

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, 2011

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, 3rd Floor  
Bethesda, MD 20814

(Address of principal executive offices,  
including zip code)

(301) 961-3400

(Registrant's telephone number)

**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 11,485,779 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 \$47.1 million.

As of February 27, 2012, there were outstanding 15,704,314 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 2012 Annual Meeting of Stockholders to be held on May 25, 2012, which Proxy Statement is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2011, are incorporated by reference in Part III of this Annual Report on Form 10-K.



Sucampo Pharmaceuticals, Inc.

Form 10-K  
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## PART I

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

### ITEM 1. BUSINESS

#### Overview

We are a global pharmaceutical company. Our mission is to develop, register and commercialize safe and effective drugs, with novel mechanisms of action, to meet the major unmet medical needs of patients on a global basis.

We are focused on the discovery, development and commercialization of proprietary drugs based on prostones and other novel drug technologies that can supplement our drug development pipeline. Prostones are a class of fatty acid compounds that occur naturally in the human body as a result of the enzymatic catalysis by 15-Prostaglandin Dehydrogenase (15-PGDH) of eicosanoids, like prostaglandins, and other docosanoid molecules specifically synthesized with 15 position keto groups.

To date, two prostone products have received marketing approval, AMITIZA® (lubiprostone) and RESCULA® (unoprostone isopropyl). A third prostone, cobiprostone, has been studied in phase II trials in humans; two other prostones have also been developed for human testing, SPI 017 and SPI 3608.

We generate revenue mainly from product royalties, development milestone payments, and clinical development activities. We expect to continue to incur significant expenses for the next several years as we continue our research and development activities and as we seek regulatory approvals for additional indications for AMITIZA, RESCULA and other compounds on an international basis. We conduct our business through our subsidiaries based in Japan, the United States, Switzerland, the United Kingdom and Luxembourg.

The therapeutic potential of prostones was first identified by one of our founders, Dr. Ryuji Ueno. Our lead compounds primarily focus on CIC-2 chloride and BK potassium related ion channels. CIC-2 channel activators restore and repair tight junctions, maintain chloride homeostasis and increase fluid. BK channel activators are neuroprotective via hyperpolarization of excitable membranes, counteract vasoconstriction by endothelin-1, relax vascular smooth muscles cells, increase microvascular circulation, stabilize the mitochondrial membrane, and decrease cell death. Both CIC-2 and BK channel activators have anti-inflammatory properties. Prostones offer a wide-ranging therapeutic potential, particularly for age-related diseases. We are focused on developing prostones to treat gastrointestinal, ophthalmologic, CNS, vascular, and respiratory diseases as well as other potential therapeutic applications.

#### *The Prostone Platform and Related Physiology*

The body produces prostaglandins to initiate and accelerate an inflammatory and immunologic response to infection, to tissue damage or injury, and to disease processes. In this way, inflammatory prostaglandins are created as an essential part of the body’s response to viral, fungal and/or bacterial infections, to parasitic invasion, to toxins, to allergens, to immuno-gens, to auto-immune diseases and to trauma. In this capacity, pro-inflammatory prostaglandins act physiologically to activate the immune system, to activate macrophages and other immuno-inflammatory response cells, to constrict peripheral blood vessels, to increase vaso-permeability, to induce blood aggregation and coagulation, and to accelerate programmed cell death (apoptosis).

Inflammatory prostaglandins work by binding to and thereby activating specific prostaglandin cell surface (DP1, DP2, EP1, EP2, EP3, EP4, and FP1) receptors and nuclear receptors (PPARS). Prostaglandin cell surface receptors specifically activate inflammatory and apoptotic response pathways within cells. At the organ level pro-inflammatory prostaglandins can affect both specific organ functions as well as full systemic functions.

We know the symptoms of the systemic prostaglandin inflammatory response to be fever, pain, swelling, blood clotting and lassitude. In this way the prostaglandin mediated immuno-inflammatory response can change both local and systemic fluid handling, blood circulation, immune cell migration, oxygenation, and membrane integrity from normal homeostatic functions. Prostaglandins, however, do not appear to play a significant, direct role in the body's conversion from an immuno-inflammatory injury response to a wound healing and restorative response. The body, therefore, must rely on other pathways to convert from an inflamed immuno-activated state to a normal homeostatic state after an immune response has peaked, after an initial injury is controlled, or after an infection has been eliminated. We believe that the action of 15-PGDH and the prostones 15-PGDH produces are essential to that wound healing response.

The direct action of 15-PGDH on prostaglandins catalyzes the oxidation of the 15 position hydroxyl group common to all pro-inflammatory prostaglandins to a 15 position keto group. This 15 keto conversion significantly reduces the resulting metabolites' physiologic affinity/activation potential for all pro-inflammatory prostaglandin cell surface receptors. Thus, high levels of 15-PGDH can rapidly metabolize and inactivate pro-inflammatory prostaglandins. 15-PGDH expression is tightly controlled. 15-PGDH expression is strongly inhibited by several early-stage, profoundly pro-inflammatory agents, such as TNF- $\alpha$ , IL-1 $\beta$  and interferon gamma. 15-PGDH expression and concentration are fully induced only after an initial immuno-inflammatory response has peaked. 15-PGDH is induced by TGF- $\beta$ , IL-10 and other wound healing agents. As natural metabolites of pro-inflammatory prostaglandins created by 15-PGDH, prostones do not activate pro-inflammatory prostaglandin receptors at physiologically-observed levels.

We believe that endogenous creation of active prostones by 15-PGDH may be as important to the wound healing process as the neutralization of the effects of prostaglandins by 15-PGDH. Ion channel function is essential to peri-cellular ion transport and thereby intra-cellular and trans-membrane fluid transport, fluid pH, fluid osmolarity and fluid volume balance. Ion channel stimulation can hyperpolarize cell membranes and stabilize intra-cellular ion stores in a fashion that can inactivate intra-cellular inflammatory signaling pathways. Ion channel stimulation can reverse intra-cellular fluid sequestration and ion gradients created by inflammatory pathway stimulation. Ion channel activation by prostones supports wound healing, tissue regeneration, and epithelial repair. All available data suggest that 15 keto fatty acids, prostones selectively and profoundly activate ion channels at the physiologic levels created by 15-PGDH. Prostone stimulation of ion channels appears to counter-act many of the immuno-inflammatory activities of prostaglandins. Ion channels are among the most active and essential trans-membrane proteins for control of cell homeostasis, metabolism, function and survival. Prostones accordingly appear to reverse immuno-inflammatory responses, to restore cells and membranes to homeostasis, to reverse peripheral vasoconstriction, to decrease peripheral vaso-permeability, to induce tight junction restoration which repairs epithelial barrier integrity, to desensitize immuno-inflammatory cell responses, to restore homeostatic fluid and electrolyte balance and to decrease or to arrest apoptotic pathway activity.

BK (also called Maxi-K) potassium ion channel activation can hyper-polarize cell membranes, stabilize intra-cellular ion levels and alter cytosolic fluid levels so as to control the activities of intra-cellular pathways, in particular inflammatory, immuno-modulatory and apoptotic response pathways. BK ion channels are particularly effective at blocking the effect of key pro-inflammatory mediators, such as endothelin, which is the most profound vasoconstrictor in the peripheral microcirculation. Excess endothelin levels leading to hypoxia, inflammation and apoptosis in the eye, has been identified as a major risk factor in the incidence and progression of neurodegeneration in retinitis pigmentosa, or RP, primary open angle glaucoma, or POAG, and age related macular degeneration, or AMD.

Other ion channels, such as the CIC-2 chloride channel, act as strong regulators of membrane permeability, integrity and function as well as trans-membrane fluid, electrolyte, oxygen, and nutritional flows. In this way, ion channels are essential to maintenance of normal cellular and organ function and homeostasis as well as cellular and tissue regeneration and repair. For Maxi-K stimulation ophthalmic, respiratory and CNS indications are particularly promising. For CIC-2 stimulation, gastroenterology, oncology and respiratory indications are particularly promising.

In the gastro-intestinal tract, prostones modulate the amount and components of trans-membrane fluid secretion and uptake that are essential to the normal function of the digestive process. Proper homeostasis of fluid uptake and the volume and contents of the lumen of the intestines are essential to maintaining proper nutritional, immunologic, cardiovascular, hepatic and renal health. By CIC-2 stimulation, prostones also modulate the production and restoration of tight junctions between cells in the mucosal membranes of the intestines. The integrity of the tight junctions in the gut is essential to proper secretion and uptake of fluids, electrolytes and nutrition while protecting the body from the toxins, immuno-gens, allergens, and pathogens taken in with food and created in the process of digestion. Recent studies have implicated excess gut permeability with significant co-morbidities, including diabetes, heart disease, obesity, infections and auto-immune diseases.

### ***Our Prostone Products, Approved and in the Clinic***

#### ***AMITIZA (lubiprostone)***

AMITIZA was approved by the U.S. Food and Drug Administration, or FDA, in 2006 for chronic treatment for chronic idiopathic constipation, or CIC, in adults of both genders and in 2008 for chronic treatment for irritable bowel syndrome with constipation, or IBS-C, in women aged 18 years and older. AMITIZA is also approved for chronic treatment of CIC in Switzerland and is under regulatory review in Japan and United Kingdom, or U.K, for chronic treatment of CIC with approval expected in both countries in 2012.

AMITIZA has a well-tolerated and well-established profile for safety and efficacy. In the past 6 years, AMITIZA has been dispensed approximately 6 million times. Post marketing safety monitoring is similar to the well-tolerated safety profile for AMITIZA seen in clinical trials. Side effects reported in clinical testing were predominantly mild to moderate and transient in nature.

Nausea was the most common side effect observed in pivotal clinical trials when 24mcg BID AMITIZA for CIC was taken without food; 29.7% of patients taking AMITIZA reported an event of nausea during the course of the full pivotal trials. The vast majority of nausea events were described as either mild (defined as noticed some nausea but had no effect on daily activities and acceptable; >64% of reported events) or moderate (defined as noticed with some impact on daily activities and acceptable; >27% of reported events). In other words, most patients reporting nausea in 24mcg BID AMITIZA CIC pivotal clinical trials, 21.9% of total patients (or 93% of the patients reporting nausea) had reported one event of nausea, 1.0% of total patients (or 4% of patients reporting nausea) reported had two events of nausea; 0.3% of total patients (or 1.4% of patients reporting nausea) reported three events of nausea and 0.3% of total patients (or 1.4% of patients reporting nausea) reported having four events of nausea.

Nausea was reduced when 24 mcg BID AMITIZA is taken with food 19.8%. Long term studies of patients who took 24 mcg BID AMITIZA with food showed only 1.08 patient days with an event of nausea per 1,000 patient days on 24mcg BID therapy and over 97% of these events were reported as mild or moderate. In patients treated up to 52 weeks in an open label safety study of AMITIZA for CIC taken with food approximately 5.2% of patients reported discontinuance for nausea.

Nausea rates for the 8 mcg BID dose for AMITIZA for IBS-C were similar to placebo (8% AMITIZA and 4% placebo) in pivotal trials. In the open label safety study with patients treated up to 52 weeks, nausea was reported by 6.5% of AMITIZA patients. Most events (99.2%) were described as mild or moderate and acceptable. In long-term safety studies with 8 mcg BID AMITIZA for IBS-C only 0.6% of patients discontinued AMITIZA because of nausea.

AMITIZA is the only medicine indicated for IBS-C and CIC and we plan to file a sNDA for AMITIZA to treat opioid bowel dysfunction, or OBD or opioid-induced constipation, or OIC, in mid-2012. All of these diseases have large patient populations, many of whom are not satisfied with their existing therapy, primarily laxatives, which are only indicated for occasional use.

Laxatives are approved for occasional (i.e., self-limited) constipation with over-the-counter , or OTC, laxatives approved for a sub-chronic seven day course and prescription PEG 3350 laxatives approved for a 14-day course of therapy. Laxatives are not approved for chronic use. Laxatives are not approved for use in IBS-C, OBD or CIC. There have been no randomized controlled trials (RCTs) of laxatives in IBS-C and there are no RCTs demonstrating laxatives relieve abdominal discomfort. A 2011 Cochrane Collaboration Review on the use of laxatives in opioid pain patients (palliative care) reported that there have been no randomized clinical trials on any laxative that evaluated laxation response rates, patient tolerability and acceptability.

AMITIZA users tend to be the most satisfied with their treatment. In market research, the majority of AMITIZA users reported a high level of satisfaction with AMITIZA (scoring 6 or 7 on a 7-point scale). In market research, physicians also rated AMITIZA higher (5 percentage point difference) than MiraLAX® in the areas of overall efficacy, provides sustained relief, increases frequency of spontaneous bowel movements, relieves abdominal pain, relieves abdominal bloating and discomfort, improves stool consistency, improves time to first bowel movement. There are no efficacy categories where MiraLAX was rated higher than AMITIZA. Overall tolerability was similar between the brands. AMITIZA was rated higher than MiraLAX in not causing changes in serum electrolytes and having low incidence of diarrhea. MiraLAX scored higher in having low incidence of nausea and no pregnancy warning.

We believe that due to the lack of best efforts by our commercial partner, AMITIZA has low patient awareness, low physician awareness of disease morbidity and co-morbidities, low therapy awareness among primary care and gastroenterology specialist physicians and inappropriate managed care restrictions on access. Better managed care treatment, as well as higher levels of both patient and physician education are required to achieve acceptable commercial utilization of AMITIZA for CIC and IBS-C, especially among primary care physicians.

Previously, three medicines used to treat IBS were either removed from the market or had severely reduced labeling due to safety concerns. An important consideration in any IBS medicine is having an established safety profile. We believe new medicines indicated for chronic treatment of CIC, IBS or OBD will have to establish a safety profile prior to extensive first line use.

#### *RESCULA (unoprostone isopropyl)*

RESCULA® (unoprostone isopropyl) first launched in Japan in 1994, expanded globally and 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. RESCULA has a well-established safety profile with global utilizations in approximately 32 million patient exposure months.

## AMITIZA in the U.S. and Canada

In October 2004, we entered into a collaboration and license agreement, or Takeda 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 Takeda Agreement, subject to its 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, or the Supplemental Takeda Agreement, which further defined certain rights and responsibilities of the parties, but did not supersede the terms of the Takeda 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.

Takeda currently promotes AMITIZA in the U.S. to only office-based specialty and a limited number of 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 reimbursement of co-promotion costs under the Supplemental Takeda Agreement expired on May 31, 2011. Co-promotion costs after May 31, 2011 are reimbursed under the Takeda Agreement. The previous reimbursement terms of the Supplemental Takeda Agreement were based on a per diem amount by the number of our sales representatives in the field promoting AMITIZA. The current terms are based on actual details presented to health care prescribers.

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce, or ICC, a demand for arbitration under the applicable provisions of the Takeda Agreement, which specify that New York law will govern the procedural and substantive aspects of the arbitration. The arbitration hearing concluded on December 20, 2011. Under a recent order from the ICC, the final arbitration award is expected by the end of April 2012. After the final arbitration award issues, one or both parties will file a court action seeking confirmation of the award. We have undertaken substantial planning in anticipation of the award. We have filed a motion for interim relief with the arbitration panel to restrain Takeda from making major unilateral decisions prior to the final arbitration award. It is not known if the issuance of the ICC arbitration award will remain on schedule or how long the court confirmation proceedings will take to conclude. We have spent and expect to spend significant resources in the dispute with Takeda, and these arbitration matters may require the continuing attention of our senior management.

We are currently pursuing approval of a third gastrointestinal indication of AMITIZA, for the treatment of either OBD or OIC in patients treated chronically with opiates other than methadone. OBD is a condition that affects greater than 10 million people in the U.S. and E.U. and is a significant unmet medical need. There are over 250 million opioid prescriptions written in the US alone on an annual basis. At any given time approximately 80.0% of patients are constipated from opioid use. 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 Takeda Agreement. In February 2012, we reported that the third phase 3 trial (OBD1033) met the primary endpoint in a phase 3 clinical trial. Patients received lubiprostone 24-mcg capsule or placebo capsule twice daily for 12 weeks. The primary endpoint was the overall spontaneous bowel movement, or SBM, response rate. The response rate for lubiprostone-treated patients was 26.9% (n=219) versus 18.6% (n=220) for placebo-treated patients (p=0.035). This data along with the data from a successful phase 3 efficacy study, OBD0631, in which statistical significance (p=0.0226) was achieved for its primary endpoint will be presented to the FDA as part of the sNDA filing in the first half of 2012. As per our agreement with Takeda, approximately half of this third phase 3 study's expenses were funded by us. We are now evaluating the performance of additional opioid-induced bowel dysfunction studies to include patients with cancer treated chronically with opiates other than methadone.

## 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, or the Abbott Agreement. Under the terms of the Abbott Agreement, Abbott received exclusive rights to commercialize lubiprostone for the treatment of CIC in Japan and also received the right of first exclusive negotiation 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, including \$15.0 million due on the first commercial sale in Japan. We have retained the development right to lubiprostone in Japan and commercialization rights to all other indications of lubiprostone and other therapeutic areas subject to Abbott's right of first exclusive negotiation.

In September 2010, we submitted a NDA, in Japan with the Pharmaceuticals and Medical Devices Agency, or PMDA, for lubiprostone at a dosage strength of 24 micrograms for the indication of CIC. We have had meetings with PMDA and anticipate a decision by the Ministry of Health, Labor and Welfare, or MHLW, on the NDA by mid-2012. 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. 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, the total prescription market for constipation patients in Japan is approximately \$483.0 million. Magnesium oxide is a leading laxative treatment for constipation in Japan and, in 2010, generated annual sales of approximately \$202.0 million. Future market growth is expected to continue to be fueled by an increasingly older population and changes in eating and lifestyle habits.

We continue to negotiate with third parties for commercial rights in Japan to the OBD indication; Abbott, under the terms of our agreement, will have forty-five days to meet the terms and conditions of any third party bona fide offer.

#### 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 submitted a filing for approval of AMITIZA to treat CIC, in the U.K and we expect a decision by the Medicines and Healthcare products Regulatory Agency, or MHRA, in the third quarter of 2012. If we receive approval in the U.K., we will seek approval in other European countries following the mutual recognition procedure or MRP.

AMITIZA is approved in Switzerland for the treatment of CIC. We are currently in discussions with the Swiss Federal Office of Public Health, or Bundesamt für Gesundheit, or the BAG, for pricing approval. In February 2012 we commenced marketing AMITIZA, on a limited basis, in Switzerland. We continue to evaluate the opportunity to commercialize AMITIZA within the European Union, or E.U.

#### 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 in the event of approval of an enhanced label from the FDA.

On March 22, 2011, we entered into a license agreement with R-Tech for unoprostone isopropyl, expanding our development and commercialization rights as well as our territories beyond our previously agreed territory of the United States and Canada to the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China, or the R-Tech Territory. We are now evaluating the opportunities to obtain an appropriate label in the E.U. and other European countries as well as obtaining reauthorization in those countries to commercialize unoprostone isopropyl.

We plan to evaluate conducting a phase 2a clinical trial in 2012 of unoprostone isopropyl for the indication of dry age-related macular degeneration, or dry AMD. If this study is successful, there would need to be further studies to be completed that may take several years before commercialization.

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 throughout the world excluding the R-Tech Territory. R-Tech is exclusively responsible for the supply of RESCULA to us within our licensed territories.



## Our Development Programs

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

### Lubiprostone (AMITIZA) in other indications

In September 2011, preclinical data were presented at the annual scientific meeting of the Japanese Biochemical Society, held in Kyoto, Japan, by Sachiko Tsukita, Ph.D., Professor at the Graduate School of Frontier Biosciences and Graduate School of Medicine, of Osaka University. These data demonstrate that lubiprostone significantly reduces expression of inflammatory cytokines ( $p < 0.01$ ) vs. the control in an animal model of inflammatory bowel disease, or IBD. In addition, lubiprostone significantly ( $p < 0.01$ ) protects the intestinal epithelial barrier function, as compared to the control. Based on this data, we will be evaluating further studies to explore the IBD indication.

### Unoprostone isopropyl (RESCULA)

We may develop RESCULA as a treatment for additional ophthalmic diseases including dry AMD. We initiated an exploratory clinical study for the ophthalmic indication of dry AMD in the second quarter of 2011, which is intended to evaluate the effects of RESCULA in a small number of patients with dry AMD. That study has concluded and we are now analyzing the data. We are considering the design of a phase 2 trial.

## Other development areas

On July 8, 2011, we obtained the development and commercial rights to a peptide compound from CuroNZ, a New Zealand company, for a loan of \$100,000 that will augment our ophthalmic development opportunities. CuroNZ has started to evaluate the lead compound for use in animal models of glaucoma and retinitis pigmentosa.

On September 8, 2011, we entered into a research and development collaboration with Numab AG, or Numab, of Wädenswil, Switzerland. In February 2012, we purchased certain equipment and leased it to Numab for its use in the development under the collaboration agreement. Under the Loan Guarantee and Development Agreement with Numab, we will have access to Numab's proprietary technology for the discovery of high-affinity antibodies against certain selected targets. We will have exclusive commercial rights to any biologic products successfully developed and commercialized in the course of the collaboration. We have agreed to provide Numab with up to CHF 5,000,000 as collateral for a loan to Numab from a third party. We may name up to four targets against which Numab will use their technology to discover high-affinity antibodies and will develop these to an investigational new drug, or IND, -ready stage. Numab is eligible for payments based on an agreed rate for the number of full time employees assigned to the development project and discovery success-dependent fees. If a biologic is successfully developed, we may enter into a license arrangement with Numab in which they will be entitled to clinical development milestone payments and increasing tiered royalties on net sales. We will be responsible for clinical development and will retain all commercial rights to any resulting biologic product. Numab has commenced work on the Company's first target.

## 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 all rights except in the R-Tech Territories. 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.	—
		Marketed in Switzerland	Pricing negotiations with government ongoing
		Marketing Authorization Application (MAA) submitted in 2011 in UK	MAA approval
		New Drug Application (NDA) submitted in 2010 to authorities (PMDA) in Japan, and updated in early 2011 with results of long-term safety study	Approval of NDA, to be followed by pricing negotiations with government
	Irritable bowel syndrome with constipation (adult women) (IBS-C)	Marketed in the U.S.; phase 4 study on higher dosage and with additional male subjects	—
	Pediatric constipation	Open-labeled clinical study completed in patients 3–17 years	Initiate well-controlled Phase 3 clinical studies
	Inflammatory bowel disease (IBD)	Preclinical	—
<b>RESCULA</b> ® (unoprostone isopropyl)	Dry age-related macular degeneration (dry AMD)	Phase 2a completed	Analyze results
		Phase 2b clinical trial design underway	Updated label and reauthorization in the EU and Switzerland
	Glaucoma and ocular hypertension	Approved in the U.S.	Updated label
	Retinitis pigmentosa	Orphan drug status achieved in the U.S. On going phase 2b trial by R-Tech	Awaiting results of R-Tech trial in this indication
<b>Cobiprostone</b>	<i>Gastrointestinal</i> Oral mucositis	Formulation development	Initiate phase 1a/b studies
	Prevention of non-steroidal anti-inflammatory drug (NSAID)-induced ulcers	Phase 2 completed	Evaluating phase 2 results
	Inflammatory bowel disease (IBD)	Preclinical	Evaluating preclinical results
	<i>Pulmonary</i> Chronic obstructive pulmonary disease (COPD)	Preclinical	Evaluating next steps
	Cystic Fibrosis	Phase 2a completed	Evaluating next steps
	<i>Dermatology</i> Wound Healing	Preclinical	Evaluating next steps
<b>SPI-3608</b>	Spinal stenosis	Preclinical	Initiate phase 1 trial
<b>SPI-017</b>	Spinal stenosis	Phase 1 completed	Evaluating phase 2 design
	Peripheral arterial disease (PAD)	Phase 1 completed	Evaluating phase 2 design

### **Acquisition activities**

Following our acquisition of Sucampo AG, or SAG, in December 2010, a patent-holding company based in Switzerland, we continue integrating SAG for future operational efficiencies through a simplified group structure and consolidation of intellectual property. On June 10, 2011, Sucampo Manufacturing & Research AG, or SMR, a direct wholly owned subsidiary of us, was merged into SAG, and SAG assumed all existing obligations of SMR. On June 28, 2011, Sucampo AG Japan, or SAG-J, an indirect wholly owned subsidiary of us, merged into Sucampo Pharma, Ltd., or SPL, and SPL assumed all existing obligations of SAG-J. On September 29, 2011, our subsidiaries SPA, SPL and Sucampo Pharma Europe Ltd, or SPE transferred certain intellectual property and licenses to SAG, and SAG entered into agreements with the subsidiaries to perform certain services for the subsidiaries related to the intellectual property, licenses and other business activities.

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

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.

### **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. We will be filing for FDA approval for the treatment of OBD in mid-2012.

#### **Chronic Idiopathic Constipation (CIC)**

**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 OTC for acute use. The most commonly used laxatives can be categorized as stimulants, stool softeners, bulk-forming agents, osmotics 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 OTC 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 OTC 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. Chronic constipation 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 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 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.

In 2011, AMITIZA generated net sales of \$226.4 million in the U.S.; AMITIZA prescriptions grew by 6.6% from 2010 to 2011. However despite Takeda's failure to use best efforts to maximize net sales, we believe AMITIZA, with a competitive marketing and sales campaign, still has great potential for future growth in the US given:

- CIC, IBS-C and OBD are large, fundamentally under-served patient populations;
- Available epidemiology indicates that approximately 12-19% (37 million to 59 million) of people in the US suffer from some form of constipation;

- We estimate that over 14 million patients suffer from IBS-C;
- We estimate that approximately 12 million patients are seeking care and have sought care and/or been diagnosed with constipation or IBS by their physician;
- There are approximately 12 million CIC and IBS-C patients who have sufficiently severe disease to actively seek chronically effective therapeutic relief on a more or less daily basis;
- These 12 million most-in-need patients regularly self-medicate with OTC laxatives;
- Most of these 12 million patients are dissatisfied with such OTC therapies;
- We believe , today only a small fraction, 3%, of the millions of the patients with at least one diagnosis claim for either constipation or IBS, as defined by ICD-9 codes, have filled a prescription for AMITIZA .
- There were 245 million courses of therapy dispensed or purchased for constipation or IBS-C;
- A much higher fraction of CIC and IBS-C patients who have gotten access to AMITIZA report satisfaction with therapy than the fraction of patients reporting satisfaction with therapy who only get access to off-label/OTC remedies;
- Many of the patients who receive AMITIZA annually, report greater satisfaction with AMITIZA than with any other therapeutic option for IBS-C or CIC;
- AMITIZA had an average length of therapy per patient of approximately 155 days compared to approximately 132 days for Zelnorm;
- Laxatives are only labeled by the FDA for short term use in the treatment of occasional (i.e., self-limited, non-chronic) constipation and are not indicated for the chronic treatment of IBS-C, CIC or OBD;
- We believe that the clinical evidence supporting off label use of laxatives in CIC and IBS-C is inadequate, because the long term safety and efficacy of laxatives have not been established in long-term well-controlled repeated clinical trials;
- Laxatives are not recommended for use in U.S. professional IBS-C treatment guidelines;
- We believe that there is no professional treatment guideline that has indicated that the highest level of clinical evidence — repeated, rigorous, robust, well designed, well controlled and statistically significant clinical trials reviewed and approved by an independent regulatory agency – is available to support the off label chronic use of OTC/Rx laxatives in CIC or IBS-C as safe and effective;
- Recent studies and a formal finding by the FDA also indicate that electrolyte imbalances, in particular serum hyperphosphatemia, caused by improper fluid and electrolyte handling induced by acute use of osmotic laxatives, can acutely induce irreversible kidney damage and death;
- This finding along with the lack of long-term safety data of OTC osmotic laxatives in CIC or IBS-C patients, underscore the safety concerns posed by off-label chronic use of osmotic laxatives that the FDA suggests is associated with hyperphosphatemia;
- In published surveys, CIC and IBS-C patients report wanting safe, reliable, chronic, relief of multiple symptoms including bloating, pain, straining and abdominal discomfort;
- In published surveys, almost half of laxative users indicate ineffective relief of multiple symptoms whereas AMITIZA has shown efficacy in treatment of multiple symptoms in CIC and IBS-C;
- AMITIZA is expected to be the first oral medicine approved for chronic use in OBD;
- OBD is a severe form of constipation affecting up to 80% of patients taking opioids;
- OBD negatively impacts the quality of life in non-cancer pain patients;
- Some patients discontinue opioid therapy and thereby endure pain rather than suffer from the constipation the opioids cause;
- We believe that all OBD patients are currently in the care of physicians and that physicians want to better treat this side effect;
- OBD occurs in approximately 4 million chronic non-cancer pain sufferers; and
- There are over 200 million prescriptions for opioids in the US and a substantial number of these are for patients with non-cancer pain.

