

**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, 2010

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_ to \_\_\_\_.

Commission File Number: 001-33609

**SUCAMPO PHARMACEUTICALS, INC.**

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

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**30-0520478**

*(I.R.S. Employer  
Identification No.)*

**4520 East-West Highway, Suite 300  
Bethesda, MD 20814**

*(Address of principal executive offices,*

**(301) 961-3400**

*(Registrant's telephone number,  
including area code)*

**Securities registered pursuant to Section 12(b) of the 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  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  No

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

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer  Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the 11,456,902 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 \$40.4 million.

As of March 1, 2011, there were outstanding 15,659,917 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 2011 Annual Meeting of Stockholders to be held on May 24, 2011, which Proxy Statement is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2010, are incorporated by reference in Part III of this Annual Report on



Sucampo Pharmaceuticals, Inc.

Form 10-K  
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## PART I

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

### ITEM 1. BUSINESS

#### Overview

We are an international pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds that occur naturally in the human body as a result of enzymatic, 15-PGDH, transformation of certain fatty acids. We conduct our business through our subsidiaries based in Japan, the United States, Switzerland, the United Kingdom and Luxembourg.

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, retinal, vascular, and respiratory diseases as well as other disorders for which there are significant 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 have received marketing approval. AMITIZA® (lubiprostone) is a U.S. Food and Drug Administration, or FDA, -approved treatment for chronic idiopathic constipation, or CIC, in adults of both genders and for irritable bowel syndrome with constipation, or IBS-C, in women aged 18 years and older. AMITIZA was approved for CIC as a subset of the larger chronic constipation, or CC, disease indication Rescula® (unoprostone isopropyl) is FDA approved for lowering of intra-ocular pressure, or IOP, in open-angle glaucoma or ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP lowering medications.

IBS-C and CIC are chronic conditions characterized by frequent and bothersome symptoms that adversely affect the quality of patients' daily lives. IBS-C patients are predominantly female with a median age of 50. CIC sufferers include a more gender balanced level of males and females but the severity and prevalence of CIC tends to increase with age. By the time most IBS-C and CIC patients seek care from a physician, many of them have typically tried dietary and lifestyle changes as well as a number of available over-the-counter, or OTC, remedies and remain unsatisfied. OTC medications include laxatives, stool softeners or fiber supplementation. While some of these OTC therapies offer limited success in acute transit-related symptoms, they often lose effect over time and offer limited effect on IBS-C or CIC symptoms. For the most part OTC remedies have limited clinical evidence of success in chronic treatment. Some pose significant issues of dependency, habituation and/or side effects. Chronic use of OTC medications is off label and is not supported by long-term, well-controlled pivotal clinical trial data. Fiber and laxatives can exacerbate bloating and abdominal pain, the same symptoms from which many patients are seeking relief and which are the most troubling to treat.

Polyethylene glycol, or PEG, and lactulose account for the majority of prescriptions in the constipation category. In 2006, a PEG brand, MiraLAX®, was approved by the FDA for over-the-counter use (OTC) for occasional constipation relief and launched in April 2007. In 2010, the MiraLAX brand had a unit share of approximately 7.0% of all OTC laxative sales according to IRI. PEG demonstrates an increase in stool frequency and consistency but is not indicated for chronic use and may not improve bloating or abdominal discomfort. According to a patient survey conducted by Johanson et al. in 2004 and published in 2007, 75.0% of respondents were not completely satisfied with the predictability of laxatives and 50.0% did not think prescription laxatives were completely effective in relieving the multiple symptoms associated with constipation. There is limited peer review literature on the epidemiology, natural history and treatment of IBS-C and CIC as compared with other major disease states. Much of the peer review literature available relates to Zelnorm, a drug withdrawn from the market for safety concerns, and PEG, which as noted above, is not approved for the treatment of either CIC or IBS-C.

Studies published in *The American Journal of Gastroenterology* estimate that approximately 42.0 million people in the United States suffer from some form of constipation. Constipation becomes chronic when a patient suffers specified symptoms for more than 12 non-consecutive weeks within a 12-month period. Chronic constipation is deemed idiopathic if it is not caused by other diseases or by use of medication. According to *The American College of Gastroenterology*, irritable bowel syndrome, or IBS, affects 58.0 million people in the United States. IBS-C accounts for approximately one third of these cases or about 19.0 million patients. According to IMS Health, there were approximately 6.5 million patient visits in 2009, during which 4.5 million annual visits were for constipation and 2.0 million patient visits were for IBS. Brand total prescriptions for AMITIZA were slightly down in 2010 compared to 2009, according to IMS Health, even though AMITIZA is the only drug approved for the safe and effective treatment of the CIC and female IBS-C patients over 18 years of age. As reported by IMS Health, the yearly change in total prescriptions for AMITIZA declined by 0.6% even though total prescriptions in the category grew by 8.9%.

Analysis of studies performed by N. J. Talley, Irritable Bowel Syndrome in a Community: Symptom Subgroups, Risk Factors, and Health Care Utilization *Am. J. Epidemiol.* (1995) 142(1): 76-83; Higgins, P.D.R., and Johanson, J. A Systematic Review of the Epidemiology of Constipation, *The American Journal of Gastroenterology* 2004; 99: 750-759. and Hungin et. al. (The prevalence, patterns and impact of irritable bowel syndrome: an international survey of 40,000 subjects, *A. P. S. Volume 17, Issue 5, pages 643-650, March 2003*) as well as 2007 U.S. census data confirm that both CIC and IBS-C are major but largely underserved medical needs in the United States. Based on the Talley, Luscombe, Johanson and IFFGD studies, 2007 U.S. census data, primary research among treating physicians and analogies to other primary care treated diseases, our commercial planning estimates that the number of CIC or IBS-C patients diagnosed and on prescriptive care is a fraction of those patients who suffer from these diseases. We believe a larger number of CIC and IBS-C patients might actively seek therapy if disease and therapy awareness is increased to demonstrate the advantages of safe and effective chronic therapies over episodic self-medication with OTC remedies. Physicians consistently report a need for efficacious treatment with demonstrated safety that provides rapid, convenient, and effective relief.

We believe that AMITIZA presents patients and healthcare practitioners with a superior therapeutic choice for the major medical needs posed by CIC and IBS-C. Among other things, we believe that the wide differences between data of projected CIC and IBS-C epidemiology and the number of annual patient visits for CIC and IBS-C in 2009 highlight the market potential for AMITIZA. In addition, the positive physician and patient response to Zelnorm, driven largely by significant marketing also highlights the market potential for AMITIZA, especially when the outcomes from pivotal clinical trials for Zelnorm are considered. Zelnorm failed to demonstrate statistically significant evidence of efficacy in two well-controlled pivotal trials in IBS-C and failed to demonstrate a statistically significant increase in spontaneous bowel movements, or SBMs, from less than three SBMs a week to three a week or more SBMs in two well-controlled pivotal chronic constipation clinical trials. Zelnorm was withdrawn from the market in 2007 by the FDA for safety concerns. In 2010, we commissioned Wolters Kluwer Health, a leading data company, to prepare a report that compared average length of therapy per patient between Amitiza and Zelnorm three years after launch. Results of the report indicated that Amitiza had an average length of therapy per patient of approximately 155 days compared to approximately 132 days for Zelnorm. AMITIZA is well tolerated, has a favorable safety record and has demonstrated statistically significant efficacy in two well-controlled pivotal trials in both IBS-C and in CIC.

#### AMITIZA in the U.S. and Canada

AMITIZA (lubiprostone) is the only FDA approved prescription therapeutic product for the treatment of CIC in adults of both genders with demonstrated safety and effectiveness for chronic use. Constipation becomes chronic when a patient suffers specified symptoms for more than 12 non-consecutive weeks within a 12-month period. CC is deemed idiopathic (CIC) if it is not caused by other diseases or by use of medications. AMITIZA is also the only FDA-approved prescription therapeutic product for chronic treatment of IBS-C in women aged 18 years and older. IBS-C is a disorder of the intestines with symptoms that include severe cramping, pain, bloating and extreme changes of bowel habits. According to *The American College of Gastroenterology*, irritable bowel syndrome affects 58.0 million people in the United States. IBS-C accounts for approximately one third of these cases or about 19.0 million patients. According disease state information from the Cleveland Clinic in 2010, approximately 15.0% of people with symptoms compatible with IBS seek medical attention. As with CIC, obtaining a diagnosis of IBS-C can take multiple primary care physician visits and oftentimes requires a referral to a gastroenterology specialist before a diagnosis is made.

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 time of the Takeda agreement, we entered into a supply and a manufacturing agreement with Takeda and R-Tech Ueno, Ltd, or R-Tech, a pharmaceutical research, development and manufacturing company in Japan 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 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, subject to their right of first refusal, 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 settlement agreement which resolved certain disputes with Takeda, and a supplemental agreement which further defined certain rights and responsibilities of the parties, but did not supersede the terms of the October 2004 collaboration and license agreement between Takeda and us, including but not limited to, Takeda's obligation to exert its best efforts to maximize the net sales revenues of AMITIZA as set forth in the collaboration agreement.

Takeda currently sells AMITIZA in the U.S., 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 part of our co-promotion activities. Takeda records all sales of AMITIZA within the U.S. and pays us a tiered royalty based on net sales. Takeda is primarily responsible for the sales and marketing of AMITIZA in the U.S. Takeda has not sought approval for either CIC or IBS-C in Canada. We are primarily responsible for AMITIZA research and development efforts and hold the new drug application, or NDA. In addition, subject to approval from Takeda, we have the right to co-promote AMITIZA in the U.S. and Canada, and to be reimbursed by Takeda for certain co-promotion expenses. We co-promote AMITIZA through our specialty sales force which focuses on the institutional marketplace, including long-term care and veteran's affairs facilities. The co-promotion terms in the supplemental agreement are subject to re-negotiation by the parties no later than 60 months after the first date we deployed our sales force, which will be April 2011; such discussions have commenced. In the event the parties fail to reach an agreement to extend the terms of this provision, the co-promotion terms of the collaboration agreement may apply. The ultimate operational and financial impacts upon us to be applied after April 2011 are subject to the final co-promotion terms to be negotiated with Takeda.

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, dated October 29, 2004. We believe that Takeda's failure to generate an appropriate level of U.S. sales of AMITIZA is the result of its materially breaches of our agreements, including, without limitation, its continuing failure to exercise its best efforts to promote, market and sell AMITIZA and to maximize its net sales revenue, and its ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We also claim 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 sent Takeda another notice of material breach in December 2010, which specifically set forth all of the claims asserted in the arbitration submission. 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. All the arbitrators have been confirmed and the arbitration proceedings have commenced. The arbitrators currently have set the hearing on our claims to conclude by late October 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. We have spent and expect to spend significant resources in the dispute with Takeda and these arbitration proceedings may require the continuing attention of our senior management.

We believe that the CIC and IBS-C market continues to present a significant opportunity for growth for our company as a result of several factors.

- AMITIZA remains the only FDA approved drug for the chronic treatment of CIC and IBS-C;
- There remains a significant undiagnosed patient population in both CIC and IBS-C;
- A large proportion of the patient population of IBS-C and CIC receiving prescriptions are receiving acute therapies not chronic therapies for these chronic conditions;
- There has been a trend to growing off label OTC use of medicines resulting in inappropriate long-term treatment of CIC and IBS-C with drugs only FDA approved for short-term use;
- AMITIZA penetration among primary care providers remains low;
- AMITIZA accounts for only 8.0% of total prescriptions written for CIC and IBS-C while Zelnorm achieved approximately 18.0% of total prescriptions for CIC and IBS-C; and
- AMITIZA prescriptions are declining in a market where total prescriptions in the category have grown at 8.9% year over year from 2009.

We are currently pursuing development of a third gastrointestinal indication of AMITIZA, for the treatment of opioid-induced bowel dysfunction, or OBD, in patients treated chronically with opiates other than methadone. Our current OBD trials do not include patients treated chronically with opiates for pain incident to cancer which would be an additional indication under the collaboration and license agreement. In May 2010, we reported data at the Digestive Disease Week, or DDW, scientific meeting from a successful phase 3 efficacy study, OBD0631, in which statistical significance ( $p=0.0226$ ) was achieved for the primary endpoint. In addition, statistically significant improvements were seen for eight of the 12 secondary endpoints in that study. In August 2010, we announced that upon review by Takeda and us, we planned to conduct a third phase 3 efficacy study of AMITIZA for this indication in order to file a supplemental new drug application, or sNDA, for this indication with the FDA. A third confirmatory study is being conducted because of the commercial opportunity of the OBD indication and the safety and efficacy of AMITIZA. That third phase 3 efficacy study was initiated in December 2010. As per our agreement with Takeda, we will fund approximately half of this third phase 3 study's expense. The second phase 3 trial, OBD0632, of AMITIZA for the treatment of OBD concluded but was not successful though not related to AMITIZA. After we advised the contract research organization, or CRO, of our concerns over its performance under the contract, we filed a lawsuit in state court in Maryland and engaged in mediation in an effort to resolve our dispute. We have not been able to resolve our dispute with the CRO. We are now evaluating the performance of additional opiate-induced bowel dysfunction studies to include patients with cancer treated chronically with opiates other than methadone. We are evaluating whether to perform the studies in Europe or Japan at this time, but may consider performing some elements of these trials in the United States at a later time.

### 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 is 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 \$22.5 million in payments from Abbott, consisting of an upfront payment and clinical and regulatory milestone payments. We could receive additional milestone payments based on achieving other specified development and commercialization goals. We have retained the right to co-promote lubiprostone in Japan as well as its development and commercialization rights to all other therapeutic areas subject to right of first refusal.

In September 2010, we submitted a marketing authorization application to the Japanese Pharmaceuticals and Medical Devices Agency for lubiprostone at a dosage strength of 24 micrograms for the indication of CIC. The submission includes the results of a pivotal phase 3 efficacy trial of lubiprostone in Japanese CIC patients which met its primary endpoint with statistical significance ( $p < 0.001$ ) and demonstrated a safety profile consistent with previously reported clinical lubiprostone data. The primary endpoint of this trial was a change in the number of SBMs at the end of the first week of treatment. This pivotal, double-blinded, placebo-controlled trial evaluated 124 Japanese CIC patients each of whom received one lubiprostone 24-mcg, or placebo, capsule twice daily for 28 days. These top-line pivotal phase 3 efficacy results were reported in June 2010. The September 2010 submission was updated in December 2010 with the complete results of the phase 3 long-term, open-label multicenter safety trial in 209 Japanese CIC patients. Top-line results from that safety trial, which were reported by us in November 2010, demonstrated that lubiprostone was safe and well-tolerated. The data from the phase 3 safety and efficacy trials have been submitted to a scientific conference, to be held in the U.S. in May 2011, for disclosure. If AMITIZA is approved for sale in Japan, it will be the first new drug indicated for constipation in Japan in more than ten years. Currently, constipation patients in Japan are treated with laxatives, which generate annual sales of approximately \$326.0 million. Magnesium oxide is a leading laxative treatment for constipation in Japan and, in 2009, generated annual sales of approximately \$129.0 million. The constipation market grew by approximately 6.0% from 2008 to 2009. Future market growth is expected to continue and fueled by an increasingly older population and changes in eating and lifestyle habits.

On December 22, 2010, Sucampo Pharma, Ltd. provided Abbott notice to initiate Abbott's 120 day negotiation rights to exercise its right of first refusal to the OBD indication for Japan, which indication in Japan will include patients with cancer treated chronically with opiates other than methadone, but may not include other OBD patients.

### 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 Europe we have received notification of a positive opinion from the Pediatric Committee of the European Medicines Agency, or EMA, in relation to the Pediatric Investigation Plan, or PIP, for AMITIZA in CIC. To file for marketing application approval, or MAA, an approved PIP is required. As a result, in anticipation of a positive EMA decision, we intend to file an MAA application no later than the end of the second quarter of 2011.

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 and is the first prescription medicine to be approved in Switzerland for the long-term treatment of CIC. We are currently pursuing approval of a pricing and reimbursement with the Swiss authorities and expect a decision in early 2011. We continue to evaluate the opportunities to obtain an appropriate label in the E.U. for chronic therapy of CIC and OBD.

## Rescula

In April 2009, we entered into agreements with R-Tech, to acquire for \$3.5 million the development and commercialization 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 its approved indication and all new ophthalmic indications developed by us. We also have the right of first refusal to commercialize Rescula in the U.S. and Canada for any additional ophthalmic indication developed by R-Tech or us. We plan to re-launch Rescula in the U.S. for its approved indication after approval of a commercially viable label from the FDA.

In June 2010, R-Tech announced the top-line results of their phase 2 clinical trial of Rescula conducted in 112 Japanese patients with retinitis pigmentosa, or RP. The primary endpoint in that trial was the change from baseline in the mean retina sensitivity of the central 2-degrees of the ocular fundus as measured with an MP-1 micro-perimeter. The results showed a dose-dependent improvement in visual function in patients with no severe adverse effects. In September 2010, Rescula received an Orphan Drug designation from the FDA for RP, meaning we have an eight year market exclusivity in the United States from the date we received first approval to market unoprostone isopropyl.

In addition, we plan to evaluate conducting a phase 2a clinical trial of unoprostone isopropyl for the indication of age-related macular degeneration, or dry AMD, in 2011. If this study is successful, there would need to be further studies to be completed that may take several years before commercialization.

R-Tech received its first marketing approval for Rescula in Japan in 1994 as a first line therapy for the treatment of glaucoma and/or ocular hypertension. In 1998, R-Tech licensed the rights to develop and commercialize Rescula in the U.S. and Europe to CibaVision, a predecessor company to Novartis AG, or 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. The negotiation with Novartis was successful, and in July 2010, Novartis returned all remaining rights to Rescula to R-Tech. We have discussed with R-Tech formal terms of a license and supply arrangement with respect to Rescula rights outside of North America and hope to finalize a formal agreement in the near future.

We continue to pursue additional intellectual property as well as further clinical development 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:
  - o NSAID-induced ulcers: 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 gastro-intestinal injuries in patients treated with non-steroidal anti-inflammatory drugs, or NSAIDs. Cobiprostone patients experienced a statistically significant reduction in the overall 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. These data were presented orally at the DDW scientific meeting in May 2010. We are evaluating a phase 2b study to complement the findings of this and earlier studies.
  - o COPD: 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 oral mucositis.
- SPI-017 is currently in preclinical and clinical testing in peripheral and central nervous system disorders. We have recently completed a phase 1 clinical program of the intravenous formulation of SPI-017 for peripheral arterial disease, or PAD, in Japan. Plans to initiate a phase 2 study for this indication in 2011 are under re-consideration in view of a major change in clinical endpoints needed to demonstrate efficacy, such that we may determine to pursue other indications for SPI-017 ahead of PAD.
- SPI-3608: A novel orally bio-available prostone, SPI-3608 will continue to undergo preclinical testing. Based on preclinical results seen to date, this compound may have potential for the management of pain caused by spinal stenosis.

## **Product Pipeline**

The table below summarizes the development status of AMITIZA, Rescula and several other prostone-based 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. Commercialization may be several years after successful completion of studies.



<b>Product/Product Candidate</b>	<b>Target Indication</b>	<b>Development Phase</b>	<b>Next Milestone</b>
<b>Amitiza</b> ® (lubiprostone)	Chronic idiopathic constipation (CIC) (adults of all ages)	Marketed in the U.S.	—
		Approved in Switzerland	Pricing negotiations with Swiss government health agency
		Phase 3 efficacy and safety trials in Japanese patients results reported	Approval of marketing authorization in Japan
	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 results reported	Phase 3 safety trial and the third efficacy trial to complete in 2011
<b>Rescula</b> ® (unoprostone isopropyl)	Dry age-related macular degeneration (dry AMD)	Preclinical	Phase 2a trial
	Glaucoma and ocular hypertension	Approved in the U.S.	Limited commercialization
<b>Cobiprostone</b>	<i>Gastrointestinal</i> Prevention of non-steroidal anti-inflammatory drug (NSAID)-induced ulcers Oral mucositis	Phase 2a trial results reported Preclinical	Phase 2b trial Phase 1 trial
	<i>Pulmonary</i> Chronic obstructive pulmonary disease (COPD)	Preclinical	Finalize inhaled formulation
	<b>SPI-3608</b>	Spinal stenosis	Preclinical

#### **Acquisition activities**

On December 23, 2010, our subsidiary, Ambrent Investments S.à r.l., or Ambrent, a company organized under the laws of Luxembourg, entered into a stock purchase agreement, or the Purchase Agreement, with Dr. Ryuji Ueno, as trustee of the Ryuji Ueno Revocable Trust under Trust Agreement dated December 20, 2002, or the Ueno Trust, Dr. Sachiko Kuno as trustee of the Sachiko Kuno Revocable Trust under Trust Agreement dated December 20, 2002, or the Kuno Trust, and together with Drs. Ueno and Kuno and Ambrent.

Pursuant to the terms of the Purchase Agreement, Ambrent acquired 100.0% of the issued and outstanding shares of capital stock of Sucampo AG, or SAG, a Swiss-based patent-holding company, and its wholly owned subsidiary, Sucampo AG Japan, Ltd., or SAG-J, a patent maintenance company. The acquisition results in us acquiring SAG and SAG-J's rights with respect to patents and other intellectual property relating to prostone products, including AMITZA, cobiprostone, SPI-017 and other compounds. Prior the acquisition, we licensed these certain rights pursuant to various licensing arrangements that required us to make royalty and milestone payments and to provide certain development funding.

