32,904
Depreciation and amortization	729	11	18	—	758
Other operating expenses	27,390	1,905	2,049	—	31,344
Income (loss) from operations	9,939	(3,007)	(4,587)	—	2,345
Interest income	1,211	—	4	(258)	957
Other non-operating expense, net	335	(440)	76	258	229
Income (loss) before income taxes	$ 11,485	$ (3,447)	$ (4,507)	$ —	$ 3,531
Capital expenditures	$ 3,291	$ 3	$ 116	$ —	$ 3,410
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 and collaboration revenue	566	—	840	(840)	566
Total revenues	112,123	—	840	(840)	112,123
Research and development expenses	39,857	2,136	5,028	(840)	46,181
Depreciation and amortization	437	3	10	—	450
Other operating expenses	31,954	1,360	1,107	—	34,421
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, 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

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

(In thousands)	Americas	Europe	Asia	Intercompany Eliminations	Consolidated
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 and collaboration revenue	565	—	840	(840)	565
Total revenues	91,891	—	840	(840)	91,891
Research and development expenses	29,909	725	1,903	(840)	31,697
Depreciation and amortization	239	2	10	—	251
Other operating expenses	40,062	400	1,082	(8)	41,536
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, net	(72)	254	(184)	153	151
Income (loss) before income taxes	$ 24,227	$ (872)	$ (2,332)	$ —	$ 21,023
Capital expenditures	$ 2,231	$ —	$ —	$ —	$ 2,231
As of December 31, 2009					
Property and equipment, net	$ 2,008	$ 34	$ 200	$ —	$ 2,242
Identifiable assets, net of intercompany loans and investments	$ 134,714	$ 864	$ 11,294	$ (1,901)	$ 144,971
As of December 31, 2008					
Property and equipment, net	$ 2,134	$ 39	$ 102	$ —	$ 2,275
Identifiable assets, net of intercompany loans and investments	$ 146,074	$ 568	$ 4,469	$ (317)	$ 150,794

15. Quarterly Financial Data (unaudited)

	2009 Quarters Ended			
(In thousands, except per share data)	December 31	September 30	June 30	March 31
Total revenues	$ 16,301	$ 17,831	$ 17,705	$ 15,514
Income (loss) from operations	$ 2,419	$ 1,420	$ 1,014	$ (2,508)
Net income (loss)	$ 1,341	$ (88)	$ (238)	$ (1,775)
Net income (loss) per share:				
Basic	$ 0.03	$ —	$ (0.01)	$ (0.04)
Diltued	$ 0.03	$ —	$ (0.01)	$ (0.04)

	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
Income (loss) from operations	$ (2,230)	$ (4,811)	$ 43,901	$ (5,789)
Net income (loss)	$ (3,004)	$ (2,426)	$ 29,876	$ 505
Net income (loss) per share:				
Basic	$ (0.07)	$ (0.06)	$ 0.72	$ 0.01
Diltued	$ (0.07)	$ (0.06)	$ 0.71	$ 0.01

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements — (Continued)

Net income (loss) per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net income (loss) 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	Balance at End of Year
Valuation allowance for deferred tax assets:				
2007	$ 9,851	$ 1,166(a)	$ (204)(b)	$ 10,813
2008	$ 10,813	$ 3,262(a)	$ (8,376)(c)	$ 5,699
2009	$ 5,699	$ 2,816(a)	$ —	$ 8,515

(a) In 2009, 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.

(b) 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 U.S.

(c) 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, 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)
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)

Exhibit Number	Description	Reference
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.	Exhibit 10.43 to the Company's Current Report on Form 10-K (filed March 16, 2009)
10.44*	Exclusive Manufacturing and Supply Agreement, dated February 23, 2009, between Sucampo Pharma, Ltd and R-Tech Ueno, Ltd.	Exhibit 10.44 to the Company's Current Report on Form 10-K (filed March 16, 2009)
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)

Exhibit Number	Description	Reference
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)
10.48*	Form of Nonstatutory Stock Option Agreement for Non-Employee Directors	Exhibit 10.1 to the Company's Current Report on Form 10-Q (filed November 6, 2009)
21	Subsidiaries of the Company	Exhibit 21 to the Company's Current Report on Form 10-K (filed March 16, 2009)
23.1	Consent of PricewaterhouseCoopers LLP, 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
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 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 15, 2010 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 15, 2010

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 15, 2010

/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 15, 2010

/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, 2009 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 15, 2010

/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, 2009 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 15, 2010

/s/ JAN SMILEK
Jan Smilek
Chief Financial Officer
(Principal Financial and Accounting Officer)