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

***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 though they are not approved for IBS-C. Zelnorm was the only FDA approved drug indicated for the treatment of IBS-C before it was withdrawn in March 2007. 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.

### ***Opioid-induced Bowel Dysfunction (OBD) or opioid-induced constipation (OIC)***

**Disease Overview.** OBD comprises a variety of gastrointestinal side effects, the most prominent of which include constipation and related symptoms, that originate from the use of narcotic medications (opioids) such as morphine. 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. OIC is the predominate subset of OBD.

**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 OIC 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, resulting in 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 or OIC, 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 ( $p=0.0226$ ). Although a positive treatment effect in favor of AMITIZA was reported, study OBD0632 did not achieve statistical significance for the primary endpoint. With respect to the conduct of study OBD0632, we filed a lawsuit against the contract research organization, or CRO, for its malperformance under the contract. A third confirmatory study was conducted and recently completed to further evaluate the safety and efficacy of AMITIZA in OBD patients.

In study OBD0631, 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. A similar result was observed in OBD0632 (change from baseline of 1.60 SBMs per week to 4.10 SBMs at Week 8) but did not achieve statistical significance.

Among the key results from OBD0631 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 was completed in December 2011. In February 2012, we reported that the third phase 3 trial (OBD1033) met the primary endpoint. Patients received lubiprostone 24mcg capsule or placebo capsule twice daily for 12 weeks. The primary endpoint was the overall SBM response rate. The response rate for lubiprostone-treated patients was 26.9% (n=219) versus 18.6% (n=220) for placebo-treated patients (p=0.035). This data along with the data from a successful phase 3 efficacy study, OBD0631, in which statistical significance (p=0.0226) was achieved for its primary endpoint and the accompanying long-term safety trial will be presented to the FDA as part of the sNDA filing in the first half of 2012 and the regulatory authorities in Europe with request for an expedited review. As per our agreement with Takeda, approximately half of this third phase 3 study's expenses were funded by us.

## **RESCULA (unoprostone isopropyl)**

### **Overview**

RESCULA was approved by the FDA, in 2000, 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. RESCULA is not currently marketed in the United States or Canada. In September 2010, RESCULA received an Orphan Drug designation from the FDA for retinitis pigmentosa. We plan to re-launch RESCULA in the U.S. for its approved indication in the event of approval of an enhanced label from the FDA. To facilitate this launch, we have placed an order with R-Tech.

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; 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 AMD.** According to the National Eye Institute, or NEI, more than 8 million people in the U.S. currently have AMD, a disease which causes damage to the retina resulting in loss of vision. AMD is the leading cause worldwide of irreversible blindness in adults. 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. We are currently awaiting the results of our phase 2a clinical trial of RESCULA for dry AMD.

## **Cobiprostone**

### **Overview**

We are developing the prostone compound cobiprostone for oral administration to treat various gastrointestinal and liver disorders, including NSAID-induced ulcers. Based on the preclinical data, we believe that cobiprostone has wound healing effects and could also be developed for IBD. We are also developing 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 CIC-2, which is known to be present in gastrointestinal, liver and lung cells. In addition, we are developing cobiprostone as a treatment for oral mucositis based on results from preclinical studies.

### **Oral Mucositis**

**Disease Overview.** Oral Mucositis refers to the inflammation of oral mucosa resulting from chemotherapy, or CT, and or radiation therapy, or RT. Oral Mucositis (or tissue swelling) symptoms include mouth pain, sores, infection, and bleeding. The condition is typically manifested as erythema or ulcerations, and may be exacerbated by local factors. Erythematous mucositis typically appears 7-10 days after initiation of high-dose cancer therapy. Oral mucositis is the primary dose limiting side effect that accounts for greater than 60.0% of the treatment interruptions. Other resulting outcomes of oral mucositis include weight loss, use of feeding tube, hospitalization and dysphagia. RT patients for Head and Neck Cancer, or HNC, are at high risk of developing oral mucositis in the 89.0%-100.0% range depending on if the radiation therapy is in combination with chemotherapy or altered fractionation RT. RT or chemotherapy receiving other cancer patients will have some level of OM (1.0%-53.0%) during the course of the treatment (e.g., 53% in GI cancers, 46% in esophageal cancer). Some chemotherapies have a higher incidence of grade 3-4 oral mucositis (e.g. Docetaxel/5FU – 66.0%)

**Current Treatment.** Oral mucositis current treatment includes basic oral care, cryotherapy, topical rinses such as lidocaine and MuGuard and Kepivance (palifermin), a growth factor. None of the above products have been completely successful in treating mucositis and a high unmet medical need exists.

**Market Opportunity.** There are approximately 350,000 head and neck cancer patients worldwide including approximately 100,000 in the U.S. While this is an orphan indication, 89.0%-100.0% of this population will get oral mucositis. In addition there are >4M stage 3-4 cancer patients worldwide (>1m in US) that are receiving high doses of CT or a combination of CT/RT that develop oral mucositis 1.0%-53.0% of the time.

**Development Status.** We have completed a preclinical study of cobiprostone in animals and have obtained positive results. Currently the spray formulation is under development and we expect to conduct phase 1a/b study in 2012.

## **Marketing and Sales**

### **AMITIZA**

## **Takeda Collaboration**

Under the Takeda Agreement, we and Takeda jointly develop and Takeda commercializes AMITIZA for gastrointestinal indications in the U.S. and Canada. We have limited co-promotion rights under the agreement. 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. We also entered into a settlement agreement and Supplemental Takeda 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 Takeda 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.

*Development Costs.* Under the Takeda Agreement, 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, 2011, Takeda paid an aggregate of \$97.1 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, 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. The reimbursement of co-promotion costs under the Supplemental Takeda Agreement expired on May 31, 2011. Co-promotion costs after May 31, 2011 are reimbursed under the Takeda Agreement. The previous reimbursement terms of the Supplemental Takeda Agreement were based on a per diem reimbursement by number of sales representatives in the field promoting AMITIZA. The current terms are based on actual details presented to health care prescribers.

*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, 2011. Subject to reaching future development and commercial milestones, we are entitled to receive an additional \$10.0 million development milestone payment upon commercial launch of the OBD indication 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.* 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 or OIC. We retain the rights to AMITIZA for all other therapeutic areas. Takeda has not sought approval for either CIC or IBS-C in Canada.



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 Abbott Agreement also grants Abbott the right of first exclusive negotiation 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, 2011, which includes a \$5.0 million milestone payment as a result of submitting a marketing application to the PMDA in September 2010. The next milestone of \$15.0 million is due upon the first commercial sale in Japan. 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, to Abbott, 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.* Abbott has a right of first exclusive negotiation to obtain a license to develop and commercialize AMITIZA in Japan for any new indications that we may develop, such as OBD or OIC. 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 lubiprostone and many other prostone compounds covered by patents and patent applications held by SAG. In addition during 2011 we consolidated our intellectual property within SAG. Our portfolio of patents includes patents or patent applications with claims directed to compositions of matter, including both compounds and pharmaceutical formulations, or methods of use, or a combination of these claims, or methods of manufacturing lubiprostone, cobiprostone, SPI-017 and SPI-3608. These include a total of 34 U.S. patents, 44 U.S. patent applications, 17 European patents, 28 European patent applications, 23 Japanese patents and 27 Japanese patent applications. 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 a 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 lubiprostone consist of 15 issued U.S. patents, 10 issued European patents, and 11 issued Japanese patents relating to compositions of matter, methods of use and methods of manufacturing. These patent rights also include various U.S., European and Japanese patent applications relating to dosing regimens, pharmaceutical formulations and other claims. The U.S. patents relating to compositions of matter expire between 2014 and 2027. The other U.S. and foreign patents expire between 2020 and 2029.

The patent rights relating to cobiprostone consist of 15 issued U.S. patents, 9 issued European patents, and 13 issued Japanese patents relating to compositions of matter, methods of use and methods of manufacturing. These patent rights also include various U.S., European and Japanese patent applications relating to dosing regimens, pharmaceutical formulations and other claims. The U.S. patents relating to compositions of matter expire between 2012 and 2020. The other U.S. and foreign patents expire between 2012 and 2029.

The patent rights relating to SPI-017 consist of 6 issued U.S. patents, 4 issued European patents and 5 issued Japanese patents relating to compositions 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 2012 and 2026.

The patent rights relating to SPI-3608 consist of 5 issued U.S. patents, 4 issued European patents and 5 issued Japanese patents relating to compositions of matter and methods of use. The U.S. patents relating to methods of use and the other U.S. and foreign patents expire between 2012 and 2026.

The patent rights relating to unoprostone isopropyl licensed by us from R-Tech consist of 13 issued U.S. patents relating to compositions of matter, methods of use, pharmaceutical formulations and other claims. The U.S. patents relating to compositions of matter expire between 2012 and 2018. The other U.S. and foreign patents expire between 2012 and 2027.

We are actively seeking to augment the patent protection of our compounds by focusing on the development of new chemical entities, or NCEs, such as lubiprostone, unoprostone isopropyl, cobiprostone, SPI-017 and SPI-3608, which have not previously received FDA approval. Upon approval by the FDA, NCEs are entitled to market exclusivity in the U.S. with respect to generic drug products for a period of five years from the date of FDA approval, even if the related patents have expired.

## Manufacturing

We do not 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 as the sole manufacturer of our products, 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, 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, 2011. 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 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 and Takeda is not required to purchase the quantity of the product and/or samples contained in its binding forecast.

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 April 2010 and from the MHRA in October 2008.

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. R-Tech has informed us that it is relocating its manufacturing facility for unoprostone isopropyl beginning April 2012 and will not be able to manufacture and supply unoprostone isopropyl for up to 18 months. In order to mitigate this risk, we have placed an order to sufficiently cover this supply period based on our forecasts for the launch of RESCULA in the U.S. and regulatory requirements in the E.U.

## 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 OTC 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:

- There are currently four drugs in development for the indication of IBS-C. From a mechanism of action, there are two drugs being designed to target serotonin receptors. The first is Renzapride, being developed by Alizyme plc. and the second is 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. The other two IBS-C compounds in development are Linaclotide, being developed by Ironwood Pharmaceuticals Inc., or Ironwood, and Placanotide being developed by Synergy Pharmaceuticals, Inc., or Synergy. Ironwood has completed phase three studies and has filed submissions in both the U.S. and E.U. Synergy has completed a phase 2a study.
- Oral opioid antagonists such as methylnaltrexone, are being developed by Progenics Pharmaceuticals, Inc., or Progenics, and Salix Pharmaceuticals, Inc., or Salix, for the treatment of opioid-induced bowel dysfunction. Progenics received FDA approval of methylnaltrexone in 2008 for the subcutaneous formulation of this drug in treating OBD in patients receiving palliative care. This formulation is also approved in the E.U. Progenics and Salix continue to move forward with an oral form of methylnaltrexone. They have completed one phase 3 clinical trial for the indication of OIC and intend to file in the US based on the results of the single pivotal, oral trial. Progenics is collaborating with Ono Pharmaceuticals Co., Ltd. in Japan in the development of methylnaltrexone 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/AstraZeneca. This oral product has also completed phase 2 studies and has initiated phase 3 studies and is being studied for an OIC indication. There are two additional products in development for the treatment of OIC. The first is TD1211 which is being developed by Theravance Inc., or Theravance, and is in phase 3, and the other is ADL5945 being developed by Adolor Corporation, or Adolor. ADL5945 is in phase 2.

- For the CIC indication, Ironwood has completed phase 3 for Linaclotide and has filed for CIC indication in the U.S. and E.U. Linaclotide is a Guanylin Agonist which is dosed at once a day. The marketing of Linaclotide will be by both Ironwood and Forrest Pharmaceuticals, Inc. in the U.S. European rights for Linaclotide are with Almirall, S.A. and Japan rights are with Astellas Pharma US, Inc.. Japanese development of Linaclotide is in phase 1. Resolor (procalopride) is being developed and marketed by Movetis N.V. for the treatment of chronic constipation in adults in the E.U. Resolor received marketing approval in the E.U., Switzerland, 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 German in January 2010, the U.K. in March 2010 and in Belgium in September 2010. Movetis was acquired by Shire in September 2010 and intends to study Resolor in the US for CIC.
- Synergy is developing Placanotide for the indication of CIC and they are in a phase 2/3 development program. Theravance is developing Velusetrag and has completed phase 2 studies in the U.S. Aryx Therapeutics, Inc. is developing ATI 7505 for the treatment of chronic constipation and they have completed phase 2 in the US. Adolor continues to develop A3309 also for the treatment of chronic constipation in the U.S. market and they have completed a phase 2 study.
- RESCULA faces many competitors which promote for primary open-angle glaucoma, or POAG, and ocular hypertension. Products such as Latanaprost, manufactured by Pfizer Inc. became generic in March 2011 which can have a significant impact usage of this prostaglandin therapy as first line therapy. Other competitive products on the market which also have sales force presence and a focus on ophthalmology include Travatan Z, Lumigan, Combigan, Asopt, Trusopt, Alphagan P and generic beta blockers. Merck & Co. Inc., or Merck recently received approval for ZIOPTAN(TM) (tafluprost ophthalmic solution) 0.0015%, a preservative-free prostaglandin analog ophthalmic solution, for reducing elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension. Prostaglandin analogues continue to have significant first line market share followed by generic beta blockers. Other products are in development for POAG and ocular hypertension. Another combination product of Travatan and Timolol, to be marketed by Alcon, Inc., has also filed an NDA.

We face similar competition from approved therapies and potential drug products for the diseases and conditions addressed by lubiprostone, 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 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 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 corrective actions including 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 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.

## ***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 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 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, which may result in extended pricing negotiations.

## ***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;
- State and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations; and
- the Patient Protection and Affordable Care Act, which among other things changes access to healthcare products and services; creates new fees for the pharmaceutical and medical device industries; changes rebates and prices for health care products and services; and requires additional reporting and disclosure.

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 payers. Third-party payers include government health administrative authorities, managed care providers, pharmacy benefit managers, private health insurers and other organizations. These third-party payers 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. 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 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 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: Denmark, Germany, the U.K. and the Netherlands),
- Cost benefit analysis

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 15, 2012.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Ryuji Ueno, M.D., Ph.D., Ph.D.	58	Chief Executive Officer, Chief Scientific Officer and Director, Chairman of the Board of Directors
James J. Egan	61	Chief Operating Officer
Cary J. Claiborne	51	Chief Financial Officer
Stanley G. Miele	47	President, Sucampo Pharma Americas, Inc. and Senior Vice President of Sales and Marketing
Gayle Dolecek	69	Executive Advisor, Research and Development Affairs and member of the Board of Directors
Thomas J. Knapp	59	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.

*Cary J. Claiborne.* Mr. Claiborne joined us March 2011 as Interim Chief Financial Officer until he was promoted to Chief Financial Officer in October 2011. Prior to joining our company, he had been President, CEO, and a member of the board of directors of New Generation Biofuels, Inc., of Columbia, Maryland, a publicly traded biofuel technology company, as well as its CFO since 2007. From December 2004 to November 2007, Mr. Claiborne had been CFO of Osiris Therapeutics, Inc., a stem cell therapeutics company. From December 2001 to June 2004, he was VP-Financial Planning & Analysis of Constellation Energy Group. From April 2000 to November 2001, he was VP-Financial Planning & Analysis of The Home Depot, Inc. From July 1997 to March 2000, he was VP-Financial Planning & Analysis at MCI Corporation. He also held a series of progressively more responsible positions in financial management and senior management, including President and CEO of New Enterprise Wholesale Services at GE Capital since 1982. Mr. Claiborne graduated from Rutgers University where he earned a B.A., Business Administration and an MBA, in Finance, from Villanova University.

*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.* In September 2011 Dr. Dolecek became our Executive Advisor, after serving as our Senior Vice President of Research and Development since May 2006, He continues as a member of our Board of Directors a position he has held 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 Senior 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 February 27, 2012, we had 108 full-time employees, including 36 with doctoral or other advanced degrees. Of our workforce, 25 employees are engaged in research and development, 45 are engaged in sales and marketing and 38 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 2009, 2010 and 2011, 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 a loss before taxes of \$6.1 million in 2011, compared to income before taxes of \$3.8 million in 2010. These results primarily reflect the expenses associated with initiating the additional phase 3 trial of lubiprostone for OBD in chronic non-cancer pain patients and the increased expenses in legal matters, including our dispute with Takeda.

Our segment in Europe recorded a loss before taxes of \$10.3 million in 2011, compared to a loss before taxes of \$6.2 million in 2010. These results primarily reflect the on-going regulatory submission for AMITIZA, the interest accruing on the loan notes issued for the December 2010 SAG acquisition and non-cash foreign exchange gains and losses.

Our segment in Asia recorded a loss before taxes of \$5.4 million in 2011, compared to a loss before taxes of \$935,000 in 2010. These results primarily reflect the reduction of revenue recognized during the year ended December 31, 2011 from the payments received from Abbott in 2009 and 2010.

(In thousands)	Americas		Europe		Asia		Consolidated	
<b>Year Ended December 31, 2011</b>								
Total revenues	\$	53,493	\$	-	\$	1,268	\$	54,761
Income (loss) before taxes		(6,384)		(10,086)		(5,444)		(21,914)
Identifiable assets		96,490		47,925		13,154		157,569
<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

## 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 February 27, 2012, we had outstanding 15,704,314 shares of class A common stock and 26,191,050 shares of class B common stock. The class B common stock represents approximately 94.3% 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 following is a list of our subsidiaries as of December 31, 2011:

<u>Subsidiary</u>	<u>State or other jurisdiction of incorporation or organization</u>
Sucampo Pharma Americas, Inc.	Delaware
Sucampo LLC	Delaware
Sucampo AG	Switzerland
Sucampo Pharma, Ltd.	Japan
Sucampo Pharma Europe Ltd.	United Kingdom
Ambrent Investments S.à r.l.	Luxembourg

Our principal executive offices are located at 4520 East-West Highway, 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

Before deciding to purchase, hold or sell our common stock, you should carefully consider the risks described below in addition to the other cautionary statements and risks described elsewhere and the other information contained in this report and in our other filings with the SEC, including subsequent Quarterly Reports on Forms 10-Q and Current Reports on Form 8-K. We operate in a rapidly changing environment that involves a number of risks. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business. These known and unknown risks could materially and adversely affect our business, financial condition, prospects, operating results or cash flows.

### Risks Related to Our Business and Industry

#### *We operate in a highly competitive industry.*

The pharmaceutical industry is highly competitive. To be successful, we must be able to, among other things, effectively discover, develop, test and obtain regulatory approvals for products. We or our partners must be able to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical professionals. Many of our competitors have greater resources than we have. This enables them, among other things, to make greater research and development investments, as well as increased levels marketing and promotion spend.

Developments by our competitors, the entry of new competitors into the markets in which we compete, or consolidation in the pharmaceutical industry could make our products or technologies less competitive or obsolete. Our future growth depends, in part, on our ability to develop and introduce products which are more effective than those developed by our competitors. Royalties or sales from our existing products may decline rapidly if a new product is introduced that represents a substantial improvement over our existing products.

#### *Our future success depends upon our ability to develop new products, and new indications for existing products, that achieve regulatory approval for commercialization.*

For our business model to be successful, we must continually develop, test and manufacture new products or achieve new indications or label extensions for the use of our existing products. Prior to commercialization, these new products and product indications must satisfy stringent regulatory standards and receive requisite approvals or clearances from regulatory authorities in the United States and other countries. The development, regulatory review and approval, and commercialization processes are time consuming, costly and subject to numerous factors that may delay or prevent the development, approval or clearance, and commercialization of new products, including legal actions brought by our competitors. To obtain approval or clearance of new indications or products in the United States, we must submit, among other information, the results of preclinical and clinical studies on the new indication or product candidate to the FDA. The number of preclinical and clinical studies that will be required for FDA approval varies depending on the new indication or product candidate, the disease or condition for which the new indication or product candidate is in development and the regulations applicable to that new indication or product candidate. Even if we believe that the data collected from clinical trials of new indications for our existing products or for our product candidates are promising, the FDA may find such data to be insufficient to support approval of the new indication or product. The FDA can delay, limit or deny approval or clearance of a new indication or product candidate for many reasons, including:

- the FDA may determine that the new indication or product candidate is not safe and effective;
- the FDA may interpret our preclinical and clinical data in different ways than we do;
- the FDA may require us to perform post-marketing clinical studies; or
- the FDA may change its approval policies or adopt new regulations.

Products that we are currently developing, other future product candidates or new indications or label extensions for our existing products, may or may not receive the regulatory approvals or clearances necessary for marketing or may receive such approvals or clearances only after delays or unanticipated costs.

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

For most of our operating history, we have been a research and 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 and 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.

***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.

***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 payers;
- 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 unable to obtain an enhanced label from our sNDA for RESCULA or appropriate pricing from Centers for Medicare & Medicaid Services, or CMS, 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 appropriate pricing, 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 the submitted sNDA;
- appropriate pricing without substantial rebates for governmental programs;
- 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 payers;
- 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.

***Our strategy of generating growth through acquisitions and in-licensing 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.

#### **Risks Related to Our Ongoing Dispute with Takeda**

***We sent Takeda notices of material breach and completed an arbitration hearing for which we await the outcome; 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 notices of material breach and completed an arbitration hearing in the ICC. We await the outcome of the arbitration where we have been seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. We are not certain when 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 successful in resolving our dispute with Takeda, we may be required to quickly expand our workforce, develop an infrastructure, plan and execute a commercialization plan and access substantial capital. 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.

***In the event of a favorable arbitration award, our future success will depend upon our ability to retain a qualified workforce, develop the infrastructure to support the workforce and commercial activities, commercialize the product, and access sufficient capital. We may also enter into a co-promotion arrangement with a pharmaceutical company to commercialize AMITIZA.***

We are expecting an arbitral award on or about April 30, 2012 and in the event the ICC determines that Takeda has breached the collaboration and license agreement and terminates that agreement, we will begin commercializing the product. To successfully promote, market and sell the product and maximize sales, we will need to hire a substantial and qualified workforce, build or contract for the infrastructure necessary to support the workforce and commercialization activities as well as the further development activities, develop and execute a commercialization plan, and access sufficient capital to support all of those activities. We may also enter into a co-promotion arrangement with a pharmaceutical company to maximize the value of AMITIZA. We may not be able to hire the qualified workforce necessary to promote, market and sell the product, to build or contract for the infrastructure to support the workforce and commercial activities, execute the commercialization efforts, or access sufficient capital to support all of the activities necessary to promote, market and sell the product. We may be unsuccessful in finding the appropriate pharmaceutical company to co-promote AMITIZA.

## Risks Related to Our 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, which may 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 previous years, we recorded a net loss in 2010 and 2011 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 \$17.3 million in 2011. 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. We will also incur significant operating expenses as we plan for a favorable arbitration award. Whether we are able to achieve sustainable operating profitability in commercialization of AMITIZA outside of the 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 and access sufficient capital. 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.

***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. In the event the Takeda Agreement and Supplemental Takeda Agreement are terminated, we will need to generate cash and cash equivalents necessary to support all of the activities necessary to develop, promote, market and sell the product. 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 under the collaboration agreements with Takeda and Abbott 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;
- increasing the workforce;
- 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.

***The Company is developing internationally and increasing its 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.

#### **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, which may 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 EMA, they may require us to perform additional clinical trials that would be costly and difficult to know if there will be successful outcomes and to 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 that may 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 and 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.

## 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 manage the growth of the 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 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. R-Tech has informed us that it is relocating its manufacturing facility for unoprostone isopropyl beginning April 2012 and will not be able to manufacture and supply unoprostone isopropyl for up to 18 months. In order to mitigate this risk, we have placed an order to sufficiently cover this supply period based on our forecasts.

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 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, which delayed our obtaining regulatory approval for one of our indications for AMITIZA and delayed 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 four foreign subsidiaries, SPL, SPE, SAG, 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, 2011, 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 near future. 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 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.

Patents 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 whether a judicial court will uphold the validity of a patent .

### **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 an enhanced label may prevent us from successfully re-launching RESCULA in United States. We are also currently seeking approval for AMITIZA for CIC in Japan and the United Kingdom. Failure to obtain regulatory approval or appropriate pricing for a product candidate will prevent us from commercializing the product candidates.

As we increase our foreign operations we are and will continue to seek approval in different territories. Different regulatory agencies may reach different decisions in assessing the approval and pricing of our product candidates. Securing regulatory approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the regulatory agencies 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;
- state and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations; and
- the Patient Protection and Affordable Care Act, which changes access to healthcare products; services and creates new fees for the pharmaceutical and medical device industries; changes rebates and prices for health care products and services; and requires additional reporting and disclosure.

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 chairman, 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 ; 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 outcome of the arbitration in our dispute with Takeda;
- 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.

## **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 offices located in Tokyo and Osaka, Japan and European offices, located in Zug, Switzerland and in Oxford, England, under short-term leases, which comprise an aggregate of 5,950 square feet of space.

### **ITEM 3. LEGAL PROCEEDINGS**

As previously reported, on March 12, 2010, we submitted for filing with the ICC, a demand for arbitration under the applicable provisions of the Takeda Agreement, which specify that New York law will govern the procedural and substantive aspects of the arbitration. We have asserted that Takeda has materially breached, without limitation, certain sections of the Takeda Agreement and Supplemental Takeda Agreement and certain state laws through Takeda's failure to, among other things, collaborate diligently and in good faith with Sucampo; to use best efforts to develop and bring AMITIZA to market; to use best efforts to promote, market, and sell AMITIZA, and to maximize AMITIZA net sales revenue; to market AMITIZA adequately to primary care physicians; to employ an appropriate sales force for AMITIZA; to detail AMITIZA at the appropriate level of quality and quantity; to consider and conduct full-scale direct-to-consumer advertising; to prepare for, launch and commercialize AMITIZA for the IBS-C indication; to obtain appropriate formulary treatment for AMITIZA; and to initiate and fund Phase IV and outcome studies for the CIC and IBS-C indications. The parties filed their submission and witness statements and the arbitration hearing on our claims concluded on December 20, 2011. Under a recent order from the ICC, the final arbitration award is expected by the end of April 2012. After the final arbitration award issues, one or both parties will file a court action seeking confirmation of the award. We have undertaken substantial planning in the event there is a favorable arbitration award. We have filed a motion for interim relief with the arbitration panel to restrain Takeda from making major unilateral decisions prior to the final arbitral award. It is not known if the issuance of the ICC arbitration award will remain on schedule or how long the court confirmation proceedings will take to conclude. We have spent and expect to spend significant resources in the dispute with Takeda, and these arbitration matters may require the continuing attention of our senior management.

As previously reported, we filed an amended lawsuit under seal in the Circuit Court for Montgomery County, Maryland against Covance that performed the clinical trials for the OBD indication. We alleged that Covance was carelessly and grossly negligent in its performance of the clinical trials Covance contracted with us to perform. As a result of Covance's negligence, we had been forced to repair the deficiencies caused by Covance, conduct a new trial and were delayed in filing for and obtaining approval for the new indication for AMITIZA. Covance's negligence resulted in additional costs for studies, re-monitoring and remediation, and lost profits from the delay in filing and obtaining approval for the new indication. On October 26, 2011, we entered into a settlement agreement with Covance, which provides that they have paid us \$10.0 million and forgiven the payment by us of outstanding payables of \$1.1 million. As a result of the settlement agreement, the lawsuit was dismissed with prejudice.

On February 21, 2012, Kimberly Young, a former employee, filed a lawsuit entitled, Kimberly Young vs. Sucampo Pharmaceuticals, in the 95<sup>th</sup> Judicial District Court of Dallas County, Texas alleging, among other things, employment discrimination based on gender in the denial of a promotion and retaliation. She is seeking damages and other relief. We believe that these claims are without merit but the ultimate outcome of these matters cannot be determined at this time.

### **ITEM 4. MINE SAFETY DISCLOSURES**

**Not applicable**



## PART II

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

Our class A common stock has been traded on The NASDAQ Global Market under the symbol "SCMP" since our initial public offering on August 2, 2007. 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.

Quarters Ended	High	Low
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
March 31, 2011	\$ 4.69	\$ 3.86
June 30, 2011	\$ 4.48	\$ 4.08
September 30, 2011	\$ 4.15	\$ 2.89
December 31, 2011	\$ 4.64	\$ 3.40

As of February 27, 2012, we had 15,704,314 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 February 27, 2012, the closing price of our class A common stock was \$7.08. As of February 27, 2012 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.