The total purchase price under the Purchase Agreement is \$80.0 million, consisting of a cash payment made in December 2010 of approximately \$28.1 million and the issuance of two subordinated unsecured promissory notes in the aggregate amount of approximately \$51.9 million. In addition, the purchase price includes a contingent payment equal to 15.0%, up to a maximum of \$40.0 million, of any cash that may be received by Drs. Ueno and Kuno in connection with the ultimate resolution of the current arbitration proceedings against Takeda. The Purchase Agreement contains customary representations, warranties and covenants, and agreements as to indemnification among the parties, subject to certain exclusions and limitations.

The Sellers, Drs. Ueno and Kuno, are related parties of our company. Dr. Ueno is our Chief Executive Officer, Chief Scientific Officer and Chairman of our Board of Directors. Dr. Kuno is our international business advisor and a member of our Board of Directors, and is also Dr. Ueno's spouse. Drs. Ueno and Kuno are co-founders and majority stockholders of our company and are also majority stockholders of R-Tech, a significant supplier to our company. Pursuant to our related person transactions policy, our Audit Committee, which consists solely of independent directors, reviewed and approved the acquisition. The purchase price for the acquisition was negotiated based on a discounted cash flow analysis of expected future payments on the licensed intellectual property rights and the estimated fair value of the acquired net assets.

The acquisition of SAG and SAG-J was accounted for as a merger of companies under common control, and accounted for at historical cost as of the earliest period presented. The financial information of these additional entities is presented in both the current and historical periods. Prior to the acquisition, SAG has paid dividends of \$13.7 million and \$2.9 million during the years ended December 31, 2010 and 2009, respectively. These dividends are included within the consolidated statements of changes in stockholders' equity together with the \$80.0 million purchase consideration as a deemed distribution due to the accounting for the common control acquisition of SAG.

#### Patent, manufacturing, license and supply arrangements

We also hold an exclusive license to develop and commercialize Rescula within the United States and Canada 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 its approved indication. 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.

We are party to exclusive supply arrangements with R-Tech to provide us with clinical and commercial supplies of Rescula and clinical supplies of AMITIZA, 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.

### **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 of elements, such as sodium, potassium, calcium and chloride. The concentration of specific ions within particular types of cells is important to many vital physiological functions, such as maintenance of the barrier membrane potential and control of the activity levels of enzymes and transport molecules within and outside of the cell. 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, cAMP levels, or binding of particular ligands to the channel. Each kind of ion preferentially moves through its own specific ion channels. Some prostones have been shown to activate or inhibit ion channels, thereby controlling the concentration of specific ions within cells and out of 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 or toxicities.

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), energy levels as well as tight junction and integrity. 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, in particular in the duodenum and jejunum, by activating the CIC-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 CIC-2 channel plays an important role in the restoration of these tight junction complexes and in the recovery of barrier function in the body. CIC-2 channels have been detected at the tight junction complex between adjacent intestinal epithelial cells. In preclinical studies, AMITIZA appeared to accelerate the recovery of the disrupted barrier function through the restoration of the tight junction structure. This may be a result of AMITIZA's specific effects on the CIC-2 channel. We believe that other prostones that act as CIC-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 for IBS-C in women aged 18 years and older with demonstrated safety and effectiveness for use beyond 12 weeks. AMITIZA is being further developed for the treatment of OBD. AMITIZA functions as an activator of the CIC-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, fluid is also allowed to pass into the intestine through these spaces between the cells. We believe that this promotes increased fluid content in the small intestine, 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 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, although there is very limited well-controlled clinical trial data in support of these alternatives in CIC or IBS-C patients. For patients who fail to respond to these approaches, physicians typically recommend laxatives, most of which are available over-the-counter for acute use. The most commonly used laxatives can be categorized as stimulants, stool softeners, bulk-forming agents, osmotic or lubricants. These agents do not have approved indications for long-term use by CIC or IBS-C patients. MiraLAX (polyethylene glycol 3350), an osmotic, was approved in late 2008 for sale as an over-the-counter treatment for up to seven days. In addition, lubricants, such as orally administered mineral oil, can be inconvenient and unpleasant for patients to ingest. For those patients who fail to respond to laxatives, Zelnorm® (tegaserod maleate), a 5-HT<sub>4</sub> 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. The FDA requested that Novartis discontinue marketing Zelnorm based on a finding of an increased risk of serious cardiovascular adverse events associated with its use. Zelnorm has subsequently been withdrawn from most international markets as well. As noted before, AMITIZA is the only FDA approved chronic therapy for CIC and there are no over-the-counter therapies with approved indications for long-term use for CIC or IBS-C. 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 chronic use in CIC.

**Market Opportunity.** Studies published in *The American Journal of Gastroenterology* estimate that approximately 42.0 million people in the United States suffer from some form of constipation. Constipation becomes chronic when a patient suffers specified symptoms for more than 12 non-consecutive weeks within a 12-month period. CC is deemed idiopathic if it is not caused by other diseases or by use of medication. AMITIZA is the only FDA approved prescription therapeutic product for the treatment of CIC in adults of both genders with demonstrated safety and effectiveness for chronic use. CIC is a chronic condition characterized by frequent and bothersome symptoms that adversely affect the quality of patients' daily lives. CIC sufferers include a gender-balanced level of males and females but the severity and prevalence of CIC tends to increase with age. By the time most CIC patients seek care from a physician, they have typically tried dietary and lifestyle changes as well as a number of available over-the-counter, or OTC, remedies and remain unsatisfied. OTC medications include laxatives, stool softeners or fiber supplementation. While some of these OTC therapies offer limited success in acute transit-related symptoms, they often lose effect over time and offer limited effect on CIC symptoms. For the most part OTC remedies have limited evidence of success in chronic treatment of IBS-C or CIC. Some OTC remedies pose significant issues of dependency, habituation and/or side effects. Chronic use of OTC medications is off label and is not supported by long-term, well-controlled pivotal clinical trial data. Fiber and laxatives can exacerbate bloating and abdominal pain, the same symptoms from which many patients are seeking relief and which are the most troubling to treat.

We believe that AMITIZA presents patients and healthcare practitioners with a superior therapeutic choice for the major medical needs posed by CIC. Analysis of studies performed by Higgins, P.D.R., and Johanson, J. A Systematic Review of the Epidemiology of Constipation, *The American Journal of Gastroenterology* 2004; 99: 750-759, as well as 2007 U.S. census data confirm that CIC is major but largely underserved medical need in the United States.

Based on the Johanson and IFFGD studies, 2007 U.S. census data, primary research among treating physicians and analogies to other primary care treated diseases, our commercial planning estimates that the number of CIC patients diagnosed and on prescriptive care is a fraction of those patients who suffer from these diseases. We believe a larger number of CIC patients might actively seek therapy if, among other things, disease and therapy awareness are increased by adequately demonstrating the advantages of Amitiza as a safe and effective chronic therapy over episodic self-medication with OTC remedies. Physicians consistently report a need for efficacious treatment with demonstrated safety that provides rapid, convenient, and effective relief.

We believe that AMITIZA, as the only FDA approved prescription medication for chronic treatment of 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 among others:

- AMITIZA remains the only FDA approved drug for the chronic treatment of CIC and IBS-C;
- There remains a significant undiagnosed patient population in both CIC and IBS-C;
- AMITIZA is approved for administration to adults, 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;
- There are no existing over-the-counter treatment options with approved indications for chronic use in CIC;
- A large proportion of the patient population of IBS-C and CIC receiving prescriptions are receiving acute therapies not chronic therapies for these chronic conditions;
- There has been a trend to growing off label OTC use of medicines resulting in inappropriate long-term treatment of CIC and IBS-C with drugs only FDA approved for short-term use;
- AMITIZA penetration among primary care providers remains low;
- AMITIZA accounts for only 8.0% of total prescriptions written for CIC and IBS-C while Zelnorm achieved approximately 18.0% of total prescriptions for CIC and IBS-C; and
- AMITIZA prescriptions are declining in a market where total prescriptions in the category have grown at 8.9% year over year from 2009.

**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 75.0% in one pivotal trial and 78.0% 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.* 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 and diarrhea, 31.0% of all trial participants reported an event of nausea. Diarrhea and headache were each reported by 13.0% 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. Nausea generally occurs within the first two days of treatment which is also when the first spontaneous bowel movement, or SBM, occurs. In addition, the experience of nausea is a single event in approximately 75.0% of the cases. The median duration of nausea is 4 days. 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.

In a 248 patient long-term study of CIC patients treated with AMITIZA administered with food, the current standard of usage, AMITIZA's status as a well tolerated and effective therapy for CIC was best characterized. In a study that also prompted patients to report adverse events, only 19.8% of patients reported an event of nausea. Of those reporting events of nausea, >90.0% reported only mild nausea. Only 13 patients, or 5.2%, enrolled on therapy discontinued therapy because of nausea over the course of the 48 week trial and the 70.0%, or 9 of those 13 patients, withdrew within the first month on therapy. Only 4 patients, or 1.6%, of treated patients withdrew for nausea in months two through 12 of the trial. There were no reported serious adverse events of nausea during the 48 week trial. Over the course of the full trial the total number of patient days was 62,325 days, the nausea event rate was 1.08 per 1,000 patient days.

*Post-marketing Studies.* In connection with our marketing approval for AMITIZA for the treatment of CIC in adults of both genders, 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 filed the results with the FDA. Subsequently the FDA has requested an additional post-marketing study to evaluate the efficacy and safety of the product in pediatric patients.

*Japanese Patients Studies.* In September 2010, we submitted a marketing authorization application to the Japanese Pharmaceuticals and Medical Devices Agency for lubiprostone at a dosage strength of 24 micrograms for the indication of CIC. The marketing application included the phase 2 and phase 3 efficacy trial results and interim results of phase 3 long-term safety trial results. The phase 3 efficacy trial enrolled 124 patients, and the results of which we reported in June 2010, met the primary endpoint with statistical significance ( $p < 0.001$ ) and demonstrated a safety profile consistent with previously reported lubiprostone clinical data. The marketing application was updated in December 2010 with the complete results of the phase 3 long-term, open-label, multi-center, confirmatory, safety trial in 209 Japanese CIC patients.

In November 2010, we reported top-line data from our phase 3 clinical trial to evaluate the long-term safety of lubiprostone in Japanese CIC patients. Those results showed that lubiprostone was safe and well-tolerated and demonstrated that the most common adverse drug reactions, or ADR, in this trial were diarrhea (37.3%), nausea (27.3%), chest discomfort (7.2%) and abdominal pain (5.3%) all of which were transient in duration. The majority of first incidences of ADRs took place during the first two weeks of treatment. The most common mild ADRs were: diarrhea, nausea, chest discomfort, vomiting, abdominal pain, abdominal discomfort and abdominal distension. The most common moderate ADRs were diarrhea, nausea, vomiting and vertigo. There were no severe ADRs. Data from patients' daily diary cards showed improvements from baseline in all efficacy endpoints, including bowel movements frequency, straining, incomplete evacuation, stool consistency, abdominal bloating and abdominal discomfort. Patients' QOL as measured by the IBS-QOL and SF-36 questionnaires, also showed improvement from baseline at Weeks 24 and 48. This long-term phase 3 safety trial was an open-label, multi-center study in which Japanese CIC patients received one 24-mcg lubiprostone capsule twice a day for up to 48 weeks. A total of 209 patients were enrolled, 173 patients completed 24 weeks of treatment and 163 patients completed 48 weeks of treatment. The number of patients completing the full 48 week treatment period exceeded the target of 35 patients. Each enrolled patient had a history of fewer than three SBMs per week for at least six months, as confirmed during a 14-day screening period. We look forward to the presentation of these data at the DDW scientific meeting in May 2011.

### ***Irritable Bowel Syndrome with Constipation (IBS-C)***

On April 29, 2008, the FDA approved our sNDA for AMITIZA for the treatment of IBS-C in women aged 18 years and older. 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 women aged 18 years and older.

**Market Opportunity.** According to *The American College of Gastroenterology*, irritable bowel syndrome affects 58.0 million people in the United States. IBS-C accounts for approximately one third of these cases or about 19.0 million patients in the U.S. Obtaining a diagnosis of IBS-C can take multiple primary care physician visits and oftentimes a referral to a gastroenterology specialist before a diagnosis is made. According to IMS Health, there were approximately 2.0 million annual patient visits for IBS in 2009 in the United States. These numbers of diagnosed annual patient visits were down from a peak in 2006 of annual IBS patient visits of 3.2 million when Zelnorm was on the market in the United States. AMITIZA is currently the only approved prescription product for the chronic treatment of IBS-C in the U.S. for women aged 18 years and older.

**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 QOL 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 QOL 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 QOL 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, 1.0% in both the AMITIZA group and the placebo group, and treatment-related adverse events, with 26.0% in the AMITIZA groups compared to 21.0% in the placebo groups. The most common treatment-related adverse events were nausea, which was reported by 8.0% of participants receiving AMITIZA and 4.0% of those receiving the placebo, and diarrhea, which was reported by 7.0% 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 5.0% reporting this adverse event.

*Post-marketing Studies.* In connection with our marketing approval for AMITIZA for the treatment of IBS-C in women aged 18 years and older, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in pediatric patients and to conduct a study utilizing a higher dose in male and female patients with IBS-C.

### ***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.** In 2008, epidemiology researchers at Boston University estimate that opioids are used by more than 10 million American adults. Of those, approximately 4.3 million U.S. adults are regular users, taking opioids at least five days per week for a minimum of four weeks. Constipation is a recognized common side-effect of opioid use. While estimates of constipation vary across numerous studies, Kalso, et al report in an extensive meta-analysis of non-cancer opioid use published in PAIN that 41.0% of opioid patients experience constipation as an adverse event.

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 OBD, could hold a competitive advantage over drugs that do not work through this mechanism of action.

**Development Status.** In September 2007, we initiated two pivotal phase 3 clinical trials, OBD0631 and OBD0632, of orally administered AMITIZA for the treatment of OBD. 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 included 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. Top-line results of these two phase 3 trials, reported in July 2009, showed that in one trial, OBD0631, lubiprostone met the primary endpoint in a statistically significant manner ( $p=0.0226$ ). Though not related to AMITIZA, study OBD0632 was not successful. Upon review by Takeda and us, a third confirmatory study is being conducted because of the commercial opportunity of the OBD indication and the safety and efficacy of AMITIZA. With respect to the conduct study of OBD study 0632, we have filed a lawsuit against the CRO for its malperformance under the contract.

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.

Data from OBD0631 were presented in May 2010 at the DDW scientific conference. In that trial, a total of 443 OBD patients were enrolled at multiple sites in the U.S. and Canada and randomized into the double-blind, placebo-controlled trial. They received one 24-mcg gel capsule of lubiprostone, or placebo, twice a day for 12 weeks. Patients in the trial were administered different opioid pain medications including fentanyl, methadone, morphine and oxycontin.

Among the key results from OBD0631 that were reported at DDW were:

- The primary efficacy endpoint, the change from baseline in SBM frequency at Week 8 in patients without reduction in dose of study medication, was met with statistical significance ( $p=0.0226$ ) by patients taking lubiprostone ( $n=167$ ) as compared to placebo ( $n=169$ ).
- Patients taking lubiprostone achieved a statistically significant ( $p=0.02$ ) greater increase in the mean number of SBMs per week in 8 of the 12 weeks of the trial, as compared to placebo patients.
- The percentage of patients who achieved a SBM within 24 hours and 48 hours was significantly higher with lubiprostone as compared to placebo ( $p=0.0126$  at 24 hours, and  $p=0.0360$  at 48 hours).
- Statistical significance was achieved for the overall change from baseline in constipation-associated symptom endpoints including: constipation severity ( $p=0.0006$ ); stool consistency ( $p<0.0001$ ); abdominal discomfort ( $p=0.0246$ ); and, straining ( $p<0.0001$ ).
- The most commonly reported adverse events in this trial were nausea, diarrhea, and abdominal distension. Overall 4.6% of patients (3.2% placebo vs. 5.9% lubiprostone) discontinued due to an adverse event.

Study OBD0632 did not meet the primary endpoint with statistical significance. However, 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 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, 15.0% for lubiprostone compared to 7.5% for placebo, and diarrhea, 8.5% for lubiprostone compared to 3.7% for placebo.

Based on a subsequent meeting with the FDA, we decided to conduct one additional phase 3 efficacy study in order to submit a sNDA for the OBD indication. This third phase 3 study of lubiprostone to evaluate its effectiveness as a treatment of OBD was initiated in December 2010 and enrollment is expected to be completed during the third quarter of 2011. If successful, the data from the trials will enable a filing of a sNDA with the FDA and the regulatory authorities in Europe with request for an expedited review.

## **Rescula (unoprostone isopropyl)**

### **Overview**

In April 2009, we licensed from R-Tech the development and commercialization rights to Rescula 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 its approved ophthalmic indications and any new such indication developed by us. We also have the right of first refusal to commercialize Rescula in the U.S. and Canada for any an additional ophthalmic indication for which unoprostone isopropyl is developed by R-Tech. We plan to re-launch Rescula in the U.S. for its approved indication after approval of a commercially viable label from the FDA. In September 2010, Rescula received an Orphan Drug designation from the FDA for retinitis pigmentosa.

Rescula was approved by the FDA for lowering of IOP in open-angle glaucoma and ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP lowering medications in 2000. Rescula 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 and facilitates aqueous humor outflow and lowers intraocular pressure by means of increased vascular perfusion facilitated by inhibition of the action of endothelin. By direct inhibition of the effect of endothelin and other vasoconstrictors, Rescula relaxes contractile cells in the trabecular meshwork, which decreases resistance across the trabecular outflow pathway. To a smaller extent, Rescula increases uveoscleral outflow, by relaxing the ciliary muscle, which permits easier passage of aqueous humor into the suprachoroidal space and by facilitating bulk post vitreal aqueous humor flow by improving choroidal blood flow. Rescula's BK channel stimulation demonstrably increases choroidal blood flow which is thought to promote aqueous humor fluid and waste product uptake by the choroid to lower IOP. 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 rhodopsin 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 50.0%, to approximately 12 million by 2020, as the population ages according to a report published by Visiongain Ltd. More than 85.0% 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 isopropyl, we believe that Rescula has the potential to be a treatment for dry AMD. As a result, we plan to initiate a phase 2a clinical trial of Rescula for dry AMD in 2011.

## 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 CLIC-2, which is known to be present in gastrointestinal, liver and lung cells. We are also developing cobiprostone as a treatment for oral mucositis based on results from preclinical 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<sup>®</sup> (rofecoxib) and Bextra<sup>®</sup> (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<sup>®</sup> (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<sup>®</sup>. 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<sup>®</sup> (esomeprazole magnesium) and Prevacid<sup>®</sup> (lansoprazole), are prescribed to treat most gastric ulcer patients, either alone or in combination with other treatments. H2 receptor blockers, such as Pepcid<sup>®</sup> (famotidine), Tagamet<sup>®</sup> (cimetidine) and Zantac<sup>®</sup> (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 completely effective in preventing NSAID-induced 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 Arthritis Foundation, up to 60.0% of patients consuming NSAIDs regularly will have GI side effects. Additionally, *The Journal of Gastroenterology* states that recent studies show more than 50.0% 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 gastro-duodenal 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 gastro-duodenal ulcers, the incidence of gastric, duodenal and gastro-duodenal 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 40.0% for placebo vs. 47.0%, 52.0% and 77.0% 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.** Peripheral vascular disease, which also is sometimes referred to as PAD, 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 PAD, but they have little or no impact on symptoms or the underlying atherosclerotic process. Palux<sup>®</sup> (alprostadil) and Liple<sup>®</sup> (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 12.0% to 20.0% of Americans age 65 and older with only 20.0% to 30.0% undergoing treatment.

**Development Status.** In 2009, we completed a phase 1a 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. In 2010, we completed a phase 1b multiple dose study in which an additional 24 healthy adult male subjects were enrolled in three dose groups receiving intravenous doses of SPI-017 ranging from 40 mcg to 120 mcg. Development of a phase 2 study for PAD is under re-construction in view of a major change in clinical endpoints required by regulatory authorities needed to demonstrate efficacy, such that we may pursue other indications for SPI-017 ahead of PAD.

**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 hospitals, long-term care facilities and Department of Defense 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.

In 2009, Sucampo Pharma Americas licensed Rescula from R-Tech. The current sales and marketing team is preparing for a re-launch of Rescula in the U.S. market based on a favorable FDA response regarding the sNDA. This aligns appropriately with our commercial strategy of focusing on targeted segments with first-in-class or best-in-class products.

**Takeda Collaboration**

In October 2004, we entered into a 16-year collaboration and license agreement with Takeda to jointly develop and for Takeda to commercialize AMITIZA for gastrointestinal indications in the U.S. and Canada. We have limited co-promotion rights under the agreement. 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.

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 hospitals, long-term care facilities and Department of Defense facilities. Through the supplemental agreement, Takeda was responsible for, among other things, development 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.

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, dated October 29, 2004. We believe that Takeda's failure to generate an appropriate level of U.S. sales of AMITIZA is the result of its materially breaches of our agreements, including, without limitation, its continuing failure to exercise its best efforts to promote, market and sell AMITIZA and to maximize its net sales revenue, and its ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We also claim 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 sent Takeda another notice of material breach in December 2010, which specifically set forth all of the claims asserted in the arbitration submission. 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. All the arbitrators have been confirmed and the arbitration proceedings have commenced. The arbitrators currently have set the hearing on our claims to conclude by late October 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. We have spent and expect to spend significant resources in the dispute with Takeda and these arbitration 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, 2010, Takeda paid an aggregate of \$94.2 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 a minimum of \$80.0 million per year for three years. After the three year period, or during April 2011, the joint commercialization committee will agree upon the level of funding. If there is no full-scale direct-to-consumer advertising campaign in a 12-month period, then the total commercialization funding commitment will at a minimum 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 professional product detail meetings with certain 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. Discussions with Takeda have commenced in the first quarter of 2011 regarding reimbursement of our specialty sales force under the supplemental agreement. In the event the parties fail to reach an agreement to extend the terms of this provision, the reimbursement terms of the collaboration agreement may apply. The ultimate operational and financial impacts upon us are subject to the final co-promotion arrangements to be negotiated with Takeda.

*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, 2010. 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.

*Administration.* Our collaboration with Takeda is administered in part by four committees consisting of an equal number of representatives from both companies. These consist of a joint steering committee, which considers 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 the chief operating officer of Takeda has the determining vote on matters arising from the joint commercialization committee. If disputes relating to an alleged breach of the agreement arise that are resolved by the chief executive officer of our company and chief operating officer of Takeda, those disputes are resolved under the breach, termination and arbitration provisions of the agreement.

*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. Takeda has not sought approval for either CIC or IBS-C in Canada.

Under the agreement, if one of our subsidiaries or licensees wishes to use certain proprietary 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 upon the first commercial sale a certain one-time fee for the use of such data or information. 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.

## **Abbott Collaboration**

In February 2009, we entered into a 19-year license, commercialization and supply agreement with Abbott 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.

*Development Costs.* 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.

*Commercialization Funding Commitment.* 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 below.

*Co-Promotion Rights.* We have retained the right to co-promote the product in Japan and all other development and commercialization rights to all other therapeutic areas and are responsible for the cost of co-promotion.

*Licensing Fees and Milestone Payments.* Abbott made an upfront payment of \$10.0 million in 2009 and has paid total development milestone payments of \$12.5 million through December 31, 2010, which includes a \$5.0 million milestone payment as a result of submitting a marketing application to the Japanese Pharmaceuticals and Medical Devices Agency in September 2010. 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, we will purchase and assume title to inventories of AMITIZA and recognize revenues from the sales of such product when earned.

*Administration.* Our collaboration efforts under the Abbott agreement are administered 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 with respect to disputes over the development of the product.

*New Indications.* Under the agreement, Abbott has a right of first refusal to obtain a license to develop and commercialize AMITIZA in Japan for any new indications that we may develop, such as OBD. We retain the rights to AMITIZA for all other therapeutic uses.

*Term.* The Abbott agreement continues until 2027 unless terminated earlier. 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, or
- insolvency of either party.

## **Intellectual Property**

Our success depends in part on our ability, and that of 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.

Through our December 2010 acquisition of SAG, we hold the ownership rights to develop and commercialize AMITIZA and many other prostone compounds covered by patents and patent applications held by SAG: these include a total of 41 U.S. patents, 33 U.S. patent applications, 18 European patents, 24 European patent applications, 22 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, SPI-017 and SPI-3608. 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 consist of 14 issued U.S. patents, seven issued European patents, and five issued Japanese patents relating to composition of matter, methods of use and manufacturing method. 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 2029.

The patent rights relating to cobiprostone consist of 15 issued U.S. patents, eight issued European patents, and ten issued Japanese patents relating to composition of matter, methods of use and manufacturing method. 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 2011 and 2029.

The patent rights relating to SPI-017 consist of nine issued U.S. patents, five issued European patents and five 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 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 2011 and 2026.

The patent rights relating to SPI-3608 consist of eight issued U.S. patents, five issued European patents and five 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 methods of use. The U.S. patents relating to methods of use and the other U.S. and foreign patents expire between 2011 and 2026.

The patent rights relating to Rescula licensed by us from R-Tech consist of 16 issued U.S. patents relating to composition of matter, methods of use, pharmaceutical formulation and other claims. The U.S. patents relating to composition of matter expire between 2012 and 2018. The other U.S. and foreign patents expire between 2011 and 2021.

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, SPI-017 and SPI-3608, which have not previously received FDA approval with the NDA filing. 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.

## **Manufacturing**

We do not now own 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 contract with R-Tech to produce AMITIZA, Rescula, cobiprostone and SPI-017 and any of our future prostone compounds.

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, 2010. 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 supply all Takeda's commercial supplies, including product samples, for AMITIZA for the U.S. and Canadian market. 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, Takeda and 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 passed cGMP inspection in April 2010 to manufacture the active pharmaceutical ingredient and the finished pharmaceutical product and has been the sole supplier of this product to the marketplace since 1994 without interruption.

In 2009, we entered into an exclusive supply agreement with R-Tech for ten years to provide us with Rescula manufacturing services 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 constipation. Additionally the evolving definition of IBS-C and the required study outcomes can have an impact on future commercialization efforts.

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 methylaltrexone, 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. Progenics is collaborating with Ono Pharmaceuticals in Japan in the development of methylaltrexone in OIC and in November 2010 announced the start of a phase 2 study in Japan. Another oral opioid 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. Resolor was launched in Germany in January 2010, the UK in March 2010 and in Belgium in September 2010. In May 2010, Movetis began a phase 3 program for the development of prucalopride in OIC. Movetis was acquired by Shire in September 2010.
- Linaclotide is being studied and developed for both IBS-C and CIC in the U.S. market. Linaclotide is a Guanylin Agonist which is dosed at once a day and has recently completed phase 3 clinical trials for both CIC and IBS-C. Linaclotide is being developed by Ironwood which signed an agreement with Forrest Pharmaceuticals in the U.S. for co-marketing rights.
- Rescula faces many competitors which promote for primary open-angle glaucoma, or POAG, and ocular hypertension. Products such as Latanaprost, manufactured by Pfizer are going generic in 2011 which can have a significant impact on monotherapy treatment. Other products are in development for POAG and ocular hypertension such as Tafuprost, marketed by Merck, which has filed an NDA, and the combination product of Travatan and Timolol, to be marketed by Alcon, has also filed an NDA.



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

## **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 its 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 analyses or even an additional 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 evaluations and are conducted in volunteers 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 pharmacology and 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 validation or information.

The pharmaceutical 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 clinical 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 at our instruction and on our behalf. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our 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 of 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., Swissmedic in Switzerland and the Ministry of Health, Labor and Welfare, or MHLW, 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. directives 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 regulations on pediatric medicines which impose certain obligations on pharmaceutical companies with respect to the investigation of their products in children.

Our subsidiaries, Sucampo Pharma Europe Ltd., Sucampo AG and Sucampo Manufacturing and Research AG may be 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 have 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. To obtain manufacturing/marketing approval, we must submit an application for approval to the MHLW with results of nonclinical and clinical studies to show the quality, efficacy and safety of a new drug. A data compliance review, GCP on-site inspection, GMP audit and detailed data review are undertaken by the Pharmaceuticals and Medical Devices Agency, or PMDA. The application is then discussed by the committees of the Pharmaceutical Affairs and Food Sanitation Council, or PAFSC, and MHLW. Based on the results of these reviews, the final decision on approval is made by the MHLW. After the approval, negotiations regarding the reimbursement price with MHLW will begin. The price will be determined within 60 to 90 days unless the applicant disagrees. In that event, the applicant and MHLW will begin another 60 to 90 day negotiation period.

## ***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. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (together, the U.S. Healthcare Reform Act), was enacted. This legislation has both current and longer-term impacts on us. The provisions of the U.S. Healthcare Reform Act are effective on various dates over the next several years. The principal provisions affecting us provide for the following:

- an increase, from 15.1% to 23.1%, in the minimum rebate on branded prescription drugs sold to Medicaid beneficiaries (effective January 1, 2010);
- extension of Medicaid prescription drug rebates to drugs dispensed to enrollees in certain Medicaid managed care organizations (effective March 23, 2010);
- expansion of the types of institutions eligible for the “Section 340B discounts” for outpatient drugs provided to hospitals meeting the qualification criteria under Section 340B of the Public Health Service Act of 1944 (effective January 1, 2010);

- discounts on branded prescription drug sales to Medicare Part D participants who are in the Medicare “coverage gap”, known as the “doughnut hole” (effective January 1, 2011); and
- for tax purposes, a non-deductible annual fee payable to the federal government based on a company’s prior-calendar-year share of branded prescription drug sales to specified government programs (effective January 1, 2011, with the total fee to be paid each year by the entire pharmaceutical industry increasing annually through 2018).

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 Switzerland, the Swiss health care system is a compulsory private system where patients pay a monthly variable fee to a registered health insurance fund. All insurers reimburse against a common national formulary, the specialitätenliste. The Federal Office of Public Health or Bundesamt für Gesundheit, or BAG, makes the decisions on reimbursement and pricing of all prescription drugs in the market with their review taking three to four months. For new drugs it is not uncommon for there to be several rounds of review. It also conducts regular price reviews of the drugs on the formulary. The Federal Commission on drugs or Arzneimittelkommission, or EAK, is a body assisting the BAG with expert advice. Once a product is approved the BAG in consultation with EAK decides whether or not the drug will appear on the specialitätenliste. After EAK’s evaluation of a drug, BAG and EAK decide on the maximum price in the market. The criteria used are:

- Internal comparison with reimbursed and non reimbursed therapeutic equivalents,
- External cross country comparison (reference countries: DK, DE, UK, NL),
- Cost benefit analysis (less important)

In Japan, pricing is established utilizing various information including reference prices from other international markets. However, the MHLW 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 1, 2011.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Ryuji Ueno, M.D., Ph.D., Ph.D.	57	Chief Executive Officer, Chief Scientific Officer and Director, Chairman of the Board of Directors
James J. Egan	60	Chief Operating Officer
Stanley G. Miele	46	President, Sucampo Pharma Americas, Inc. and Senior Vice President of Sales and Marketing
Gayle R. Dolecek	68	Senior Vice President of Research and Development and member of the Board of Directors
Thomas J. Knapp	58	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 August 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 on the board of directors and the CEO of NeuroNZ Limited, a privately held company based in Auckland, New Zealand. From 2004 to 2005, he was on the board of directors of Viteris Holdings, Inc. 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 he served 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.

*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 Laboratories' 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 1, 2011, we had 93 full-time employees, including 37 with doctoral or other advanced degrees. Of our workforce, 24 employees are engaged in research and development, 41 are engaged in sales and marketing and 28 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.

## Research and Development

For information regarding research and development expenses incurred during 2008, 2009 and 2010, see Item 7, “*Management Discussion and Analysis of Financial Condition and Results of Operations—Research and Development Expense*”.

## Financial Information About Geographic Areas

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 that depend on the development status of these geographies. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other factors.

The financial results of our segments reflect their varying stages of development. Our Americas segment recorded income before taxes of \$3.8 million in 2010, compared to income before taxes of \$18.9 million in 2009. These results primarily reflect the completion of the initial two phase 3 clinical trials of Amitiza for the treatment of OBD and cobiprostone for the prevention of NSAID-induced ulcers in 2009 offset by an increase in general and administrative expenses resulting from the ongoing legal matters, including our dispute with Takeda.

Our segment in Europe recorded a loss before taxes of \$6.2 million in 2010, compared to a loss before taxes of \$4.3 million in 2009. These results primarily reflect the foreign exchange losses within European subsidiaries and the ongoing regulatory costs towards filing an MAA in Europe.

Our segment in Asia recorded a loss before taxes of \$935,000 in 2010 compared to a loss before taxes of \$4.7 million in 2009. These results reflect the revenue recognized from the \$5.0 million payment earned from Abbott in September 2010 combined with ongoing development and regulatory costs.

(In thousands)	Americas	Europe	Asia	Consolidated
<b>Year Ended December 31, 2010</b>				
Total revenues	\$ 50,756	\$ -	\$ 11,114	\$ 61,870
Income (loss) before taxes	3,820	(6,205)	(935)	(3,320)
Identifiable assets	102,096	30,789	16,388	149,273
<b>Year Ended December 31, 2009</b>				
Total revenues	\$ 57,887	\$ -	\$ 9,464	\$ 67,351
Income (loss) before taxes	18,886	(4,298)	(4,727)	9,861
Identifiable assets	132,903	34,140	12,962	180,005
<b>Year Ended December 31, 2008</b>				
Total revenues	\$ 112,123	\$ -	\$ -	\$ 112,123
Income (loss) before taxes	51,293	(4,675)	(6,180)	40,438
Identifiable assets	145,853	29,962	6,539	182,354

## 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 1, 2011, we had outstanding 15,659,917 shares of class A common stock and 26,191,050 shares of class B common stock. The class B common stock represents approximately 94.4% 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 20.0% 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.

The current corporate structure consists of a public holding company named Sucampo Pharmaceuticals, Inc., which has seven 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; Sucampo Pharma Europe Ltd., based in Oxford, U.K., in which we conduct operations in Europe and the rest of the world; Sucampo AG and Sucampo Manufacturing & Research AG, based in Switzerland, Sucampo AG Japan, based in Osaka, Japan and Ambrent Investments S.à r.l., based in Luxembourg.

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 notices of material breach and filed an arbitration demand; if our dispute with Takeda continues or escalates, we could be required to commit significant financial resources and management time and if we are not successful in our dispute with Takeda, we may remain in an unsuccessful collaboration agreement and not have the cash resources needed for future expansion of our business.***

We believe Takeda has breached its obligations to us by not generating an appropriate level of U.S. sales of AMITIZA and other failures of performance under our agreements. We have sent Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. notices of material breach and initiated arbitration in the International Court of Arbitration, International Chamber of Commerce. 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. Arbitration proceedings have commenced and though the arbitrators currently have set the hearing on our claims to conclude by late October 2011, we are not certain when the hearing will conclude or the arbitration will finally be resolved.

If the arbitration continues for a longer period of time or escalates we will likely spend additional significant resources and will likely require significant continuing attention from our senior management. If we are unsuccessful in resolving our dispute with Takeda, we may be required to remain in a long-term unsuccessful relationship with Takeda or we may not be able to fund future expansion of our operations.

### **Risks Related to Our Limited Commercial Operations**

***Any acquisitions we make could disrupt our business and seriously harm our financial condition.***

We may, from time to time, consider acquisitions of complementary companies, products or technologies. Acquisitions involve numerous risks, including difficulties in the assimilation of the acquired businesses, the diversion of our management's attention from other business concerns and potential adverse effects on existing business relationships with current customers and suppliers. In addition, any acquisitions could involve the incurrence of substantial additional indebtedness. We cannot assure you that we will be able to successfully integrate any acquisitions that we pursue or that such acquisitions will perform as planned or prove to be beneficial to our operations and cash flow. Any such failure could seriously harm our business, financial condition and results of operations.

The acquisition of SAG resulted in the issuance of two subordinated unsecured promissory notes in the aggregate amount of approximately \$51.9 million. If we do not generate sufficient cash flows from our operations, we may not be able to pay the obligations of the notes on a timely basis and adversely affect our operating results. Our failure to comply with the covenants and/or obligations related to the notes could result in an event of default, which could result in an immediate acceleration of the outstanding balance of the notes that could materially and adversely affect our operating results and our financial condition.

***Although we have reported profits in the last few years, we recorded a net loss in 2010 and we may not regain or maintain operating profitability in the future which could force us to delay, reduce or abandon our commercialization efforts or product development programs.***

We initiated commercial sales of our first product, AMITIZA, for the treatment of CIC in adults of both genders in April 2006 and for the treatment of IBS-C in May 2008 for women aged 18 years and older 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 \$2.8 million in 2010. 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, conduct development of the prostone technology, seek regulatory approvals for additional indications and additional territories for AMITIZA and for other drug candidates, plan for commercialization of Rescula, seek licensing opportunities for third-party products, and enforce contractual obligations of our partners. Whether we are able to achieve sustainable operating profitability in commercialization of AMITIZA outside U.S. and Canada and Rescula within and outside of the United States, 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 IBS-C in women aged 18 years and older 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 by Takeda and continued development of AMITIZA by us. The growth in sales of AMITIZA will depend on several factors, including the following:

- the best efforts of Takeda to commercialize and maximize net sales revenue;
- resolution of our dispute with Takeda;
- our ability to complete clinical trials and secure regulatory approval of lubiprostone in Japan and the ability of Abbott to obtain appropriate pricing and successfully commercialize lubiprostone;
- 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 successful commercialization of these indications within and outside the U.S.; and
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities for these 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.

***If we are unable to obtain a commercially viable label from our sNDA for Rescula for lowering of IOP in primary open-angle glaucoma, or POAG, and ocular hypertension patients who are intolerant of or are insufficiently responsive to other IOP lowering medications and other indications for which we are developing this drug, or experience significant delays in doing so, our ability to generate significant product-based revenues and achieve profitability will be jeopardized.***

In the near term, our ability to generate additional revenues will depend on the successful commercialization and continued development of Rescula by us. Such development and commercialization of Rescula will depend on several factors, including the following:

- approval by FDA of submitted commercially viable sNDA;
- our ability to complete clinical trials and secure regulatory approval of unoprostone isopropyl for glaucoma in countries outside of the United States;
- the ability of R-Tech, which has the exclusive right to manufacture and supply Rescula, 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 Rescula for the treatment of other ophthalmic indications, 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 commercializing Rescula or are significantly delayed in doing so, our business will be materially harmed.

***We are predominantly a research & development company and rely on certain third parties for the successful commercialization of our drug products. The success of other third parties will affect the company's ability to continue to develop new drug candidates and its ability to reduce its reliance on the performance of other third parties.***

For most of our operating history, we have been a research & development 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, pursuing the regulatory approval processes for AMITIZA and Rescula, and planning the commercialization of Rescula. We have relied upon the collaboration agreement with Takeda and Abbott to commercialize AMITIZA. To make the transition to a fully integrated company, we will need to continue to staff and retain qualified human resources, contract with third parties to manufacture a commercial scale product, conduct the sales and marketing activities on our own or with third parties 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 Rescula 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 Rescula, and to pursue regulatory approvals for AMITIZA, Rescula 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, for the development of the prostone technology and the other principal members of our executive and scientific teams to successfully transform a pre-commercial stage company to a global pharmaceutical company. 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.

## Risks Related to Product Pipeline

***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 and commercialize the prostone pipeline will be impaired and jeopardize our business.***

Before obtaining regulatory approval for the sale of our product candidates from the prostone pipeline, 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, is subject to varying regulatory requirements 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;
- clinical research organizations we retain to conduct clinical trials may not perform according to the terms of the contract, causing delays or negative results in the clinical trials;
- 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;
- we face 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 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 and smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies; 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, 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 to improve the current label or address regulatory authorities concerns about 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 perform additional clinical trials that would be costly and difficult to know if there will be successful outcomes, submit data from supplemental clinical trials in addition to data from the clinical trials that supported our U.S. filings with the FDA. In connection with labeling submission for Rescula, we will conduct additional trials, may be required or we may elect to conduct additional trials that have uncertain outcomes. 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 the existing marketing approval for AMITIZA or Rescula or could force us to stop selling AMITIZA or not sell Rescula. Inconsistent trial results could also lead to delays in obtaining marketing approval in the U.S. for other indications for AMITIZA, Rescula 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 from Linaclotide, Rescula 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, Rescula or the other product candidates that we are developing or that would render AMITIZA, Rescula 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.

***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 March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (Healthcare Reform Act), was enacted in the United States. This legislation may have both immediate and long-term impacts on us. A number of the provisions of those laws require rulemaking action by governmental agencies to implement, which has not yet occurred. The laws change access to health care products and services and create new fees for the pharmaceutical and medical device industries. Future rulemaking could increase rebates, reduce prices or the rate of price increases for health care products and services, or require additional reporting and disclosure. We cannot predict the timing or impact of any future rulemaking.

***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 limited experience in completing acquisitions with third parties as well as performing under in-licensing agreements 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 continued to finance our operations by 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 but not for future research and development programs. Our future funding requirements, however, will depend on many factors, including:

- actual levels of AMITIZA and Rescula 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 qualified human 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 Abbott; 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, Rescula 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, potential sales of Rescula 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, unoprostone isopropyl, 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 unoprostone isopropyl, 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. 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.

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.

***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 have experienced significant difficulties with Takeda's performance under that agreement and Takeda has failed to, among other things, use its best efforts to market, promote, and sell AMITIZA and maximize the net sales revenue. We are also party to an agreement with Abbott for the development and commercialization of lubiprostone in Japan. Under the Abbott agreement, we are not certain that Abbott will obtain pricing that will allow us to earn a reasonable rate of return on the development of AMITIZA 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 (CRO), 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. We have experienced a CRO not performing under its contract that resulted in an unsuccessful outcome of a clinical trial and delayed our obtaining regulatory approval for one of our indications for AMITIZA and thus delaying our efforts to commercialize AMITIZA for that indication.

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 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 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, 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 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, unoprostone isopropyl, cobiprostone and SPI-017;
- a decision whether to engage R-Tech in the future to manufacture and supply compounds other than AMITIZA, unoprostone isopropyl, cobiprostone and SPI-017;
- a decision whether to renegotiate the terms of our existing agreements with R-Tech; 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 R-Tech, 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 six foreign subsidiaries, Sucampo Pharma, Ltd., Sucampo Pharma Europe, Ltd., Sucampo AG, Sucampo AG Japan Ltd., Sucampo Manufacturing & Research AG and Ambrent Investments S.à r.l. We expect to operate through a consolidated organizational structure and we expect to enter into commercial transactions with some of these entities or future subsidiaries on an ongoing basis. As a result of these transactions, we will be subject to complex transfer pricing and other tax 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 or other policies, we could become subject to significant tax liabilities and penalties related to prior, existing and future related party agreements. As of December 31, 2010, 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, 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 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 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. We have certain patents on our products that expire in the next couple of years. We may not be able to use other existing patents or patent applications to successfully protect our products from generic competition. 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 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 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 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.

## **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. We are currently seeking approval of a sNDA from the FDA for Rescula and failure to obtain approval of a commercially viable label will prevent us from re-launching Rescula in United States. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidates.

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.