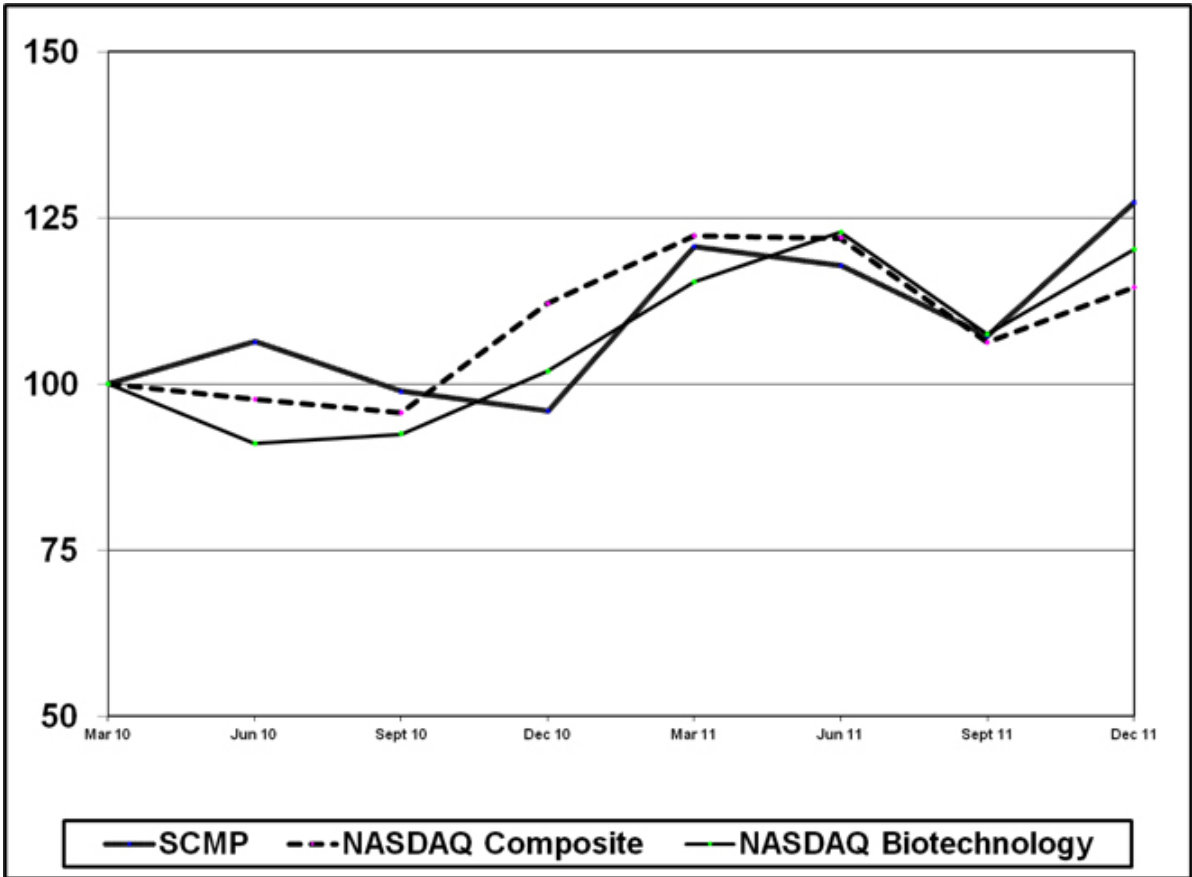
On December 11, 2008, we announced a stock repurchase program to which we are authorized to purchase up to \$10.0 million of our class A common stock from time to time in open-market transactions. On September 8, 2011, our Board of Directors authorized the repurchase of up to an aggregate of \$2.0 million of our class A common stock out of the \$10.0 million authorized by the Board of Directors on December 9, 2008. During the fourth quarter and twelve months ended December 31, 2011, we repurchased 144,713 and 186,987 shares, respectively, of our class A common stock under this program at a cost of \$550,982 and \$700,042, respectively. We did not repurchase any of our equity securities in 2010 or 2009.

Period	Issuer Purchases of Equity Securities			
	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1 - 31, 2011	28,841	3.68	28,841	1,928,885
November 1 - 30, 2011	74,468	3.74	74,468	1,854,417
December 1 - 31, 2011	41,404	3.91	41,404	1,813,013
Total	144,713	3.78	144,713	5,596,315

#### 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 March 1, 2010, 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 FINANCIAL DATA**

We have derived the following consolidated financial data as of December 31, 2010 and 2011 and for the years ended December 31, 2009, 2010 and 2011 from our audited Consolidated Financial Statements appearing elsewhere in this Annual Report. We have derived the following consolidated financial data as of December 31, 2007, 2008 and 2009 and for the years ended December 31, 2007 and 2008 from audited Consolidated Financial Statements, which are not included in this Annual Report. The information set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and related footnotes appearing elsewhere in this Annual Report on Form 10-K.

(In thousands, except per share data)	Year Ended December 31,				
	2011	2010	2009	2008	2007
<b>Statement of operations data</b>					
Revenues	\$ 54,761	\$ 61,870	\$ 67,351	\$ 112,123	\$ 91,937
Operating expenses:					
Research and development	33,497	23,955	32,906	46,181	31,697
Settlement of legal dispute	(11,100)	-	-	-	-
General and administrative	41,270	27,867	15,000	15,075	21,998
Selling and marketing	8,783	10,201	10,030	10,895	13,474
Total operating expenses	<u>72,450</u>	<u>62,023</u>	<u>57,936</u>	<u>72,151</u>	<u>67,169</u>
Income (loss) from operations	(17,689)	(153)	9,415	39,972	24,768
Total non-operating income (expense), net	(4,225)	(3,167)	446	466	2,969
Income (loss) before income taxes	(21,914)	(3,320)	9,861	40,438	27,737
Income tax benefit (provision)	4,608	565	(5,084)	(8,925)	(8,641)
Net income (loss)	<u>\$ (17,306)</u>	<u>\$ (2,755)</u>	<u>\$ 4,777</u>	<u>\$ 31,513</u>	<u>\$ 19,096</u>
Basic net income (loss) per share	<u>\$ (0.41)</u>	<u>\$ (0.07)</u>	<u>\$ 0.11</u>	<u>\$ 0.75</u>	<u>\$ 0.51</u>
Diluted net income (loss) per share	<u>\$ (0.41)</u>	<u>\$ (0.07)</u>	<u>\$ 0.11</u>	<u>\$ 0.75</u>	<u>\$ 0.51</u>
Weighted average common shares outstanding - basic	<u>41,839</u>	<u>41,848</u>	<u>41,844</u>	<u>41,787</u>	<u>37,778</u>
Weighted average common shares outstanding - diluted	<u>41,839</u>	<u>41,848</u>	<u>41,866</u>	<u>41,973</u>	<u>38,226</u>

(In thousands)	December 31,				
	2011	2010	2009	2008	2007
<b>Balance sheet data:</b>					
Cash and cash equivalents	\$ 50,662	\$ 49,243	\$ 61,420	\$ 93,704	\$ 77,912
Investments, current	24,452	54,524	72,434	42,750	52,398
Working capital	67,835	94,541	127,313	128,901	139,664
Total assets	<u>157,569</u>	<u>149,273</u>	<u>180,005</u>	<u>182,354</u>	<u>174,317</u>
Notes payable, current	20,400	19,522	-	-	-
Notes payable, non-current	39,227	44,439	-	-	-
Total liabilities	<u>118,975</u>	<u>95,443</u>	<u>34,693</u>	<u>40,159</u>	<u>38,104</u>
Retained earnings (deficit)	(38,936)	(21,630)	33,150	31,310	30,947
Total stockholders' equity	<u>38,594</u>	<u>53,830</u>	<u>145,312</u>	<u>142,195</u>	<u>136,213</u>

## 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 fatty acid compounds that occur naturally in the human body as a result of the enzymatic catalysis by 15-Prostaglandin Dehydrogenase (15-PGDH) of eicosanoids, like prostaglandins, and other docosanoid molecules specifically synthesized with 15 position keto groups. AMITIZA (lubiprostone) is approved for the treatment of CIC, in adults of both genders, and for the treatment of IBS-C, in women aged 18 years and older. We are currently developing AMITIZA for the treatment of OBD or OIC.

In the U.S. and Canada, AMITIZA is being marketed and developed under a collaboration and license agreement with Takeda, for gastrointestinal indications. Under the Takeda Agreement, 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.

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.

We conduct our business through our subsidiaries based in the U.S., Switzerland, Japan, Luxembourg and the U.K. 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 or OIC in patients treated chronically with opiates other than methadone. We will be filing a sNDA with the FDA in mid-2012 for approval of the indication of OBD or OIC.

*AMITIZA (lubiprostone) in Japan.* We are awaiting approval of our marketing application to PMDA for AMITIZA at a dosage strength of 24 micrograms for the indication of CIC. Once we receive approval, we will engage in pricing negotiations with MHLW and hope to conclude those negotiations in 2012. Abbott will commercialize AMITIZA after we conclude the pricing negotiations.

We are continuing to negotiate with third parties for the OBD indication after Abbott failed to conclude its exclusive negotiation right to the OBD indication.

*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. Though we are currently in discussions with the BAG, for pricing approval, we have commenced marketing AMITIZA, on a limited basis, in Switzerland. We continue to evaluate the opportunities to obtain an appropriate label in the E.U. for chronic therapy of CIC and OBD.

*RESCULA (unoprostone isopropyl).* We plan to re-launch RESCULA in the U.S. for its approved indication in the event of the approval of an enhanced label from the FDA. We have placed an order with R-Tech for a supply of RESCULA in anticipation of the launch for RESCULA, to mitigate the risk from the 18 month cessation of manufacturing by R-Tech and to provide an appropriate supply for regulatory requirements in the E.U. and Switzerland. Additionally, we plan to initiate clinical trials of RESCULA for the indication of dry AMD, in 2012.

Under the terms of the R-Tech agreements, we made an upfront payment of \$3.0 million and will make another \$3.0 million milestone payment in the first quarter of 2012. We may be required to pay up to \$2.5 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.

On March 22, 2011, we entered into a license agreement with R-Tech for unoprostone isopropyl, expanding our development and commercialization rights as well as our territories beyond our previously agreed territory of the United States and Canada to the rest of the world, with the exception of the R-Tech Territory. We are now evaluating the opportunities to obtain an appropriate label in the E. U. and other European countries as well as obtaining reauthorization in those countries to commercialize unoprostone isopropyl.

*Cobiprostone.* We are developing cobiprostone as a potential treatment for various gastrointestinal and liver disorders, including the oral mucositis. 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 oral mucositis.

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

### ***Upfront Payment***

Upon signing the Abbott Agreement, 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 PMDA for AMITIZA at a dosage strength of 24 micrograms for the indication of CIC in October 2010.

Though we anticipate approval by and successful conclusion of pricing negotiations with MHLW in 2012, Abbott must commercialize AMITIZA in 2012 – a commercial sale of AMITIZA – for us to receive the milestone payment of \$15.0 million. 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, to Abbott, 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	Revenue Recognized for the Year Ended			Foreign	Amount
	Received	December 31,				
	Through	2009	2010	2011	Effects	December 31,
	December 31,					2011
	2011					
<b>Collaboration revenue:</b>						
Up-front payment associated with the Company's obligation to participate in joint committees	\$ 846	\$ 38	\$ 47	\$ 52	\$ (151)	\$ 860
<b>Research and development revenue:</b>						
Up-front payment - remainder	\$ 9,154	\$ 5,112	\$ 3,471	\$ 520	\$ (152)	\$ 203
Development milestone payment	12,500	4,314	7,587	697	(371)	273
Total	\$ 21,654	\$ 9,426	\$ 11,058	\$ 1,217	\$ (523)	\$ 476

## Financial Terms of our License and Collaboration Agreement with Takeda

### Upfront Payment

Upon signing the Takeda Agreement, 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.

We may receive \$10.0 million from Takeda upon the commercial launch of AMITIZA for OBD or other additional indication.

### 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:

- Any additional research and development expense in excess of \$50.0 million shall be shared equally between Takeda and us. As of December 31, 2011, 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%. Through December 31, 2011, we had incurred \$2.4 million of these expenses, of which we were reimbursed approximately \$1.6 million by Takeda.
- The expense of clinical development 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, 2011, 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 conducted clinical trials of AMITIZA for the treatment of OBD or OIC. Through December 31, 2011, we had incurred \$70.4 million of reimbursable expenses.

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 Supplemental Takeda Agreement (which co-promotion expense reimbursement provision expired in May 2011) and the Takeda Agreement, Takeda agreed to reimburse a portion of our expenses related to our specialty sales force. We recognized \$3.4 million, \$4.4 million and \$4.5 million of co-promotion revenue reflecting these reimbursements for the years ended December 31, 2011, 2010 and 2009, 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. We have not been reimbursed for any of these expenses.

#### **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, 2011, 2010 and 2009 we recognized a total of \$41.5 million, \$40.3 million and \$38.3 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, 2011.

#### **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, 2011	Revenue Recognized for the Year Ended December 31,			Accounts Receivable for the Year Ended December 31, 2011 (1)	Amount Deferred at December 31, 2011
		Through 2009	2010	2011		
<i>Collaboration revenue:</i>						
Up-front payment associated with our obligation to participate in joint committees	\$ 2,375	\$ 758	\$ 147	\$ 147	\$ -	\$ 1,323
<i>Research and development revenue:</i>						
Up-front payment - remainder	\$ 17,624	\$ 17,624	\$ -	\$ -	\$ -	\$ -
Development milestones	130,000	130,000	-	-	-	-
Reimbursement of research and development expenses	97,122	86,757	5,473	8,032	5,918	2,778
Total	\$ 244,746	\$ 234,381	\$ 5,473	\$ 8,032	\$ 5,918	\$ 2,778
Product royalty revenue	\$ 177,836	\$ 106,814	\$ 40,300	\$ 41,517	\$ 10,795	\$ -
Co-promotion revenue	\$ 25,206	\$ 18,021	\$ 4,417	\$ 3,378	\$ 610	\$ -

(1) Includes billed and unbilled accounts receivable.

## Financial Terms of our Supply Agreement with R-Tech

Under the exclusive supply agreement with R-Tech, R-Tech has 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 and \$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 for 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, 2011 and 2010, respectively, which is recorded as contract revenue. During the years ended December 31, 2011, 2010 and 2009, we purchased clinical supplies from R-Tech of approximately \$72,000, \$344,000 and \$205,000, respectively, under the terms of this agreement.

Under the exclusive manufacturing and supply agreement with R-Tech to manufacture and supply lubiprostone for clinical and commercial supplies within Europe, there have been no clinical supply purchases in 2011, 2010 or 2009. During the years ended December 31, 2011, 2010 and 2009, we purchased approximately \$125,000, \$110,000 and \$692,000, respectively, of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch in Europe. Subsequent to the 2009 purchase, we withdrew our European MAA, and recorded a write down of inventory in 2009 of \$658,000 to reflect the fair value of this inventory.

Under the two-year exclusive clinical manufacturing and supply agreement with R-Tech for cobiprostone and SPI-017 and during the years ended December 31, 2010 and 2009, we purchased from R-Tech approximately \$48,000 and \$1.1 million, respectively, of clinical supplies under the terms of this agreement. There were no such clinical supplies purchases in 2011.

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. During the years ended December 31, 2011, 2010 and 2009, we purchased approximately \$166,000, \$267,000 and \$381,000, respectively, of commercial supplies of lubiprostone from R-Tech under this agreement. During the year ended December 31, 2009, we purchased approximately \$262,000 of clinical supplies from R-Tech under this agreement. There were no such clinical supplies purchases in 2011 and 2010 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. Under the terms of those 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, which we are planning to do in 2012.

Under the terms of the 2011 agreement, we may be required to pay up to \$103.0 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of \$3.0 million is payable upon the earlier of product approval within the SAG Territories or by March 15, 2012, SAG will be responsible for all development, regulatory, and commercialization activities.

R-Tech has informed us that it is relocating its manufacturing facility for unoprostone isopropyl beginning April 2012 and will not be able to manufacture and supply unoprostone isopropyl for up to 18 months. In order to mitigate this risk, in February 2012 we placed an order for approximately \$6.0 million to supply sufficient quantities of unoprostone isopropyl to meet our anticipated commercial and clinical requirements.



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

(In thousands)	Year Ended December 31,		
	2011	2010	2009
Clinical supplies	\$ 72	\$ 392	\$ 1,556
Other research and development services	104	69	100
Commercial supplies	155	376	1,039
	<u>\$ 331</u>	<u>\$ 837</u>	<u>\$ 2,695</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 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 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 to Abbott of such product when earned.

Takeda reimbursements of co-promotion costs under the Supplemental Takeda Agreement (which co-promotion expense reimbursement provision expired in May 2011) and the Takeda 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 Takeda 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 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 Agreement and Abbott Agreement 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, for service based and market condition options we have chosen to use:

- the straight-line method of allocating compensation cost for service based options and graded vesting for market condition options;
- the Black-Scholes-Merton option pricing formula for time based options and the Monte Carlo simulation model for the market condition options as our chosen option-pricing models.
- the simplified method to calculate the expected term for options as discussed under the SEC's guidance for share-based payments for service based options; 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 Financial Accounting Standards Board or, 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, stock compensation, and the transfer of intellectual property 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 net deferred tax assets in certain jurisdictions. We recorded a valuation allowance of \$4.5 million and \$9.6 million as of December 31, 2011 and 2010, respectively, against the net deferred tax assets in certain jurisdictions which resulted in a net deferred tax liability of \$22.9 million and a net deferred asset of \$3.3 million as of December 31, 2011 and 2010, 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.

During 2011, SPA, SPL and SPE transferred certain intellectual property and licenses to SAG. Since the transfer of these assets was to a subsidiary, the recognition of a deferred tax asset by SAG is prohibited and the net tax effect of the transaction is deferred in consolidation. The deferred tax liability generated from this transaction is offset by a deferred charge that will be amortized over ten years. The total deferred charge is \$29.8 million after \$764,000 of current year amortization expense.

As of December 31, 2011 and 2010, we had foreign net operating loss carry forwards of \$16.4 million and \$24.2 million, respectively. Approximately \$9.2 million of the foreign net operating losses, or NOLs, begin to expire in December 2015, and \$7.2 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 50.0% percent likely to be realized upon settlement.

We have recorded a non-current income tax liability of approximately \$1.5 million including interest for uncertain tax positions as of December 31, 2011. 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, 2011 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 \$69,000, \$75,000 and \$60,000 of interest recorded in 2011, 2010 and 2009, respectively, related to uncertain tax positions. We have identified no uncertain tax positions 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 may enter into transactions with our affiliates or other parties we determine as related, such transactions may include sales and purchases of product, borrowing and lending. 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, 2011 and December 31, 2010

#### Revenues

The following table summarizes our revenues for the years ended December 31, 2011 and 2010:

(In thousands)	Year Ended December 31,	
	2011	2010
Research and development revenue	\$ 9,249	\$ 16,540
Product royalty revenue	41,517	40,300
Co-promotion revenue	3,378	4,417
Contract and collaboration revenue	617	613
Total	<u>\$ 54,761</u>	<u>\$ 61,870</u>

Total revenues were \$54.8 million in 2011 compared to \$61.9 million in 2010, a decrease of \$7.1 million or 11.5%.

#### Research and development revenue

Research and development revenue was \$9.2 million in 2011 compared to \$16.5 million in 2010, a decrease of \$7.3 million or 44.1%. The decrease was primarily due to the completion of clinical activity in 2010 on our Japanese development program for lubiprostone under the Abbott Agreement, while we await a response to the NDA filing. The revenue recognized under the Abbott Agreement decreased to \$1.2 million for the year ended December 31, 2011 from \$11.0 million for the year ended December 31, 2010. We are recognizing the revenue from the payments from Abbott using a percentage-of-completion model over the estimated term of the CIC development program. The revenue recognized under the Takeda Agreement increased to \$8.0 million for the year ended December 31, 2011 from \$5.5 million for the year ended December 31, 2010. We are recognizing the revenue from the payments from Takeda using a time-based model over the estimated performance period.

#### Product royalty revenue

Product royalty revenue represents royalty revenue earned on net sales of AMITIZA in the United States. In 2011, we recognized \$41.5 million of product royalty revenue compared to \$40.3 million in 2010, an increase of \$1.2 million or 3.0%.

#### Co-promotion revenue

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force. In 2011, we recognized \$3.4 million of co-promotion revenues compared to \$4.4 million in 2010, a decrease of \$1.0 million as a result of a change in the method of reimbursement following the ending of the applicable provision in the Supplemental Takeda Agreement.

#### Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2011 and 2010:

(In thousands)	Year Ended December 31,	
	2011	2010
Direct costs:		
Lubiprostone	\$ 23,998	\$ 17,248
Cobiprostone	520	598
SPI-017	611	2,230
Unoprostone isoproypl	2,961	1,231
Other	3,694	342
Total	<u>31,784</u>	<u>21,649</u>
Indirect costs	1,713	2,306
Total	<u>\$ 33,497</u>	<u>\$ 23,955</u>

Total research and development expenses in 2011 were \$33.5 million compared to \$24.0 million in 2010, an increase of \$9.5 million or 39.8%. The increase was primarily due to expenses associated with the third phase 3 trial of lubiprostone for OBD patients and remonitoring costs of which 50.0% are reimbursed by Takeda, as well as increases in other development activities. Due to the method adopted for revenue recognition, certain expense are reimbursed and included as revenue, as described in the accounting policies, there may be timing differences between the costs incurred and the recognition of cost reimbursement.

### **General and Administrative Expenses**

The following summarizes our general and administrative expenses for years ended December 31, 2011 and 2010:

<b>(In thousands)</b>	<b>Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Salaries, benefits and related costs	\$ 6,670	\$ 5,567
Legal, consulting and other professional expenses	27,225	15,337
Other expenses	7,375	6,963
Total	<u>\$ 41,270</u>	<u>\$ 27,867</u>

General and administrative expenses were \$41.3 million in 2011 compared to \$27.9 million in 2010, an increase of \$13.4 million or 48.1%. The increase was primarily attributable to an increase in legal, consulting and other professional expenses, which relate primarily to costs incurred in connection with ongoing legal matters, including our dispute with Takeda, a separate dispute with Covance that was settled in October 2011 and SAG integration activities.

### **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 \$8.8 million in 2011 compared to \$10.2 million in 2010, a decrease of \$1.4 million or 13.9%. The decrease in selling and marketing expenses relates primarily to the timing of pre-commercialization activities for RESCULA in the U.S. and lower co-promotion activities as a result of the end of the Supplemental Takeda Agreement for reimbursement of those activities. 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, 2011 and 2010:

<b>(In thousands)</b>	<b>Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Interest income	\$ 249	\$ 608
Interest expense	(2,455)	(75)
Other expense, net	(2,019)	(3,700)
Total	<u>\$ (4,225)</u>	<u>\$ (3,167)</u>

Interest income was \$249,000 in 2011 compared to \$608,000 in 2010, a decrease of \$359,000, or 59.0%. The decrease was primarily due to lower interest rates earned by our investments and a shift in the composition of our portfolio from Auction Rate Securities or ARS, which bear higher interest rates, to other types of investments. Our investment in ARS was redeemed in June 2010.

Interest expense was \$2.5 million in 2011 compared to \$75,000 in 2010, an increase of \$2.4 million, including \$2.3 million on the notes payable issued for the December 2010 SAG acquisition and \$168,000 on the notes payable issued on SPL's borrowings.

Other expense, net was \$2.0 million in 2011 compared to \$3.7 million in 2010, a decrease of \$1.7 million, or 45.4%. The majority of the decrease is from non-cash foreign exchange losses that are unrealized and relate to amounts held within subsidiaries.

### **Income Taxes**

For the years ended December 31, 2011 and 2010, our consolidated effective income tax rate was 21.0% and 17.0%, respectively. For the years ended December 31, 2011 and 2010, we recorded a tax benefit of \$4.6 million and \$565,000, respectively. The change in our effective tax rate in 2011 from 2010 was attributable primarily to the change in the mix of earnings by jurisdiction and the continuation of foreign losses that are not benefited due to full valuation allowances. As of December 31, 2011, our remaining valuation allowance against our deferred tax assets was \$4.5 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, 2010 and December 31, 2009

### Revenues

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

(In thousands)	Year Ended December 31,	
	2010	2009
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
Total	<u>\$ 61,870</u>	<u>\$ 67,351</u>

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 Abbott Agreement. The research and development revenue recognized under the Takeda Agreement 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 Abbott Agreement 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%.

#### 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.

### 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
Unoprostone isopropyl	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 the OBD indication.

### 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 on-going 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 unrealized foreign exchange losses are, 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 and the continuation of foreign losses that are not benefited due to full valuation allowances. 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.

### **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 a loss before taxes of \$6.1 million in 2011, compared to income before taxes of \$3.8 million in 2010. These results primarily reflect the expenses associated with initiating the additional phase 3 trial of lubiprostone for OBD in chronic non-cancer pain patients, these costs have not been allocated across all segments, a separate dispute with Covance that was settled in October 2011, and the increased expenses in legal matters, including our dispute with Takeda.

Our segment in Europe recorded a loss before taxes of \$10.3 million in 2011, compared to a loss before taxes of \$6.2 million in 2010. These results primarily reflect the on-going regulatory submission for AMITIZA, the interest accruing on the loan notes issued for the December 2010 SAG acquisition and non-cash foreign exchange gains and losses.

Our segment in Asia recorded a loss before taxes of \$5.4 million in 2011, compared to a loss before taxes of \$935,000 in 2010. These results primarily reflect the reduction of revenue recognized during the year ended December 31, 2011 from the payments received from Abbott in 2009 and 2010.

<b>(In thousands)</b>	<b>Americas</b>	<b>Europe</b>	<b>Asia</b>	<b>Consolidated</b>
<b>Year Ended December 31, 2011</b>				
Total revenues	\$ 53,493	\$ -	\$ 1,268	\$ 54,761
Income (loss) before taxes	(6,384)	(10,086)	(5,444)	(21,914)
Identifiable assets	96,490	47,925	13,154	157,569
<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



## Liquidity and Capital Resources

### Sources of Liquidity

We require cash principally to meet our operating expenses. We finance our operations principally from cash generated from revenues, cash and cash equivalents on hand and to a lesser extent from the sale of securities through the exercise of stock options. Revenues generated from operations principally consist of a combination of upfront payments, milestone and royalty payments and research and development expense reimbursements received from Takeda, Abbott and other parties.

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

(In thousands)	Year Ended December 31,	
	2011	2010
Cash and cash equivalents	\$ 50,662	\$ 49,243
Restricted cash, current	15,113	15,113
Restricted cash, non-current	2,129	-
Investments, current	24,452	54,524
Investments, non-current	998	5,028
Total	<u>\$ 93,354</u>	<u>\$ 123,908</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, 2011 and 2010, our restricted cash consisted primarily of the collateral to SPL's loan with The Bank of Tokyo-Mitsubishi UFJ, Ltd. and with Numab's loan with Zurcher Kantonbank.

As of December 31, 2011, our short-term investments consisted of corporate bonds, U.S. government securities, U.S. corporate commercial paper, corporate bonds and variable rate demand notes which have short-term maturities of one year or less. Our non-current investments consisted of U.S. government securities.

### Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2011, 2010 and 2009:

(In thousands)	Year Ended December 31,		
	2011	2010	2009
Cash provided by (used in):			
Operating activities	\$ (19,655)	\$ (3,350)	\$ 4,969
Investing activities	27,901	(11,856)	(35,455)
Financing activities	(8,081)	(1,635)	(2,846)
Effect of exchange rates	1,254	4,664	1,048
Net increase (decrease) in cash and cash equivalents	<u>\$ 1,419</u>	<u>\$ (12,177)</u>	<u>\$ (32,284)</u>

#### Year ended December 31, 2011

Net cash used in operating activities was \$20.0 million for the year ended December 31, 2011. This reflected a net loss of \$17.3 million, a decrease in deferred revenue of \$1.9 million and changes in other operating assets and liabilities.

Net cash provided by investing activities of \$27.9 million for the year ended December 31, 2011 primarily reflected our proceeds from the sales and maturities of investments, offset in part by purchases of investments, intangible assets and an increase in restricted cash.

Net cash used in financing activities of \$8.1 million for the year ended December 31, 2011 primarily reflected a payment of \$7.5 million on our notes payable and purchases under the stock repurchase program.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for year ended December 31, 2011 was an increase of \$1.6 million.

### **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 Agreement and Abbott Agreement 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.

### **Commitments and Contingencies**

As of December 31, 2011, our principal outstanding contractual obligations related to our office leases in the U.S., Switzerland, Japan and the U.K. The following table summarizes these significant contractual obligations at December 31 for the indicated year:

<b>(In thousands)</b>	<b>Notes</b>	<b>Operating</b>	<b>Total</b>
	<b>Payable</b>	<b>Lease</b>	
	<b>2011</b>	<b>2010</b>	
Due in one year	\$ 20,400	\$ 1,457	\$ 21,857
Due in two years	8,281	1,036	9,317
Due in three years	8,490	1,024	9,514
Due in four years	8,708	1,052	9,760
Due in five years	8,937	1,084	10,021
Thereafter	4,811	139	4,950
<b>Total</b>	<b>\$ 59,627</b>	<b>\$ 5,792</b>	<b>\$ 65,419</b>

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 CROs 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, 2011, our current commitments to CROs will be \$7.4 million through 2013.
- Any contingent liability under the agreement with Numab in the event that Numab defaults under its loan with Zurcher Kantonalbank up to a maximum potential amount of \$4.8 million. As of December 31, 2011 the potential amount of payments in the event of Numab's default was \$1.6 million.

### **Off-Balance Sheet Arrangements**

As of December 31, 2011, 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:

- Staff, development and commercialization activities in the event of a favorable arbitration award in our dispute with Takeda;
- our share of the on-going development program of AMITIZA in the U.S.;
- development, regulatory and marketing efforts in Europe and Asia for lubiprostone;
- development and regulatory activities for unoprostone isopropyl in the U.S. and Canada and other countries except Japan, Korea, Taiwan and The People's Republic of China;
- development, marketing and manufacturing activities at SAG;
- activities to resolve our on-going legal matters;
- 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;
- research and development activities for other prostone compounds, including cobiprostone and SPI-017;
- other business development activities, including partnerships, alliances and investments in or acquisitions of other businesses, products and technologies;
- the expansion of our commercialization activities including the purchase of inventory;
- continuing purchase of shares of our class A common stock up to \$2.0 million pursuant to the recently implemented repurchase program, and if we elect to do so, increasing the repurchase program up to \$10.0 million previously approved by our Board;
- the satisfaction of the conditions of our loan note obligations; and
- the growth from AMITIZA and RESCULA.

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 future expenditures we may incur to increase revenue from AMITIZA or in our dispute with Takeda;
- if we prevail in our arbitration with Takeda we may need to assume the responsibility for the commercialization of AMITIZA in the U.S. and Canada;
- 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, 2011, 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 Switzerland, Japan and U.K. 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**

In June 2011, the FASB issued an accounting update on Comprehensive Income-Topic 220: Presentation of Comprehensive Income, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, we must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. This update will be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. The Company's adoption of this guidance did not impact the Company's results of operations, financial statement presentation or disclosures.

In May 2011, the FASB issued authoritative guidance on amendments to achieve common fair value measurement and disclosure requirements in U.S.GAAP and International Financial Reporting Standards, or IFRSs. The guidance amends fair value measurement, to ensure that fair value has the same meaning in U.S. GAAP and IFRS. IFRS improves the comparability of the fair value measurement and disclosure requirements in GAAP and IFRS. This guidance applies to all entities that measure assets, liabilities or instruments classified in shareholder's equity at fair value, or provide fair value disclosures for items not recorded at fair value. This guidance results in common fair value measurement and disclosure requirements in U.S. GAAP and IFRSs. Consequently, this guidance changes the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. For many of the requirements, this guidance will not result in a change in the application of the requirements in the existing fair value measurement guidance, however clarifies the FASB's intent about the application of existing fair value measurement requirements. Other requirements change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. This guidance is effective for public companies for interim and annual periods beginning after December 15, 2011 and should be applied prospectively. Early application is not permitted. We are continuing to evaluate the impact that this amendment would have on its financial condition and results of operation upon adoption.

## **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, 2011.

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, 2011 and December 31, 2010, approximately 16.7% and 27.6%, 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 Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of December 31, 2011. 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 Chief Financial Officer have concluded that, as of December 31, 2011, 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 Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

### *Changes in Internal Controls*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### *Management's report on internal control over financial reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended) for the Company. Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2011. 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, 2011.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2011 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)*

Cary J. Claiborne  
*Chief Financial Officer*  
*(Principal Financial Officer)*

## ITEM 9B. OTHER INFORMATION

None.

## **PART III**

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

The following information will be included in our proxy statement or Proxy Statement for our 2012 Annual Meeting to be filed within 120 days after the fiscal year end of December 31, 2011, 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 executive officers required by this item will be set forth under the heading “Executive Officers”;
- 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 codes 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 codes 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 our Proxy Statement.

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

The information regarding security ownership of our beneficial owners, management and related stockholder matters is incorporated into this section by reference from the section captioned “Stock Ownership Information” in our Proxy Statement. The information regarding the securities authorized for issuance under our equity compensation plan is incorporated into this section by reference from the section captioned “Equity Compensation Plan Information” of our Proxy Statement.

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

The information required by this item is incorporated by reference to the information provided under the heading “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)
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)
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^	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)
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	Exhibit 10.49 to the Company's Current Report on Form 10-K (filed March 8, 2011)
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.	Exhibit 10.50 to the Company's Current Report on Form 10-K (filed March 8, 2011)
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 2, 2011)
10.55^	Consulting Agreement, dated January 13, 2011, between the Company and Jan Smilek	Exhibit 99.2 to the Company's Current Report on Form 8-K (filed February 2, 2011)
10.56	Form of Sucampo Pharmaceuticals, Inc. Duration and Performance-Based Stock Option Incentive Award	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed May 6, 2011)
10.57	Exclusive License for Development and Commercialization of Unoprostone dated March 22, 2011, between Sucampo Manufacturing & Research AG and R-Tech Ueno, Ltd.	Exhibit 10.3 to the Company's Current Report on Form 10-Q (filed May 10, 2011)
10.58*	Loan Guarantee and Development Agreement, dated September 8, 2011, between Numab AG and Sucampo AG	Included herewith
10.59	Form of Settlement and Mutual Release Agreement, dated October 26, 2011, between Sucampo Pharmaceuticals, Inc. and Covance Inc.	Exhibit 10.2 to the Company's Current Report on Form 10-Q (filed November 9, 2011)
10.60	Employment Agreement, effective as of October 17, 2011, between the Company and Cary J. Claiborne	Included herewith
101.[INS]†	XBRL Instance Document	Included herewith
101.[SCH]†	XBRL Taxonomy Extension Schema Document	Included herewith
101.[CAL]†	XBRL Taxonomy Extension Calculation Linkbase Document	Included herewith
101.[LAB]†	XBRL Taxonomy Extension Label Linkbase Document	Included herewith
101.[PRE]†	XBRL Taxonomy Extension Presentation Linkbase Document	Included herewith

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.

† Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.

## Signatures

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

Sucampo Pharmaceuticals, Inc.

March 15, 2012

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

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

Signature	Title	Date
<u>/s/ RYUJI UENO</u> Ryuji Ueno, M.D., Ph.D., Ph.D.	Chief Executive Officer (Principal Executive Officer), Chief Scientific Officer and Chairman	March 15, 2012
<u>/s/ CARY J. CLAIBORNE</u> Cary J. Claiborne	Chief Financial Officer (Principal Financial Officer)	March 15, 2012
<u>/s/ WILLIAM L. ASHTON</u> William L. Ashton	Director	March 15, 2012
<u>/s/ ANTHONY C. CELESTE</u> Anthony C. Celeste	Director	March 15, 2012
<u>/s/ GAYLE R. DOLECEK</u> Gayle R. Dolecek, P.D.	Director	March 15, 2012
<u>/s/ DANIEL P. GETMAN</u> Daniel P. Getman	Director	March 15, 2012
<u>/s/ SACHIKO KUNO</u> Sachiko Kuno, Ph.D.	Director	March 15, 2012
<u>/s/ TIMOTHY I. MAUDLIN</u> Timothy I. Maudlin	Director	March 15, 2012

**SUCAMPO PHARMACEUTICALS, INC.**  
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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 accompanying 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, 2011 and December 31, 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 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, 2011, 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.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland  
March 15, 2012



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

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>ASSETS:</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 50,662	\$ 49,243
Investments, current	24,452	54,524
Product royalties receivable	10,795	10,516
Unbilled accounts receivable	2,036	1,097
Accounts receivable, net	4,616	731
Prepaid and income taxes receivable	2,845	702
Deferred tax assets, current	163	243
Deferred charge, current	3,057	-
Restricted cash, current	15,113	15,113
Prepaid expenses and other current assets	1,177	2,374
<b>Total current assets</b>	<b>114,916</b>	<b>134,543</b>
Investments, non-current	998	5,028
Property and equipment, net	1,669	2,025
Intangibles assets, net	8,364	3,070
Deferred tax assets, non-current	2,089	4,178
Deferred charge, non-current	26,751	-
Restricted cash, non-current	2,129	-
Other assets	653	429
<b>Total assets</b>	<b>\$ 157,569</b>	<b>\$ 149,273</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 6,978	\$ 4,199
Accrued expenses	13,648	10,216
Deferred revenue, current	3,888	4,987
Deferred tax liability, current	2,167	1,078
Notes payable, current	20,400	19,522
<b>Total current liabilities</b>	<b>47,081</b>	<b>40,002</b>
Notes payable, non-current	39,227	44,439
Deferred revenue, non-current	7,045	8,321
Deferred tax liability, non-current	23,019	-
Other liabilities	2,603	2,681
<b>Total liabilities</b>	<b>118,975</b>	<b>95,443</b>
<b>Commitments and contingencies (Notes 10 and 13)</b>		
<b>Stockholders' equity:</b>		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2011 and 2010; no shares issued and outstanding at December 31, 2011 and 2010	-	-
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2011 and 2010; 15,690,780 and 15,659,917 shares issued and outstanding at December 31, 2011 and 2010, respectively	157	156
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2011 and 2010; 26,191,050 shares issued and outstanding at December 31, 2011 and 2010	262	262
Additional paid-in capital	59,957	58,468
Accumulated other comprehensive income	17,854	16,574
Treasury stock, at cost; 186,987 shares	(700)	-
Accumulated deficit	(38,936)	(21,630)
<b>Total stockholders' equity</b>	<b>38,594</b>	<b>53,830</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 157,569</b>	<b>\$ 149,273</b>

The accompanying notes are an integral part of these Consolidated Financial Statements.

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

	Year Ended December 31,		
	2011	2010	2009
<b>Revenues:</b>			
Research and development revenue	\$ 9,249	\$ 16,540	\$ 23,957
Product royalty revenue	41,517	40,300	38,250
Co-promotion revenue	3,378	4,417	4,541
Contract and collaboration revenue	617	613	603
Total revenues	<u>54,761</u>	<u>61,870</u>	<u>67,351</u>
<b>Operating expenses:</b>			
Research and development	33,497	23,955	32,906
Settlement of legal dispute	(11,100)	-	-
General and administrative	41,270	27,867	15,000
Selling and marketing	8,783	10,201	10,030
Total operating expenses	<u>72,450</u>	<u>62,023</u>	<u>57,936</u>
Income (loss) from operations	(17,689)	(153)	9,415
<b>Non-operating income (expense):</b>			
Interest income	249	608	965
Interest expense	(2,455)	(75)	-
Other expense, net	(2,019)	(3,700)	(519)
Total non-operating income (expense), net	<u>(4,225)</u>	<u>(3,167)</u>	<u>446</u>
Income (loss) before income taxes	(21,914)	(3,320)	9,861
Income tax benefit (provision)	4,608	565	(5,084)
Net income (loss)	<u>\$ (17,306)</u>	<u>\$ (2,755)</u>	<u>\$ 4,777</u>
<b>Net income (loss) per share:</b>			
Basic net income (loss) per share	<u>\$ (0.41)</u>	<u>\$ (0.07)</u>	<u>\$ 0.11</u>
Diluted net income (loss) per share	<u>\$ (0.41)</u>	<u>\$ (0.07)</u>	<u>\$ 0.11</u>
Weighted average common shares outstanding - basic	<u>41,839</u>	<u>41,848</u>	<u>41,844</u>
Weighted average common shares outstanding - diluted	<u>41,839</u>	<u>41,848</u>	<u>41,866</u>
<b>Comprehensive income (loss):</b>			
Net income (loss)	\$ (17,306)	\$ (2,755)	\$ 4,777
<b>Other comprehensive income gain (loss):</b>			
Unrealized loss on investments, net of tax effect	(2)	(18)	(55)
Foreign currency translation	1,282	3,745	822
Comprehensive income (loss)	<u>\$ (16,026)</u>	<u>\$ 972</u>	<u>\$ 5,544</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)	Treasury Stock		Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			Shares	Amount		
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
Employee stock option expense	-	-	-	-	1,370	-	-	-	-	1,370
Stock issued upon exercise of stock options	27,500	1	-	-	106	-	-	-	-	107
Stock issued under employee stock purchase plan	3,363	-	-	-	13	-	-	-	-	13
Foreign currency translation	-	-	-	-	-	1,282	-	-	-	1,282
Unrealized loss on investments, net of tax effect	-	-	-	-	-	(2)	-	-	-	(2)
Treasury stock, at cost	-	-	-	-	-	-	186,987	(700)	-	(700)
Net loss	-	-	-	-	-	-	-	-	(17,306)	(17,306)
Balance at December 31, 2011	<u>15,690,780</u>	<u>\$ 157</u>	<u>26,191,050</u>	<u>\$ 262</u>	<u>\$ 59,957</u>	<u>\$ 17,854</u>	<u>186,987</u>	<u>\$ (700)</u>	<u>\$ (38,936)</u>	<u>\$ 38,594</u>

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,		
	2011	2010	2009
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ (17,306)	\$ (2,755)	\$ 4,777
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>			
Depreciation and amortization	1,308	964	789
Loss on disposal of property and equipment	12	1	-
Deferred tax provision (benefit)	26,228	(99)	13
Deferred charge	(29,808)	-	-
Stock-based compensation	1,370	1,260	374
Amortization of premiums on investments	651	1,617	1,415
Notes payable paid-in-kind interest	2,288	-	-
Gain on trading securities	-	(1,086)	(2,092)
Loss on settlement rights on auction rate securities	-	1,086	1,732
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable	(3,885)	(218)	32
Unbilled accounts receivable	(939)	(453)	3,729
Product royalties receivable	(280)	507	(1,298)
Inventory	(127)	-	-
Prepaid and income taxes receivable and payable, net	(2,173)	(2,689)	1,586
Accounts payable	2,872	893	1,679
Accrued expenses	523	3,329	(3,269)
Deferred revenue	(1,940)	(6,525)	(4,564)
Other assets and liabilities, net	1,215	818	66
Net cash provided by (used in) operating activities	<u>(19,991)</u>	<u>(3,350)</u>	<u>4,969</u>
<b>Cash flows from investing activities:</b>			
Purchases of investments	(20,598)	(84,857)	(150,712)
Proceeds from the sales of investments	7,380	25,855	9,504
Maturities of investments	46,665	90,492	109,163
Purchases of property and equipment	(284)	(333)	(495)
Proceeds from disposals of property and equipment	25	5	-
Issuance of notes receivable	(100)	-	-
Purchases of intangible assets	(3,000)	-	(2,915)
Acquisition of SAG	-	(28,118)	-
Restricted cash	(2,187)	(14,900)	-
Net cash provided by (used in) investing activities	<u>27,901</u>	<u>(11,856)</u>	<u>(35,455)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from notes payable	-	12,079	-
Repayment of notes payable	(7,500)	-	-
Proceeds from exercise of stock options	106	-	-
Purchase of treasury stock	(700)	-	-
Proceeds from employee stock purchase plan	13	14	19
Dividend payments	-	(13,728)	(2,865)
Net cash used in financing activities	<u>(8,081)</u>	<u>(1,635)</u>	<u>(2,846)</u>
Effect of exchange rates on cash and cash equivalents	<u>1,590</u>	<u>4,664</u>	<u>1,048</u>
Net increase (decrease) in cash and cash equivalents	1,419	(12,177)	(32,284)
Cash and cash equivalents at beginning of period	49,243	61,420	93,704
Cash and cash equivalents at end of period	<u>\$ 50,662</u>	<u>\$ 49,243</u>	<u>\$ 61,420</u>
<b>Supplemental cash flow disclosures:</b>			
Cash paid for interest	<u>\$ 171</u>	<u>\$ 2</u>	<u>\$ -</u>
Tax refunds received	<u>\$ 245</u>	<u>\$ 126</u>	<u>\$ -</u>
Tax payments made	<u>\$ 1,476</u>	<u>\$ 2,683</u>	<u>\$ 1,233</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Purchase of intangible assets included in accrued expenses	<u>\$ 3,000</u>	<u>\$ -</u>	<u>\$ 500</u>
Loan notes issued for acquisition of SAG	<u>\$ -</u>	<u>\$ 51,882</u>	<u>\$ -</u>

The accompanying notes are an integral part of these Consolidated Financial Statements.

## 1. Business Organization and Basis of Presentation

### *Description of the Business*

Sucampo Pharmaceuticals, Inc., or the Company, is a global pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones and other novel drug technologies. Prostones are a class of fatty acid compounds that occur naturally in the human body as a result of the enzymatic catalysis by 15-Prostaglandin Dehydrogenase (15-PGDH) of eicosanoids, like prostaglandins, and other docosanoid molecules specifically synthesized with 15 position keto groups.

The Company generates revenue mainly from product royalties, development milestone payments, and clinical development activities. The Company expects to continue to incur significant expenses for the next several years as the Company continues its research and development activities and as the Company seeks regulatory approvals for additional indications for AMITIZA, RESCULA and other compounds on an international basis. The Company conducts business through subsidiaries based in Japan, the United States, Switzerland, the United Kingdom and Luxembourg.

In January 2006, the Company received marketing approval from the U.S. Food and Drug Administration, or FDA for 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 the October 2004 collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda Agreement. The Company is primarily responsible for clinical development activities under the Takeda Agreement while Takeda is responsible for commercialization of AMITIZA. 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. AMITIZA is currently being developed for the treatment of opioid bowel dysfunction, or OBD or opioid-induced constipation, or OIC. Takeda also holds marketing rights to AMITIZA in Canada, but has not yet commercialized it there. The Company, in 2006, entered into a supplemental agreement with Takeda Pharmaceutical Company Limited, or the Supplemental Takeda Agreement, which consists of certain key funding streams, including reimbursements of co-promotion costs and reimbursements of the costs of miscellaneous marketing activities. The reimbursement of co-promotion costs under the Supplemental Takeda Agreement expired on May 31, 2011. Co-promotion costs after May 31, 2011 are reimbursed under the Takeda Agreement. The previous reimbursement terms of the Supplemental Takeda Agreement were based on a per diem amount by the number of sales representatives in the field promoting AMITIZA. The current terms are based on actual details presented to health care prescribers.

We submitted for filing with the International Court of Arbitration, International Chamber of Commerce, or ICC a demand for arbitration under the applicable provisions of the Takeda Agreement, which specify that New York law will govern the procedural and substantive aspects of the arbitration. The parties filed submission and witness statements and the arbitration hearing on the Company's claims concluded on December 20, 2011.

In Switzerland, we are currently in discussions with the Swiss Federal Office of Public Health, or Bundesamt für Gesundheit, or the BAG for pricing approval. In February 2012 the Company started to market AMITIZA, on a limited basis, in Switzerland.

In Japan, lubiprostone is being developed under a license, commercialization and supply agreement with Abbott Japan Co. Ltd., or Abbott, for lubiprostone in Japan, or the Abbott Agreement. The Company has filed a new drug application, or a NDA, for AMITIZA for the treatment of CIC in Japan with the Pharmaceuticals and Medical Devices Agency, or PMDA. The Company anticipates a decision by the PMDA and the conclusion of pricing negotiations with the Ministry of Health, Labor and Welfare, or MHLW in 2012. The Company continues to negotiate with third parties for the OBD indication, and Abbott will have 45 days to meet the terms and conditions of any third party bona fide offer.

SPE submitted a filing for approval of AMITIZA to treat CIC on August 4, 2011 in the U. K., and the Company expects a decision by the Medicines and Healthcare products Regulatory Agency, or MHRA in the third quarter of 2012. The Company continues to evaluate the opportunities in the E. U.

Following the Company's acquisition of Sucampo AG, or SAG, the Company began and has continued integrating SAG for future operational efficiencies through a simplified group structure and consolidation of intellectual property. On September 29, 2011 the Company's subsidiaries Sucampo Pharma Americas Inc, or SPA, Sucampo Pharma Ltd, or SPL and Sucampo Pharma Europe Ltd, or SPE transferred certain intellectual property and licenses to SAG, and SAG entered into agreements with the subsidiaries to perform certain services related to the intellectual property, licenses and other business activities. As a result of these agreements SAG is now our principal operating company.

On September 29, 2011, SPA transferred its rights to unoprostone isopropyl to SAG. SAG entered into an agreement with SPA to perform certain activities related to those rights. On March 22, 2011, SAG entered into a license agreement with R-Tech for unoprostone isopropyl, expanding the Company's development and commercialization rights as well as its territories beyond their previously agreed territory of the United States and Canada to the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China, or the R-Tech Territory, or the SAG Territories. SAG is now evaluating the opportunities to obtain an appropriate label in the E.U. and other European countries as well as obtaining reauthorization in those countries to commercialize unoprostone isopropyl.

Other prostone compounds in the Company's development plan include cobiprostone for the treatment of oral mucositis in cancer patients and wound healing. Additionally, the Company is evaluating SPI-017 for use as a treatment of treatment for the management of pain caused by spinal stenosis.

In July 2011, the Company obtained the development and commercial rights to a peptide compound from CuroNZ, a New Zealand company, for a loan of \$100,000 that will augment the Company's ophthalmic development opportunities. Loan and accrued interest of approximately \$101,000 is recorded as other assets in the Consolidated Balance Sheets at December 31, 2011.

In September 2011, the Company entered into a Loan Guarantee and Development Agreement, or Numab Agreement, with Numab AG, or Numab. Numab is considered a related party as a result of a ownership interest by one of the Company's executive officers. It provides the Company with access to Numab's proprietary technology for the discovery of high-affinity antibodies against certain selected targets. The Company will have exclusive commercial rights to any biologic products successfully developed and commercialized in the course of the collaboration. The Numab Agreement presents an opportunity to maximize the Company's knowledge of a variety of targets that result in several large, underserved patient populations. By applying Numab's antibody technology to these targets, the Company plans to develop biologic products with a different mechanism of action that will be complementary to the prostone-based compounds the Company now has in development. Under the terms of the Numab Agreement, the Company will provide Numab with up to CHF 5.0 million as collateral and will serve as guarantor for a loan to Numab from a third party. The Company may name up to four targets against which Numab will use their proprietary technology to discover high-affinity antibodies and to develop these to an investigation new drug, or IND, ready stage. Numab is eligible for full time equivalent based payments and discovery success dependent fees. Any success dependent fees will result in a corresponding reduction in the amount of the available guarantee. Should Numab default its loan obligations, the collateral may be called upon to meet Numab's obligation under its loan agreement. As of December 31, 2011, the collateral of \$2.1 million has been deposited by the Company and Numab has utilized CHF 1.5 million of its loan available. In reviewing the amount outstanding, the Company has recorded a liability of \$495,000 in respect to the collateral being called upon to meet potential loan default by Numab. If a biologic is successfully developed, Numab and the Company may enter into a license arrangement in which Numab will be entitled to clinical development milestone payments and increasing tiered royalties on net sales. The Company will be responsible for clinical development and will retain all commercial rights to any resulting biologic product.

### ***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: SAG, based in Zug, Switzerland, in which the company conducts certain worldwide and European operations; SPL, based in Tokyo and Osaka, Japan, in which the Company conducts its Asian operations; SPA, based in Bethesda, Maryland, in which the Company conducts operations in North and South America; SPE, based in Oxford, U.K., and Ambrent Investments S.à r.l., based in Luxembourg which conduct operations in Europe;. All significant inter-company balances and transactions have been eliminated.

The acquisition of SAG and its subsidiary in 2010 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 a maturity, at date of purchase, of 90 days or less at the time of purchase.

### *Restricted Cash*

Restricted cash consists of approximately \$17.2 million and \$15.1 million at December 31, 2011 and December 31, 2010, 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 (see Note 12 below), SAG's Numab Agreement (see Note 13 below) and operating leases.

### *Current and Non-Current Investments*

Current and non-current investments consist primarily of U.S. government agencies securities, corporate bonds, mutual funds, variable rate demand notes 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. The Company's investment in ARS was redeemed in June 2010.

### *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, 2011 and 2010, approximately \$15.6 million, or 16.7%, and \$34.1 million, or 27.6%, 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 96.9%, 81.4%, 85.3%, of the Company's total revenues for the years ended December 31, 2011, 2010 and 2009, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 100.0% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at December 31, 2011 and 2010. Revenues from another unrelated party, Abbott, accounted for 2.3%, 18.0% and 14.1% of the Company's total revenues for the years ended December 31, 2011, 2010 and 2009. The Company depends significantly upon the collaborations with Takeda and Abbott and its activities may be impacted if these relationships are disrupted (Note 13).

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 carrying amount of the short and long-term debt at December 31, 2011 and 2010 approximated its fair value due to the fact that the interest rates are determined based by reference to interbank rates.

#### ***Accounts Receivable and Unbilled Accounts Receivable***

Accounts receivable represent mainly amounts due under the Takeda Agreement and the Abbott Agreement (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. No allowance was recorded in 2011 or 2010.

#### ***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, 2011, 2010 or 2009 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 Agreement and Abbott Agreement, including the related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 13 below.



The Company applies a time-based model of revenue recognition for cash flows associated with research and development deliverables under the Takeda 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 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, to Abbott, of such product when earned.

The Company also entered into the Supplemental Takeda Agreement consisting 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 recognized as revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts. Co-promotion costs after May 31, 2011 are reimbursed under the Takeda Agreement and the amounts recognized are based on amounts billed for actual details presented to health care prescribers.

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 Agreement and Abbott Agreement 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 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, 2011 and 2010, total deferred revenue was approximately \$10.9 million and \$13.3 million, respectively.

Total deferred revenue consists of the following as of:

(In thousands)	December 31,	
	2011	2010
Deferred revenue, current	\$ 3,888	\$ 4,987
Deferred revenue, non-current	7,045	8,321
	<u>\$ 10,933</u>	<u>\$ 13,308</u>
Deferred revenue to related parties, included in total deferred revenue:		
Deferred revenue to related parties, current	\$ 433	433
Deferred revenue to related parties, non-current	5,063	5,839
Total	<u>\$ 5,496</u>	<u>\$ 6,272</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 CROs and clinical site costs. The Company analyzes the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs, when evaluating the adequacy of the accrued liabilities for research and development. The Company makes significant judgments and estimates in determining the accrued balance in any accounting period.

#### **Employee Stock-Based Compensation**

The Company applied accounting guidance for share-based awards that requires the measurement and recognition of expense for all share-based compensation of employees and directors to be based on estimated fair values of the share-based awards. This guidance requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service period in the Company's consolidated statement of operations.

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

The assumptions used to estimate the fair value of the service condition stock options granted for the three years ended December 31, 2011 were as follows:

	Year Ended December 31,		
	2011	2010	2009
Expected volatility	55% - 64%	51% - 63%	47% - 55%
Risk-free interest rate	1.30% - 3.30%	1.89% - 3.24%	2.67% - 3.11%
Expected term (in years)	2.10 - 6.25	5.00 - 6.25	6.00 - 7.00
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. The Company has used a lattice based model to determine the expected term for its market condition share-based awards.

**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 2011 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, 2011, 2010 and 2009, 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, 2011 was as follows:

(In thousands)	Year Ended December 31,		
	2011	2010	2009
Research and development expense	\$ 234	\$ 252	\$ 96
General and administrative expense	964	729	193
Selling and marketing expense	172	279	85
Total	<u>1,370</u>	<u>1,260</u>	<u>374</u>
Employee stock-based compensation expense per basic and diluted share of common stock	<u>\$ 0.03</u>	<u>\$ 0.03</u>	<u>\$ 0.01</u>

### 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 against deferred tax assets in certain foreign tax jurisdictions, which resulted in a net deferred tax liability of \$22.9 million and a deferred tax asset of \$3.3 million as of December 31, 2011 and December 31, 2010, 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.

During 2011, SPA, SPL and SPE transferred certain intellectual property and licenses to SAG. Since the transfer of these assets was to a related party, the recognition of a deferred tax asset by SAG is prohibited and the net tax effect of the transaction is deferred in consolidation. The tax liability generated from this transaction is offset by a deferred charge that will be amortized over ten years. The total deferred charge is \$29.8 million after \$764,000 of current year amortization expense.