***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 orphan drug designation for Rescula for the treatment of retinitis pigmentosa. 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 or Rescula 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 or Rescula 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 1,923,885 shares of class A common stock and 26,191,050 shares of class B common stock, representing approximately 95.1% 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 75.0% 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.

#### **Risks Related to Our Foreign Operations**

***The Company is developing internationally the increasing foreign operations and exposure to fluctuations in foreign currency exchange rates may increase.***

We expect that we will continue to expand our international operations in the future. International operations inherently subject us to a number of risks and uncertainties, including:

- changes in international regulatory and compliance requirements that could restrict our ability to manufacture, market and sell its products;
- political and economic instability;
- diminished protection of intellectual property in some countries outside of the United States;

- trade protection measures and import or export licensing requirements;
- difficulty in staffing and managing international operations;
- differing labor regulations and business practices;
- potentially negative consequences from changes in or interpretations of tax laws;
- changes in international medical reimbursement policies and programs;
- financial risks such as longer payment cycles, difficulty collecting accounts receivable and exposure to fluctuations in foreign currency exchange rates; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' and service providers' activities that may fall within the purview of the Foreign Corrupt Practices Act.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations.

As we expand our existing international operations, we may encounter new risks. For example, as we focus on building our business in new geographic regions, we must continue to develop relationships with qualified local distributors and trading companies. If we are not successful in developing and maintaining these relationships, we may not be able to grow revenue in these geographic regions. These or other similar risks could adversely affect our revenue and profitability.

#### **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.

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 5,550 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, dated October 29, 2004. We believe that Takeda's failure to generate an appropriate level of U.S. sales of AMITIZA is the result of its materially breaches of our agreements, including, without limitation, its continuing failure to exercise its best efforts to promote, market and sell AMITIZA and to maximize its net sales revenue, and its ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We also claim 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 sent Takeda another notice of material breach in December 2010, which specifically set forth all of the claims asserted in the arbitration submission. 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. All the arbitrators have been confirmed and the arbitration proceedings have commenced. The arbitrators currently have set the hearing on our claims to conclude by late October 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. We have spent and expect to spend significant resources in the dispute with Takeda and these arbitration proceedings may require the continuing attention of our senior management.

On December 9, 2010, we filed an amended lawsuit under seal In Circuit Court for Montgomery County, Maryland against the CRO that performed the clinical trials for the OBD indication. We have alleged that the CRO materially breached the contract by failing to use its best efforts to perform the services and performed the clinical trials in a careless and grossly negligent manner. We are seeking damages for, among other things, the expenses relating to the additional trial that we are conducting and all available monetary relief, attorneys' fees and costs. After filing the lawsuit, we have engaged in mediation to resolve our dispute. The mediation has not been successful, so we are pursuing our claims in the lawsuit. We have spent and expect to spend significant resources in the dispute with the CRO and these court 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, 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
March 31, 2010	\$ 4.33	\$ 3.39
June 30, 2010	\$ 4.11	\$ 3.46
September 30, 2010	\$ 3.84	\$ 3.28
December 31, 2010	\$ 3.84	\$ 3.26

As of March 1, 2011, we had 15,659,917 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 1, 2011, the closing price of our class A common stock was \$4.21. As of March 1, 2011, we had 26,191,050 shares of class B common stock outstanding held by one stockholder of record.

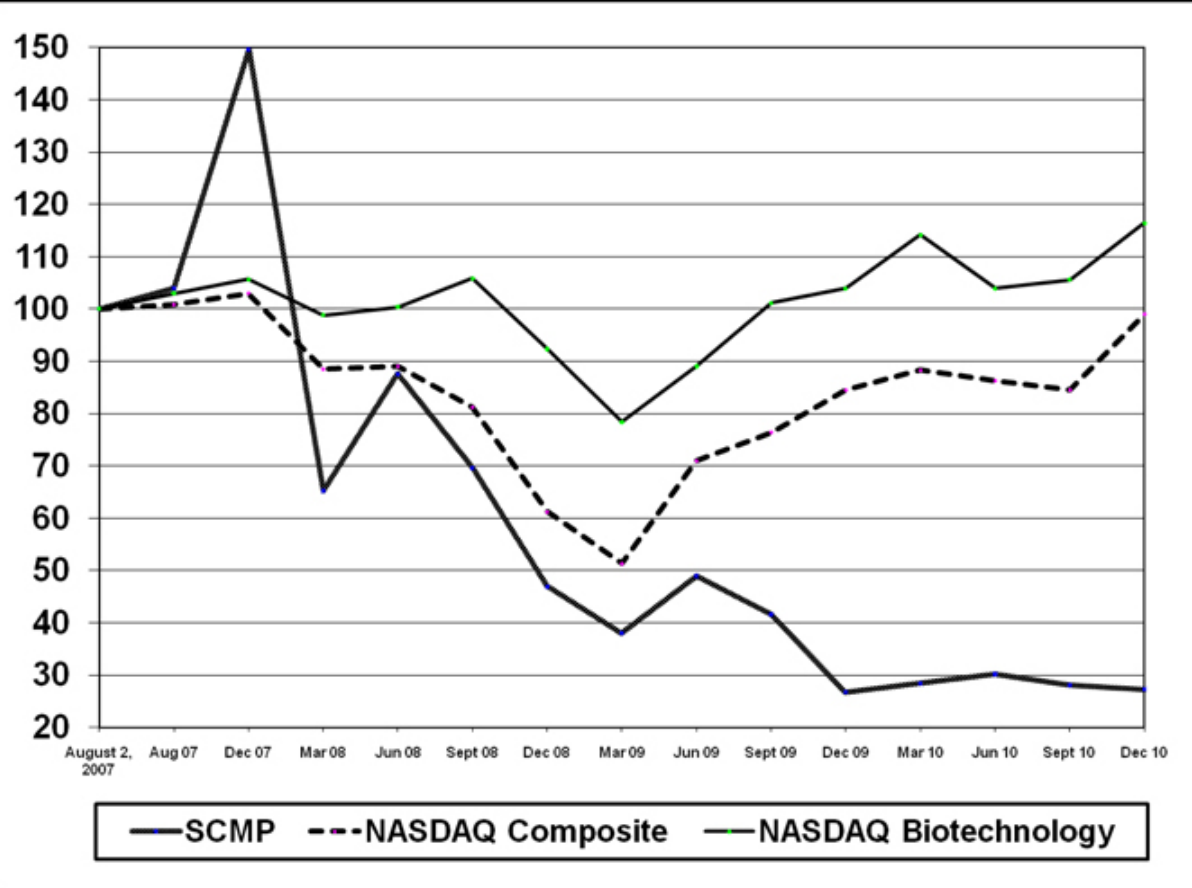
We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, to support our growth strategy and do not anticipate paying cash dividends in the foreseeable future.

On December 9, 2008, our Board of Directors authorized and approved a stock repurchase program, under which we may use up to \$10.0 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 2010, 2009 or 2008.

#### Stock Performance Graph

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

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



## ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

In December 2010, we acquired all of the capital stock of SAG and SAG-J. Accordingly, we have presented our financial statements on a consolidated basis as a merger of entities under common control for all periods presented to reflect this transaction. We have derived the following consolidated financial data as of December 31, 2009 and 2010 and for the years ended December 31, 2008, 2009 and 2010 from our audited consolidated financial statements. Consolidated balance sheets as of December 31, 2009 and 2010 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, 2008, 2009 and 2010 and notes thereto appear elsewhere in this Annual Report. We have derived the following consolidated financial data as of December 31, 2006, 2007 and 2008 and for the years ended December 31, 2006 and 2007 from unaudited 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.

(In thousands, except per share data)	Year Ended December 31,				
	2006	2007	2008	2009	2010
<b>Statement of operations data</b>					
Revenues	\$ 60,593	\$ 91,937	\$ 112,123	\$ 67,351	\$ 61,870
Operating expenses:					
Research and development	19,204	31,697	46,181	32,906	23,955
General and administrative	13,251	21,998	15,075	15,000	27,867
Selling and marketing	11,179	13,474	10,895	10,030	10,201
Total operating expenses	43,634	67,169	72,151	57,936	62,023
Income (loss) from operations	16,959	24,768	39,972	9,415	(153)
Total non-operating income (expense), net	49,753	2,969	466	446	(3,167)
Income (loss) before income taxes	66,712	27,737	40,438	9,861	(3,320)
Income tax benefit (provision)	1,343	(8,641)	(8,925)	(5,084)	565
Net income (loss)	\$ 68,055	\$ 19,096	\$ 31,513	\$ 4,777	\$ (2,755)
Basic net income (loss) per share	\$ 1.98	\$ 0.51	\$ 0.75	\$ 0.11	\$ (0.07)
Diluted net income (loss) per share	\$ 1.96	\$ 0.51	\$ 0.75	\$ 0.11	\$ (0.07)
Weighted average common shares outstanding - basic	34,383	37,778	41,787	41,844	41,848
Weighted average common shares outstanding - diluted	34,690	38,226	41,973	41,866	41,848

(In thousands)	December 31,				
	2006	2007	2008	2009	2010
<b>Balance sheet data:</b>					
Cash and cash equivalents	\$ 74,413	\$ 77,912	\$ 93,704	\$ 61,420	\$ 49,243
Short-term investments	29,399	52,398	42,750	72,434	54,524
Working capital	92,977	139,664	128,901	127,313	95,619
Total assets	147,470	174,317	182,354	180,005	149,273
Notes payable, current	-	-	-	-	19,522
Notes payable, net of current portion	-	-	-	-	44,439
Total liabilities	45,605	38,104	40,159	34,693	95,443
Convertible preferred stock	20,288	-	-	-	-
Retained earnings (deficit)	36,710	30,947	31,310	33,150	(21,630)
Total stockholders' equity	101,865	136,213	142,195	145,312	53,830

## 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 pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds that occur naturally in the human body as a result of enzymatic, 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<sup>®</sup> (lubiprostone), for the treatment of chronic idiopathic constipation, or CIC, in adults of both genders. In April 2008, the FDA approved AMITIZA for its second indication for the treatment of irritable bowel syndrome with constipation, or IBS-C, in women aged 18 years and older. 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 AMITIZA research and development efforts, 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.

In our opinion, AMITIZA sales have been adversely affected by material breaches by Takeda of the collaboration and license agreement and related agreements and unless we prevail in the arbitration described below, we could continue to be adversely affected.

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, dated October 29, 2004. We believe that Takeda's failure to generate an appropriate level of U.S. sales of AMITIZA is the result of its materially breaches of our agreements, including, without limitation, its continuing failure to exercise its best efforts to promote, market and sell AMITIZA and to maximize its net sales revenue, and its ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We also claim 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 sent Takeda another notice of material breach in December 2010, which specifically set forth all of the claims asserted in the arbitration submission. 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. All the arbitrators have been confirmed and the arbitration proceedings have commenced. The arbitrators currently have set the hearing on our claims to conclude by late October 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. We have spent and expect to spend significant resources in the dispute with Takeda and these arbitration proceedings may require the continuing attention of our senior management.

In April 2010, we incorporated another wholly owned subsidiary, Sucampo Manufacturing & Research AG, in Wollerau, Switzerland, whose operations will focus on managing specific manufacturing, commercial, research and intellectual property activities.

In December 2010, we acquired Sucampo AG, or SAG, a Swiss-based patent-holding company, and its wholly-owned subsidiary SAG-J, a patent maintenance company. This acquisition enables us to control and provides exclusive ownership of the patents and other intellectual property underlying our current and future prostone products, including AMITIZA, cobiprostone, SPI-017 and other compounds other than those patents currently held by R-Tech Ueno, Ltd., or R-Tech, a pharmaceutical research, development and manufacturing company in Japan. It eliminates future royalty and milestone payment obligations to third-party companies outside of us and our wholly-owned subsidiaries, and removes certain mandatory funding requirements for the development of early-stage compounds that would otherwise be needed to maintain rights to the promising drug candidates generated by the prostone technology platform.

The acquisition of SAG and SAG-J was accounted for as a merger of companies under common control and accounted for at historical cost. The financial information of these acquired entities is presented in our consolidated financial statements and management's discussion and analysis of financial condition and results of operations for all periods presented.

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 exclusive rights to develop and commercialize AMITIZA and all other prostone compounds covered by patents.

Drs. Ryuji Ueno and Sachiko Kuno, our founders, are married to each other and directly or indirectly own the majority of our common stock and a majority of the stock of R-Tech. 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 Japan, the United States, Switzerland and the United Kingdom. Our reportable geographic segments are comprised of the Americas, Europe and Asia 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 geographies. 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.* We currently are pursuing development of a third gastrointestinal indication of AMITIZA for the treatment of OBD in patients treated chronically with opiates other than methadone. In July 2009, we reported top-line results for the two identically-designed efficacy studies conducted by a contract research organization, or CRO, one of which met the primary endpoint by demonstrating a statistically significant change from baseline in the frequency of spontaneous bowel movements, or SBM, at week 8 of treatment when compared to placebo. We have filed a lawsuit against the CRO over its conduct of the studies. Based on a recent meeting with the FDA, we decided to conduct one additional phase 3 efficacy study in order to submit a supplemental new drug application, or sNDA, for the OBD indication. This study was initiated in December 2010.

In connection with our marketing approval of AMITIZA for the treatment of CIC in adults of both genders, 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 women aged 18 years and older, 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 Japan.* In September 2010, we submitted a marketing application to the Japanese Pharmaceuticals and Medical Devices Agency for lubiprostone at a dosage strength of 24 micrograms for the indication of CIC. The marketing application was submitted with phase 2 and phase 3 efficacy trial results. The phase 3 trial which enrolled 124 patients and the results of which we reported in June 2010, met the primary endpoint with statistical significance ( $p < 0.001$ ) and demonstrated a safety profile consistent with previously reported lubiprostone clinical data. The marketing application was updated in December 2010 with the complete results of the phase 3 long-term, open-label, multi-center, confirmatory, safety trial in 209 Japanese CIC patients.

In November 2010, we reported top-line data from our phase 3 clinical trial to evaluate the long-term safety of lubiprostone in Japanese CIC patients. Those results showed that lubiprostone was safe and well-tolerated and demonstrated that the most common adverse drug reactions, or ADR, in this trial were diarrhea (37.3%), nausea (27.3%), chest discomfort (7.2%) and abdominal pain (5.3%) all of which were transient in duration. The majority of first incidences of ADRs took place during the first two weeks of treatment. The most common mild ADRs were: diarrhea, nausea, chest discomfort, vomiting, abdominal pain, abdominal discomfort and abdominal distension. The most common moderate ADRs were diarrhea, nausea, vomiting and vertigo. There were no severe ADRs. Data from patients' daily diary cards showed improvements from baseline in all efficacy endpoints, including bowel movements frequency, straining, incomplete evacuation, stool consistency, abdominal bloating and abdominal discomfort. Patients' quality of life, or QOL, as measured by the IBS-QOL and SF-36 questionnaires, also showed improvement from baseline at Weeks 24 and 48. This long-term phase 3 safety trial was an open-label, multi-center study in which Japanese CIC patients received one 24-mcg lubiprostone capsule twice a day for up to 48 weeks. A total of 209 patients were enrolled, 173 patients completed 24 weeks of treatment and 163 patients completed 48 weeks of treatment. The number of patients completing the full 48 week treatment period exceeded the target of 35 patients. Each enrolled patient had a history of fewer than three SBMs per week for at least six months, as confirmed during a 14-day screening period.



On December 22, 2010, Sucampo Pharma, Ltd. provided Abbott notice to initiate Abbott's 120 day negotiation rights to exercise its right of first refusal to the OBD indication for Japan, which indication in Japan will include patients with cancer treated chronically with opiates other than methadone, but may not include other OBD patients.

*AMITIZA (lubiprostone) in other countries.* 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 November 2009, we obtained a marketing authorization for lubiprostone in Switzerland for the long-term treatment of adult patients with CIC. This is AMITIZA's first European regulatory approval and is the first prescription medicine to be approved in Switzerland for the long-term treatment of CIC. We are currently pursuing the pricing approval with the Swiss authorities and expect a decision in 2011. We continue to evaluate the opportunities to obtain an appropriate label in the E.U. for chronic therapy of CIC and OBD.

*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. We also have the right of first refusal to commercialize Rescula in the U.S. and Canada for any an additional indication for which unoprostone isopropyl is developed by R-Tech. We plan to re-launch Rescula in the U.S. for its approved indication after approval of a commercially viable label from the FDA. In September 2010, Rescula received an Orphan Drug designation from the FDA for retinitis pigmentosa. Additionally, we plan to initiate clinical trials of Rescula for the indication of dry age-related macular degeneration, or dry AMD, in 2011.

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 its approved indication.

*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 potential treatment for wound healing.

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 2a 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 2a 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 peripheral and central nervous system disorders. We initially focused on developing an intravenous formulation of this product candidate for the treatment of peripheral arterial disease, or PAD. We have recently completed a phase 1 clinical program of the intravenous formulation of SPI-017 for PAD in Japan. Plans to initiate a phase 2 study for this indication in 2011 are under re-consideration in view of a major change in clinical endpoints needed to demonstrate efficacy, such that SPI-017 may pursue other indications ahead of PAD.

## **Financial Terms of our License, Commercialization and Supply Agreement with Abbott**

In February 2009, we entered into a 19-year license, commercialization and supply agreement with Abbott 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 2009 agreement with Abbott, we received a non-refundable upfront payment of \$10.0 million.

### ***Product Development Milestone Payments***

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

- \$7.5 million upon the initiation of the phase 3 clinical trial for lubiprostone for the treatment of CIC in Japanese patients in May 2009;
- \$5.0 million as a result of submission of a marketing application to the Japanese Pharmaceuticals and Medical Devices Agency for lubiprostone at a dosage strength of 24 micrograms for the indication of CIC in Japanese patients in October 2010.

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, we 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)	Cash Received Through December 31, 2010	Revenue Recognized for the Year Ended December 31,		Foreign Currency Effects	Amount Deferred at December 31, 2010
	2009	2010			
<b>Collaboration revenue:</b>					
Up-front payment associated with our obligation to participate in joint committees	\$ 846	\$ 38	\$ 47	\$ (107)	\$ 868
<b>Research and development revenue:</b>					
Up-front payment - remainder	\$ 9,154	\$ 5,112	\$ 3,471	\$ (136)	\$ 707
Development milestone payment	12,500	4,314	7,587	(349)	948
<b>Total</b>	<b>\$ 21,654</b>	<b>\$ 9,426</b>	<b>\$ 11,058</b>	<b>\$ (485)</b>	<b>\$ 1,655</b>

### 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 aged 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, 2010, the related aggregate research and development expense incurred was \$44.5 million.

- For research and development expenses relating to changing or expanding the labeling of AMITIZA to treat CIC and IBS-C, Takeda is responsible for 70.0% of these expenses and we are responsible for 30.0%. 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 2006, are being shared 70.0% by Takeda and 30.0% by us. Through December 31, 2010, we had incurred \$2.4 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, 2010, we had incurred \$8.1 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, 2010 we had incurred \$53.0 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 \$4.4 million, \$4.5 million and \$4.8 million of co-promotion revenue reflecting these reimbursements for the years ended December 31, 2010, 2009 and 2008, 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, 2010, 2009 and 2008, we recognized a total of \$40.3 million, \$38.3 million and \$34.4 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, 2010.

***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, 2010	Revenue Recognized for the Year Ended December 31,				Accounts Receivable for the Year Ended December 31, 2010 (1)	Amount Deferred at December 31, 2010
		Through 2007	2008	2009	2010		
<b>Collaboration revenue:</b>							
Up-front payment associated with our obligation to participate in joint committees	\$ 2,375	\$ 464	\$ 147	\$ 147	\$ 147	\$ -	\$ 1,470
<b>Research and development revenue:</b>							
Up-front payment - remainder	\$ 17,624	\$ 17,624	\$ -	\$ -	\$ -	\$ -	\$ -
Development milestones	130,000	80,000	50,000	-	-	-	-
Reimbursement of research and development expenses	94,175	49,934	22,293	14,530	5,473	1,097	3,042
Total	\$ 241,799	\$ 147,558	\$ 72,293	\$ 14,530	\$ 5,473	\$ 1,097	\$ 3,042
<b>Product royalty revenue</b>	\$ 136,598	\$ 34,126	\$ 34,438	\$ 38,250	\$ 40,300	\$ 10,516	\$ -
<b>Co-promotion revenue</b>	\$ 21,780	\$ 8,654	\$ 4,826	\$ 4,541	\$ 4,417	\$ 658	\$ -

(1) Includes billed and unbilled accounts receivable.

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, 2010 and 2009, respectively, which is recorded as contract revenue. During the years ended December 31, 2010, 2009 and 2008, we purchased clinical supplies from R-Tech of \$344,000, \$205,000 and \$58,000, 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. There were no such clinical supply purchases in 2010, 2009 or 2008. During the years ended December 31, 2010 and 2009, we purchased \$110,000 and \$692,000, respectively, of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch in Europe. There were no such commercial supplies purchases in 2008. Subsequent to the purchase, we withdrew our European marketing application approval, or 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, 2010, 2009 and 2008, we purchased from R-Tech \$48,000, \$1.1 million and \$1.9 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. During the years ended December 31, 2010 and 2009, we purchased \$267,000 and \$381,000, respectively, of commercial supplies of lubiprostone from R-Tech under this agreement. There were no such commercial supplies purchases in 2008. During the year ended December 31, 2009, we purchased \$262,000 of clinical supplies from R-Tech under this agreement. There were no such clinical supplies purchases in 2010 and 2008 from R-Tech under this agreement.