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 \$1.5 million and \$1.4 million, including interest for uncertain tax positions, as of December 31, 2011 and 2010, 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, 2011 and 2010 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. All of the unrecognized tax benefits could affect the effective tax rate if recognized in the future.

### ***Deferred Charge***

Certain intellectual property was transferred within the group resulting in a gain in the sellers' tax jurisdiction and a difference in the buyer's tax jurisdiction between the new tax basis and the carrying amount of those assets. The FASB guidance on income taxes precludes the Company from including the effects of any intercompany transfers in the financial statements, and so the net tax effect of an intercompany transaction is deferred in consolidation.

These deferred tax effects include the reversal of any existing deferred tax asset (and its related valuation allowance, if any) or liability and any taxes currently payable resulting from the intercompany transaction when the asset remains in the consolidated group for financial reporting purposes. This deferred effect is not the result of a temporary difference and is therefore classified as a deferred charge on the Consolidated Balance Sheet separate from the Company's deferred tax assets.

Since the deferred charge is not part of the deferred tax assets, it is not subject to revaluation for tax rate changes and realizability as prescribed by the FASB's guidance on income taxes. Thus, the deferred charge will remain fixed and will be amortized over the determined life of 10 years and be included as part of the provision for income taxes as a permanent difference.

## ***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.

Following the transfer of certain intellectual property to SAG, the company has reviewed the functional currency of SAG and determined that it is appropriate to change its functional currency to U.S. dollars from Swiss francs effective October 1, 2011.

## ***Other Comprehensive Income***

Comprehensive income consists of net income plus certain other items that are recorded directly to stockholders' equity. The Company has reported comprehensive income in the Consolidated Statements of Operations and Comprehensive Income (Loss).

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

The functional currency of Sucampo AG was changed to the U.S. Dollar from the Swiss Franc on October 2011 on a prospective basis. The historical cumulative translation adjustment from Sucampo AG at the time of the change will not change in future periods.

## ***Segment Information***

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

## ***Recent Accounting Pronouncements***

In June 2011, the FASB issued an accounting update on Comprehensive Income-Topic 220: Presentation of Comprehensive Income, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, the Company must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. This update will be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. The Company's adoption of this guidance did not impact the Company's results of operations, financial statement presentation or disclosures.

In May 2011, the FASB issued authoritative guidance on amendments to achieve common fair value measurement and disclosure requirements in U.S. GAAP and International Financial Reporting Standards, or IFRSs. The guidance amends fair value measurement, to ensure that fair value has the same meaning in U.S. GAAP and IFRS. IFRS improves the comparability of the fair value measurement and disclosure requirements in GAAP and IFRS. This guidance applies to all entities that measure assets, liabilities or instruments classified in shareholder's equity at fair value, or provide fair value disclosures for items not recorded at fair value. This guidance results in common fair value measurement and disclosure requirements in U.S. GAAP and IFRSs. Consequently, this guidance changes the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. For many of the requirements, this guidance will not result in a change in the application of the requirements in the existing fair value measurement guidance, however clarifies the FASB's intent about the application of existing fair value measurement requirements. Other requirements change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. This guidance is effective for public companies for interim and annual periods beginning after December 15, 2011 and should be applied prospectively. Early application is not permitted. The Company is continuing to evaluate the impact that this amendment would have on its financial condition and results of operation upon adoption.

### **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 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.

### **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, 2011, is shown below:

(in thousands, except per share data)	December 31,		
	2011	2010	2009
<b>Basic net income (loss) per share:</b>			
Net income (loss)	\$ (17,306)	\$ (2,755)	\$ 4,777
Weighted average class A and B common shares outstanding	41,839	41,848	41,844
Basic net income (loss) per share	\$ (0.41)	\$ (0.07)	\$ 0.11
<b>Diluted net income (loss) per share:</b>			
Net income (loss)	\$ (17,306)	\$ (2,755)	\$ 4,777
Weighted average class A and B common shares outstanding for diluted net income per share	41,839	41,848	41,844
Assumed exercise of stock options under the treasury stock method	-	-	22
	41,839	41,848	41,866
Diluted net income (loss) per share	\$ (0.41)	\$ (0.07)	\$ 0.11

For the years listed above, the potentially dilutive securities used in the calculations of diluted net income per share as of December 31, 2011, 2010 and 2009 are as follows:

(In thousands)	December 31,		
	2011	2010	2009
Employee stock options	-	-	227
Non-employee stock options	-	-	-

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, 2011, 2010 and 2009:

(In thousands)	December 31,		
	2011	2010	2009
Employee stock options	3,595	1,554	685
Non-employee stock options	450	450	450

## 5. Current and Non-Current Investments

At December 31, 2011 and 2010, current and non-current investments consisted of the following securities:

(In thousands)	December 31, 2011			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
<i>Current:</i>				
U.S. commercial paper	\$ 1,997	\$ 3	\$ -	\$ 2,000
U.S. government securities	3,250	-	-	3,250
Corporate bonds	7,002	8	(3)	7,007
Variable rate demand notes	12,195	-	-	12,195
Total	<u>\$ 24,444</u>	<u>\$ 11</u>	<u>\$ (3)</u>	<u>\$ 24,452</u>
<i>Non-current:</i>				
U.S. government securities	\$ 1,000	\$ -	\$ (2)	\$ 998
Total	<u>\$ 1,000</u>	<u>\$ -</u>	<u>\$ (2)</u>	<u>\$ 998</u>

(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>

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

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:

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
<b>December 31, 2011</b> <b>(In thousands)</b>				
U.S. government securities	\$ -	\$ 4,248	\$ -	\$ 4,248
U.S. commercial paper	-	2,000	-	2,000
Corporate bonds	-	7,007	-	7,007
Money market funds	12,885	-	-	12,885
Variable rate demand notes	-	12,195	-	12,195
Total assets measured at fair value	\$ 12,885	\$ 25,450	\$ -	\$ 38,335

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
<b>December 31, 2010</b> <b>(In thousands)</b>				
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	\$ 1,783	\$ 58,549	\$ -	\$ 60,332

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.

## 6. Property and Equipment

Property and equipment consists of the following as of:

<b>(In thousands)</b>	December 31,	
	2011	2010
Computer and office machines	\$ 2,181	\$ 2,206
Furniture and fixtures	438	364
Leasehold improvements	1,495	1,414
Other	-	46
Total cost	4,114	4,030
Less: accumulated depreciation	(2,445)	(2,005)
Total	\$ 1,669	\$ 2,025

Depreciation expense for the years ended December 31, 2011, 2010 and 2009 was approximately \$591,000, \$604,000 and \$543,000, respectively.

The leasehold improvements as of December 31, 2011 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 to acquire all patents and other intellectual property rights related to RESCULA for its FDA approved indication and any new indications for unoprostone isopropyl 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. In September 2011, SPA transferred those rights to SAG, and SAG entered into an agreement with SPA to perform certain activities relate to those rights. The Company plans to re-launch RESCULA in the U.S. for its approved indication after approval of an enhanced label from the FDA.

Under the terms of the 2009 R-Tech agreement, 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, 2011, both of which are reflected in other non-current assets in the accompanying Consolidated Balance Sheets. 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 \$341,000, respectively, for the years ended December 31, 2011 and 2010. The annual amortization expense will be approximately \$341,000 through April 2019.

On March 22, 2011, SAG entered into a license agreement with R-Tech for unoprostone isopropyl, expanding the Company's development and commercialization rights as well as its territories beyond their previously agreed territory of the United States and Canada to the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China, or the R-Tech Territory, or the SAG Territories.

SAG made an upfront payment to R-Tech of \$3.0 million, which is reflected in other non-current assets in the accompanying Consolidated Balance Sheets, and may be required to pay up to \$103.0 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of \$3.0 million is payable upon the earlier of product approval within the SAG Territories or by March 15, 2012. The liability is reflected in accrued expenses in the accompanying Consolidated Balance Sheets. SAG will be responsible for all development, regulatory, and commercialization activities. The Company is amortizing the \$6.0 million over the 10-year life of the license agreement, which management believes approximates the useful life of the underlying rights and data. Amortization expense was \$453,000 for the year ended December 31, 2011. The annual amortization expense will be approximately \$613,000 through March 2021.

## 8. Accrued Expenses

Accrued expenses consist of the following as of:

(In thousands)	December 31,	
	2011	2010
Research and development costs	\$ 5,622	\$ 4,146
Employee compensation	1,607	1,795
Selling and marketing costs	76	305
Legal service fees	1,955	2,620
RESCULA milestones	3,500	500
Other accrued expenses	888	850
Total	\$ 13,648	\$ 10,216

## 9. Other Liabilities

Other liabilities consist of the following as of:

(In thousands)	December 31,	
	2011	2010
Deferred leasehold incentive	\$ 609	\$ 727
Deferred rent expense	514	525
Other liabilities	1,480	1,429
Total	\$ 2,603	\$ 2,681

## 10. Commitments and Contingencies

### Operating Leases

The Company leases office space in the U.S., Switzerland, Japan and U.K., under operating leases through 2017. Total future minimum, non-cancelable lease payments under operating leases, are as follows as of December 31, 2011:

(In thousands)	Notes Payable	Operating Lease Obligations	Total
Due in one year	\$ 20,400	\$ 1,457	\$ 21,857
Due in two years	8,281	1,036	9,317
Due in three years	8,490	1,024	9,514
Due in four years	8,708	1,052	9,760
Due in five years	8,937	1,084	10,021
Thereafter	4,811	139	4,950
Total	\$ 59,627	\$ 5,792	\$ 65,419

Rent expense for all operating leases was \$1.6 million, \$1.3 million and \$1.3 million for the years ended December 31, 2011, 2010 and 2009, respectively.

### 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, 2011 were approximately \$7.4 million.

## 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, 2011, 2010 and 2009, which is recorded as contract revenue. During the years ended December 31, 2011, 2010 and 2009, the Company purchased from R-Tech of approximately \$72,000, \$344,000, and \$205,000, 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, 2011 and 2010. During the years ended December 31, 2011, 2010 and 2009, the Company purchased approximately \$125,000, \$110,000 and \$692,000, respectively, of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch in Europe. Subsequent to the 2009 purchase, we withdrew our European MAA and recorded a write down of inventory in 2009 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 2011, 2010 or 2009.

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 additional two year terms. During the years ended December 31, 2010 and 2009, the Company purchased from R-Tech \$48,000 and \$1.1 million, respectively, of clinical supplies under the terms of this agreement. There were no clinical supplies purchased in 2011.

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, 2011, 2010 and 2009 the Company purchased approximately \$166,000, \$267,000 and \$381,000, respectively, of commercial supplies of lubiprostone from R-Tech under this agreement. During the year ended December 31, 2009, we purchased approximately \$262,000 of clinical supplies from R-Tech under this agreement. There were no such clinical supplies purchases in 2011 and 2010 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.

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

(In thousands)	Year Ended December 31,		
	2011	2010	2009
Clinical supplies	\$ 72	\$ 392	\$ 1,556
Other research and development services	104	69	100
Commercial supplies	155	376	1,039
	<u>\$ 331</u>	<u>\$ 837</u>	<u>\$ 2,695</u>

(In thousands)	Year Ended December 31,	
	2011	2010
Deferred revenue, current	\$ 433	\$ 433
Deferred revenue, non-current	5,063	5,839
	<u>\$ 5,496</u>	<u>\$ 6,272</u>

Drs. Ryuji Ueno and Sachiko Kuno, are married to each other and, directly or indirectly, own the majority of the stock of R-Tech. 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, as an advisor on international business development.

#### **Numab AG**

In September 2011, the Company entered into a Loan Guarantee and Development Agreement, or Numab Agreement, with Numab AG, or Numab. Numab is considered a related party as a result of a ownership interest by one of the Company's executive officers. Under the terms of the Numab Agreement, the Company will provide Numab with up to CHF 5.0 million as collateral and will serve as guarantor for a loan to Numab from a third party. The Company may name up to four targets against which Numab will use their proprietary technology to discover high-affinity antibodies and to develop these to an investigation new drug, or IND, ready stage. Numab is eligible for full time equivalent based payments and discovery success dependent fees. Any success dependent fees will result in a corresponding reduction in the amount of the available guarantee. Should Numab default its loan obligations, the collateral may be called upon to meet Numab's obligation under its loan agreement. If a biologic is successfully developed, Numab and the Company may enter into a license arrangement in which Numab will be entitled to clinical development milestone payments and increasing tiered royalties on net sales. The Company will be responsible for clinical development and will retain all commercial rights to any resulting biologic product.

#### **12. Notes Payable**

In November 2010, SPL 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, SPL and the Bank. Borrowings may be used to finance research and development activities, for working capital needs and for the general corporate purposes of SPL. 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 was 1.33%. The outstanding loan balances included in the accompanying Consolidated Balance Sheets were \$12.9 million and \$12.0 million as of December 31, 2011 and 2010. 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 SPL'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, current in the accompanying Consolidated Balance Sheets as of December 31, 2011 and 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. The interest rate beginning December 1, 2011 is 4.7%.

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. In November 2011, Ambrent made the first principal payment of \$7.5 million. Interest paid-in kind was \$2.3 million for the year ended December 31, 2011.

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 at their carrying amount consist of the following:

(In thousands)	Year Ended December 31,	
	2011	2010
Loan agreement, The Bank of Tokyo-Mitsubishi UFJ, Ltd	\$ 12,900	\$ 12,022
Promissory notes, Sellers of SAG	46,727	51,939
	<u>\$ 59,627</u>	<u>\$ 63,961</u>
Notes payable, current	\$ 20,400	\$ 19,522
Notes payable, non-current	39,227	44,439
	<u>\$ 59,627</u>	<u>\$ 63,961</u>

### 13. Collaboration and License Agreements

#### *Abbott license and commercialization and supply agreement*

In February 2009, the Company entered into the Abbott Agreement to develop and commercialize lubiprostone for the treatment of CIC in Japan. Additionally, the agreement grants Abbott the right of exclusive negotiation to any additional indications for which lubiprostone is developed in Japan under all relevant patents, know-how and trademarks. Under the terms of the Abbott 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.

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 PMDA 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. Under the Abbott Agreement we could receive additional milestone payments based on achieving other specified development and commercialization goals, including \$15.0 million due on the first commercial sale in Japan, 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 Agreement. The following table summarizes the cash streams and related revenue recognized or deferred for this agreement:

(In thousands)	Cash Received Through December 31, 2011	Revenue Recognized for the Year Ended December 31,			Foreign Currency Effects	Amount Deferred at December 31, 2011
	2009	2010	2011			
<b>Collaboration revenue:</b>						
Up-front payment associated with the Company's obligation to participate in joint committees	\$ 846	\$ 38	\$ 47	\$ 52	\$ (151)	\$ 860
<b>Research and development revenue:</b>						
Up-front payment - remainder	\$ 9,154	\$ 5,112	\$ 3,471	\$ 520	\$ (152)	\$ 203
Development milestone payment	12,500	4,314	7,587	697	(371)	273
<b>Total</b>	<b>\$ 21,654</b>	<b>\$ 9,426</b>	<b>\$ 11,058</b>	<b>\$ 1,217</b>	<b>\$ (523)</b>	<b>\$ 476</b>

#### ***Takeda collaboration and license agreement***

In October 2004, the Company entered into Takeda Agreement 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 the Supplemental Takeda Agreement, 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 Takeda Agreement concerning the co-promotion reimbursement for the Company's sales force expired in May 2011 and the reimbursement terms of the Takeda Agreement apply.

The Company has received a total of \$150.0 million in upfront and development milestone payments through December 31, 2011 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 Takeda Agreement, 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 Takeda Agreement, which are described in more detail below:

(In thousands)	Cash Received Through December 31, 2011	Revenue Recognized for the Year Ended December 31,			Accounts Receivable for the Year Ended December 31, 2011 (1)	Amount Deferred at December 31, 2011
		Through 2009	2010	2011		
<i>Collaboration revenue:</i>						
Up-front payment associated with the Company's obligation to participate in joint committees	\$ 2,375	\$ 758	\$ 147	\$ 147	\$ -	\$ 1,323
<i>Research and development revenue:</i>						
Up-front payment - remainder	\$ 17,624	\$ 17,624	\$ -	\$ -	\$ -	\$ -
Development milestones	130,000	130,000	-	-	-	-
Reimbursement of research and development expenses	97,122	86,757	5,473	8,032	5,918	2,778
Total	\$ 244,746	\$ 234,381	\$ 5,473	\$ 8,032	\$ 5,918	\$ 2,778
<i>Product royalty revenue</i>	\$ 177,836	\$ 106,814	\$ 40,300	\$ 41,517	\$ 10,795	\$ -
<i>Co-promotion revenue</i>	\$ 25,206	\$ 18,021	\$ 4,417	\$ 3,378	\$ 610	\$ -

(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, 2011, 2010 and 2009, 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, 2011 and 2010 was approximately \$1.3 million and \$1.5 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 \$41.5 million, \$40.3 million and \$38.3 million for the years ended December 31, 2011, 2010 and 2009, respectively. This revenue is recorded as product royalty revenue in the Consolidated Statements of Operations and Comprehensive Income (Loss).
- The Company has provided development work necessary for an NDA submission to the FDA for the treatment of CIC and IBS-C indications. Takeda funded the initial \$30.0 million of development costs, the Company was obligated to fund the first \$20.0 million in excess of the initial \$30.0 million funded by Takeda and the two parties are to equally share any required development costs in excess of \$50.0 million. Although there was no defined performance period for this development work, the period to perform the work would not exceed the term of the Takeda Agreement. In January 2006, the Company received approval for its NDA for AMITIZA to treat CIC and completed and submitted the supplemental NDA for IBS-C to the FDA in June 2007.



The Company initially deferred the residual amount of the \$20.0 million upfront payment totaling approximately \$17.6 million, development milestone payments received totaling \$50.0 million, and reimbursement of the initial \$30.0 million of research and development costs for the development of AMITIZA for CIC and IBS-C indications. These deferred amounts were applied towards the unit of accounting that combines the participation in the joint development committee and the development of CIC and IBS-C and was recognized over the performance period of developing the CIC and IBS-C NDA submissions. The Company completed the development of the CIC and IBS-C in June 2007 and filed a sNDA for IBS-C. This was the culmination of the performance period. In June 2007, the Company also recognized as revenue, in full, \$30.0 million from Takeda upon the filing of the sNDA for AMITIZA to treat IBS-C. The Company received a \$50.0 million development milestone from Takeda as a result of the FDA's approval on April 29, 2008 of the sNDA for IBS-C in 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 Takeda 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 is obligated to perform studies for the development of an additional indication for OBD. Takeda is obligated to fund all development work up to a maximum aggregate of \$50.0 million for each additional indication and \$20.0 million for each new formulation. If development costs exceed these amounts, Takeda and the Company shall equally share such excess costs. There is no defined performance period, but the performance period will not exceed the term of the Takeda Agreement. The Company decided to conduct one additional phase 3 efficacy study in order to submit a sNDA for the OBD indication. In February 2012, the Company announced that lubiprostone met the primary endpoint in a phase 3 clinical trial for the treatment of OBD in patients with chronic, non-cancer pain, excluding those taking methadone.
- 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 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, 2011, 2010 and 2009, the Company recognized approximately \$8.0 million, \$5.5 million and \$14.5 million related to these three deliverables as research and development revenue in the Consolidated Statements of Operations and Comprehensive Income (Loss), respectively.

On February 1, 2006, the Company entered into the Supplemental Takeda Agreement, 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 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, under the Supplemental Takeda Agreement:

- The Company is obligated to co-promote AMITIZA with Takeda by employing a sales force to supplement Takeda's sales activities. Takeda is obligated to reimburse the Company a specified amount per day per sales force representative. In May 2011, the term of this reimbursement arrangement under the Supplemental Takeda Agreement ceased five years following the first date that the Company deployed sales representatives. The Company has recognized approximately \$3.4 million, \$4.4 million and \$4.5 million of revenues for the years ended December 31, 2011, 2010 and 2009, 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 views the deliverables under the Supplemental Takeda Agreement as economically independent of those in the 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 Takeda Agreement.

On September 8, 2011, we entered into a research and development collaboration with Numab AG, or Numab, of Wädenswil, Switzerland. Under the Loan Guarantee and Development Agreement with Numab, we will have access to Numab's proprietary technology for the discovery of high-affinity antibodies against certain selected targets. We will have exclusive commercial rights to any biologic products successfully developed and commercialized in the course of the collaboration. We have agreed to provide Numab with up to CHF 5 million as collateral for a loan to Numab from a third party. We may name up to four targets against which Numab will use their technology to discover high-affinity antibodies and will develop these to an investigational new drug, or IND, -ready stage. Numab is eligible for payments based on an agreed rate for the number of full time employees assigned to the development project and discovery success-dependent fees. If a biologic is successfully developed, we may enter into a license arrangement with Numab in which they will be entitled to clinical development milestone payments and increasing tiered royalties on net sales. We will be responsible for clinical development and will retain all commercial rights to any resulting biologic product. Numab has commenced work on the Company's first target.

## **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.

### ***Treasury Stock***

On December 11, 2008, the Company announced a stock repurchase program under which we are authorized to purchase up to \$10.0 million of our class A common stock from time to time in open-market transactions. On September 8, 2011, the Company's Board of Directors authorized the repurchase of up to an aggregate of \$2.0 million of the Company's class A common stock out of the \$10.0 million authorized by the Board of Directors on December 9, 2008. In 2011, the Company repurchased 186,987 shares of its class A common stock under this program at a cost of \$700,042, these shares are not retired and are recorded at cost. The Company did not repurchase any of our equity securities in 2010 or 2009.

### ***Stock Option Plan***

On February 15, 2001, the Company adopted the 2001 Stock Incentive Plan, or 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.

On June 5, 2006, the Company's Board of Directors approved a 2006 Stock Incentive Plan, which has been amended and restated, or the 2006 Incentive Plan, and reserved 8,500,000 shares of class A common stock for issuance under that plan. At December 31, 2011, a total of 5,094,620 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. 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, 2010, 2011 and 2012 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.

On May 2, 2011, the Board of Directors of the Company amended the previously approved annual stock option grants for its non-employee directors to an annual grant of 30,000 stock options on the date of each annual meeting of stockholders. Such grants would consist of 60.0% service based options and 40.0% market condition based options

A summary of the employee stock option activity for the year ended December 31, 2011 under the Company's 2001 Incentive Plan is presented below.

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2010	345,100	\$ 10.44		
Options expired	(154,700)	10.99		
Options outstanding, December 31, 2011	<u>190,400</u>	10.00	4.33	\$ -
Options exercisable, December 31, 2011	<u>190,400</u>	10.00	4.33	\$ -

A summary of the employee stock option activity for the year ended December 31, 2011 under the Company's 2006 Incentive Plan is presented below:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2010	1,201,650	\$ 5.69		
Options granted	2,572,860	4.32		
Options exercised	(27,500)	3.85		
Options forfeited	(229,481)	4.21		
Options expired	(112,149)	5.60		
Options outstanding, December 31, 2011	<u>3,405,380</u>	4.75	8.87	\$ -
Options exercisable, December 31, 2011	<u>543,147</u>	7.02	6.98	\$ -

During the year ended December 31, 2011, the Company made a grant of time-based and market condition options to all eligible employees and independent directors. The aggregate options totaled 2,572,860 shares of the Company's class A common stock, consisting of 873,352 shares of time-based options and 1,699,508 shares of market condition options. The market condition options (a) vest in certain percentages based on the attainment of specific stock price targets over a 30-day trading period so long as the individual is in continuous service with the Company on each such date, (b) have an exercise price equal to the closing price of the Company's class A common stock on the Nasdaq Global Market on the date of grant, and (c) must vest within a term of four years from such date. These options must be exercised within a term of ten years from the date of grant. The percentages and target prices are: 40.0% at \$8.00 per share, 40.0% at \$12.00 per share and 20.0% at \$16.00 per share. The Company determined that the market condition options should be classified as equity instruments, and selected, in accordance with GAAP, a lattice option-pricing model to estimate the fair value of those options. A lattice option-pricing model produces an estimated fair value of the option based on the assumed changes in the price of the underlying share over successive periods of time.

The time-based stock options (a) vest in equal annual installments over the four-year period commencing on the first anniversary of the date of grant (*i.e.*, the first 25.0% of the stock option grant would vest on the first anniversary of the date of grant) so long as the individual is in continuous service with the Company on each such date and (b) have an exercise price equal to the closing price of the Company's class A common stock on the Nasdaq Global Market on the date of grant. These options must be exercised within a term of ten years from such date. All options that were granted on May 2, 2011 have an exercise price equal to the fair market value of the stock price, or \$4.41 per share of class A common stock, on the date of the grant.

The weighted average grant date fair value of options granted during the years ended December 31, 2011, 2010 and 2009 were \$1.81, \$2.05 and \$2.73, respectively. The total intrinsic value of options exercised during the year ended December 31, 2011 was approximately \$12,000. No options were exercised during the years ended December 31, 2010 and 2009. As of December 31, 2011, approximately \$4.0 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards are expected to be recognized over a weighted average period of 3.14 years. When an option is exercised, the Company issues a new share of class A common stock.

The Company granted 510,000 stock options with an exercise price of \$5.85 per share to non-employees in August 2005 under the 2001 Incentive Plan. As of December 31, 2011 and 2010, 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 3.33 and 4.33 years, respectively, as of both December 31, 2011 and 2010.

#### **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, 2011, 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 3,363 and 4,187 shares of common stock were purchased under the ESPP during the years ended December 31, 2011 and 2010, respectively. The Company received approximately \$13,000, \$14,000 and \$19,000 upon purchase of shares under the ESPP for the years ended December 31, 2011, 2010 and 2009, 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 Consolidated Statement of Changes in Stockholders' Equity.

#### **15. Income Taxes**

Income (loss) before income taxes is as follows:

	<b>Year Ending December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
U.S.	\$ (9,670)	\$ (3,819)	\$ 11,514
Foreign	(12,244)	499	(1,653)
	<u>\$ (21,914)</u>	<u>\$ (3,320)</u>	<u>\$ 9,861</u>

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

(In thousands)	Year Ended December 31,		
	2011	2010	2009
<b>Current tax provision (benefit):</b>			
U.S. Federal	\$ (597)	\$ (1,063)	\$ 2,765
U.S. State	(194)	128	785
Foreign	550	469	1,521
<b>Total current tax provision (benefit)</b>	<b>(241)</b>	<b>(466)</b>	<b>5,071</b>
<b>Deferred provision (benefit):</b>			
U.S. Federal	(1,369)	(44)	644
U.S. State	385	(56)	71
Foreign	(3,383)	1	(702)
<b>Total deferred provision (benefit)</b>	<b>(4,367)</b>	<b>(99)</b>	<b>13</b>
<b>Total income tax provision (benefit)</b>	<b>\$ (4,608)</b>	<b>\$ (565)</b>	<b>\$ 5,084</b>

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

(In thousands)	December 31,	
	2011	2010
<b>Deferred tax assets:</b>		
Foreign net operating loss carryforwards	\$ 5,638	\$ 8,419
U.S. net operating loss carryforwards	903	-
Deferred revenue	2,547	3,316
Accrued expenses	1,043	800
Tax benefits on stock options	1,960	1,883
Other	869	284
<b>Gross deferred tax assets</b>	<b>12,960</b>	<b>14,702</b>
<b>Deferred tax liabilities:</b>		
Property and equipment	(339)	(518)
Intangibles	(30,918)	(144)
Accrued expenses	(3)	(1,013)
Other	(167)	(26)
<b>Gross deferred tax liabilities</b>	<b>(31,427)</b>	<b>(1,701)</b>
Less: valuation allowance	(4,467)	(9,658)
<b>Net deferred tax assets</b>	<b>\$ (22,934)</b>	<b>\$ 3,343</b>

The net deferred tax asset as of December 31, 2011 and 2010 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:

(In thousands)	Year Ended December 31,		
	2011	2010	2009
Federal tax provision (benefit)	34.0%	34.0%	34.0%
State taxes, net of federal tax benefit	0.4%	3.7%	6.3%
General business credits	1.6%	18.5%	-1.4%
Changes in valuation allowance	-3.7%	-11.8%	27.7%
Nondeductible expenses	-6.4%	-13.7%	-3.3%
Changes in other tax matters	-4.9%	-13.6%	-11.7%
	<u>21.0%</u>	<u>17.1%</u>	<u>51.6%</u>

At December 31, 2011 and 2010, the Company had foreign net operating loss carry forwards, or NOLs, of \$16.4 million and \$24.0 million, respectively. Approximately \$9.2 million of the foreign NOLs begin to expire in December 2015, and \$7.2 million of the foreign NOLs do not expire. As of December 31, 2011 and 2010, the Company had U.S. net operating losses of \$1.8 million and \$0, respectively. These losses begin to expire in 2031. The U.S. had research and development credits of approximately \$472,000 and \$0, as of December 31, 2011 and 2010, respectively.