In April 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 its approved ophthalmic indication and any new ophthalmic indication developed by us. We have the right of first refusal to commercialize Rescula in the U.S. and Canada any additional ophthalmic indication 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 us 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:

(In thousands)	Year Ended December 31,		
	2010	2009	2008
Clinical supplies	\$ 392	\$ 1,556	\$ 1,917
Other research and development services	69	100	118
Commercial supplies	376	1,039	-
	<u>\$ 837</u>	<u>\$ 2,695</u>	<u>\$ 2,035</u>

### 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, when 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.

## ***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 CRO's. In addition, we make estimates of costs incurred to date but not yet invoiced to us in relation to external 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 the 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 \$9.7 million and \$8.6 million as of December 31, 2010 and 2009, respectively, which resulted in a net deferred tax asset of \$3.3 million and \$3.3 million as of December 31, 2010 and 2009, 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, 2010 and 2009, we had foreign net operating loss carry forwards of \$24.2 million and \$11.0 million, respectively. Approximately \$13.7 million of the foreign NOLs begin to expire in December 2015, and \$10.5 million of the foreign NOLs do not expire.

We followed the FASB's 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 \$1.4 million including interest for uncertain tax positions as of December 31, 2010. 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, 2010 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 approximately \$75,000 and \$60,000 of interest recorded in 2010 and 2009, respectively, 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.

### **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.

### **Results of Operations**

#### **Comparison of years ended December 31, 2010 and December 31, 2009**

#### **Revenues**

The following table summarizes our revenues for the years ended December 31, 2010 and 2009:

<b>(In thousands)</b>	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Research and development revenue	\$ 16,540	\$ 23,957
Product royalty revenue	40,300	38,250
Co-promotion revenue	4,417	4,541
Contract and collaboration revenue	613	603
<b>Total</b>	<b>\$ 61,870</b>	<b>\$ 67,351</b>

Total revenues were \$61.9 million in 2010 compared to \$67.4 million in 2009, a decrease of \$5.5 million or 8.2%.

#### **Research and development revenue**

Research and development revenue was \$16.5 million in 2010 compared to \$24.0 million in 2009, a decrease of \$7.5 million or 31.0%. The decrease was primarily due to reduced revenue recognized in respect to the OBD program for AMITIZA in the U.S., partially offset by \$11.0 million in revenue recognized under the agreement with Abbott. The research and development revenue recognized under the agreement with Takeda in the U.S. decreased to \$5.5 million for the year ended December 31, 2010 from \$14.5 million for the year ended December 31, 2009, generally reflecting the July 2009 completion of the two phase 3 efficacy trials funded by Takeda and the change in estimated costs and timeline to complete the OBD program, including an additional phase 3 efficacy trial. Since Takeda funds the first \$50.0 million of the development expenses for the OBD program and we and Takeda share equally development costs that exceed that amount, we expect to fund about 50.0% of the upcoming phase 3 trial.

The research and development revenue recognized under the agreement with Abbott increased to \$11.0 million for the year ended December 31, 2010 from \$9.4 million for the year ended December 31, 2009, reflecting the revenue recognized from the \$5.0 million milestone payment earned in September 2010 upon filing the Japanese marketing application. We recognize the revenue from the payments from Abbott using a percentage-of-completion model over the estimated term of the CIC development program.

### Product royalty revenue

Product royalty revenue represents royalty revenue earned on net sales of AMITIZA in the United States. In 2010, we recognized \$40.3 million of product royalty revenue compared to \$38.2 million in 2009, an increase of \$2.1 million or 5.4%, reflecting mainly a higher price as the volume declined throughout the year.

### Co-promotion revenue

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force. In 2010, we recognized \$4.4 million of co-promotion revenues compared to \$4.5 million in 2009. The co-promotion reimbursement is capped at \$4.5 million annually for 12-month periods ending March 31.

### Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2010 and 2009:

(In thousands)	Year Ended December 31,	
	2010	2009
<b>Direct costs:</b>		
Amitiza	\$ 17,248	\$ 25,017
Cobiprostone	598	2,294
SPI-017	2,230	2,752
Rescula	1,231	235
Other	342	530
Total	<u>21,649</u>	<u>30,828</u>
<b>Indirect costs</b>	<u>2,306</u>	<u>2,078</u>
Total	<u>\$ 23,955</u>	<u>\$ 32,906</u>

Total research and development expenses in 2010 were \$24.0 million compared to \$32.9 million in 2009, a decrease of \$8.9 million or 27.2%. The decrease was primarily due to the July 2009 completion of the initial two phase 3 pivotal clinical trials of AMITIZA for the treatment of OBD and the July 2009 completion of the phase 2 clinical trial of cobiprostone for the prevention of NSAID-induced ulcers, partially offset by expenses associated with initiating the additional phase 3 trial of lubiprostone for OBD patients.

### General and Administrative Expenses

The following summarizes our general and administrative expenses for years ended December 31, 2010 and 2009:

(In thousands)	Year Ended December 31,	
	2010	2009
Salaries, benefits and related costs	\$ 5,567	\$ 4,036
Legal, consulting and other professional expenses	15,337	5,800
Other expenses	6,963	5,164
Total	<u>\$ 27,867</u>	<u>\$ 15,000</u>

General and administrative expenses were \$27.9 million in 2010 compared to \$15.0 million in 2009, an increase of \$12.9 million or 85.8%. The increase in salaries, benefits and related costs was primarily attributable to an increase in the number of key personnel and a change in the incentive compensation plans for 2010. The increase in legal, consulting and other professional expenses relates primarily to costs incurred in connection with ongoing legal matters, including our dispute with Takeda, as well as our acquisition of SAG.

### Selling and Marketing Expenses

Selling and marketing expenses represent costs we incur to co-promote AMITIZA, including salaries, benefits and related costs of 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 \$10.2 million in 2010 compared to \$10.0 million in 2009, an increase of \$200,000 or 1.7%. Part of the AMITIZA co-promotion expenses are funded by Takeda and recorded as co-promotion revenue.

## Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the years ended December 31, 2010 and 2009:

(In thousands)	Year Ended December 31,	
	2010	2009
Interest income	\$ 608	\$ 965
Interest expense	(75)	\$ -
Other expense, net	(3,700)	(519)
Total	<u>\$ (3,167)</u>	<u>\$ 446</u>

Interest income was \$608,000 in 2010 compared to \$965,000 in 2009, a decrease of \$357,000, or 37.0%. The decrease was primarily due to lower 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. Our investment in ARS was redeemed in June 2010.

Other expense, net was \$3.7 million in 2010 compared to \$519,000 in 2009, an increase of \$3.2 million, or 612.9%. The majority of these foreign exchange losses are unrealized, non-cash and relate to amounts held within subsidiaries.

## Income Taxes

For the years ended December 31, 2010 and 2009, our consolidated effective income tax rate was 17.0% and 51.6%, respectively. For the years ended December 31, 2010 and 2009, we recorded a tax benefit of \$565,000 and a tax provision of \$5.1 million, respectively. The change in our effective tax rate in 2010 from 2009 was attributable primarily to the change in the mix of earnings by jurisdiction, the continuation of foreign losses that are not benefited due to full valuation allowances and an increase in non-deductible expenses in the U.S. As of December 31, 2010, our remaining valuation allowance against our deferred tax assets was \$9.7 million solely relating to foreign jurisdictions, where it is not more likely than not that these deferred tax assets would be realized.

## 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:

(In thousands)	Year Ended December 31,	
	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	<u>\$ 67,351</u>	<u>\$ 112,123</u>

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 women aged 18 years and older 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 as the volume was essentially flat.

### 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:

(In thousands)	Year Ended December 31,	
	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	<u>30,828</u>	<u>43,953</u>
Indirect costs	2,078	2,228
Total	<u>\$ 32,906</u>	<u>\$ 46,181</u>

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	\$ 4,036	\$ 4,468
Legal, consulting and other professional expenses	5,800	2,992
Other expenses	5,164	7,615
Total	<u>\$ 15,000</u>	<u>\$ 15,075</u>

General and administrative expenses were \$15.0 million in 2009 compared to \$15.1 million in 2008, a decrease of \$75,000 or 0.5%. 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 relates primarily to costs incurred in connection with ongoing legal matters, including our dispute with Takeda, as well as our acquisition of SAG.

### ***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 marketing authorization application for lubiprostone.

### ***Non-Operating Income and Expense***

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

<b>(In thousands)</b>	<b>Year Ended December 31,</b>	
	<b>2009</b>	<b>2008</b>
Interest income	\$ 965	\$ 3,344
Other expense, net	(519)	(2,878)
Total	\$ 446	\$ 466

Interest income was \$965,000 in 2009 compared to \$3.3 million in 2008, a decrease of \$2.4 million, or 72.0%. 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 expense, net was \$519,000 in 2009 compared to \$2.9 million in 2008, a decrease of \$2.4 million, or 82.0%. The majority of the non-cash expense related to unrealized foreign exchange losses arising from revaluing amounts held within subsidiaries to their functional currencies.

### ***Income Taxes***

For the years ended December 31, 2009 and 2008, our consolidated effective tax rate was 51.6% and 22.1%, respectively. For the years ended December 31, 2009 and 2008, we recorded a tax provision of \$5.1 million and \$8.9 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 in 2009 that are not benefited due to full valuation allowances. As of December 31, 2009, our remaining valuation allowance against our deferred tax assets was \$8.6 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.

### ***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 that depend on the development status of these geographies. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other factors.

The financial results of our segments reflect their varying stages of development. Our Americas segment recorded income before taxes of \$3.8 million in 2010, compared to income before taxes of \$18.9 million in 2009. These results primarily reflect the completion of the initial two phase 3 clinical trials of AMITIZA for the treatment of OBD and cobiprostone for the prevention of NSAID-induced ulcers in 2009 offset by an increase in general and administrative expenses resulting from the ongoing legal matters, including our dispute with Takeda.

Our segment in Europe recorded a loss before taxes of \$6.2 million in 2010, compared to a loss before taxes of \$4.3 million in 2009. These results primarily reflect the foreign exchange losses within European subsidiaries and the ongoing regulatory costs towards filing an MAA in Europe.

Our segment in Asia recorded a loss before taxes of \$935,000 in 2010 compared to a loss before taxes of \$4.7 million in 2009. These results reflect the revenue recognized from the \$5.0 million payment earned from Abbott in September 2010 combined with ongoing development and regulatory costs.

(In thousands)	Americas	Europe	Asia	Consolidated
<b>Year Ended December 31, 2010</b>				
Total revenues	\$ 50,756	\$ -	\$ 11,114	\$ 61,870
Income (loss) before taxes	3,820	(6,205)	(935)	(3,320)
Identifiable assets	102,096	30,789	16,388	149,273
<b>Year Ended December 31, 2009</b>				
Total revenues	\$ 57,887	\$ -	\$ 9,464	\$ 67,351
Income (loss) before taxes	18,886	(4,298)	(4,727)	9,861
Identifiable assets	132,903	34,140	12,962	180,005
<b>Year Ended December 31, 2008</b>				
Total revenues	\$ 112,123	\$ -	\$ -	\$ 112,123
Income (loss) before taxes	51,293	(4,675)	(6,180)	40,438
Identifiable assets	145,853	29,962	6,539	182,354

## 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, restricted cash and investments consist of the following:

(In thousands)	Year Ended December 31,	
	2010	2009
Cash and cash equivalents	\$ 49,243	\$ 61,420
Restricted cash	15,113	213
Investments, current	54,524	72,434
Investments, non-current	5,028	19,167
Total	<u>\$ 123,908</u>	<u>\$ 153,234</u>

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, 2010, our restricted cash represents cash that serves as collateral in reference to our The Bank of Tokyo-Mitsubishi UFJ, Ltd loan agreement and other cash that is restricted from withdrawal.

As of December 31, 2010, our short-term investments consisted of corporate bonds, U.S. government securities, U.S. Treasury notes and bills, U.S. corporate commercial paper, municipal securities, certificates of deposits and variable rate demand notes which have short-term maturities of one year or less. Our non-current investments consisted of corporate bonds.

## Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2010, 2009 and 2008:

(In thousands)	Year Ended December 31,		
	2010	2009	2008
Cash provided by (used in):			
Operating activities	\$ (3,350)	\$ 4,969	\$ 31,512
Investing activities	(11,856)	(35,455)	10,461
Financing activities	(1,635)	(2,846)	(30,272)
Effect of exchange rates	4,664	1,048	4,091
Net increase (decrease) in cash and cash equivalents	<u>\$ (12,177)</u>	<u>\$ (32,284)</u>	<u>\$ 15,792</u>

### Year ended December 31, 2010

Net cash used in operating activities was \$3.4 million for the year ended December 31, 2010. This reflected a net loss of \$2.8 million, a decrease in deferred revenue of \$6.5 million relating to the previously received funds under the Takeda and Abbott agreements that were recognized as revenue during the period, offset in part by an increase in accrued expenses of \$3.3 million and changes in other operating assets and liabilities.

Net cash used in investing activities of \$11.9 million for the year ended December 31, 2010 primarily reflected our proceeds from the sales and maturities of investments, more than offset by purchases of investments, an increase in restricted cash and our acquisition of SAG.

Net cash used in financing activities of \$1.6 million for the year ended December 31, 2010 resulted from the dividends paid by SAG prior to the acquisition but included under accounting for common control, offset in part by proceeds of our notes and the proceeds we received under our employee stock purchase plan.

### Year ended December 31, 2009

Net cash provided by operating activities was \$5.0 million for the year ended December 31, 2009. This reflected a net income of \$4.8 million, which included a non-cash unrealized loss on settlement rights on auction rate securities of \$1.7 million offset by a decrease of \$4.6 million in deferred revenue and other 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 purchases of investments and the Rescula license, offset in part by proceeds from the sales and maturities of investments.

Net cash used in financing activities of \$2.8 million for the year ended December 31, 2009 resulted from the dividends paid by SAG prior to the acquisition but included under accounting for common control, offset in part by the proceeds we received under our employee stock purchase plan.

### Year ended December 31, 2008

Net cash provided by operating activities was \$31.5 million for the year ended December 31, 2008. This reflected net income of \$31.5 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 \$4.2 million, a non-cash unrealized gain on settlement rights on auction rate securities of \$2.8 million and changes in other operating assets and liabilities. 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 provided by investing activities of \$10.5 million for the year ended December 31, 2008 reflected purchases of investments, more than offset by proceeds from the sales and maturities of investments and repayment of notes receivable.

Net cash used in financing activities of \$30.3 million for the year ended December 31, 2008 resulted from the dividends paid by SAG prior to the acquisition but included under accounting for common control, offset in part by the proceeds we received under our employee stock purchase plan and proceeds received from the exercise of stock options.

## Commitments and Contingencies

As of December 31, 2010, our principal outstanding contractual obligations related to our office leases in the United States, the United Kingdom and Japan. The following table summarizes these significant contractual obligations at December 31 for the indicated year:

### (In thousands)

2011	\$	1,288
2012		1,136
2013		997
2014		1,024
2015		1,052
2016 and thereafter		1,223
Total minimum lease payments	\$	<u>6,720</u>

The above table does not include:

- 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, 2010, our current commitments to CRO's will be \$13.2 million through 2013.

The aggregated scheduled maturities of notes payable as of December 31, 2010 were as follows:

### (In thousands)

Due in one year	\$	19,522
Due in two years		7,500
Due in three years		3,717
Due in four years		3,800
Due in five years		3,884
Thereafter		25,538
	\$	<u>63,961</u>

## Off-Balance Sheet Arrangements

As of December 31, 2010, 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.;
- development and regulatory efforts in Europe and Asia for lubiprostone;
- development and regulatory activities for Rescula in the U.S. and Canada;
- activities to resolve our ongoing legal matters;
- research and development activities for other prostone compounds, including cobiprostone and SPI-017;
- other business development activities, including investments in or acquisitions of other businesses, products and technologies;
- the expansion of our commercialization activities in the U.S. and the initiation of commercialization efforts in non-U.S. markets;
- capital expenditures to support the growth of our business;
- 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; and



- meet the conditions of our loan note obligations.

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 dispute 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, 2010, 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, Switzerland 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 via derivative instruments.

### **Accounting Pronouncements**

Recent accounting pronouncements applicable to our financial statements are described in Note 2 to the accompanying consolidated financial statements included in this Annual Report on Form 10-K.

## **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 United States 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 attempting to limit default risk, market risk and reinvestment risk. We attempt to 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, 2010.

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, 2010 and December 31, 2009, approximately 27.6% and 39.8%, respectively, of our cash, cash equivalents, restricted cash and investments is 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.

## **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 Principal Financial and Accounting 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, 2010. 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 the evaluation we carried out, our Chief Executive Officer and Principal Financial and Accounting Officer have concluded that, as of December 31, 2010, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified under the applicable rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Principal Financial and Accounting 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, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except for the internal controls related to the acquisition of SAG and SAG-J.

As described elsewhere in this report, we acquired SAG and SAG-J on December 23, 2010. We are in the process of integrating SAG and SAG-J. As a result, we have not fully evaluated the internal control over financial reporting of SAG and SAG-J. Specifically, as permitted by SEC rules and regulations, we excluded from our evaluation of the effectiveness of the internal control over financial reporting from our Annual Report on Form 10-K for our fiscal year ended December 31, 2010 the activities of SAG and SAG-J. The process of integrating SAG and SAG-J into our evaluation of internal control over financial reporting may result in future changes to our internal control over financial reporting. SAG and SAG-J will be part of our evaluation of the effectiveness of internal control over financial reporting in our Annual Report on Form 10-K for our fiscal year ending December 31, 2011, in which report we will be initially required to include the SAG and SAG-J in our annual assessment.

### ***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, 2010. 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, 2010.

In accordance with guidance issued by the SEC, companies are permitted to exclude acquisitions from their final assessment of internal controls over financial reporting during the year of the acquisition while integrating the acquired operations. Management's evaluation of internal control over financial reporting excluded the internal control activities of SAG and SAG-J, which the Company acquired on December 23, 2010. SAG and SAG-J accounted for \$26.9 million, or 18.0% of total assets of the Company, at December 31, 2010 and did not account for any of the revenues of the Company for the year ended December 31, 2010.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2010 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)*

Andrew P. Smith  
*(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, 2010, 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 expert” 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 and 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 equity compensation plan information required under this item is incorporated by reference to the information provided under the heading “Stock Ownership Information” and “Equity Compensation Plan Information” of the Proxy Statement to be filed within 120 days after the fiscal year end of December 31, 2010.

### 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 “Related Party 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 “Independent Registered Public Accounting Firm’s Fees” and “Pre-Approval Policy and Procedures” 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-36. 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.