As of December 31, 2011 and 2010, the Company had a valuation allowance on its deferred tax assets of \$4.5 million and \$9.6 million, respectively. The net decrease in the valuation allowance of \$5.1 million was due primarily to the recognition of gain in local tax jurisdictions on the transfer of certain intellectual property to SAG as well as the release of the valuation allowance in certain jurisdictions that management believes the deferred tax assets are more likely than not to be utilized. Please refer to the income tax and deferred charge policy for further description of this intercompany transaction.

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, 2011 and 2010 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 \$1.5 million and \$1.4 million, including interest for uncertain tax positions as of December 31, 2011 and 2010, 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, 2011 and 2010 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,		
	2011	2010	2009
Balance at January 1	\$ 1,245	\$ 1,200	\$ 913
Increases for tax positions taken during prior periods	22	3	83
Decreases in unrecognized tax benefits related to settlements with taxing authorities	(71)	-	-
Increases for tax positions taken during current period	30	42	204
Balance at December 31	<u>\$ 1,226</u>	<u>\$ 1,245</u>	<u>\$ 1,200</u>

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision. During 2011, 2010 and 2009, the Company recorded approximately \$69,000, \$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.

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. Currently, tax years 2008, 2009, 2010 and 2011 remain open and subject to examination in the major tax jurisdictions in which tax returns are filed.

## **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:

(In thousands)	Americas	Europe	Asia	Consolidated
<b>Year Ended December 31, 2011</b>				
Research and development revenue	\$ 8,033	\$ -	\$ 1,216	\$ 9,249
Product royalty revenue	41,517	-	-	41,517
Co-promotion revenue	3,378	-	-	3,378
Contract and collaboration revenue	565	-	52	617
Total revenues	53,493	-	1,268	54,761
Research and development expenses	24,058	4,354	5,085	33,497
Settlement for legal dispute	(11,100)	-	-	(11,100)
Depreciation and amortization	535	730	43	1,308
Other operating expenses	46,326	1,092	1,327	48,745
Income (loss) from operations	(6,582)	(5,920)	(5,187)	(17,689)
Interest income	240	6	3	249
Interest expense	-	(2,288)	(167)	(2,455)
Other non-operating expense, net	(42)	(1,884)	(93)	(2,019)
Income (loss) before income taxes	\$ (6,384)	\$ (10,086)	\$ (5,444)	\$ (21,914)
Capital expenditures	\$ 145	\$ 6,006	\$ 133	\$ 6,284
<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
<b>As of December 31, 2011</b>				
Property and equipment, net	\$ 1,359	\$ 16	\$ 294	\$ 1,669
Identifiable assets, net of intercompany loans and investments	\$ 96,490	\$ 47,925	\$ 13,154	\$ 157,569
<b>As of December 31, 2010</b>				
Property and equipment, net	\$ 1,750	\$ 24	\$ 251	\$ 2,025
Identifiable assets, net of intercompany loans and investments	\$ 102,096	\$ 30,789	\$ 16,388	\$ 149,273



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

<b>(In thousands, except per share data)</b>	<b>2011 Quarters Ended</b>			
	<b>December 31</b>	<b>September 30</b>	<b>June 30</b>	<b>March 31</b>
Total revenues	\$ 14,215	\$ 14,372	\$ 14,000	\$ 12,174
Income (loss) from operations	\$ 3,609	\$ (4,522)	\$ (7,615)	\$ (9,161)
Net income (loss)	\$ 2,700	\$ (4,078)	\$ (9,019)	\$ (6,909)
Net income (loss) per share:				
Basic	\$ 0.06	\$ (0.10)	\$ (0.22)	\$ (0.17)
Diluted	\$ 0.06	\$ (0.10)	\$ (0.22)	\$ (0.17)

<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	\$ 20,908	\$ 13,775	\$ 14,836
Income (loss) from operations	\$ (7,068)	\$ 5,635	\$ (109)	\$ 1,389
Net income (loss)	\$ (6,314)	\$ 1,584	\$ (29)	\$ 2,004
Net income (loss) per share:				
Basic	\$ (0.15)	\$ 0.04	\$ -	\$ 0.05
Diluted	\$ (0.15)	\$ 0.04	\$ -	\$ 0.05

Net income (loss) per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net income (loss) per share information may not equal annual net income (loss) per share.

Schedule II – Valuation and Qualifying Accounts

(In thousands)	Balance at Beginning of Year	Additions Charged to Costs and Expenses	Deductions	Balance at End of Year
Valuation allowance for deferred tax assets:				
2009	\$ 6,782	\$ 1,802(a)	\$ -	\$ 8,584
2010	\$ 8,584	\$ 1,074(a)	\$ -	\$ 9,658
2011	\$ 9,658	\$ 932(b)	\$ (6,123)(b)	\$ 4,467

(a) In 2010 and 2009, 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 2011 the net decrease in the valuation allowance of \$5.2 million was due primarily to the recognition of gains in local tax jurisdictions on the transfer of certain intellectual property to SAG as well as the partial release of valuation allowances in certain jurisdictions that management believes the deferred tax assets are more likely than not to be utilized.

**Sucampo Pharmaceuticals, Inc.**  
**Exhibit Index**

Exhibit Number	Description	Reference
2.1	Agreement and Plan of Reorganization	Exhibit 3.1 to the Company's Current Report on Form 8-K (filed December 29, 2008)
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)
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)
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	Exhibit 10.49 to the Company's Current Report on Form 10-K (filed March 8, 2011)
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.	Exhibit 10.50 to the Company's Current Report on Form 10-K (filed March 8, 2011)
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 2, 2011)
10.55^	Consulting Agreement, dated January 13, 2011, between the Company and Jan Smilek	Exhibit 99.2 to the Company's Current Report on Form 8-K (filed February 2, 2011)
10.56	Form of Sucampo Pharmaceuticals, Inc. Duration and Performance-Based Stock Option Incentive Award	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed May 6, 2011)
10.57	Exclusive License for Development and Commercialization of Unoprostone dated March 22, 2011, between Sucampo Manufacturing & Research AG and R-Tech Ueno, Ltd.	Exhibit 10.3 to the Company's Current Report on Form 10-Q (filed May 10, 2011)
10.58*	Loan Guarantee and Development Agreement, dated September 8, 2011, between Numab AG and Sucampo AG	Included herewith
10.59	Form of Settlement and Mutual Release Agreement, dated October 26, 2011, between Sucampo Pharmaceuticals, Inc. and Covance Inc.	Exhibit 10.2 to the Company's Current Report on Form 10-Q (filed November 9, 2011)
10.60	Employment Agreement, effective as of October 17, 2011, between the Company and Cary J. Claiborne	Included herewith
101.[INS]†	XBRL Instance Document	Included herewith
101.[SCH]†	XBRL Taxonomy Extension Schema Document	Included herewith
101.[CAL]†	XBRL Taxonomy Extension Calculation Linkbase Document	Included herewith
101.[LAB]†	XBRL Taxonomy Extension Label Linkbase Document	Included herewith
101.[PRE]†	XBRL Taxonomy Extension Presentation Linkbase Document	Included herewith
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. Included herewith Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of the Principal Financial Officer pursuant to 18 U.S.C. Included herewith Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

^ Compensatory plan, contract or arrangement.

\* Confidential treatment has been granted for portions of this exhibit.

† Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.



## Loan Guarantee and Development Agreement

This **Loan Guarantee and Development Agreement** ("Agreement") dated September 8, 2011 (the "Effective Date"), by and between **Numab AG**, a corporation formed under the laws of Switzerland with an address of c/o Penta Treuhand GmbH, Glärnischstrasse 13, 8800 Thalwil ("Numab") and **Sucampo AG**, a corporation formed under the laws of Switzerland with an address of Graben 5, CH-6300 Zug, Switzerland ("Sucampo") (each a "Party" and collectively, the "Parties").

WHEREAS, Numab possesses proprietary technology and has the know-how to discover high-affinity antibodies and stable antibody fragments and to develop such protein therapeutics until clinical proof of concept;

WHEREAS, Sucampo is interested in engaging Numab to develop antibodies against certain selected targets in order to obtain a product candidate to be the subject of further preclinical and clinical research in accordance with the terms set forth herein; and

WHEREAS, in partial consideration for certain services as described herein, Sucampo will provide a loan guarantee to secure Numab's financing to enable Numab to begin its operations and provide such services to Sucampo.

**NOW, THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties intending to be legally bound, hereby agree as follows:

### 1. Definitions

- 1.1 "Affiliate" shall mean any company, corporation or other form of legal entity which controls, is controlled by or is under common control with a Party, whereby "control" means ownership of 50% or more of the securities or other ownership interest representing the equity of an entity or the power to exercise 50% or more of the voting securities in an entity or otherwise the power to control or direct the management of an entity.
- 1.2 "Antibody/ies" shall mean antibody/ies or antibody derivative(s), which also includes antibody fragments and bispecific antibody formats

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- 1.3 “CDA” shall mean the Confidential Disclosure Agreement dated March 1, 2011 by and between the Parties (with Numab at that time having a provisional pre-registration name of B1 Biotherapeutics).
- 1.4 “Co-exclusive” and “Co-exclusivity” shall mean the right of a Party and one (but not more) other party, including the other Party, to use and exploit, including the right to sub-license, the respective Intellectual Property Rights and other rights for which Co-Exclusivity is agreed upon.
- 1.5 “Commercialization Agreement” shall mean an agreement between Sucampo and Numab with respect to the further development and commercialization of one or more Compounds and in accordance with Section 6.2.
- 1.6 “Commercialization Criteria” shall mean criteria mutually agreed for each Discovery Project and shall include IP and exclusivity assurances acceptable to Sucampo.
- 1.7 “Commercialization Option” shall mean an option granted by Numab to Sucampo to enter into a Commercialization Agreement with respect to a Compound according to the terms as set forth below in Section 6.2.
- 1.8 “Commercialization Option Period” shall mean, with respect to each Discovery Project, the period beginning with the payment of the applicable Success Fee and ending the later of (i) nine (9) months after the IND Ready Criteria were achieved for the respective Discovery Project; or (ii) six (6) months after Sucampo’s obligations under the Loan Guarantee end, during which Sucampo may exercise its Commercialization Option for the given Discovery Project.
- 1.9 “Compound Patents” shall have the meaning set forth in Section 8.2.2.
- 1.10 “Confidential Information” shall mean any business, financial, marketing, technical, scientific or other information or, including samples, that is disclosed by one (the “Disclosing Party”) to the other Party (the “Recipient”) under the CDA or this Agreement, but shall not include information (a) that previously to the disclosure by the Disclosing Party was known to the Recipient free of any obligation towards the Disclosing Party to keep it confidential, (b) which becomes generally available to the public through no wrongful act of the Recipient; (c) that is rightfully received from a third party under no obligation of confidence to such third party; or (d) that is independently developed by the Recipient without reference to information which has been disclosed pursuant to this Agreement or under the CDA.

Confidential Information includes not only written or other tangible information, but also information transferred orally, visually, electronically or by any other means.

- 1.11 "Compound" shall mean an Antibody to a Sucampo Target.
- 1.12 "Discovery Project" shall mean activities to meet the IND Ready Criteria for a Compound.
- 1.13 "Discovery Project No. 1" shall have the meanings set forth in Section 4 below.
- 1.14 "Effective Date" shall have the meaning set forth in the first paragraph of this Agreement.
- 1.15 "Escrowed Targets" shall mean the Targets identified and deposited in escrow pursuant to Section 3.4.3 below.
- 1.16 "FTE Rate" shall mean the yearly costs for a Full Time Equivalent (total yearly cost for a lab employee including overhead, standard consumables, infrastructure costs and equipment costs). The [...] as of the Effective Date and shall be adjusted yearly according to the inflation index as published by the Swiss Federal Office for Statistics (*Bundesamt für Statistik; Landesindex der Konsumentenpreise*).
- 1.17 "Indebtedness" shall mean any form of debt financing, loan, credit line or the like provided by a third party, but shall exclude any form of equity financing, leasing or supplier credits.
- 1.18 "IND Ready Criteria" shall mean objective specifications defining *ex vivo* primary pharmacodynamic and biophysical characteristics that will be agreed upon between the Parties for an Antibody against a Sucampo Target. The IND Ready Criteria shall be included in each Research Plan. IND Ready Criteria shall be defined such that it supports subsequent preclinical development including current Good Manufacturing Practice (cGMP) manufacturing process development and preclinical safety and toxicology studies to satisfy the Investigational New Drug (IND) requirements for biologics in accordance with the US Food and Drug Administration (FDA) or other regulatory authority current regulations and/or guidance. Finally, Antibodies produced in a generic lab scale process according to Section 3.9.2 could possibly be used for non-Good Laboratory Practice (GLP) in vitro and animal studies to assess pharmacokinetic and pharmacology.
- 1.19 "Intellectual Property Rights" means: (i) any and all European and/or foreign patent applications, letters patent, patents, or any division, continuation, continuation-in-part, reissue, or extension thereof, and any applications (including provisional applications) therefore; (ii) any and all trade secrets, know-how, and trade secret rights arising under the laws of Switzerland and/or laws of foreign countries; and (iii) all rights pursuant to (i) and (ii) hereinbefore as may hereafter come into existence, and all renewals and extensions thereof, regardless of whether such rights arise under the laws of Switzerland or any other state, country or jurisdiction.

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- 1.20 “Joint Scientific Committee” or “JSC” shall be the joint committee to be established by the Parties and with the tasks and responsibilities as set forth in Section 3.1 below.
- 1.21 “Loan” shall mean the financing obtained by Numab from a bank or other institution reasonably acceptable to Sucampo in an amount not greater than CHF 5 million at a market rate of interest and for a term not to exceed five (5) years.
- 1.22 “Loan Agreement” shall mean the agreement between Numab and any bank or other institution for the Loan, a copy of which shall be provided to Sucampo by Numab as per Section 12.10 hereunder within two (2) business days of the completed execution of the Loan Agreement.
- 1.23 “Loan Guarantee” shall mean the cash collateral to be provided by Sucampo for the Loan reasonably acceptable in form and substance to Sucampo.
- 1.24 “Maximally Available Target Exclusivity” shall have the meaning as set forth in Section 3.3.4.
- 1.25 “New IND Ready Criteria” shall mean modified criteria that are mutually defined in the event that the IND Ready Criteria for a given Discovery Project were not met.
- 1.26 “Numab” shall have the meaning set forth in the first paragraph of this Agreement.
- 1.27 “Party”/“Parties” shall have the meaning set forth in the first paragraph of this Agreement.
- 1.28 “Reasonable Best Efforts” shall mean at least the same effort as a pharmaceutical company with comparable financial, personnel and operating resources applies to develop one of its own products and the same effort that a pharmaceutical drug development company with comparable financial, personnel and operating resources would apply to develop a product containing the Compound or compound.
- 1.29 “Research Plan” shall mean a written plan that details the activities to be performed for a Discovery Project.

- 1.30 “Restricted Target(s)” shall mean a Target that cannot be a Sucampo Target or a Target for which full exclusivity is not available for Sucampo as set forth in Section 3.4.
- 1.31 “Sucampo Target(s)” shall mean Target(s) chosen by Sucampo in its exercise of a Target Option.
- 1.32 “Sucampo Patents” shall have the meaning set forth in Section 8.2.1.
- 1.33 “Success Fee” shall mean payment to be made by Sucampo to Numab after the IND Ready Criteria for a given Discovery Project were achieved in accordance with Section 5.
- 1.34 “Target” shall mean a secreted or at least partially extra-cellularly exposed protein against which Antibodies shall be discovered.
- 1.35 “Target Nomination Period” shall have the meaning as set forth in Section 3.2.1.
- 1.36 “Target Option” shall mean an option granted by Numab to Sucampo to select a Target against which Numab shall initiate a Discovery Project.
- 1.37 “Territory” shall mean worldwide.
- 1.38 “Third Party Target” shall have the meaning set forth in Section 3.4.5.

## 2. **Loan Guarantee**

- 2.1 Numab will be responsible for obtaining the Loan and providing a true and correct copy of the Loan Agreement and any amendments thereto to Sucampo and Sucampo shall provide the Loan Guarantee for the Loan. The Loan shall be senior to any other Indebtedness incurred by Numab from the Effective Date through the termination of this Agreement. The Loan Guarantee shall be provided by Sucampo as follows
- (a) in an amount of CHF 2 million as cash collateral to be wire transferred by Sucampo to a respective blocked account with the bank granting the Loan to Numab within ten (10) days following Sucampo’s receipt of copy of the Loan Agreement; and
  - (b) thereafter in amounts of CHF 0.5 million up to the maximum aggregate amount of CHF 5 million as cash collateral to be wire transferred by Sucampo to a respective blocked account with the bank granting the Loan to Numab each time within thirty (30) days following receipt of a respective request from Numab to Sucampo.

- 2.2 In the event Sucampo is required to pay a Success Fee in connection with Discovery Project No. 1, such Success Fee shall reduce the Loan Guarantee in an amount of up to CHF 3 million pursuant to the terms of the Loan Guarantee and Loan Agreement but in no event shall be the Loan Guarantee be less than CHF 2.2 million. In the event Sucampo is required to pay a Success Fee for Discovery Projects Nos. 2, 3, or 4,, the amount of such Success Fee (irrespective of any credit granted against such Success Fee pursuant to Section 5.1 below) shall reduce the remaining outstanding balance of the Loan Guarantee pursuant to the terms of the Loan Guarantee and Loan Agreement until Sucampo is released from such Loan Guarantee.
- 2.3 Numab shall comply with all terms of the Loan Agreement. Any default under or material breach of the Loan Agreement which leads to a termination for cause of the Loan Agreement by the lending bank shall be deemed a material breach of this Agreement.
- 2.4 To secure the Loan Guarantee, Numab shall enter into the Security Agreement attached hereto as Exhibit A pursuant to which Numab shall grant to Sucampo a security interest in certain collateral as set forth in such Security Agreement.

### 3. **Development**

#### 3.1 Joint Scientific Committee Formation and Operative Rules.

Within thirty (30) days following the Effective Date, the Parties shall establish a Joint Scientific Committee (the "JSC") which shall operate under the rules and have the tasks and responsibilities as follows:

- (a) Composition. The JSC shall be composed of not more than three (3) named representatives of each Party. Each Party may change its representatives to the JSC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Discovery Project(s). Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JSC meetings, subject to an outside consultant's written agreement to comply with confidentiality and non use obligations equivalent to those set forth in Section 7 below. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives. The JSC shall be chaired by a representative of Numab who shall provide Sucampo with an agenda reasonably in advance of all meetings. Sucampo shall have the right to include items on the agenda for JCC meetings. All decisions of the JSC shall be unanimous, with the representatives of each Party attending having collectively one vote irrespective of the number of representatives being present. If the JSC cannot or does not, after good faith efforts and within fifteen (15) days, reach agreement on an issue, such issue shall be referred to the Chief Executive Officers of each of the Parties (or their respective designees) who shall use their good faith efforts to mutually agree upon the proper course of action to resolve the dispute. If the Chief Executive Officers (or their respective designees) cannot or do not, after good faith efforts, reach agreement on an issue, then no resolution shall be deemed to be adopted on the respective item.

- (b) Responsibilities. The Joint Committee's responsibilities shall include the following:
- (i) discussion and approval of IND Ready Criteria for each Discovery Project for which Sucampo has exercised its Target Option pursuant to Section 3.5 below;
  - (ii) review and approval of the Research Plan(s) pursuant to Section 3.6 below;
  - (iii) determination, discussion and approval of Commercialization Criteria following Sucampo's exercise of a Target Option pursuant to Section 3.7.1 below;
  - (iv) if applicable, discussion and approval of study designs for animal studies pursuant to Section 3.7.2 below;
  - (v) if applicable, determination and approval of additional research activities and/or New IND Ready Criteria pursuant to Section 3.9 below;
  - (vi) if applicable, approval of any study designs regarding clinical and/or preclinical activities related to a Compound and approval of the CRO agreements related to such studies pursuant to Section 6.2.4(f) below;
  - (vii) generally encouraging and facilitating ongoing cooperation and communication between the Parties with respect to the Discovery Projects; and
  - (viii) such other tasks and responsibilities as the Parties may mutually agree from time to time.
- (c) Meetings. The JSC shall meet as deemed necessary by the JSC members, but at least two (2) times per calendar year at a location as is mutually agreed by the Parties. Alternatively, the JSC may meet by means of teleconference, videoconference or other similar communications equipment. Each Party will be responsible for all of its own expenses of participating in JSC meetings. The first JSC meeting shall take place upon establishing the JSC pursuant to this Section 3.1.
- (d) Minutes. The chairman of the JSC shall be responsible for preparing definitive minutes of each JSC meeting and shall circulate a draft of the minutes of each meeting to all members of the JSC for comments as promptly as practicable after such meeting. Final minutes shall be approved as standard agenda item in the next meeting of the JSC

3.2 Target Options.

- 3.2.1 Sucampo shall have the right to four (4) Target Options (Target Options 1, 2, 3 and 4, respectively). Each Target Option may be exercised at any time after the Effective Date and until six (6) months after the Loan Guarantee has been fully released (“Target Nomination Period”).
- 3.2.2 Prior to expiration of the Target Nomination Period, the Parties may negotiate an extension of the Target Nomination Period and payment of an extension fee.
- 3.2.3 As of the Effective Date, Sucampo hereby exercises Target Option 1 and selects [...\*\*\*...], jointly, as the Sucampo Targets to be the subject of Discovery Project No. 1. For the avoidance of doubt, Discovery Project No. 1 shall only account for one (1) Target Option.

3.3 Exclusivity. Numab hereby grants to Sucampo the Maximally Available Target Exclusivity for each Sucampo Target during the time required to complete the Discovery Project and until the expiration of the Commercialization Option Period.

3.4 Restricted Targets.

- 3.4.1 Numab shall retain Co-exclusivity with Sucampo related to all rights granted to Sucampo hereunder on [...\*\*\*...].
- 3.4.2 [...\*\*\*...] are not available to be named as a Sucampo Target. [...\*\*\*...] is currently under discussion with third parties. In the event that such discussions do not lead to the conclusion of an agreement with third parties and Numab would not elect [...\*\*\*...] as a Restricted Target, [...\*\*\*...] would become available for Sucampo as a Sucampo Target. Upon notification that [...\*\*\*...] is available, Sucampo shall have sixty (60) days to nominate [...\*\*\*...] as a Target within the Target Nomination Period.
- 3.4.3 Three (3) additional specified Targets will be nominated by Numab within sixty (60) days from the Effective Date to be reserved for collaboration projects with third parties (the “Escrowed Targets”). Unless otherwise agreed upon by Numab, the Escrowed Targets shall not be available to Sucampo under this Agreement. Within sixty (60) days from the Effective Date, Numab shall place the identity of the Escrowed Targets in escrow with an independent party mutually agreed upon by the Parties subject to an escrow agreement mutually agreeable to the Parties. In the event that Sucampo notifies Numab of its interest in a Target and Numab asserts that such Target is an Escrowed Target, the independent third party shall confirm to Sucampo within thirty (30) days following Numab's assertion that the Target nominated by Sucampo is an Escrowed Target.

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- 3.4.4 All other Targets will be made available to Sucampo to the maximum possible degree of exclusivity available at the time of nomination, which will depend on Numab's obligations to third parties as set forth in Section 3.4.5 below ("Maximally Available Target Exclusivity").
- 3.4.5 Sucampo acknowledges that Numab will be engaged and engaging during the term of this Agreement in projects for third parties that may involve Targets selected by such third parties ("Third Party Targets"). If, prior to its selection by Sucampo, a certain Third Party Target has been licensed exclusively to a third party or is subject to an active collaboration discussion with a third party for an exclusive license (subject to proof by written records, whereas the name of the third party and critical terms discussed will be redacted), Numab will not be obligated to make such Third Party Target available to Sucampo; provided, however, that if such collaboration discussions do not lead to an agreement with such third party, Numab shall inform Sucampo that the respective Third Party Target is a Target and allow Sucampo to nominate such Target within the Target Nomination Period. If, prior to its selection by Sucampo, a certain Third Party Target has been licensed non-exclusively to a third party, or is subject to an active collaboration discussion with a third party for a non-exclusive license (subject to proof by written records, whereas the name of the third party and critical terms discussed will be redacted), it will be made available to Sucampo on a Co-exclusive basis and Sucampo will be granted a Co-exclusive license; provided, however, that if such collaboration discussions do not lead to an agreement between Numab and such third party, Numab shall inform Sucampo that the respective Third Party Target has become a Target and, at Sucampo's option, Numab shall grant full exclusivity to Sucampo with respect to such Target for which previously Co-exclusivity had been granted to Sucampo. The grant of Co-exclusivity will have the same financial terms (Success Fees, milestone payments and royalties) as agreed herein for full exclusivity.

- 3.5 IND Ready Criteria. Upon exercise of a Target Option, the Parties shall through the JSC use good faith efforts to agree upon IND Ready Criteria with respect to the applicable Sucampo Target(s). The IND Ready Criteria will be agreed upon prior to the initiation of the Discovery Project. IND Ready Criteria for each Antibody and Compound shall be in writing and shall be attached hereto as an appendix and shall be deemed a part of this Agreement.
- 3.6 Research Plans.
- 3.6.1 For each Target Option exercised by Sucampo, Numab will draft a Research Plan. Numab shall present each Research Plan to the JSC within ninety (90) days after Sucampo's written notice of its exercise of such Target Option.
- 3.6.2 The JSC shall have thirty (30) days to review and approve the Research Plan in good faith. If the Research Plan is not approved, Numab shall have thirty (30) days to revise and resubmit the Research Plan to the JSC which shall review and approve within thirty (30) days. If the Research Plan is not approved after such resubmittal, Sucampo may proceed to develop such Sucampo Target with a third party. In such case such Target shall no more be considered a Sucampo Target and the Target Option used by Sucampo when nominating such Target shall be available to Sucampo again for selection of another Target.
- 3.6.3 Upon approval of the Research Plan by JSC and subject to the agreement on the Commercialization Criteria pursuant to Section 3.7, Numab shall use Reasonable Best Efforts to complete the Discovery Project in accordance with such Research Plan within the time period set forth in the Research Plan.
- 3.6.4 Each Research Plan approved by the JSC pursuant to Section 3.6.2 shall be attached hereto as an appendix and shall be deemed a part of this Agreement.
- 3.7 Commercialization Criteria.
- 3.7.1 Upon exercise of a Target Option, the Parties through the JSC shall use good faith efforts to agree upon Commercialization Criteria with respect to the Compound(s) intended to be developed pursuant to a Discovery Project. The Commercialization Criteria will be agreed upon prior to the initiation of the Discovery Project. Commercialization Criteria for each Compound shall be in writing and shall be attached hereto as an appendix and shall be deemed a part of this Agreement.

3.7.2 In the event Sucampo desires a specific Discovery Project to have results from animal studies included in the Commercialization Criteria, Sucampo and Numab shall discuss through the JSC the design of the animal studies, and, if there is agreement thereon, Sucampo, at its sole discretion, may ask Numab to manage such animal studies. In the event Sucampo selects Numab and Numab reasonably accepts such selection, the management of the agreed animal studies by Numab shall be conducted at Numab's FTE Rate plus Numab's direct costs of external contractors.

3.8 Numab Capacity Limitations. Sucampo acknowledges that [...\*\*\*...]. Sucampo further acknowledges that Numab may have additional discovery obligations to third parties that occurred prior to Sucampo's exercise of a Target Option. Numab shall have the right to undertake such third party discovery obligations and may delay the commencement of a Discovery Project hereunder; provided that (i) upon Sucampo's exercise of a Target Option, Numab shall not undertake any further obligations to any third party that would delay the commencement and completion of the Discovery Project with respect to such Target Option; and (ii) Numab shall not delay a Discovery Project in favor of any third party for more than ten (10) months after Sucampo's exercise of a Target Option.

3.9 Discovery Projects.

3.9.1 Numab shall use Reasonable Best Efforts to execute each Discovery Project pursuant to its respective Research Plan and to meet the applicable IND Ready Criteria.

3.9.2 For each Discovery Project, an Antibody shall be produced in a generic lab-scale process in amounts and quality sufficient to characterize its pharmacodynamic and biophysical properties according to the agreed IND Ready Criteria. In the event that Sucampo needs additional quantity of the Antibody or Compound, Sucampo may either negotiate with Numab or with a third party to produce additional amounts of the Antibody. If necessary, upon Sucampo's request Numab shall grant such third party the right to manufacture such additional amounts of the Antibody or Compound, provided that such third party is not a direct competitor of Numab and agrees to reasonable confidentiality and non-use obligations of the Intellectual Property Rights to be licensed to such third party for such manufacturing of Compound. The Parties agree that Contract Manufacturing Organizations (CMOs) shall not be considered direct competitors of Numab, provided that such CMO is not otherwise an Affiliate of a non-CMO direct competitor of Numab.

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3.9.3 Upon Numab's achievement of the IND Ready Criteria for a Discovery Project, Sucampo shall, within thirty (30) days after Numab provides written notification of the achievement of the IND Ready Criteria, notify Numab in writing whether Sucampo agrees that the IND Ready Criteria have been met for a given Discovery Project. In the event that Sucampo has not replied to such written notification by Numab at the expiration of the thirty (30) day period, the achievement of the IND Ready Criteria shall be deemed accepted by Sucampo.

(a) In the event Sucampo agrees that the IND Ready Criteria have been met, Sucampo shall pay the Success Fee for the achievement of the respective IND Ready Criteria in accordance with Section 5.1 or 5.2, respectively. Upon payment of the applicable Success Fee, Sucampo may at any time until the expiration of the Commercialization Option Period exercise its Commercialization Option with respect to such Discovery Project.

(b) In the event IND Ready Criteria for a Discovery Project are not met, Sucampo may elect, within sixty (60) days after Numab has provided written notice of its failure to meet the IND Ready Criteria, to continue to pursue the Discovery Project. The JSC will, after such election by Sucampo, determine whether additional research is needed to achieve the IND Ready Criteria and/or determine New IND Ready Criteria for such Discovery Project. Each Party shall have the opportunity to approve any additional research and New IND Ready Criteria, such approval shall not be unreasonably withheld or delayed and shall not be conditioned on Numab's other research obligations.

(c) Notwithstanding the above, if Sucampo does not elect to continue with such Discovery Project or the Parties agree to abandon a Discovery Project with respect to a Sucampo Target because the IND Ready Criteria or the New IND Ready Criteria (as the case may be) were not met (but not for any other reason) and thereafter Numab elects to re-initiate on its own behalf or on behalf of a third party further research on the abandoned Sucampo Target, Numab shall be required to obtain a license from Sucampo to the Intellectual Property Rights (if any) developed for such Sucampo Target prior to the Discovery Project having been abandoned on such commercial terms as the Parties may reasonably agree. In the event that Numab obtains access to substantial new or additional research tools and technology that may increase the chances of success to meet the IND Ready Criteria or the New IND Ready Criteria for an abandoned Discovery Project as agreed to by the JSC, Sucampo shall have the right of first negotiation to initiate a new Discovery Project for the Sucampo Target. In the event that Sucampo elects not to exercise its right of first negotiation, or the Parties cannot agree on the terms discussed under the right of first negotiation within seventy-five (75) days of the election of Sucampo to exercise its right of first negotiations, Sucampo may elect either to retain the Intellectual Property Rights to such Target upon the [...\*\*\*...] of the agreed Success Fee for that Target, or to relinquish any further rights to the such Target and the Intellectual Property Rights related thereto.

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4. **Discovery Project No. 1**

- 4.1 The Discovery Project described in this Section 4 shall be “Discovery Project No. 1”.
- 4.2 Discovery Project No. 1 shall have two parts: [...\*\*\*...]. Part A of Discovery Project No. 1 shall be the discovery of an [...\*\*\*...]; Part B of Discovery Project No. 1 shall be the discovery of an [...\*\*\*...]; and Part C of Discovery Project No. 1 shall be the [...\*\*\*...].
- 4.3 IND Ready Criteria for Parts A and C of Discovery Project No. 1 are set forth in Appendix A. The Parties agree that there will not be separate IND Ready Criteria for Part B of Discovery Project No. 1.
- 4.4 Projected completion of Discovery Project No. 1 in its entirety is [...\*\*\*...].

5. **Fees**

- 5.1 Discovery Project No. 1. Sucampo shall pay to Numab a Success Fee of [...\*\*\*...] after Numab meets the IND Ready Criteria for Part A of Discovery Project No. 1. The Success Fee for Discovery Project No. 1 shall be payable within thirty (30) days of receipt by Sucampo of an invoice from Numab, which invoice will be issued promptly after the achievement of the IND Ready Criteria for Part A of Discovery Project No. 1 has been accepted by Sucampo pursuant to Section 3.9.3. For the performance [...\*\*\*...] FTE Rate. Those activities being reimbursed on an FTE Rate basis shall be outlined in the Research Plan for Discovery Project No. 1. [...\*\*\*...] the remaining outstanding balance of the Loan Guarantee pursuant to Section 2.2. FTE costs shall be invoiced and paid on a quarterly basis.

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- 5.2 Other Discovery Projects. The Success Fee for each of Discovery Project Nos. 2, 3 and 4 is [...\*\*\*...] and shall be payable within thirty (30) days of receipt by Sucampo of an invoice from Numab (such payment to be used in accordance with Section 2.2), which invoice shall be issued promptly after the achievement of the IND Ready Criteria for the respective Discovery Project has been accepted by Sucampo pursuant to Section 3.9.3 for each of the Discovery Projects Nos. 2 through 4.
- 5.3 Bispecific Antibodies. If a Discovery Project (other than Discovery Project No. 1) involves the production of a [...\*\*\*...], the provisions related to Discovery Project No. 1 in Section 5.1 above shall apply *mutatis mutandis* for such Discovery Project and Numab's additional effort [...\*\*\*...] to be invoiced quarterly by Numab and paid within thirty (30) days of receipt by Sucampo.
- 5.4 Additional Research; New IND Ready Criteria. [...\*\*\*...] to be invoiced quarterly by Numab and paid within thirty (30) days of receipt of such invoice(s) by Sucampo. Upon meeting the New IND Ready Criteria or meeting the original IND Ready Criteria through such research outside the original Research Plan, [...\*\*\*...] (as the case may be), such payment to be used in accordance with Section 2.2.

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5.5 Late Payments. In the event that amount due for a given Discovery Project is invoiced by Numab and not paid by Sucampo within thirty (30) days of invoice receipt, any such unpaid amount shall automatically accrue interest as from the day immediately following the due date at the rate of 1% per month until paid. Notwithstanding the preceding sentence, any non-payment of a Success Fee or any undisputed FTE amount due shall constitute a material breach of this Agreement; provided that Sucampo shall only dispute FTE amounts due hereunder in good faith.

6. **License and Commercialization**

6.1 Commercialization Option. Upon exercise by Sucampo of a Commercialization Option, the Parties shall negotiate in good faith to agree on a development plan and execute a Commercialization Agreement for the applicable Compound. The development plan shall be drafted by Sucampo and be subject to Numab's approval, which approval shall not be unreasonably withheld, conditioned or delayed. Sucampo may elect to extend the Commercialization Option Period for any Discovery Project for up to three (3) one-year periods upon payment of an extension fee of [...\*\*\*...] for each such one (1) year extension.

6.2 Commercialization Agreement. A Commercialization Agreement shall incorporate the following terms:

6.2.1 License Grant. Numab shall grant Sucampo a worldwide exclusive (pursuant to Sections 6.2.4(c) and 6.2.4(d) below) license, with the right to sublicense, under Numab's Intellectual Property Rights to develop, use, make, have made, export, commercialize, promote, offer for sale, sell and manufacture the Compound in a respective pharmaceutical product subject to the terms of the Commercialization Agreement.

6.2.2 Assignment. Numab shall assign to Sucampo the Intellectual Property Rights as set forth in Section 8.2.

6.2.3 Compound. The Compound shall be the IND Ready Antibody and/or [...\*\*\*...] and discovered during one or more Discovery Project(s).

6.2.4 Other Terms of License.

(a) Field of License: all uses.

(b) Territory: worldwide.

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- (c) Compound-specific Degree of Exclusivity: is composed of the Maximally Available Target Exclusivity and the Degree of Compound Exclusivity.
- (d) Degree of Compound Exclusivity: Full exclusivity on Compound.
- (e) Diligence: Sucampo will apply Reasonable Best Efforts to further develop and commercialize a pharmaceutical product containing the Compound throughout the Territory.
- (f) To ensure Reasonable Best Efforts by Sucampo, Numab shall accept, if Sucampo elects to do so, to perform any preclinical and clinical development activities on Sucampo's behalf at the FTE Rate and at direct external costs, whereas the clinical and/or preclinical study designs shall be approved by the JSC negotiating a Contract Research Organization agreement mutually agreed upon by the Parties.
- (g) Milestone Payments: [...\*\*\*...].
- (h) Royalties: [...\*\*\*...] on aggregate annual global net sales between [...\*\*\*...], [...\*\*\*...] on aggregate annual global net sales above [...\*\*\*...]. Royalties are payable on a country-by-country basis for the longer of (i) expiration of the last to expire patents licensed or assigned hereunder by Numab to Sucampo and covering the Compound, or (ii) fifteen (15) years after the first commercial sale with appropriate reductions in royalties for entry of any generic to the market in the relevant county, provided, however, that if the Compound is part of a pharmaceutical product which incorporates two or several active pharmaceutical ingredients, only the sales for such pharmaceutical product that can be allocated to the Compound applying generally accepted industry standards for such allocation, shall be relevant to calculate the royalties payable.

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- (i) Other terms that are customary for such an agreement (including confidentiality, development reporting, patent prosecution, sales reporting, audit and inspection rights, termination and effects of termination provisions).
- (j) Applicable law: Swiss law.

7. **Confidentiality**

- 7.1 **CDA**. The CDA shall be and hereby is terminated as of the Effective Date and its provisions be replaced by the provisions set forth in this Section 7, provided that any and all Confidential Information disclosed by the Disclosing Party to the Recipient during the term of the CDA shall be treated as Confidential Information (as defined in Section 1.9 above) and be subject o the provisions of this Section 7.
- 7.2 **Protection**. The Recipient (as defined in Section 1.9 above) will hold the Confidential Information of the Disclosing Party (as defined in Section 1.9 above) in confidence and trust, and will not disclose, or provide access to, any Confidential Information of the Disclosing Party, directly or indirectly, to any person except as expressly permitted by this Section 7 or with the prior written consent of the Disclosing Party. The Recipient shall protect the Confidential Information of the Disclosing Party with the same degree of care it protects similar information of its own, but in no event shall Recipient use less than a reasonable degree of care. The Recipient may make only such copies of the Confidential Information of the Disclosing Party as are necessary for the respective Discovery Project(s) and to perform its obligations hereunder. Any such copies must reproduce proprietary or confidentiality markings included therein
- 7.3 **Permitted Disclosure**.
- 7.3.1 Recipient may disclose the Confidential Information of the Disclosing Party pursuant to statutory or regulatory authority or a court order, provided the Recipient promptly notifies the Disclosing Party of such requirement (where permitted) with reasonably sufficient time to oppose such disclosure, and the scope of such disclosure is limited to the extent possible.

- 7.3.2 The Recipient may disclose the Confidential Information of the Disclosing Party within its organization and to its professional advisors, but only to those having a need to know for the purposes of this Agreement, are informed of its confidential nature, and expressly agree to be bound by (or by reason of their employment or service agreement or professional secrecy obligations have a duty to comply with) the terms of this Section 7.
- 7.4 Use. Subject to the other terms of this Agreement, Recipient shall use the Confidential Information of the Disclosing Party solely for the express purpose of performing its rights and obligations under this Agreement. Furthermore, each Party shall be permitted to use any and all data, material and other information generated in performing the Discovery Projects to support the application of all Intellectual Property Rights owned by such Party pursuant to Section 8.2 below, provided that any such use by either Party shall not jeopardize the filing of any patent owned by the other Party, and provided further, that the foregoing shall not be construed as a license grant to or under any Intellectual Property Rights from either Party to the other Party outside of or in addition to the respective license grants explicitly made elsewhere in this Agreement.
- 7.5 Publicity. Each of Numab and Sucampo agrees not to disclose at any time to any third party, whether by way of press release, announcement or in any other manner, without the prior written consent of the other Party, the existence, intent or terms of this Agreement. The Parties agree to announce the collaboration pursuant to this Agreement by means of a press release with mutually agreed wording not later than forty-five (45) days after the Effective Date. However, either Party may at any time make any disclosures required by law upon prior written notice to the other Party provided that the disclosing Party first gives the other Party assistance as reasonably requested in obtaining an order protecting the information from disclosure. Notwithstanding the provisions in this Section 7.5, Numab may disclose and make accessible this Agreement and its terms to potential investors and other third parties in the context of a financing round for Numab (including in the context of a due diligence), provided always that any such third parties are informed of the confidential nature hereof, and expressly agree to be bound by (or by reason of their service agreement or professional secrecy obligations have a duty to comply with) confidentiality and non-use obligations at least as stringent as the terms of this Section 7.
- 7.6 Survival. The provisions of this Section 7 shall survive for a period of five (5) years after the expiration or termination of this Agreement.
- 7.7 Equitable Relief. Each Party acknowledges that the other would suffer immediate and irreparable harm for which monetary damages would be an inadequate remedy if it were to breach its obligations under this Section 7. Each Party expressly agrees that the other may obtain equitable relief, including injunctive relief, to protect its intellectual property rights and interests under this Agreement, in addition to such other remedies as may be available at law or in equity.

8. **Intellectual Property**

8.1 Inventorship. Inventorship of any patent applications related to any Sucampo Target or Antibody identified pursuant to a Discovery Project shall be determined in accordance with applicable law.

8.2 Ownership.

8.2.1 Sucampo shall be the owner of all Intellectual Property Rights specific to the Sucampo Targets, their mechanism of action and methods of use (the "Sucampo Patents"); provided, however, Sucampo and Numab shall jointly own the patent application specific to the [...\*\*\*...], its mechanism of action and methods of use. Numab hereby agrees to assign and hereby does assign to Sucampo all of its rights, title and interest in and to such Sucampo Patents. To the extent a third party that was requested by Numab to perform any services or create any work and thereby became the owner of any rights specific to Sucampo Targets, Numab shall secure access and use of such rights and then assign them to Sucampo in accordance with this Section 8.2.1.

8.2.2 Numab shall be the owner of all patents and patent applications directed to compositions of matter related to any Compound identified by Numab (the "Compound Patents") and upon the execution of a Commercialization Agreement, [...\*\*\*...]:

(i) Sucampo shall be the owner of all patents and patent applications directed to compositions of matter related to any [...\*\*\*...] and Numab hereby agrees to assign and hereby does assign all of its rights, title and interest in and to such patent or patent application, and, to the extent a third party that was requested by Numab to perform any services or create any work and thereby became the owner of any rights specific to Sucampo Targets, to secure access and use of such rights and then assign them to Sucampo in accordance with this Section 8.2.2(i); and

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(ii) any patent or patent application directed solely to any [...\*\*\*...] shall be owned by Numab and Numab shall grant Sucampo a Co-exclusive license to such patent or patent application.

8.2.3 [...\*\*\*...] under and pursuant to this Section 8.2 shall not affect in any way the commercial terms related to any Discovery Project and/or Compound as set forth in Section 5 or for the Commercialization Agreement set forth in Section 6.2, which commercial terms shall remain in full force and effect as [...\*\*\*...] would have been agreed upon or made.

8.2.4 Numab shall be the owner of all Intellectual Property Rights related to discoveries, inventions or improvements made or reduced to practice during the term or in the context of the performance of this Agreement which are not Sucampo Patents pursuant to Section 8.2.1 or Compound Patents pursuant to Section 8.2.2.

8.3 Filing; Prosecution; Maintenance. Filing, prosecution and maintenance of any patent applications and patents directly related to a Compound or to a Sucampo Target shall be coordinated between and jointly conducted by the Parties regardless of ownership, provided that each Party shall be responsible for all costs and expenses related to the filing, prosecution and maintenance of the patents and patent applications owned by such Party. Upon execution of a Commercialization Agreement, for patents and patent applications exclusively licensed to Sucampo and with respect to patents or patent applications assigned to Sucampo pursuant to Section 8.2.1, Sucampo shall bear any and all direct costs and expenses, incurred after the date of the exercise of the respective Commercialization Option by Sucampo, for the filing, prosecution and maintenance (including patent attorney fees) and may elect to take the lead and responsibility on such filing, prosecution and maintenance. In addition, Sucampo shall reimburse Numab upon execution of a Commercialization Agreement for any and all direct cost and expenses for the filing, prosecution and maintenance (including patent attorney fees) related to any such patents and patent applications exclusively licensed to or assigned to Sucampo, which Numab incurred as from the initiation of the nationalization phase of such patents and patent applications. In case of any patent or patent application Co-exclusively licensed to Sucampo, Numab shall retain the lead on the filing, prosecution and maintenance and any and all direct costs and expenses (including patent attorney fees) shall be shared equally between the Parties.

8.4 No Other Rights Granted. Except for those expressly provided for herein, Sucampo will not acquire any right or license with respect to any Intellectual Property Rights or to any other rights or interests whatsoever, including without limitation in the software, Confidential Information or know-how that Numab develops or has developed at their cost and expense as part of the methodology of or technology for developing the Sucampo Targets).

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9. **Term; Termination**

- 9.1 **Term.** This Agreement shall commence on the Effective Date and, unless terminated earlier in accordance with this Section 9, shall expire upon the expiration of the last to expire Commercialization Option Period.
- 9.2 **Termination for Cause.** Either Party may terminate this Agreement in the event the other Party materially breaches this Agreement and fails to cure such breach within thirty (30) days after written notice of such breach has been provided to such breaching Party.
- 9.3 **Survival.** Sections 1, 7, 8, 9.3, 9.4, 11 and 12 shall survive termination or expiration of this Agreement.
- 9.4 **Effects on Termination or Expiration of Agreement.**
- 9.4.1 The termination or expiration of this Agreement shall not relieve either Party from its obligations accrued prior to such termination or expiration. In addition, the election by either Party to terminate this Agreement pursuant to Section 9.2 shall not in any way limit or restrict any and all rights or claims such terminating Party may have under any applicable law.
- 9.4.2 Unless the Parties have entered into a Commercialization Agreement, within thirty (30) days after termination or expiration of this Agreement, each Party shall, upon the other's request, return the other Party's Confidential Information or provide a written certification to the other Party detailing the destruction of the Confidential Information, provided that each Party may retain one (1) copy of each item of Confidential Information of the other Party in confidential files for the sole purpose of determining its continuing obligations with respect thereto after termination or expiration of this Agreement.
- 9.4.3 In the event that Numab terminates this Agreement based on Section 9.2 (Termination for Cause), including for non-payment of any amount payable by Sucampo (including a Success Fee or an invoice for FTE costs), (i) any and all rights granted to Sucampo pursuant to the Discovery Project for which the Success Fee or FTE costs were unpaid (including without limitation Commercialization Options, license grants to Intellectual Property Rights and rights to be assigned Compound Patents in such Discovery Project) shall terminate, and (ii) all Target Options not yet exercised by Sucampo shall be suspended until the non-paid amount payable has been paid, and (iii) Numab may suspend any and all activities in Discovery Projects, for which the Success Fee has not been paid yet, until the non-paid amount payable has been paid. For clarity, (i) any Commercialization Option resulting from a Discovery Project for which the respective Success Fee and all other payments have been fully paid by Sucampo shall not be affected by such termination and remain in full force and effect in accordance with the terms of this Agreement, and (ii) any Commercialization Agreement executed by the Parties with respect to any Compound(s) prior to such termination shall be unaffected by such termination of this Agreement, and (iii) the provisions of this paragraph shall not apply to any Intellectual Property Rights related to the Compound(s) for which a Commercialization Agreement has been executed.

10. **Warranties**

- 10.1 Each Party represents to the other Party that it is duly incorporated and in good standing in its respective state of incorporation, that it has the authority to enter into and perform this Agreement and that the execution and delivery of this Agreement does not violate any agreement or judicial order to which it is a party or by which it is bound.
- 10.2 Numab represents and warrants that (i) it will perform each Discovery Project with Reasonable Best Efforts and in a reasonably efficient, professional and workman like manner; and (ii) its performance of each Discovery Project does, to the best of Numab's knowledge as of the Effective Date, not infringe or misappropriate the intellectual property rights of any third party.
- 10.3 The Parties acknowledge and agree that the discovery of Compounds which meet the agreed IND Ready Criteria is a complex task, and, therefore, Numab may not and does not make any representation or give any warranty that any Compound(s) developed hereunder will be commercially successful or fit for any particular purpose, or any other representation or warranty except as explicitly set forth in this Section 10.

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11. **Limitation of Liability; Indemnification**

- 11.1 **Limitation of Liability.** NOTWITHSTANDING ANY PROVISIONS IN THIS AGREEMENT TO THE CONTRARY, UNDER NO CIRCUMSTANCES WILL EITHER PARTY BE LIABLE TO THE OTHER UNDER, OR WITH RESPECT TO ANY SUBJECT MATTER OF, THIS AGREEMENT FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES, SUCH AS, BUT NOT LIMITED TO, LOSS OF REVENUE OR ANTICIPATED PROFITS OR LOST BUSINESS EVEN IF INFORMED OF THE POSSIBILITY THEREOF. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE AND APPLY TO ALL CAUSES OF ACTION IN THE AGGREGATE INCLUDING, WITHOUT LIMITATION, BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY, AND MISREPRESENTATION EXCEPT GROSS NEGLIGENCE OR WILLFUL INTENT.
- 11.2 **Numab Indemnification.** Numab shall indemnify Sucampo, its Affiliates, agents and their respective directors, officers, employees, successors and assigns ("**Sucampo Indemnified Parties**") against, and agrees to hold each of them harmless from, any and all claims, demands, costs, expenses, obligations, liabilities, damages, recoveries and deficiencies, including, without limitation, interest, penalties, court costs, costs and expenses (including the reasonable fees and expenses of external counsel) (the "**Damages**") incurred or suffered by any of them arising out of or resulting from: (i) any breach of any representation or warranty made by Numab in this Agreement; (ii) the gross negligence or willful misconduct of Numab, its employees or its agents, while performing under this Agreement; and (iii) the enforcement by Sucampo of this Section 11.2.
- 11.3 **Sucampo Indemnification.** Sucampo shall indemnify and hold harmless Numab, its Affiliates, agents and their respective directors, officers, employees, successors and assigns ("**Numab Indemnified Parties**") from and against any and all Damages incurred or suffered by any of them arising out of or resulting from: (i) breach of any representation or warranty made by Sucampo in this Agreement; (ii) the gross negligence or willful misconduct of Sucampo, its employees or its agents, while performing under this Agreement; and (iii) the enforcement by Numab of this Section 11.3.
- 11.4 **Indemnification Procedure.** A Party seeking indemnification ("**Indemnified Party**") shall reasonably notify the Party responsible for indemnification ("**Indemnifying Party**") of a claim for indemnification, including the nature of the third party's claim. With respect to a third party's claims, (a) the Indemnified Party shall reasonably assist the Indemnifying Party and shall have the right to participate in the defense at its own expense; (b) in no event shall the Indemnifying Party settle the claim without the Indemnified Party's prior written consent (not to be unreasonably withheld, conditioned or delayed); and (c) the Indemnified Party shall not enter into any settlement that affects the Indemnifying Party's rights or interest without the Indemnifying Party's prior written approval (not to be unreasonably withheld, conditioned or delayed). In the event the Indemnified Party fails to promptly notify the Indemnifying Party of a claim for indemnification, such failure shall not relieve the Indemnifying Party of its obligations under this Section 11, except to the extent such failure materially prejudices the Indemnifying Party.

12. **Miscellaneous**

- 12.1 **Governing Law.** This Agreement shall be governed and construed under the laws of Switzerland without reference to its conflict of laws principles.
- 12.2 **Dispute Resolution.** If any dispute, controversy or claim arises out of this Agreement, the Parties agree that they will attempt in good faith to resolve the matter through negotiations within thirty (30) days of the written notice of such dispute, controversy or claim. If negotiations fail to resolve a dispute, controversy or claim, the matter will be submitted to arbitration pursuant to Section 12.3. By agreeing to these dispute resolution terms, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue an injunction under Section 7 (Confidentiality).
- 12.3 **Jurisdiction.** Any dispute, controversy or claim arising out of or related to this Agreement that is not resolved pursuant to Section 12.2 shall be settled by final and binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce (the "ICC") in effect on the Effective Date. Judgment upon the award rendered by the arbitrators may be entered in any court of competent jurisdiction. The place of arbitration shall be Zurich, Switzerland. The arbitration shall be conducted in the English language by three (3) neutral arbitrators. Sucampo shall select one (1) arbitrator and Numab shall select one (1) arbitrator. The third arbitrator shall be selected by mutual agreement of the two (2) arbitrators selected by the Parties; provided, that if the third arbitrator cannot be so selected within thirty (30) days after selection of the two (2) arbitrators selected by the Parties, the third arbitrator shall be selected by the ICC. At least one (1) arbitrator shall have knowledge and experience in the biologics industry and at least one (1) arbitrator shall have experience in Swiss law and technology licensing. By agreeing to the terms of this Section 12.3, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue an injunction under Section 7 (Confidentiality).



- 12.4 Assignment and Subcontracting. Each Party may assign its rights and obligations under this Agreement to a third party only subject to the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed); provided, however, that either Party may assign this Agreement to any of its Affiliates upon notice to the other Party and without the other Party's prior approval. Numab may and will sub-contract certain portions of its obligations to specialized third parties if and to the extent deemed reasonable by Numab.
- 12.5 Entire Agreement. This Agreement, together with all appendices hereto, represent the entire agreement between the Parties relating to the subject matter hereof and supersede all other prior agreements between the Parties with respect to the subject matter hereto. This Agreement shall be construed according to its fair meaning and not strictly for or against any Party.
- 12.6 Waiver; Amendment. The failure of any Party to promptly exercise its rights granted herein, or to require strict performance of any obligation of the other Party will not be deemed a waiver of such right or of the right to demand subsequent performance of any and all obligations by any other Party in the future. This Agreement may be amended only in writing signed by authorized officers of each Party.
- 12.7 Headings. The section and subsection headings used in this Agreement are inserted for convenience of reference only and will not be construed to affect the interpretation or construction of this Agreement.
- 12.8 Interpretation. Unless the context requires otherwise, all words used in this Agreement in the singular will extend to and include the plural, all words in the plural will extend to and include the singular and all words in any gender will extend to and include all genders.
- 12.9 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signature.
- 12.10 Notices. Each notice, request, demand or other communication by a Party to the another Party pursuant to this Agreement will be in writing, and (excluding purchase orders, acknowledgments of orders and routine documentation and correspondence) will be personally delivered, sent by recognized overnight commercial delivery services (e.g. Federal Express, UPS) postage prepaid, or sent by facsimile (promptly confirmed by hardcopy delivery pursuant to this Section), addressed to the address of the receiving Party as follows:

If to Sucampo:  
Address: Graben 5, CH-6300 Zug, Switzerland  
Attn: Andrew Smith  
Fax: +41 44 250 75 26

with a cc by email to: Attention: Sucampo General Counsel, at [tknapp@sucampo.com](mailto:tknapp@sucampo.com)

If to Numab:  
Address: c/o PentaTreuhand GmbH, Glärnischstrasse 13, 8800 Thalwil, Switzerland  
Attn: Chief Business Officer  
Fax: (To be designated after the Effective Date)

with a cc by email to: Ralf Rosenow, Blum&Grob Attorneys at Law Ltd, Zurich Switzerland, at [r.rosenow@blumgrob.ch](mailto:r.rosenow@blumgrob.ch)

or to such other persons and addresses as will be furnished by like notice by such Party or person. Any notice given in accordance with this provision will be deemed to have been given and effective (i) immediately upon personal delivery; (ii) upon confirmation of transmission if sent by facsimile (promptly confirmed by hardcopy delivery), or (iii) after three (3) business days after such notice is deposited with a recognized overnight commercial delivery service addressed to the receiving Party at its address listed above.

- 12.11 Severability. Wherever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or the effectiveness or validity of any provision in any other jurisdiction, and this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had been replaced by such valid legal and enforceable provision that best reflects the Parties' common intent when agreeing to the invalid, illegal or unenforceable provision.
- 12.12 No Relationship between the Parties. Neither Party shall represent itself as the agent or legal representative of the other or as joint venturers for any purpose whatsoever, and neither Party shall have any right to create or assume any obligations of any kind, express or implied, for or on behalf of the other in any way whatsoever.

12.13 All persons executing this Agreement on behalf of either Party represent and warrant that they have full right and authority to execute this Agreement on such Party's behalf.