<b>Exhibit Number</b>	<b>Description</b>	<b>Reference</b>
2.1	Agreement and Plan of Reorganization	Exhibit 3.1 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 <sup>^</sup>	Amended and Restated 2001 Stock Incentive Plan	Exhibit 10.1 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.2 <sup>^</sup>	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 <sup>^</sup>	2006 Employee Stock Purchase Plan	Exhibit 10.3 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.4 <sup>^</sup>	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 <sup>^</sup>	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 <sup>^</sup>	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 <sup>^</sup>	Non-employee Director Compensation Summary	Exhibit 10.7 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.8 <sup>^</sup>	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)
10.1	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)
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)
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)
2.2	Stock Purchase Agreement, dated December 23, 2010, by and among Dr. Ryuji Ueno, as trustee of the Ryuji Ueno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Sachiko Kuno as trustee of the Sachiko Kuno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Ryuji Ueno, Dr. Sachiko Kuno, Ambrent Investments S.à.r.l., and Sucampo Pharmaceuticals, Inc	Exhibit 2.1 to the Company's Current Report on Form 8-K (filed December 29, 2010)
10.49	Special Agreement, dated November 22, 2010, between Sucampo Pharma, Ltd., Osaka, Japan, a wholly-owned subsidiary of the Company, and The Bank of Tokyo-Mitsubishi UFJ, Ltd	Included herewith
10.50	Agreement on Bank Overdrafts, dated November 18, 2010, between Sucampo Pharma, Ltd., Osaka, Japan, a wholly-owned subsidiary of the Company, and The Bank of Tokyo-Mitsubishi UFJ, Ltd	Included herewith
10.51	Subordinated Unsecured Promissory Note, dated December 23, 2010, between Ambrent Investments S.à r.l., as borrower, and Ryuji Ueno Revocable Trust Under Trust Agreement dated December 20, 2002, as lender	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed December 29, 2010)
10.52	Subordinated Unsecured Promissory Note, dated December 23, 2010, between Ambrent Investments S.à.r.l., as borrower, and Sachiko Kuno Revocable Trust Under Trust Agreement dated December 20, 2002, as lender	Exhibit 10.2 to the Company's Current Report on Form 8-K (filed December 29, 2010)



10.53	Non-Competition Agreement, dated as of December 23, 2010 by and among Dr. Ryuji Ueno, as trustee of the Ryuji Ueno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Sachiko Kuno as trustee of the Sachiko Kuno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Ryuji Ueno, Dr. Sachiko Kuno, Ambrent Investments S.à r.l., and Sucampo Pharmaceuticals, Inc	Exhibit 10.3 to the Company's Current Report on Form 8-K (filed December 29, 2010)
10.54^	Separation Agreement and General Release, dated January 28, 2011, between the Company and Jan Smilek	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed February 22, 2011)
10.55^	Consulting Agreement, dated January 28, 2011, between the Company and Jan Smilek	Exhibit 99.2 to the Company's Current Report on Form 8-K (filed February 22, 2011)
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 granted 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 8, 2011

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ RYUJI UENO</u> Ryuji Ueno, M.D., Ph.D., Ph.D.	Chief Executive Officer (Principal Executive Officer), Chief Scientific Officer and Director	March 8, 2011
<u>/s/ ANDREW P. SMITH</u> Andrew P. Smith	Principal Financial and Accounting Officer	March 8, 2011
<u>/s/ WILLIAM L. ASHTON</u> William L. Ashton	Director	March 8, 2011
<u>/s/ ANTHONY C. CELESTE</u> Anthony C. Celeste	Director	March 8, 2011
<u>/s/ GAYLE R. DOLECEK</u> Gayle R. Dolecek P.D.	Director	March 8, 2011
<u>/s/ ANDREW J. FERRARA</u> Andrew J. Ferrara	Director	March 8, 2011
<u>/s/ SACHIKO KUNO</u> Sachiko Kuno Ph.D.	Director	March 8, 2011
<u>/s/ TIMOTHY I. MAUDLIN</u> Timothy I. Maudlin	Director	March 8, 2011

**SUCAMPO PHARMACEUTICALS, INC.**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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## 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 (collectively, the "Company") at December 31, 2010 and December 31, 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 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, 2010, 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 integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

As described in the Report of Management on Internal Control Over Financial Reporting under Item 9A, management has excluded Sucampo AG ("SAG") and Sucampo AG-Japan Ltd. ("SAG-J") from its assessment of internal control over financial reporting as of December 31, 2010 because these entities were acquired by the Company in late 2010. The acquisition was accounted for as a merger of companies under common control. We have also excluded SAG and SAG-J from our audit of internal control over financial reporting. SAG and SAG-J are included in the consolidated results on which we are reporting and their total assets and total revenues represent 18% and 0%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2010.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland  
March 8, 2011

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

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 49,243	\$ 61,420
Investments, current	54,524	72,434
Product royalties receivable	10,516	11,023
Unbilled accounts receivable	1,097	644
Accounts receivable, net	731	512
Prepaid and income taxes receivable	702	-
Deferred tax assets, net	243	315
Restricted cash	15,113	213
Prepaid expenses and other current assets	2,374	3,175
Total current assets	134,543	149,736
Investments, non-current	5,028	19,167
Property and equipment, net	2,025	2,274
Deferred tax assets, non-current	4,178	3,995
Other assets	3,499	4,833
Total assets	\$ 149,273	\$ 180,005
<b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
Current liabilities:		
Accounts payable	\$ 4,199	\$ 3,210
Accrued expenses	10,216	6,695
Deferred revenue, current	4,987	10,565
Income taxes payable	-	1,953
Notes payable, current	19,522	-
Total current liabilities	38,924	22,423
Notes payable, non-current	44,439	-
Deferred revenue, non-current	8,321	8,643
Other liabilities	3,759	3,627
Total liabilities	95,443	34,693
Commitments (Note 10)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2010 and 2009; no shares issued and outstanding at December 31, 2010 and 2009	-	-
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2010 and 2009; 15,659,917 and 15,655,730 shares issued and outstanding at December 31, 2010 and 2009, respectively	156	156
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2010 and 2009; 26,191,050 shares issued and outstanding at December 31, 2010 and 2009	262	262
Additional paid-in capital	58,468	98,897
Accumulated other comprehensive income	16,574	12,847
(Accumulated deficit) retained earnings	(21,630)	33,150
Total stockholders' equity	53,830	145,312
Total liabilities and stockholders' equity	\$ 149,273	\$ 180,005

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

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

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Revenues:</b>			
Research and development revenue	\$ 16,540	\$ 23,957	\$ 72,293
Product royalty revenue	40,300	38,250	34,438
Co-promotion revenue	4,417	4,541	4,826
Contract and collaboration revenue	613	603	566
Total revenues	<u>61,870</u>	<u>67,351</u>	<u>112,123</u>
<b>Operating expenses:</b>			
Research and development	23,955	32,906	46,181
General and administrative	27,867	15,000	15,075
Selling and marketing	10,201	10,030	10,895
Total operating expenses	<u>62,023</u>	<u>57,936</u>	<u>72,151</u>
Income (loss) from operations	(153)	9,415	39,972
<b>Non-operating income (expense):</b>			
Interest income	608	965	3,344
Interest expense	(75)	-	-
Other expense, net	(3,700)	(519)	(2,878)
Total non-operating income (expense), net	<u>(3,167)</u>	<u>446</u>	<u>466</u>
Income (loss) before income taxes	(3,320)	9,861	40,438
Income tax benefit (provision)	565	(5,084)	(8,925)
Net income (loss)	<u>\$ (2,755)</u>	<u>\$ 4,777</u>	<u>\$ 31,513</u>
<b>Net income (loss) per share:</b>			
Basic net income (loss) per share	<u>\$ (0.07)</u>	<u>\$ 0.11</u>	<u>\$ 0.75</u>
Diluted net income (loss) per share	<u>\$ (0.07)</u>	<u>\$ 0.11</u>	<u>\$ 0.75</u>
Weighted average common shares outstanding - basic	<u>41,848</u>	<u>41,844</u>	<u>41,787</u>
Weighted average common shares outstanding – diluted	<u>41,848</u>	<u>41,866</u>	<u>41,973</u>
<b>Comprehensive income:</b>			
Net income (loss)	\$ (2,755)	\$ 4,777	\$ 31,513
<b>Other comprehensive income gain (loss):</b>			
Unrealized gain (loss) on investments, net of tax effect	(18)	(55)	79
Foreign currency translation	3,745	822	4,022
Comprehensive income	<u>\$ 972</u>	<u>\$ 5,544</u>	<u>\$ 35,614</u>

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)

	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				
Balance at December 31, 2007	15,538,518	\$ 155	26,191,050	\$ 262	\$ 96,941	\$ 7,979	\$ 30,875	136,212
Employee stock option expense	-	-	-	-	686	-	-	686
Stock issued upon exercise of stock options	111,880	1	-	-	869	-	-	870
Stock issued under employee stock purchase plan	1,451	-	-	-	8	-	-	8
Foreign currency translation	-	-	-	-	-	4,022	-	4,022
Unrealized gain on investments, net of tax effect	-	-	-	-	-	79	-	79
Dividend payments	-	-	-	-	-	-	(31,150)	(31,150)
Net income	-	-	-	-	-	-	31,513	31,513
Balance at December 31, 2008	15,651,849	156	26,191,050	262	98,504	12,080	31,238	142,240
Employee stock option expense	-	-	-	-	374	-	-	374
Stock issued under employee stock purchase plan	3,881	-	-	-	19	-	-	19
Foreign currency translation	-	-	-	-	-	822	-	822
Unrealized loss on investments, net of tax effect	-	-	-	-	-	(55)	-	(55)
Dividend payments	-	-	-	-	-	-	(2,865)	(2,865)
Net income	-	-	-	-	-	-	4,777	4,777
Balance at December 31, 2009	15,655,730	156	26,191,050	262	98,897	12,847	33,150	145,312
Employee stock option expense	-	-	-	-	1,260	-	-	1,260
Stock issued under employee stock purchase plan	4,187	-	-	-	14	-	-	14
Foreign currency translation	-	-	-	-	-	3,745	-	3,745
Unrealized loss on investments, net of tax effect	-	-	-	-	-	(18)	-	(18)
Deemed dividend for SAG acquisition	-	-	-	-	(41,703)	-	(38,297)	(80,000)
Dividend payments	-	-	-	-	-	-	(13,728)	(13,728)
Net loss	-	-	-	-	-	-	(2,755)	(2,755)
Balance at December 31, 2010	15,659,917	\$ 156	26,191,050	\$ 262	\$ 58,468	\$ 16,574	\$ (21,630)	\$ 53,830

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,		
	2010	2009	2008
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ (2,755)	\$ 4,777	\$ 31,513
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>			
Depreciation and amortization	964	789	478
(Gain) loss on disposal of property and equipment	1	-	(7)
Deferred tax provision (benefit)	(99)	13	(4,214)
Stock-based compensation	1,260	374	686
Amortization of premiums on investments	1,617	1,415	-
(Gain) loss on trading securities	(1,086)	(2,092)	3,178
(Gain) loss on settlement rights on auction rate securities	1,086	1,732	(2,818)
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable	(218)	32	1,016
Unbilled accounts receivable	(453)	3,729	1,510
Product royalties receivable	507	(1,298)	(1,058)
Prepaid and income taxes receivable and payable, net	(2,689)	1,586	(1,091)
Accounts payable	893	1,679	831
Accrued expenses	3,329	(3,269)	933
Deferred revenue	(6,525)	(4,564)	13,972
Other assets and liabilities, net	818	66	(13,417)
Net cash provided by (used in) operating activities	<u>(3,350)</u>	<u>4,969</u>	<u>31,512</u>
<b>Cash flows from investing activities:</b>			
Purchases of investments	(84,857)	(150,712)	(116,679)
Proceeds from the sales of investments	25,855	9,504	46,610
Maturities of investments	90,492	109,163	69,000
Purchases of property and equipment	(333)	(495)	(489)
Proceeds from disposals of property and equipment	5	-	12
Proceeds from repayment of notes receivable	-	-	12,007
Purchases of intangible assets	-	(2,915)	-
Acquisition of SAG	(28,118)	-	-
Restricted cash	(14,900)	-	-
Net cash provided by (used in) investing activities	<u>(11,856)</u>	<u>(35,455)</u>	<u>10,461</u>
<b>Cash flows from financing activities:</b>			
Proceeds from notes payable	12,079	-	-
Proceeds from exercise of stock options	-	-	870
Proceeds from employee stock purchase plan	14	19	8
Dividend payments	(13,728)	(2,865)	(31,150)
Net cash used in financing activities	<u>(1,635)</u>	<u>(2,846)</u>	<u>(30,272)</u>
Effect of exchange rates on cash and cash equivalents	<u>4,664</u>	<u>1,048</u>	<u>4,091</u>
Net increase (decrease) in cash and cash equivalents	(12,177)	(32,284)	15,792
Cash and cash equivalents at beginning of period	61,420	93,704	77,912
Cash and cash equivalents at end of period	<u>\$ 49,243</u>	<u>\$ 61,420</u>	<u>\$ 93,704</u>
<b>Supplemental cash flow disclosures:</b>			
Cash paid for interest	\$ 2	\$ -	\$ -
Tax refunds received	\$ 126	\$ -	\$ 1,957
Tax payments made	\$ 2,683	\$ 1,223	\$ 11,383
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Purchase of intangible assets included in accrued expenses	\$ -	\$ 500	\$ -
Loan notes issued for acquisition of SAG	\$ 51,882	\$ -	\$ -

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. is an international pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds that occur naturally in the human body as a result of enzymatic, 15-PGDH, transformation of certain fatty acids. The Company is focused on developing prostones for the treatment of gastrointestinal, ophthalmic, 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. 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 women aged 18 years and older. 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.

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, or Takeda, dated October 29, 2004. The Company believes that Takeda's failures to generate an appropriate level of U.S. sales of AMITIZA is the result of its materially breaches of the Company's agreements, including, without limitation, Takeda's continuing failure to exercise its best efforts to promote, market and sell AMITIZA and to maximize its 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 also claims 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 sent Takeda another notice of material breach in December 2010, which specifically set forth all of the claims asserted in the arbitration submission. The Company is seeking all appropriate relief, including production by Takeda of all information to which it is entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. All the arbitrators have been confirmed and the arbitration proceedings have commenced. The arbitrators currently have set the hearing on the Company's claims to conclude by late October 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. The Company has spent and expects to spend significant resources in the dispute with Takeda and these arbitration proceedings may require the continuing attention of the Company's senior management.

In April 2009, the Company acquired the rights to Rescula that allow the Company to commercialize Rescula in the U.S. and Canada for its approved indication and any new indication developed by the Company. The Company plans to re-launch Rescula in the U.S. for its approved indication after approval of a commercially viable label from the FDA. In September 2010, Rescula received an Orphan Drug designation from the FDA for retinitis pigmentosa. Additionally, the Company plans to evaluate conducting a phase 2a clinical trial of unoprostone isopropyl for the indication of age-related macular degeneration, or dry AMD, in 2011.

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, non-alcoholic fatty liver disease, disorders associated with cystic fibrosis and chronic obstructive pulmonary disease, or COPD. In July 2009, the Company reported top-line results from its phase 2a clinical trial of orally administered cobiprostone for the prevention of gastric ulcers and other gastrointestinal 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. The Company is evaluating a phase 2b study to complement the findings of earlier studies. The Company is also designing a preclinical study of cobiprostone for use as a treatment for COPD and as a potential treatment for oral mucositis.

## SUCAMPO PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements – (Continued)

- SPI-017 for the treatment of peripheral and central nervous system disorders. The Company has recently completed a phase 1 clinical program of the intravenous formulation of SPI-017 for peripheral arterial disease, or PAD, in Japan and plans to initiate a phase 2 study for this indication in 2011.
- SPI-3608 potentially for the management of pain caused by spinal stenosis. SPI-3608 is a novel orally bioavailable prostone and will continue to undergo preclinical testing.

In December 2010, the Company acquired Sucampo AG, or SAG, a related party Swiss-based patent-holding company, including its wholly-owned subsidiary Sucampo AG Japan Ltd., or SAG-J, a patent maintenance company (Note 3). This acquisition enables the Company to control and provide exclusive ownership of the patents and other intellectual property underlying the Company's current and future prostone products, including AMITIZA, cobiprostone, SPI-017 and other compounds. The acquisition of SAG eliminates future royalty and milestone payment obligations to third-party companies outside of the Company and its wholly-owned subsidiaries, and removes certain mandatory funding requirements for the development of early-stage compounds that would otherwise be needed to maintain rights to the promising drug candidates generated by the prostone technology platform.

Drs. Ryuji Ueno and Sachiko Kuno, are married to each other and, directly or indirectly, own the majority of the stock of R-Tech Ueno, Ltd, or R-Tech, a pharmaceutical research, development and manufacturing company in Japan. Drs. Ueno and Kuno also are controlling stockholders of the Company. 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.

#### ***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 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; Sucampo Pharma Europe, Ltd., based in Oxford, U.K., in which the Company conducts operations in Europe and the rest of the world; Ambrent Investments S.à.r.l., based in Luxembourg; Sucampo AG, based in Zug, Switzerland and its wholly owned subsidiary, Sucampo AG Japan, based in Osaka, Japan. In April 2010, the Company incorporated another wholly owned subsidiary, Sucampo Manufacturing & Research AG, in Wollerau, Switzerland, whose operations will focus on managing specific manufacturing, commercial, research and intellectual property activities. All significant inter-company balances and transactions have been eliminated.

The acquisition of SAG and its subsidiary was accounted for as a merger of companies under common control and accounted for at historical cost. The financial information of these acquired entities is included in these consolidated financial statements for all periods presented.

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.

#### ***Restricted Cash***

Restricted cash consists of approximately \$15.1 million and \$213,000 at December 31, 2010 and December 31, 2009, respectively. Restricted cash represents cash required to be deposited with financial institutions in connection with the Sucampo Pharma, Ltd. and The Bank of Tokyo-Mitsubishi UFJ, Ltd. loan agreement and operating leases.

## SUCAMPO PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements – (Continued)

#### *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. On June 8, 2010, the Company's remaining ARS were redeemed at par value of \$10.0 million per the agreement with the ARS broker. The redemption of the ARS and the related settlement rights in 2010 are described in Note 5 below.

#### *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, 2010 and 2009, approximately \$34.1 million, or 27.6%, and \$60.9 million, or 39.8%, respectively, of the Company's cash, cash equivalents, restricted cash and investments were 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 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 81.4%, 85.3% and 99.6%, of the Company's total revenues for the years ended December 31, 2010, 2009 and 2008, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 100% and 96.5% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at December 31, 2010 and 2009, respectively. Revenues from another unrelated party, Abbott Japan Co. Ltd., or Abbott, accounted for 18.0% and 14.1% of the Company's total revenues for the years ended December 31, 2010 and 2009. There was no corresponding revenue for 2008. The Company depends significantly upon the collaborations with Takeda and Abbott and its activities may be impacted if these relationships are disrupted (Note 13).

**Notes to Consolidated Financial Statements – (Continued)**

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 11).

***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. The fair value of short and long-term debt at December 31, 2010 approximates their carrying values since the debt was incurred near year end.

***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 13). 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 2010 or 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, 2010, 2009 or 2008 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 13.

**Notes to Consolidated Financial Statements – (Continued)**

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.

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. At December 31, 2010 and 2009, total deferred revenue was approximately \$13.3 million and \$19.2 million, respectively.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

Total deferred revenue consists of the following as of:

<b>(In thousands)</b>	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Deferred revenue, current	\$ 4,987	\$ 10,565
Deferred revenue, non-current	8,321	8,643
	<u>\$ 13,308</u>	<u>\$ 19,208</u>
Deferred revenue to related parties, included in total deferred revenue:		
Deferred revenue to related parties, current	433	431
Deferred revenue to related parties, non-current	5,839	6,256
<b>Total</b>	<u>\$ 6,272</u>	<u>\$ 6,687</u>

***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.

***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.

***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.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

The Company's determination of fair value of share-based awards on the date of grant using an option-pricing model is affected by the Company's stock price and assumptions regarding a number of highly complex and subjective variables.

The assumptions used to estimate the fair value of stock options granted for the three years ended December 31, 2010 were as follows:

	Year Ended December 31,		
	2010	2009	2008
Expected volatility	51% - 63%	47% - 55%	53% - 56%
Risk-free interest rate	1.89% - 3.24%	2.67% - 3.11%	2.78% - 3.45%
Expected term (in years)	5.00 - 6.25	6.00 - 7.00	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 a maturity that approximates the expected term of the share-based awards.

**Expected Term:** 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 2010 has been reduced for estimated forfeitures as such expense is based upon awards expected to ultimately vest. Accounting 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, 2010, 2009 and 2008, 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, 2010 was as follows:

(In thousands)	Year Ended December 31,		
	2010	2009	2008
Research and development expense	\$ 252	\$ 96	\$ 245
General and administrative expense	729	193	199
Selling and marketing expense	279	85	242
Total	1,260	374	686
Employee stock-based compensation expense per basic and diluted share of common stock	\$ 0.03	\$ 0.01	\$ 0.02

## SUCAMPO PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements – (Continued)

#### ***Income Taxes***

The Company accounts for income taxes under the asset and liability method in accordance with the relevant accounting guidance for income taxes. Under the asset and liability method, the current income tax provision or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Tax rate changes are reflected in the income tax provision during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

Significant judgment is required in determining the provision for income taxes and, in particular, any valuation allowance recorded against the Company's net deferred tax assets. The Company has recorded a valuation allowance, which resulted in a net deferred tax asset of \$3.3 million as of December 31, 2010 and December 31, 2009, 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 50.0% likely to be realized upon settlement.

The Company has recorded a non-current income tax liability of approximately \$1.4 million and \$1.3 million, including interest for uncertain tax positions, as of December 31, 2010 and 2009, 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, 2010 and 2009 mainly pertained to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes, as well as uncertain tax positions related to related party interest in foreign jurisdictions.

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).



**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

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

**Segment Information**

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

**Change in Estimate**

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

During 2008, as a result of lower-than-expected patient enrollment in one 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. The Company further revised the estimated timeline and costs associated with a separate study and recorded a change in estimate during 2010, 2009 and 2008 related to the amount of research and development revenues.

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

<b>(in thousands, except per share data)</b>	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Decrease in revenue and income before income taxes	\$ 1,562	\$ (4,785)	\$ (6,523)
Impact on basic net income (loss) per share	.02	(0.07)	(0.09)
Impact on diluted net income (loss) per share	.02	(0.07)	(0.09)

**Recent Accounting Pronouncements**

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 adopted the guidance effective January 1, 2010 and such adoption did not have an impact on the Company's consolidated financial statements.

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.

**Notes to Consolidated Financial Statements – (Continued)**

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 adopted the relevant guidance effective January 1, 2010 and such adoption did not have a material impact on the Company's consolidated financial statements.

In March 2010, the FASB issued authoritative guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. Under this guidance, an accounting policy election can be made to recognize arrangement consideration received for achieving specified performance measures during the period in which the milestones are achieved, provided certain criteria are met. This guidance is limited to transactions involving research or development. This guidance is effective for annual and interim reporting periods beginning on or after June 15, 2010 and may be early adopted. Since the Company elected to continue to use the existing revenue models, the relevant guidance has not been adopted.

**3. Acquisition of Sucampo AG and Sucampo AG Japan**

On December 23, 2010, the Company's subsidiary, Ambrent Investments S.à r.l., or Ambrent, a company organized under the laws of Luxembourg, entered into a stock purchase agreement, or the Purchase Agreement, with Dr. Ryuji Ueno, as trustee of the Ryuji Ueno Revocable Trust under Trust Agreement dated December 20, 2002, or the Ueno Trust, Dr. Sachiko Kuno as trustee of the Sachiko Kuno Revocable Trust under Trust Agreement dated December 20, 2002, or the Kuno Trust, and together with Drs. Ueno and Kuno and Ambrent, to acquire SAG, a Swiss-based patent-holding company, and its wholly-owned subsidiary SAG-J, a patent maintenance company.

The Sellers, Drs. Ueno and Kuno, are related parties of the Company. Dr. Ueno is the Company's Chief Executive Officer, Chief Scientific Officer and Chairman of the Board of Directors. Dr. Kuno is the Company's international business advisor and a member of its Board of Directors, and is also Dr. Ueno's spouse. Drs. Ueno and Kuno are co-founders and majority stockholders of the Company and are also majority stockholders of R-Tech, a significant supplier to the Company. Pursuant to the Company's related person transactions policy, the Company's Audit Committee, which consists solely of independent directors, reviewed and approved the acquisition. The purchase price for the acquisition was negotiated based on a discounted cash flow analysis of expected future payments on the licensed intellectual property rights and the estimated fair value of the acquired net assets.

The total purchase price under the Purchase Agreement is \$80.0 million, consisting of a cash payment made in December 2010 of approximately \$28.1 million and the issuance of two subordinated unsecured promissory notes in the aggregate amount of approximately \$51.9 million. In addition, the purchase price includes a contingent payment equal to 15.0%, up to a maximum of \$40.0 million, of any cash that may be received by the Company in connection with the ultimate resolution of the current arbitration proceedings against Takeda. This contingent payment has not been recorded as a liability within these financial statements given the common control nature of the transaction.

The purchase agreement contains customary representations, warranties and covenants, and agreements as to indemnification among the parties, subject to certain exclusions and limitations.

The acquisition of SAG and SAG-J was accounted for as a merger of companies under common control, and accounted for at historical costs as of the earliest period presented. The financial information of these additional entities is presented in both the current and historical periods. Prior to the acquisition, SAG has paid dividends of \$13.7 million and \$2.9 million during the years ended December 31, 2010 and 2009, respectively. These dividends are included within the consolidated statements of changes in stockholders' equity together as a reduction of retained earnings. The \$80.0 million purchase consideration has been treated as a deemed distribution due to the accounting for the common control acquisition of SAG and has been included in stockholders' equity as a reduction of \$38.3 million in retained earnings and a \$41.7 million reduction in additional paid in capital.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

**4. 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.

The computation of net income (loss) per share for the three years ended December 31, 2010, is shown below:

<b>(in thousands, except per share data)</b>	<b>December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Basic net income (loss) per share:</b>			
Net income (loss)	\$ (2,755)	\$ 4,777	\$ 31,513
Weighted average class A and B common shares outstanding	41,848	41,844	41,787
Basic net income (loss) per share	\$ (0.07)	\$ 0.11	\$ 0.75
<b>Diluted net income (loss) per share:</b>			
Net income (loss)	\$ (2,755)	\$ 4,777	\$ 31,513
Weighted average class A and B common shares outstanding for diluted net income per share	41,848	41,844	41,787
Assumed exercise of stock options under the treasury stock method	-	22	186
	41,848	41,866	41,973
Diluted net income (loss) per share	\$ (0.07)	\$ 0.11	\$ 0.75

For the years listed above, the potentially dilutive securities used in the calculations of diluted net income per share as of December 31, 2010, 2009 and 2008 are as follows:

<b>(In thousands)</b>	<b>December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Employee stock options	-	227	5
Non-employee stock options	-	-	470

For the years listed above, the following securities were excluded from the computation of diluted net income (loss) per share as their effect would be anti-dilutive as of December 31, 2010, 2009 and 2008:

<b>(In thousands)</b>	<b>December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Employee stock options	1,554	685	772
Non-employee stock options	450	450	-

**5. Current and Non-Current Investments**

At December 31, 2010 and 2009, current and non-current investments consisted of the following securities:

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements – (Continued)

(In thousands)	December 31, 2010			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
<i>Current:</i>				
U.S. Treasury bills and notes	\$ 1,002	\$ 1	\$ -	\$ 1,003
U.S. commercial paper	999	-	-	999
U.S. government securities	16,525	7	(4)	16,528
Municipal securities	17,582	6	(12)	17,576
Certificates of deposits	750	-	-	750
Corporate bonds	6,665	5	(2)	6,668
Variable rate demand notes	11,000	-	-	11,000
Total	<u>\$ 54,523</u>	<u>\$ 19</u>	<u>\$ (18)</u>	<u>\$ 54,524</u>

<i>Non-current:</i>				
Corporate bonds	\$ 5,019	\$ 11	\$ (2)	\$ 5,028
Total	<u>\$ 5,019</u>	<u>\$ 11</u>	<u>\$ (2)</u>	<u>\$ 5,028</u>

(In thousands)	December 31, 2009			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
<i>Current:</i>				
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	<u>\$ 72,390</u>	<u>\$ 58</u>	<u>\$ (14)</u>	<u>\$ 72,434</u>

<i>Non-current:</i>				
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	<u>\$ 20,258</u>	<u>\$ 12</u>	<u>\$ (1,103)</u>	<u>\$ 19,167</u>

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). On June 8, 2010, the Company's remaining ARS were redeemed per the settlement agreement with the ARS broker at par value of \$10.0 million, which also terminated the related settlement rights.

The Company performs fair value measurements in accordance with the FASB's guidance for fair value measurements and disclosures, which defines fair value as the exchange price that would be received for selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy is established which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company classifies its investments into the following categories based on the three levels of inputs used to measure fair value:

Level 1: quoted prices in active markets for identical assets or liabilities;

Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements – (Continued)

Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

December 31, 2010 (In thousands)	Fair Value Measurements at Reporting Date Using			Total
	Quoted Prices in Active Markets for identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
U.S. Treasury bills and notes	\$ 1,003	\$ -	\$ -	\$ 1,003
U.S. government securities	16,528	-	-	16,528
U.S. commercial paper	-	999	-	999
Corporate bonds	11,696	-	-	11,696
Municipal securities	17,576	-	-	17,576
Certificates of deposits	-	750	-	750
Money market funds	780	-	-	780
Variable rate demand notes	11,000	-	-	11,000
Total assets measured at fair value	\$ 58,583	\$ 1,749	\$ -	\$ 60,332

December 31, 2009 (In thousands)	Fair Value Measurements at Reporting Date Using			Total
	Quoted Prices in Active Markets for identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
U.S. Treasury bills and notes	\$ 2,999	\$ -	\$ -	\$ 2,999
U.S. government securities	34,090	-	-	34,090
U.S. commercial paper	-	3,000	-	3,000
Corporate bonds	17,709	-	-	17,709
Municipal securities	28,287	-	-	28,287
Auction rate securities	-	-	8,914	8,914
Settlement rights for auction rate securities*	-	-	1,086	1,086
Certificates of deposits	-	1,747	-	1,747
Money market funds	8,759	-	-	8,759
Total assets measured at fair value	\$ 91,844	\$ 4,747	\$ 10,000	\$ 106,591

\*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, 2010:

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

<b>(In thousands)</b>	<b>Auction Rate Securities and Related Settlement Rights</b>
Balance at December 31, 2009	\$ 10,000
Redemptions	(10,000)
Balance at December 31, 2010	\$ -

If quoted prices in active markets for identical assets and liabilities are not available to determine fair value, then the Company uses quoted prices for similar assets and liabilities or inputs other than the quoted prices that are observable, either directly or indirectly. This pricing methodology applies to the Company's Level 2 investments.

The fair value of the Company's auction rate security holdings and settlement rights as of December 31, 2009 were estimated based on an internal pricing model and categorized in Level 3 of the fair value hierarchy. The pricing model takes into consideration the characteristics of the underlying securities as well as multiple inputs, including counterparty credit quality, expected timing of redemptions and the yield premium that a market participant would require over otherwise comparable securities. These inputs require significant management judgment.

**6. Property and Equipment**

Property and equipment consists of the following as of:

<b>(In thousands)</b>	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Computer and office machines	\$ 2,206	\$ 1,858
Furniture and fixtures	364	360
Leasehold improvements	1,414	1,399
Other	46	41
Total cost	4,030	3,658
Less: accumulated depreciation	(2,005)	(1,384)
Total	\$ 2,025	\$ 2,274

Depreciation expense for the years ended December 31, 2010, 2009 and 2008 was approximately \$604,000, \$543,000 and \$462,000, respectively.

The leasehold improvements as of December 31, 2010 are related to tenant improvements to the Company's headquarters in Bethesda, Maryland.

**7. Intangible Assets**

In April 2009, the Company entered into two agreements with R-Tech, a Japanese manufacturing and research and development company that is majority owned by the Company's founders, to acquire all patents and other intellectual property rights related to Rescula® (unoprostone isopropyl) for its FDA approved indication and any new indications in the U.S. and Canada. Although Rescula eye drops have been approved by the FDA since 2000, Rescula is not currently marketed in the U.S. or Canada. The Company plans to re-launch Rescula in the U.S. for its approved indication after approval of a commercially viable label from the FDA.

Under the terms of the R-Tech agreements, the Company 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, 2010, 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 \$341,000 and \$228,000, respectively, for the years ended December 31, 2010 and 2009. The annual amortization expense will be approximately \$342,000 through April 2019.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

**8. Accrued Expenses**

Accrued expenses consist of the following as of:

<b>(In thousands)</b>	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Research and development costs	\$ 4,400	\$ 3,624
Employee compensation	1,795	879
Selling and marketing costs	305	731
Legal service fees	2,620	396
Other accrued expenses	1,096	1,065
Total	<u>\$ 10,216</u>	<u>\$ 6,695</u>

**9. Other Liabilities**

Other liabilities consist of the following as of:

<b>(In thousands)</b>	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Deferred leasehold incentive	\$ 727	\$ 844
Deferred rent expense	525	508
Deferred tax liability	1,077	977
Other liabilities	1,430	1,298
Total	<u>\$ 3,759</u>	<u>\$ 3,627</u>

**10. Commitments**

*Operating Leases*

The Company leases office space in the United States, United Kingdom and Japan under operating leases through 2017. Total future minimum, non-cancelable lease payments under operating leases, are as follows as of December 31, 2010:

<b>(In thousands)</b>	
2011	\$ 1,288
2012	1,136
2013	997
2014	1,024
2015	1,052
2016 and thereafter	1,223
Total minimum lease payments	<u>\$ 6,720</u>

Rent expense for all operating leases was \$1.3 million, \$1.3 million and \$1.2 million for the years ended December 31, 2010, 2009 and 2008, respectively.

## Notes to Consolidated Financial Statements – (Continued)

**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 through 2013 under these agreements as of December 31, 2010 were approximately \$13.2 million. This amount does not include expected costs relating to the phase 2 studies for Rescula, for which the CRO agreement has not been finalized as of December 31, 2010.

**11. 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).

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 in April 2006. The Company has recognized revenue of \$419,000 for the years ended December 31, 2010 and 2009, which is recorded as contract revenue. During the years ended December 31, 2010, 2009 and 2008, the Company purchased from R-Tech \$344,000, \$205,000 and \$58,000, 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 (see Note 13).

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, 2010 and 2009. During the years ended December 31, 2010 and 2009, the Company purchased \$110,000 and \$692,000, respectively, of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch in Europe. There were no such commercial supplies purchases in 2008. Subsequent to the purchase, the Company withdrew its European marketing application 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 2010, 2009 or 2008.



**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

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, 2010, 2009 and 2008, the Company purchased from R-Tech \$48,000, \$1.1 million and \$1.9 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. During the years ended December 31, 2010 and 2009, the Company purchased \$267,000 and \$381,000, respectively, of commercial supplies of lubiprostone from R-Tech under this agreement. There were no such commercial supplies purchases in 2008. During the year ended December 31, 2009, the Company purchased \$262,000 of clinical supplies from R-Tech under this agreement. There were no such clinical supplies purchases in 2010 and 2008 from R-Tech under this agreement.

In April 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 its approved indication 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 7 above.

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 2010 or 2009.

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

<b>(In thousands)</b>	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Clinical supplies	\$ 392	\$ 1,556	\$ 1,917
Other research and development services	69	100	118
Commercial supplies	376	1,039	-
	<u>\$ 837</u>	<u>\$ 2,695</u>	<u>\$ 2,035</u>

<b>(In thousands)</b>	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Deferred revenue, current	\$ 433	\$ 431
Deferred revenue, non-current	5,839	6,256
	<u>\$ 6,272</u>	<u>\$ 6,687</u>

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

**12. Notes Payable**

In November 2010, Sucampo Pharma, Ltd., entered into a ¥1,000,000,000, approximating \$12.0 million as of the closing date, secured term loan agreement with The Bank of Tokyo-Mitsubishi UFJ, Ltd, or the Bank. The loan agreement provides for the extension of credit for the period of one year that can be renewed annually upon the agreement of the Company, Sucampo Pharma, Ltd and the Bank. Borrowings may be used to finance research and development activities, for working capital needs and for the general corporate purposes of Sucampo Pharma, Ltd. The loan bears annual interest based on the three-month Tokyo Interbank Offer Rate, or TIBOR, plus 1% and is reset quarterly. The interest rate for the first three months is 1.34%. In connection with the loan agreement, the Company and the Bank executed a guarantee agreement which provides full guarantee by the Company on behalf of Sucampo Pharma, Ltd's obligation to the Bank. The loan agreement includes representations, covenants, and events of default customary for financing transactions of this type. Additionally, the Company agreed to maintain an amount of collateral that would not fall below 90.0% of the initial balance throughout the term of the loan. The Company deposited \$14.9 million with the Bank and the deposit bears annual interest of 0.4%, which is recorded as restricted cash in the accompanying consolidated balance sheet as of December 31, 2010.

*Subordinated Unsecured Promissory Notes*

In connection with the acquisition, referred to in Note 3, of SAG and SAG-J, Ambrent issued a subordinated unsecured promissory note, or notes, to the Ueno Trust and Kuno Trust. Each of the notes was issued with an initial principal balance of approximately \$25.94 million, or approximately \$51.9 million in the aggregate. The interest rate for the notes is equal to the per annum rate of interest determined on the basis of the sum of London Interbank Offered Rate, or LIBOR, plus 4.0%, and will be reset every six months on December 1st and June 1st of each year, with the first reset on May 31, 2011.

The notes provide for a semi-annual repayment schedule of interest and principal over a seven-year period on each June 1st and December 1st, provided that, until December 1, 2012, all accrued and unpaid interest will not be paid in cash and will instead be added to the principal balance of the notes, and Ambrent will make only two scheduled principal payments on December 1, 2011 and December 1, 2012.

The notes can be prepaid at any time without penalty. In addition, the notes provide for a mandatory prepayment (i) in full in the event of an acquisition by an unaffiliated third party in an all-cash acquisition of all of the issued and outstanding shares of capital stock of the Company or (ii) either in full or in part in certain change of control transactions involving the Company where an unaffiliated third party acquires a majority of the Company's voting stock.

Notes payable consist of the following as of:

<b>(In thousands)</b>	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Loan agreement, The Bank of Tokyo-Mitsubishi UFJ, Ltd	\$ 12,022	\$ -
Promissory notes, Sellers of SAG	51,939	-
	<u>\$ 63,961</u>	<u>\$ -</u>
Notes payable, current	\$ 19,522	\$ -
Notes payable, non-current	44,439	-
	<u>\$ 63,961</u>	<u>\$ -</u>

The aggregated scheduled maturities of notes payable as of December 31, 2010 were as follows:

<b>(In thousands)</b>	
Due in one year	\$ 19,522
Due in two years	7,500
Due in three years	3,717
Due in four years	3,800
Due in five years	3,884
Thereafter	25,538
	<u>\$ 63,961</u>

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements – (Continued)

13. Collaboration and License Agreements

*Abbott license and commercialization and supply agreement*

In February 2009, the Company entered into an exclusive 19-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. 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.

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.

To date, the Company has received a total of \$22.5 million in up-front and development milestone payments under this agreement, including a \$5.0 million development milestone payment, received in October 2010, for the submission of a marketing application to the Japanese Pharmaceuticals and Medical Devices Agency for lubiprostone at a dosage strength of 24 micrograms for the indication of CIC in Japanese adults, as well as \$10.0 million and \$7.5 million in up-front and development milestone payments, respectively, in 2009. Subject to future development and commercial milestones, the Company will receive additional development milestone and commercial milestone payments under this agreement with Abbott, although there can be no assurance that the Company will receive any such payments.

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. The following table summarizes the cash streams and related revenue recognized or deferred for this agreement:

(In thousands)	Cash Received Through December 31, 2010	Revenue Recognized for the Year Ended December 31,		Foreign Currency Effects	Amount Deferred at December 31, 2010
	2009	2010			
<i>Collaboration revenue:</i>					
Up-front payment associated with the Company's obligation to participate in joint committees	\$ 846	\$ 38	\$ 47	\$ (107)	\$ 868
<i>Research and development revenue:</i>					
Up-front payment - remainder	\$ 9,154	\$ 5,112	\$ 3,471	\$ (136)	\$ 707
Development milestone payment	12,500	4,314	7,587	(349)	\$ 948
Total	\$ 21,654	\$ 9,426	\$ 11,058	\$ (485)	\$ 1,655

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements – (Continued)

*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 provision in the supplemental agreement concerning the co-promotion reimbursement for the Company's sales force is subject to negotiation by the parties no later than 60 months after the first date the Company deploys its sales force which will be April 2011; such discussions have commenced. In the event the parties fail to reach an agreement to extend the terms of this provision, the reimbursement terms of the collaboration agreement may apply, but the impact is unknown.

The Company has received a total of \$150.0 million in upfront and development milestone payments through December 31, 2010 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.

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, 2010	Revenue Recognized for the Year Ended December 31,				Accounts Receivable for the Year Ended December 31, 2010 (1)	Amount Deferred at December 31, 2010
		Through 2007	2008	2009	2010		
<i>Collaboration revenue:</i>							
Up-front payment associated with the Company's obligation to participate in joint committees	\$ 2,375	\$ 464	\$ 147	\$ 147	\$ 147	\$ -	\$ 1,470
<i>Research and development revenue:</i>							
Up-front payment - remainder	\$ 17,624	\$ 17,624	\$ -	\$ -	\$ -	\$ -	\$ -
Development milestones	130,000	80,000	50,000	-	-	-	-
Reimbursement of research and development expenses	94,175	49,934	22,293	14,530	5,473	1,097	3,042
Total	\$ 241,799	\$ 147,558	\$ 72,293	\$ 14,530	\$ 5,473	\$ 1,097	\$ 3,042
<i>Product royalty revenue</i>	\$ 136,598	\$ 34,126	\$ 34,438	\$ 38,250	\$ 40,300	\$ 10,516	\$ -
<i>Co-promotion revenue</i>	\$ 21,780	\$ 8,654	\$ 4,826	\$ 4,541	\$ 4,417	\$ 658	\$ -

(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, 2010, 2009 and 2008, 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, 2010 and 2009 was approximately \$1.5 million and \$1.6 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 \$40.3 million, \$38.3 million and \$34.4 million for the years ended December 31, 2010, 2009 and 2008, respectively. This revenue is recorded as product royalty revenue in the consolidated statements of operations and comprehensive income (loss).

## SUCAMPO PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements – (Continued)

- 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.

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 supplemental new drug application, or 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 women aged 18 years and older and recognized the payment as research and development revenue during the year ended December 31, 2008.

During 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 70.0% of the labeling studies and the Company is obligated to fund the remaining 30.0%. 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. Ased on a subsequent meeting with the FDA, the Company decided to conduct one additional phase 3 efficacy study in order to submit a sNDA for the OBD indication. This third phase 3 study of lubiprostone to evaluate its effectiveness as a treatment of OBD was initiated in December 2010.
- The Company is obligated to perform all development work necessary for phase 4 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 4 study for CIC in 2009.

The Company has assessed these required deliverables to determine which deliverables are considered separate units of accounting. As a result of the Company and Takeda agreeing to perform and fund these studies simultaneously, the Company determined that there is no objective and reliable evidence to determine the fair value for each of the studies. Accordingly, the Company has combined these three required deliverables as a single unit of accounting. All cash payments from Takeda related to these three deliverables are deferred upon receipt and recognized over the estimated performance period to complete the three studies using the time-based model. During the years ended December 31, 2010, 2009 and 2008, the Company recognized approximately \$5.5 million, \$14.5 million and \$22.3 million related to these three deliverables as research and development revenue in the consolidated statements of operations and comprehensive income (loss), respectively.

**Notes to Consolidated Financial Statements – (Continued)**

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 \$4.4 million, \$4.5 million and \$4.8 million of revenues for the years ended December 31, 2010, 2009 and 2008, 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 of reimbursements of miscellaneous costs for the year ended December 31, 2008. This amount is recorded as co-promotion revenue in the consolidated statements of operations and comprehensive income. No such amount was recorded for the years ended December 31, 2010 or 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.

#### **14. 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.

##### ***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, 2010, 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. 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, or the 2006 Incentive Plan, and reserved 8,500,000 shares of class A common stock for issuance under that plan. At December 31, 2010, a total of 7,298,350 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 5.0% 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, 2009 and 2010 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, 2010 under the Company's 2001 Incentive Plan is presented below.

	<u>Shares</u>	<u>Weighted Average Exercise Price Per Share</u>	<u>Weighted Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value</u>
Options outstanding, December 31, 2009	358,700	\$ 10.43		
Options expired	(13,600)	10.00		
Options outstanding, December 31, 2010	<u>345,100</u>	10.44	3.12	\$ -
Options exercisable, December 31, 2010	<u>345,100</u>	10.44	3.12	\$ -

A summary of the employee stock option activity for the year ended December 31, 2010 under the Company's 2006 Incentive Plan is presented below:

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

	<u>Shares</u>	<u>Weighted Average Exercise Price Per Share</u>	<u>Weighted Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value</u>
Options outstanding, December 31, 2009	509,800	\$ 8.58		
Options granted	709,000	3.77		
Options forfeited	(3,150)	13.45		
Options expired	(14,000)	10.45		
Options outstanding, December 31, 2010	<u>1,201,650</u>	5.69	8.60	\$ -
Options exercisable, December 31, 2010	<u>515,367</u>	7.38	7.90	\$ -

The weighted average grant date fair value of options granted during the years ended December 31, 2010, 2009 and 2008 were \$2.05, \$2.73 and \$5.88, respectively. The total intrinsic value of options exercised during the year ended December 31, 2008 was \$95,000. No options were exercised during the years ended December 31, 2010 and 2009. As of December 31, 2010, approximately \$1.4 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 2.93 years. When an option is exercised, the Company issues a new share of class A common stock.

The Company granted (i) annual stock options for 80,000 shares of class A common stock to its independent directors and (ii) fully vested stock options for 177,000 shares of class A common stock to its non-executive employees, both under the Company's 2006 Incentive Plan, during the year ended December 31, 2010.

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, 2010 and 2009, 450,000 options were outstanding and exercisable. These non-employee stock options vested immediately and have a weighted average exercise price per share of \$5.85 and \$5.85 and remaining contractual life of 4.33 and 5.33 years, respectively, as of both December 31, 2010 and 2009.

**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, 2010, 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 10.0% of compensation during the plan period. The purchase price per share is 95.0% of market price at the end of each plan period, which is generally three months. A total of 4,187 and 3,881 shares of common stock were purchased under the ESPP during the years ended December 31, 2010 and 2009, respectively. The Company received approximately \$14,000, \$19,000 and \$8,000 upon purchase of shares under the ESPP for the years ended December 31, 2010, 2009 and 2008, respectively.

**Dividends**

Amounts paid as dividends by SAG, prior to being acquired by the Company, together with the purchase consideration for acquiring SAG are recorded as dividends within the statement of changes in stockholders' equity.

**15. Income Taxes**

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



SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements – (Continued)

(In thousands)	Year Ended December 31,		
	2010	2009	2008
<b>Current tax provision (benefit):</b>			
Federal	\$ (1,063)	\$ 2,765	\$ 9,899
State	128	785	2,661
Foreign	469	1,521	580
Total current tax provision (benefit)	(466)	5,071	13,140
<b>Deferred provision (benefit):</b>			
Federal	(44)	644	(3,450)
State	(56)	71	(951)
Foreign	1	(702)	187
Total deferred provision (benefit)	(99)	13	(4,214)
Total income tax provision (benefit)	\$ (565)	\$ 5,084	\$ 8,925

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

(In thousands)	December 31,	
	2010	2009
<b>Deferred tax assets:</b>		
Foreign net operating loss carryforwards	\$ 8,419	\$ 3,396
Deferred revenue	3,316	5,930
Allowance for doubtful accounts	-	30
Accrued expenses	800	2,313
Tax benefits on stock options	1,883	1,561
Other	284	336
Gross deferred tax assets	14,702	13,566
<b>Deferred tax liabilities:</b>		
Property and equipment	(518)	(642)
Intangibles	(144)	(58)
Accrued expenses	(1,013)	(919)
Other	(26)	(30)
Gross deferred tax liabilities	(1,701)	(1,649)
Less: valuation allowance	(9,658)	(8,584)
Net deferred tax assets	\$ 3,343	\$ 3,333

The net deferred tax asset as of December 31, 2010 and 2009 represents the amount the Company believes is more likely than not to be utilized.

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

SUCAMPO PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements – (Continued)

(In thousands)	Year Ended December 31,		
	2010	2009	2008
Federal tax provision (benefit)	34.0%	34.0%	35.0%
State taxes, net of federal tax benefit	3.7%	6.3%	4.6%
General business credits	18.5%	-1.4%	-0.6%
Changes in valuation allowance	-11.8%	27.7%	-12.7%
Nondeductible expenses	-13.7%	-3.3%	0.8%
Changes in other tax matters	-13.6%	-11.7%	-5.0%
	<u>17.0%</u>	<u>51.6%</u>	<u>22.1%</u>

At December 31, 2010 and 2009, the Company had foreign net operating loss carry forwards, or NOLs, of \$24.2 million and \$11.0 million, respectively. Approximately \$13.7 million of the foreign NOLs begin to expire in December 2015, and \$10.5 million of the foreign NOLs do not expire. There were no U.S. general business credits as of December 31, 2010 and 2009.

As of December 31, 2010 and 2009, the Company had a valuation allowance on its deferred tax assets of \$9.7 million and \$8.6 million, respectively. The increase in the valuation allowance of \$1.1 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, 2010 and 2009 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 \$1.4 million and \$1.3 million, including interest for uncertain tax positions as of December 31, 2010 and 2009, 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. The liability for uncertain tax positions as of December 31, 2010 and 2009 mainly pertains to the Company’s interpretation of nexus in certain states related to revenue sourcing for state income tax purposes, as well as uncertain tax positions related to related party interest in foreign jurisdictions.

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

	Year Ended December 31,		
	2010	2009	2008
Balance at January 1	\$ 1,200	\$ 913	\$ 206
Increases for tax positions taken during prior periods	3	83	-
Increases for tax positions taken during current period	42	204	707
Balance at December 31	<u>\$ 1,245</u>	<u>\$ 1,200</u>	<u>\$ 913</u>

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision. During 2010 and 2009, the Company recorded approximately \$75,000 and \$60,000, respectively, 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. Certain uncertain tax position may be subject to indemnification from the sellers of SAG should the Company ultimately be required to pay these amounts. To the extent that any such indemnifications are received in the future, such amount will be recorded as a capital contribution.

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

In 2009, the Company was under examination by the United States 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.

**16. 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, that depend on the development status of these geographies. Such measures include the progress of its research and development activities, collaboration and licensing efforts, commercialization activities and other factors. 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:

<b>(In thousands)</b>	<b>Americas</b>	<b>Europe</b>	<b>Asia</b>	<b>Consolidated</b>
<b>Year Ended December 31, 2010</b>				
Research and development revenue	\$ 5,473	\$ -	\$ 11,067	\$ 16,540
Product royalty revenue	40,300	-	-	40,300
Co-promotion revenue	4,417	-	-	4,417
Contract and collaboration revenue	566	-	47	613
Total revenues	50,756	-	11,114	61,870
Research and development expenses	12,769	944	10,242	23,955
Depreciation and amortization	895	12	57	964
Other operating expenses	33,822	1,979	1,303	37,104
Income (loss) from operations	3,270	(2,935)	(488)	(153)
Interest income	596	3	9	608
Interest expense	-	(57)	(18)	(75)
Other non-operating expense, net	(46)	(3,216)	(438)	(3,700)
Income (loss) before income taxes	\$ 3,820	\$ (6,205)	\$ (935)	\$ (3,320)
Capital expenditures	\$ 298	\$ 3	\$ 32	\$ 333
<b>Year Ended December 31, 2009</b>				
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	-	38	603
Total revenues	57,887	-	9,464	67,351
Research and development expenses	18,863	1,090	12,953	32,906
Depreciation and amortization	729	11	49	789
Other operating expenses	20,697	2,165	1,379	24,241
Income (loss) from operations	17,598	(3,266)	(4,917)	9,415
Interest income	953	4	8	965
Other non-operating expense, net	335	(1,036)	182	(519)
Income (loss) before income taxes	\$ 18,886	\$ (4,298)	\$ (4,727)	\$ 9,861
Capital expenditures	\$ 3,291	\$ 3	\$ 116	\$ 3,410

**SUCAMPO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements – (Continued)**

<b>(In thousands)</b>	<b>Americas</b>	<b>Europe</b>	<b>Asia</b>	<b>Consolidated</b>
<b>Year Ended December 31, 2008</b>				
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	-	-	566
Total revenues	<u>112,123</u>	<u>-</u>	<u>-</u>	<u>112,123</u>
Research and development expenses	39,017	2,136	5,028	46,181
Depreciation and amortization	437	20	21	478
Other operating expenses	23,409	987	1,096	25,492
Income (loss) from operations	49,260	(3,143)	(6,145)	39,972
Interest income	2,431	908	5	3,344
Other non-operating expense, net	(398)	(2,440)	(40)	(2,878)
Income (loss) before income taxes	<u>\$ 51,293</u>	<u>\$ (4,675)</u>	<u>\$ (6,180)</u>	<u>\$ 40,438</u>
Capital expenditures	<u>\$ 389</u>	<u>\$ 42</u>	<u>\$ 58</u>	<u>\$ 489</u>
<b>As of December 31, 2010</b>				
Property and equipment, net	<u>\$ 1,750</u>	<u>\$ 24</u>	<u>\$ 251</u>	<u>\$ 2,025</u>
Identifiable assets, net of intercompany loans and investments	<u>\$ 102,096</u>	<u>\$ 30,789</u>	<u>\$ 16,388</u>	<u>\$ 149,273</u>
<b>As of December 31, 2009</b>				
Property and equipment, net	<u>\$ 2,008</u>	<u>\$ 34</u>	<u>\$ 232</u>	<u>\$ 2,274</u>
Identifiable assets, net of intercompany loans and investments	<u>\$ 132,903</u>	<u>\$ 34,140</u>	<u>\$ 12,962</u>	<u>\$ 180,005</u>

**17. Quarterly Financial Data (unaudited)**

<b>(In thousands, except per share data)</b>	<b>2010 Quarters Ended</b>			
	<b>December 31</b>	<b>September 30</b>	<b>June 30</b>	<b>March 31</b>
Total revenues	\$ 12,351	\$ 20,907	\$ 13,774	\$ 14,838
Income (loss) from operations	\$ (7,068)	\$ 5,635	\$ (110)	\$ 1,390
Net income (loss)	\$ (6,314)	\$ 1,584	\$ (29)	\$ 2,004
Net income (loss) per share:				
Basic	\$ (0.15)	\$ 0.04	\$ -	\$ 0.05
Diltued	<u>\$ (0.15)</u>	<u>\$ 0.04</u>	<u>\$ -</u>	<u>\$ 0.05</u>
<b>2009 Quarters Ended</b>				
<b>(In thousands, except per share data)</b>	<b>December 31</b>	<b>September 30</b>	<b>June 30</b>	<b>March 31</b>
Total revenues	\$ 16,301	\$ 17,831	\$ 17,705	\$ 15,514
Income (loss) from operations	\$ 4,143	\$ 2,917	\$ 2,865	\$ (510)
Net income (loss)	\$ 3,031	\$ (656)	\$ 1,998	\$ 404
Net income (loss) per share:				
Basic	\$ 0.07	\$ (0.02)	\$ 0.05	\$ 0.01
Diltued	<u>\$ 0.07</u>	<u>\$ (0.02)</u>	<u>\$ 0.05</u>	<u>\$ 0.01</u>

**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.

The Company incorrectly classified certain variable rate demand notes, or VRDNs, as cash equivalents rather than short-term investments in its previously filed 2010 quarterly financial statements. These misclassifications resulted in immaterial errors to the Company's quarterly balance sheets. Additionally, the misclassifications resulted in immaterial errors to the Company's quarterly statements of cash flows, whereby cash balances and net cash provided by investing activities were overstated by \$14.7 million, \$19.1 million and \$19.1 million for the first, second and third quarters, respectively. The Company plans to present the corrected 2010 quarterly cash flow statements on a comparative basis when the respective 2011 quarterly financial statements are filed.

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:				
2008	\$ 14,274	\$ 884(a)	\$ (8,376)(b)	\$ 6,782
2009	\$ 6,782	\$ 1,802(a)	\$ -	\$ 8,584
2010	\$ 8,584	\$ 1,074(a)	\$ -	\$ 9,658

- (a) In 2010, 2009 and 2008, 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 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**

<b>Exhibit Number</b>	<b>Description</b>	<b>Reference</b>
2.1	Agreement and Plan of Reorganization	Exhibit 3.1 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 <sup>^</sup>	Amended and Restated 2001 Stock Incentive Plan	Exhibit 10.1 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.2 <sup>^</sup>	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 <sup>^</sup>	2006 Employee Stock Purchase Plan	Exhibit 10.3 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.4 <sup>^</sup>	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 <sup>^</sup>	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 <sup>^</sup>	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 <sup>^</sup>	Non-employee Director Compensation Summary	Exhibit 10.7 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.8 <sup>^</sup>	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 <sup>^</sup>	Form of Executive Employment Agreement	Exhibit 10.10 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.1	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)
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)
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)
2.2	Stock Purchase Agreement, dated December 23, 2010, by and among Dr. Ryuji Ueno, as trustee of the Ryuji Ueno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Sachiko Kuno as trustee of the Sachiko Kuno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Ryuji Ueno, Dr. Sachiko Kuno, Ambrent Investments S.à.r.l., and Sucampo Pharmaceuticals, Inc	Exhibit 2.1 to the Company's Current Report on Form 8-K (filed December 29, 2010)
10.49	Special Agreement, dated November 22, 2010, between Sucampo Pharma, Ltd., Osaka, Japan, a wholly-owned subsidiary of the Company, and The Bank of Tokyo-Mitsubishi UFJ, Ltd	Included herewith
10.50	Agreement on Bank Overdrafts, dated November 18, 2010, between Sucampo Pharma, Ltd., Osaka, Japan, a wholly-owned subsidiary of the Company, and The Bank of Tokyo-Mitsubishi UFJ, Ltd	Included herewith
10.51	Subordinated Unsecured Promissory Note, dated December 23, 2010, between Ambrent Investments S.à.r.l., as borrower, and Ryuji Ueno Revocable Trust Under Trust Agreement dated December 20, 2002, as lender	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed December 29, 2010)
10.52	Subordinated Unsecured Promissory Note, dated December 23, 2010, between Ambrent Investments S.à.r.l., as borrower, and Sachiko Kuno Revocable Trust Under Trust Agreement dated December 20, 2002, as lender	Exhibit 10.2 to the Company's Current Report on Form 8-K (filed December 29, 2010)
10.53	Non-Competition Agreement, dated as of December 23, 2010 by and among Dr. Ryuji Ueno, as trustee of the Ryuji Ueno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Sachiko Kuno as trustee of the Sachiko Kuno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Ryuji Ueno, Dr. Sachiko Kuno, Ambrent Investments S.à.r.l., and Sucampo Pharmaceuticals, Inc	Exhibit 10.3 to the Company's Current Report on Form 8-K (filed December 29, 2010)
10.54^	Separation Agreement and General Release, dated January 28, 2011, between the Company and Jan Smilek	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed February 22, 2011)

10.55^	Consulting Agreement, dated January 28, 2011, between the Company and Jan Smilek	Exhibit 99.2 to the Company's Current Report on Form 8-K (filed February 22, 2011)
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 granted for portions of this exhibit.

[inside square: Please place a revenue stamp here]  
 [revenue stamp: 000200; 200 yen; MD772]  
 [right of square: place half seal impression here]

**SPECIAL AGREEMENT**

(Date of execution)  
 November 22, 2010

To: The Bank of Tokyo-Mitsubishi UFJ, Ltd.

Debtor	Address: Name:	2-2-2 Uchisaiwai-cho, Chiyoda-ku, Tokyo Sucampo Pharma, Ltd. Ryuji Ueno, Representative Director	[seal: Representative Director, Sucampo Pharma, Ltd.]
Joint and Several Guarantor	Address: Name	4520 East West Highway, Third Floor Bethesda, MD 20814 U.S.A. Sucampo Pharmaceuticals, Inc. [signature: Jan Smilek]	[blank circle]

A special agreement is hereby entered into as set forth below in connection with the borrowing that has been advanced by the Bank of Tokyo-Mitsubishi UFJ, Ltd. (hereinafter referred to as "Bank") to the account number 0001 in accordance with the terms and conditions of the Agreement on Bank Overdrafts (Through an Account Used Exclusively for the Purpose of Bank Overdrafts) Agreement dated November 18, 2010 (the said borrowing shall be hereinafter referred to as "Borrowing"):

**DETAILS**

1. Applicable Rate of Interest

- (1) The applicable rate of interest shall be the base rate of interest, which is defined in Numbered Item 2 of the present paragraph, prevailing two business days prior to the effective date of borrowing with a per annum rate of 1.00% added thereto, and interest shall be calculated on a pro rata basis using a 365 day year.
- (2) The base rate of interest shall be the rate of interest that is determined in a rational manner by the Bank for a specific period of time based on the offered rates on the funds provided in borrowing and lending transactions for yen funds in the financial market.

2. Period of Interest Rate

The period of interest rate shall be the same as the period of borrowing, which commences on the effective date of borrowing and ends on the date of final repayment.

3. Repayment Prior to Maturity

It is hereby acknowledged that [the debtor] shall not be permitted to make any partial prepayments or repayment prior to the maturity of the Borrowing that have not been provided for under the aforesaid Bank Overdrafts Agreement, provided, however, that in the event that [the debtor] must, for an unavoidable reason, make partial prepayments or repayment prior to the maturity of the Borrowing outside the terms and conditions of the said agreement and has obtained the consent of the Bank in this regard, the debtor shall, as soon as the Bank so requests, immediately make payment of the interest that has accrued up to the scheduled date of repayment before maturity as well as settlement money as provided for in the paragraph below.

4. Settlement Money

The amount of settlement money shall be calculated in accordance with the formula described below, provided, however, that there shall be no settlement money if the result of the calculation using the said formula is a negative amount:

Amount of repayment before maturity  $\times$  (Market rate of interest on the Borrowing\*1 - Market rate of interest prevailing at the time of repayment before maturity\*2)  $\times$  Remaining period at the time of repayment before maturity (number of days)\*3 / 365 days

- \*1: The rate of interest at which the Bank procures funds.
- \*2: The rate of interest at which the Bank can reinvest funds in the market during the remaining period.
- \*3: The period between the date of repayment before maturity and the date of next review of the rate of interest (or the date of final repayment, if there are no reviews of the rate of interest).

5. Acceleration of the Date of Repayment

In the event that the acceleration of the date of repayment is enforced against the debtor, the debtor shall, as soon as the Bank so requests, make payment thereto of the settlement amount that has been calculated in accordance with the preceding paragraph.

END

(Domestic yen spread lending, and account used exclusively for the purpose of bank overdrafts) Spread:

For Bank Use Only Interest rate S4 (Interest rate 8)

Sep. 2010 OS Corporate (this document to be saved for 10 years after repayment)

Inspected by: [seal: K. Yoshida]	Seal verified by: [seal: K. Matsumoto]	Administered by: [seal: K. Matsumoto]
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box]

AGREEMENT ON BANK OVERDRAFTS (THROUGH AN ACCOUNT USED EXCLUSIVELY FOR THE PURPOSE OF BANK OVERDRAFTS) (CUSTOMER COPY)

Overdraft Limit No. 0010

November 18, 2010

To: The Bank of Tokyo-Mitsubishi UFJ, Ltd.

Address: Fukoku Seimei Bldg. 17<sup>th</sup> Floor, 2-2-2  
Uchisaiwai-cho, Chiyoda-ku, Tokyo [seal: Representative Director,  
Name: Sucampo Pharma, Ltd. Sucampo Pharma, Ltd.]  
Ryuji Ueno, Representative Director

Address:  
Joint and Several Guarantor: [seal underneath: DUPLICATE]

Address:  
Joint and Several Guarantor:

For the purpose of using a current account to enter into a bank overdraft transaction (through an exclusive account) with the Bank of Tokyo-Mitsubishi UFJ, Ltd., the above captioned party hereby gives assurance on complying with the article provided for below, in addition to the provisions of each of the articles set forth in the Agreement on Bank Transactions that has been separately entered into with the said bank.

Outline of Transaction:

Limit on the principal amount of overdraft:	(Please place the "¥" symbol before the figure)	Billion ¥ 1	Million 000	Thousand 000	Yen 000
Date of maturity of the transaction:	November 18, 2011 In the absence of an expression of intention to the contrary by either of the parties hereto prior to the day immediately before the above date of maturity of the transaction, the said date of maturity shall be extended for a period of (6, 12) months, and, thereafter, shall be extended in the same manner.				
Deposit account used for the purpose of repayment:	[The Bank of Tokyo-Mitsubishi UFJ, Ltd.] Doujima Branch	Current Savings	Account No. 5306239	Account Holder The above captioned party	

Article 1 (Transaction Procedures)

1. For the purpose of entering into the bank overdraft transaction provided for in the present agreement, the above captioned party shall separately submit the request form for the opening of an account which will be used exclusively for the purpose of bank overdrafts.
2. When the above captioned party wishes to utilize a bank overdraft, it shall submit the request form for fund withdrawal prescribed by the Bank of Tokyo-Mitsubishi UFJ, Ltd. in order to withdraw the necessary funds. In the case where there is more than one account in use, then the said party shall, after having obtained the consent of the said bank, designate the specific account to be used for the purpose of overdraft.
3. The fund withdrawals referred to in the preceding paragraph may be made until the date of maturity of the transaction within the amount that remains after the balance of overdraft is subtracted from the limit on the principal amount of overdraft indicated above.
4. The Bank of Tokyo-Mitsubishi UFJ, Ltd. may, at its sole discretion, allow [the above captioned party] to withdraw funds beyond the limit on the principal amount of overdraft indicated above. If such case occurs, [the said party] shall immediately make payment of the amount in excess of the said limit, if so requested by the bank.
5. The account used exclusively for the purpose of bank overdrafts provided for under the present agreement shall be used only for overdrafts based on the request form for fund withdrawal referred to in Paragraph 2 above of the present article, and shall not, unless the consent of the Bank of Tokyo-Mitsubishi UFJ, Ltd. has been obtained, be used to clear notes and checks, or to debit funds through bank account transfers. In addition, the said account shall not be used for receiving funds that are remitted from the above captioned party, or any third parties. Furthermore, [the said bank] shall not provide any forms used to issue notes or checks.

(Please see reverse side for additional terms and conditions)

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 8, 2011 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 8, 2011

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**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 registrant's 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 8, 2011

/s/ RYUJI UENO

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Ryuji Ueno, M.D., Ph.D., Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

**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 registrant's 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 8, 2011

/s/ ANDREW P. SMITH

Andrew P. Smith  
(Principal Accounting Officer)

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**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, 2010 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 8, 2011

/s/ RYUJI UENO

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Ryuji Ueno, M.D., Ph.D., Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

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**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, 2010 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 8, 2011

/s/ ANDREW P. SMITH

Andrew P. Smith  
(Principal Accounting Officer)

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