IN WITNESS WHEREOF, the authorized representatives of the Parties have executed this Agreement on September 8, 2011 ("Effective Date").

**Numab AG**

/s/ Peter Hirschvogel  
Name: Peter Hirschvogel  
Title: Director

**Sucampo AG**

/s/ Ryuji Ueno  
Name: Ryuji Ueno  
Title: Director

Page 27 of 31, not including Exhibit A (Patent Pledge Agreement)

*Confidential*

*Loan Guarantee & Development Agreement  
Numab AG and Sucampo AG  
1109.08*

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**Appendix A: IND Ready Criteria for Discovery Project 1**

IND Ready Criteria for Part A of Discovery Project 1 [...\*\*\*...]

IND Ready Criteria for Part C of Discovery Project 1 [...\*\*\*...]

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*1109.08*

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[...\*\*\*...]

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*Loan Guarantee & Development Agreement*

*Numab AG and Sucampo AG*

*1109.08*

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*Loan Guarantee & Development Agreement  
Numab AG and Sucampo AG  
1109.08*

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**PATENT PLEDGE AGREEMENT**

between

**David Urech**

[...\*\*\*...]  
[...\*\*\*...]  
[...\*\*\*...]

(the "**Applicant**")

and

**Numab AG**

c/o Penta Treuhand GmbH  
Glärmischstrasse 13  
8800 Thalwil  
Switzerland

(the "**Pledgor**")

and

**Sucampo AG**

Graben 5  
6300 Zug  
Switzerland

(the "**Pledgee**")

**WHEREAS:**

- (1) The Pledgee and the Pledgor have entered into a loan guarantee and development agreement pursuant to which the Pledgor will develop certain antibodies for commercialization by the Pledgee and the Pledgee agreed to grant a cash collateral to secure the Loan (the "**Development Agreement**").
- (2) The Pledgor will enter into a loan agreement with Zurich Cantonal Bank, Zurich, Switzerland (the "**Bank**") for a loan in the amount of CHF up to 5,000,000 (the "**Loan Agreement**").
- (3) To secure any claims of the Bank against the Pledgor under the Loan Agreement the Pledgee will grant a cash collateral in the maximum amount of CHF 5,000,000 to the Bank (the "**Loan Guarantee**") according to the loan guarantee agreement between the Pledgee and the Bank (the "**Loan Guarantee Agreement**").

- (4) To secure the Loan Guarantee the Pledgor shall pledge to the Pledgee the Existing Patent as set out in Schedule 1 and all Future Patents (as defined below).
- (5) The Applicant is currently the holder of the Existing Patent, which will be assigned and transferred to the Pledgor in accordance with Section 2. below.

**NOW, THEREFORE, IT IS AGREED** as follows:

## Definitions

"**Agreement**" means this agreement, together with the schedules hereto, as it may be amended, restated, supplemented or otherwise modified from time to time;

"**Enforcement**" means the enforcement of the Pledge and realization of the Pledged Patents in accordance with the terms of this Agreement;

"**Event of Default**" means any event or circumstance under which the Bank enforces the Loan Guarantee;

"**Existing Patents**" means the Patents set out in Schedule 1 hereto;

"**Future Patents**" means all future Patents the Pledgor will file during the Term of this Agreement which (i) constitute Sucampo Patents or Compound Patents (as defined in the Development Agreement); or (ii) claim priority (directly or indirectly) to the Existing Patents;

"**Patents**" means any patent or application for a patent;

"**Patent Office**" means any governmental, intergovernmental, or governmentally authorized national or supranational body responsible for receiving and examining applications for and issuing, extending or maintaining Patents;

"**Pledge**" means a pledge pursuant to Art. 899 *et seq.* of the Swiss Civil Code of the Pledged Patents in accordance with the terms of this Agreement;

"**Pledged Patents**" means the Existing patent and all Future Patents for which the Pledgor has exercised the option pursuant to Section 3.(b), which are subject to the Pledge hereunder;

"**Secured Obligation**" means any and all amounts for which the Bank has enforced the Loan Guarantee against the Pledgee under the Loan Guarantee Agreement.

All other capitalized terms used herein but not defined shall have the meaning ascribed to such terms in the Development Agreement.

## undertaking to assign and transfer the Existing Patent

The Applicant hereby undertakes and agrees to assign and transfer the Existing Patent to the Pledgor by executing and filing with the competent Patent Office all documents required for that purpose within five (5) business days following the mutual execution of this Agreement. Upon recording of such assignment and transfer of the Existing Patent to the Pledgor and prompt notification thereof by the competent Patent Office, Pledgor shall notify the Pledgee accordingly and provide a copy of the notification by the competent Patent Office to the Pledgee (the "**Assignment Notice**").

## Pledge

- (a) The Pledgor herewith agrees (i) to pledge to the Pledgee the Existing Patent, together with all rights, claims or benefits pertaining thereto as security for the Secured Obligation until such time as the Loan Guarantee has been released and discharged in full by the Bank, and no further Secured Obligations are capable of arising and, therefore, the Pledgor agrees (ii) to do everything necessary or advisable in the opinion of the Pledgee to effect the Pledge.
- (b) In addition, the Pledgor herewith grants the Pledgee the right and option to include any Future Patents to be pledged by Pledgor to Pledgee under this Agreement, which option may be exercised by written notice from Pledgee to Pledgor upon any Future Patent coming into existence or any time thereafter during the term of this Agreement.
- (c) For the purpose of effecting the Pledge, the Pledgor undertakes to notify all competent Patent Offices by filing the respective Notice to Pledge substantially in the form as set forth in Schedule 3 hereto to the competent patent Offices to register the Pledge in such Patent registers in all those jurisdictions in which such a registration of the Pledge is possible.

## Pledgor's Obligations

With effect from the date of this Agreement the Pledgor herewith agrees to

- (a) promptly execute and deliver at Pledgee's expenses all further instruments and documents, and take all further action, that the Pledgee may reasonably request, in order to (i) perfect, protect, maintain, renew and enforce the Pledge under this Agreement, (ii) facilitate the exercise of the Pledgee's rights and remedies under this Agreement;
- (b) to do all acts which are or will be necessary to maintain and process Pledged Patents, to maintain the registrations relating to the Pledged Patents and the full validity thereof, including payment of any application, registration or renewal fee, respectively, and to maintain the protection of the Pledged Patents, including to take all reasonable action necessary or useful to defend any related challenges and/or to prevent unauthorized use thereof;
- (c) to notify the Pledgee as soon as reasonably possible of any actual, threatened or suspected infringement of the Pledged Patents or of any other event or circumstances which may be expected to have a material adverse effect on (i) the validity or enforceability of the Pledge or (ii) the validity or enforceability of the Pledged Patents;
- (d) to do all commercially reasonable and useful acts which are or will be necessary to defend against the registration of any intellectual property rights by third parties which could endanger the validity or enforceability of the Pledged Patents;
- (e) to inform the Pledgee immediately upon filing of any application for any Future Patent that may come into existence after the date hereof and, following the exercise of the option under Section 3.(b) above, to execute upon request of the Pledgee any declaration or other written instrument and do all other reasonable acts required or useful to secure or perfect the Pledge also in respect of such Future Patents; and
- (f) to deliver to the Pledgee no later than ten (10) business days following the end of each calendar year an update of Schedule 1, containing a list of all Pledged Patents as of 31 December of the preceding calendar year, accompanied by a duly signed notice substantially in the form as set forth in Schedule 2.



## **Delivery of Documents**

- (a) Within five (5) business days following receipt of the Assignment Notice, the Pledgor shall deliver to the Pledgee copies of duly signed letters in the form as set forth in Schedule 3, with respect to the Existing Patent filed with the competent Patent Office pursuant to Section 3.(c) above.
- (b) Each time within ten (10) business days following receipt of Pledgee's notice exercising the option under Section 3.(b) above related to any Future Patent, Pledgor shall deliver to Pledgee copies of the duly signed letters in the form substantially as set forth in Schedule 3 with respect to such Future Patent filed with the competent Patent Office(s) pursuant to Section 3.(c).
- (c) After the Pledge has been registered by the competent Patent Office, the Pledgor shall deliver to the Pledgee copies of such entries in the applicable Patent registers.

## **Representations and Warranties**

The Pledgor represents and warrants to the Pledgee as of the date of this Agreement that:

- (a) the Pledgor is duly incorporated and organized and validly existing under the laws of Switzerland and has the full corporate power and authority to own and use its assets and properties and to conduct its business as the same is presently conducted;
- (b) the Applicant is the sole legal and beneficial owner of the Existing Patent and has the legal capacity to assign and transfer the Existing Patent free of any pledge, mortgage, lien or encumbrance or licences in favour of third parties;
- (c) all details regarding the Existing Patent set out in Schedule 1 are correct and complete;
- (d) to the knowledge of the Pledgor, no claims, actions, proceedings, arbitrations or investigations are pending or threatened against or relating to the Existing Patent which could lead to a (total or partial) annulment of any of the Existing Patent;
- (e) this Agreement (i) constitutes legal and valid obligations binding on the Applicant and the Pledgor (to the extent applicable to each of them), and (ii) is enforceable against the Applicant and the Pledgor, respectively, in accordance with its terms.

## **Enforcement**

- (a) On and at any time after the occurrence of an Event of Default, the Pledgee shall be entitled, but not obligated, at its discretion and irrespective of any other security granted to the Pledgee, to enforce the Pledge by official enforcement proceedings pursuant to the Swiss Act on Debt Collection and Bankruptcy.
- (b) Failure by the Pledgee to exercise its enforcement hereunder shall not prejudice any of the rights the Pledgee may have under this Agreement, nor shall such failure constitute a waiver of any obligation of the Pledgor hereunder.

## Release

- (a) When the Loan Guarantee has been released and discharged in full by the Bank to the Pledgee in accordance with the terms of the Loan Guarantee Agreement, the Pledged Patents or any remainder thereof shall be released from the Pledge and the option of the Pledgee pursuant to Section 3.(b) above shall terminate and cease to exist.
- (b) Within ten (10) business days upon the release of the Pledged Patents pursuant to Section (a) hereinabove, the Pledgee undertakes to file the respective Notice of release substantially in the form as set forth in Schedule 4 hereto to the competent Patent Office(s) to register the release of the Pledge on the Pledged Patents in such Patent registers in all those jurisdictions in which a registration of the Pledge had been recorded. At the same time, Pledgee shall deliver true and complete copies of such Notices to release filed to Pledgor.

## use and exploitation of pledged patents

Nothing in this Agreement or the Pledge shall limit, restrict or otherwise hinder, and, subject to the terms of the Development Agreement, Pledgor is fully entitled to, use, exploit, and commercialize the technology or any part covered by any Pledged Patent or to enter into any legal instrument, including license agreements, with third parties aiming at the exploitation of the technology covered by any Pledged Patents.

## Assignments and Transfers

- (a) The rights and the obligations of either party under this Agreement may not be assigned or transferred without the prior written consent of the other party.

## Cost and Expenses / Indemnity

- (a) Subject to (b) Hereinbelow, all third party fees, cost and expenses related to or charged or incurred in connection with the registration of the Pledge and the release and de-registration of the Pledge, including without limitation filing fees, cost of local agents in the jurisdictions where the Pledge is to be recorded and later de-recorded with Patent Offices, translation cost etc., shall be born solely by Pledgee, and Pledgee shall within ten (10) business days upon first request and presentation of respective invoices and/or receipts for any such fees, cost, expenses incurred or paid by Pledgor, reimburse Pledgor any and all such amounts actually incurred and paid by Pledgor.
- (b) Any and all third party fees and expenses related to the assignment and transfer of the Existing Patent pursuant to Section 2. above shall be borne by the Pledgor.
- (c) All other costs and expenses in relation to this Agreement and the matters contemplated by this Agreement not referred to in (a) and (b) hereinabove, including in particular any costs and expenses in relation to the preparation, negotiation and execution of this Agreement, shall be born by the party as it incurred such cost and expenses.

## Waivers and Modifications

- (a) This Agreement and the rights of each party hereunder may be waived, amended or modified only specifically and in writing signed by the parties hereto. Delay in exercising or non-exercising of any such right is not a waiver of that right.

- (b) This Agreement and the documents referred to in it contain the whole agreement between the parties relating to the Pledge contemplated by this Agreement and supersede all previous agreements between the parties related to the subject matter hereof.

### **Severability**

If any provision of this Agreement is or becomes illegal, invalid or unenforceable in any jurisdiction, such illegality, invalidity or unenforceability shall not affect:

- (a) the validity or enforceability in that jurisdiction of any other provision of this Agreement; or
- (b) the validity or enforceability in any other jurisdiction or any other provision of this Agreement;

and the parties to this Agreement shall negotiate in good faith a provision to replace the relevant provision reflecting as closely as possible the original intention and the purpose of this Agreement.

### **Law and Jurisdiction**

- (a) This Agreement shall be governed by and construed in accordance with the laws of Switzerland.
- (b) Any and all disputes arising out of, or in connection with, this Agreement (including disputes on its proper conclusion, validity and binding effect) shall exclusively be brought before the competent court of Zug.

IN WITNESS WHEREOF, the authorised representatives of the Parties have executed this Agreement on September \_\_, 2011.

**The Pledgee:**

**Sucampo AG**

By: \_\_\_\_\_  
Ryuji Ueno  
Director

**The Applicant:**

\_\_\_\_\_  
David Urech

**The Pledgor:**

**Numab AG**

By: \_\_\_\_\_  
Peter Hirschvogel  
Sole member of the board of directors

SCHEDULE 1  
Existing Patent

Application Number: [...\*\*\*...]  
Priority Date: [...\*\*\*...]  
Applicant: [...\*\*\*...]  
Title: [...\*\*\*...]

**\*Confidential Treatment Requested**

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*Confidential*

*Patent Pledge Agreement, 1 109  
Numab AG and Sucampo AG, also Exhibit A to Loan Agreement*

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SCHEDULE 2  
Form of Notice

[Letterhead of Pledgor]

To: [Pledgee]

[Place], [date]

**NOTICE REGARDING STATUS OF PLEDGED PATENTS**

Dear Sirs,

We refer to the pledge agreement regarding the pledge of patents that we entered into with you on September [7], 2011 (the "**Pledge Agreement**").

Any capitalised term used in this notice shall have the meaning assigned to such term in the Pledge Agreement.

With reference to Clause 4.(f) of the Pledge Agreement, we are sending you an updated list of all Pledged Patents.

We herewith confirm the Pledge over the Pledged Patents and, if any of the Pledged Patents have not yet been validly pledged to you, we herewith pledge such Pledged Patents to you, including all rights, claims or benefits pertaining thereto, in accordance with the terms and conditions of the Pledge Agreement.

Yours sincerely,

[Pledgor]

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SCHEDULE 3  
Form of Notification to competent Patent Office

[Letterhead of Pledgor]

To: [competent Patent Office]

[Place], [date]

**NOTIFICATION REGARDING THE PLEDGE OF CERTAIN PATENTS**

Dear Sirs,

We are the owner of the following patent registered with you under [*description of the registration number*] (the "**Patent**"). We herewith notify you that we have pledged the Patent to Sucampo AG, Graben 5, 6300 Zug, Switzerland (the "**Pledgee**").

We, therefore, kindly ask you to register the pledge of the Patent in favour of the Pledgee and to provide us with an excerpt of the register confirming that the pledge has been registered.

We kindly ask you not to de-register the pledge unless you have received a written instruction from the Pledgee.

Yours sincerely,

[Pledgor]

SCHEDULE 4  
Form of Notice to Release to competent Patent Office

[Letterhead of Pledgee]

To: [competent Patent Office]

[Place], [date]

**NOTIFICATION REGARDING RELEASE OF THE PLEDGE OF CERTAIN PATENTS**

Dear Sirs,

As per notice of Numab AG, [ADDRESS], Switzerland sent to you on [DATE] to notify you of the pledge in our favour of the patent(s) registered with you under [description of the registration number] (the "**Patent**"), we herewith notify you that the pledge on the Patent has terminated and the patent has been released from such pledge.

We, therefore, kindly ask you to de-register and delete the pledge of the Patent in our favour and to provide us with an excerpt of the register confirming that the pledge has been de-registered and deleted.

Yours sincerely,

[Pledgee]



## EMPLOYMENT AGREEMENT

**THIS EMPLOYMENT AGREEMENT** (the "Agreement"), dated as of October 24, 2011, is hereby entered into in the State of Maryland by and between SUCAMPO PHARMACEUTICALS, INC., a Delaware corporation (the "Company"), and Cary Claiborne ("Executive").

**WHEREAS**, Executive has been the interim Chief Financial Officer of the Company since March 9, 2011;

**WHEREAS**, Executive possesses certain skills, experience or expertise which will be of use to the Company;

**WHEREAS**, the parties acknowledge that Executive's abilities and services are unique and will significantly enhance the business prospects of the Company; and

**WHEREAS**, in light of the foregoing, the Company desires to employ Executive as the Chief Financial Officer as of October 17, 2011 (the "Effective Date") and Executive desires to obtain such employment.

**NOW, THEREFORE**, in consideration of the promises and the mutual covenants and agreements herein contained, the Company and Executive hereby agree as follows:

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## **Article 1. Employment Agreement**

### **1.1 Employment and Duties**

The Company offers and Executive hereby accepts employment with the Company for the Term (as hereinafter defined) as its Chief Financial Officer, and in connection therewith, to perform such duties as Executive shall reasonably be assigned by Executive's supervisor and/or by the Company's Board of Directors. Executive hereby warrants and represents that Executive has no contractual commitments or other obligations to third parties inconsistent with Executive's acceptance of this employment and performance of the obligations set forth in this Agreement. Executive shall perform such duties and carry out Executive's responsibilities hereunder faithfully and to the best of Executive's ability, and shall devote Executive's full business time and best efforts to the business and affairs of the Company during normal business hours (exclusive of periods of vacation, sickness, disability, or other leaves to which Executive is entitled). Executive will perform all of Executive's responsibilities in compliance with all applicable laws and will ensure that the operations that Executive manages are in compliance with all applicable laws.

## **Article 2. Employment Term**

### **2.1 Term**

The term of Executive's employment hereunder (the "Term") shall be deemed to commence on the Effective Date and shall end on the second anniversary of the Effective Date, unless sooner terminated as hereinafter provided; provided, however, that the Term shall be automatically renewed and extended for an additional period of one (1) year on each anniversary thereafter unless either party gives a Notice of Termination (as defined below) to the other party at least sixty (60) days prior to such anniversary.

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## 2.2 Survival on Merger or Acquisition

In the event the Company is acquired during the Term, or is the non-surviving party in a merger, or sells all or substantially all of its assets, this Agreement shall not automatically be terminated, and the Company agrees to use its best efforts to ensure that the transferee or surviving company shall assume and be bound by the provisions of this Agreement.

## **Article 3. Compensation and Benefits**

### 3.1 Compensation

(a) Base Salary. The Company shall pay Executive a salary at an annual rate that is not less than Two Hundred and Ninety Four Thousand and no/100 dollars (\$294,000.00), to be paid in bi-weekly installments, in arrears (the "Base Salary"). Thereafter, the Base Salary will be reviewed by the Compensation Committee of the Board of Directors ("Compensation Committee") at least annually, and the Committee's recommendation shall be reviewed and approved by the Board of Directors. The Base Salary may, in the sole discretion of the Board of Directors, be increased, but not decreased (unless mutually agreed by Executive and the Company).

(b) Stock Compensation. At least annually for the Term of this Agreement, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors. In the event that, during the Term (i) the Company is acquired or is the non-surviving party in a merger, or (ii) the Company sells all or substantially all of its assets, or (iii) in the event of the death of Executive, all unvested restricted stock awards and incentive stock options having previously been awarded to Executive shall immediately vest and may be exercised in accordance with the terms of the Plan and the Executive's grant award.

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(c) Bonuses. Executive shall be eligible to receive an annual bonus award in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified from time to time. Recommendations concerning the decision to make an award and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.

(d) Withholding Taxes. All compensation due to Executive shall be paid subject to withholding by the Company to ensure compliance with all applicable laws and regulations.

### 3.2 Participation in Benefit Plans

Executive shall be entitled to participate in all employee benefit plans or programs of the Company offered to other employees to the extent that Executive's position, tenure, salary, and other qualifications make Executive eligible to participate in accordance with the terms of such plans. The Company does not guarantee the continuance of any particular employee benefit plan or program during the Term, and Executive's participation in any such plan or program shall be subject to all terms, provisions, rules and regulations applicable thereto.

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### 3.3 Expenses

The Company will pay or reimburse Executive for all reasonable and necessary out-of-pocket expenses incurred by Executive in the performance of Executive's duties under this Agreement. Executive shall provide to the Company detailed and accurate records of such expenses for which payment or reimbursement is sought, and Company payments shall be in accordance with the regular policies and procedures maintained by the Company from time to time.

### 3.4 Professional Organizations

During the Term, Executive shall be reimbursed by the Company for the annual dues payable for membership in professional societies associated with subject matter related to the Company's interests. New memberships for which reimbursement will be sought shall be approved by the Company in advance.

### 3.5 Parking

During the Term, the Company shall either provide parking for Executive's automobile at the Company's expense or reimburse Executive for such expense.

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## Article 4. Termination of Employment

### 4.1 Definitions

As used in Article 4 of this Agreement, the following terms shall have the meaning set forth for each below:

(a) "Benefit Period" shall mean the six (6) month period commencing on the Date of Termination which occurs in connection with a termination of employment described in the first sentence of Section 4.4(a), or a period ending when Executive becomes eligible for group medical benefits coverage from another source, whichever is shorter.

(b) "Cause" shall mean any of the following:

(i) the gross neglect or willful failure or refusal of Executive to perform Executive's duties hereunder (other than as a result of Executive's death or Disability);

(ii) perpetration of an intentional and knowing fraud against or affecting the Company or any customer, supplier, client, agent or employee thereof;

(iii) any willful or intentional act that could reasonably be expected to injure the reputation, financial condition, business or business relationships of the Company or Executive's reputation or business relationships;

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(iv) conviction (including conviction on a *nolo contendere* plea) of a felony or any crime involving fraud, dishonesty or moral turpitude;

(v) the material breach by Executive of this Agreement (including, without limitation, the Employment Covenants set forth in Article 5 of this Agreement); or

(vi) the failure or continued refusal to carry out the directives of Executive's supervisor or the Board of Directors that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; provided, however, that Cause shall not exist if such refusal arises from Executive's reasonable, good faith belief that such failure or refusal is required by law.

(c) "Date of Termination" shall mean the date specified in the Notice of Termination (as hereinafter defined) (except in the case of Executive's death, in which case the Date of Termination shall be the date of death); provided, however, that if Executive's employment is terminated by the Company other than for Cause, the date specified in the Notice of Termination shall be at least thirty (30) days from the date the Notice of Termination is given to Executive.

(d) "Notice of Termination" shall mean a written notice from the Company to Executive that indicates Section 2 or the specific provision of Section 4 of this Agreement relied upon as the reason for such termination or nonrenewal, the Date of Termination, and, in the case of termination or non-renewal by the Company for Cause, in reasonable detail, the facts and circumstances claimed to provide a basis for termination or nonrenewal.

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(e) "Good Reason" shall mean:

- (i) Company effects a material diminution of Executive's position, authority or duties;
- (ii) any requirement that Executive, without his/her consent, move his/her regular office to a location more than fifty (50) miles from Company's executive offices;
- (iii) the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
- (iv) any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within twenty-one (21) days. If either condition is not met, Executive shall not have a Good Reason to terminate Executive's employment.

(f) "Change in Control" shall mean:

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(i) the acquisition by any person of beneficial ownership of fifty percent (50%) or more of the outstanding shares of the Company's voting securities; or

(ii) the Company is the non-surviving party in a merger; or

(iii) the Company sells all or substantially all of its assets; provided, however, that no "Change in Control" shall be deemed to have occurred merely as the result of a refinancing by the Company or as a result of the Company's insolvency or the appointment of a conservator; or

(iv) the Compensation Committee of the Company, in its sole and absolute discretion determines that there has been a sufficient change in the share ownership or ownership of the voting power of the Company's voting securities to constitute a change of effective ownership or control of the Company.

#### 4.2 Termination Upon Death or Disability

This Agreement and Executive's employment hereunder, shall terminate automatically and without the necessity of any action on the part of the Company upon the death of Executive. In addition, if at any time during the Term, Executive shall become physically or mentally disabled (as determined by an independent physician competent to assess the condition at issue), whether totally or partially, so that Executive is unable substantially to perform Executive's duties and services hereunder, with or without reasonable accommodation, for either (i) a period of sixty (60) consecutive calendar days, or (ii) ninety (90) consecutive or non-consecutive calendar days during any consecutive five (5) month period (the "Disability Date"), the Company may terminate this Agreement and Executive's employment hereunder by written notice to Executive after the Disability Date (but before Executive has recovered from such disability).

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#### 4.3 Company's and Executive's Right to Terminate

This Agreement and Executive's employment hereunder may be terminated at any time by the Company for Cause or, if without Cause, upon thirty (30) days prior written notice to Executive. In the event the Company should give Executive notice of termination without Cause, the Company may, at its option, elect to provide Executive with thirty (30) days' salary in lieu of Executive's continued active employment during the notice period. This Agreement and Executive's employment hereunder may be terminated by Executive at any time for Good Reason and, if without Good Reason, upon thirty (30) days prior written notice to the Company.

#### 4.4 Compensation Upon Termination

(a) Severance. In the event the Company terminates Executive's employment without Cause or pursuant to Section 4.2 due to the disability of Executive, or elects not to renew this Agreement under circumstances where Executive is willing and able to execute a new agreement providing terms and conditions substantially similar to those in this Agreement, or in the event Executive terminates employment for Good Reason, Executive shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement of any COBRA continuation premium payments made by Executive for the Benefit Period, and (iii) a lump sum severance payment equal to six (6) months of Executive's then current Base Salary to be made not later than ten (10) business days following the expiration of the revocation period in Executive's Release (as provided in Section 4.4(c) below) without any revocation having occurred. Notwithstanding the foregoing, the Company shall, to the extent necessary and only to the extent necessary, modify the timing of delivery of severance benefits to Executive if the Company reasonably determines that the timing would subject the severance benefits to any additional tax or interest assessed under Section 409A of the Internal Revenue Code. In such event, the payments will be made as soon as practicable without causing the severance benefits to trigger such additional tax or interest under Section 409A of the Internal Revenue Code. In the event this Agreement is terminated (or not renewed) for any reason other than by the Company without Cause or pursuant to Section 4.2 due to the disability of Executive or by Executive for Good Reason, Executive shall not be entitled to the continuation of any compensation, bonuses or benefits provided hereunder, or any other payments following the Date of Termination, other than Base Salary earned through such Date of Termination.

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(b) Change in Control. In the event that Executive is terminated other than for "Cause" within eighteen (18) months following the occurrence of a "Change in Control" of the Company, then Executive shall be entitled to a severance payment in an amount that is two (2) times the amount specified in Section 4.4(a), clause (iii) above (the "Change in Control Severance Payment"). In the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (the "Code"). If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code.

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(c) Release. Anything to the contrary contained herein notwithstanding, as a condition to Executive receiving severance benefits to be paid pursuant to this Section 4.4, Executive shall execute and deliver to the Company a general release in the form attached hereto as Exhibit A. The Company shall have no obligation to provide any severance benefits to Executive until it has received the general release from Executive and any revocation or rescission period applicable to the Release shall have expired without revocation or rescission.

## **Article 5. Employment Covenants**

### **5.1 Definitions**

As used in this Article 5 of the Agreement, the following terms shall have the meaning set forth for each below:

(a) "Affiliate" shall mean a person or entity that directly or indirectly through one or more intermediaries, controls or is controlled by, or under common control with another person or entity, including current and former directors and officers of such an entity.

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(b) "Confidential Information" shall mean all confidential and proprietary information of the Company, its Predecessors and Affiliates, whether in written, oral, electronic or other form, including but not limited to trade secrets; technical, scientific or business information; processes; works of authorship; Inventions; discoveries; developments; systems; chemical compounds; computer programs; code; algorithms; formulae; methods; ideas; test data; know how; functional and technical specifications; designs; drawings; passwords; analyses; business plans; information regarding actual or demonstrably anticipated business, research or development; marketing, sales and pricing strategies; and information regarding the Company's current and prospective consultants, customers, licensors, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii) Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.

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(c) "Executive Work Product" shall mean all Confidential Information and Inventions conceived of, created, developed or prepared by Executive (whether individually or jointly with others) before or during Executive's employment with the Company, during or outside of working hours, which relate in any manner to the actual or demonstrably anticipated business, research or development of the Company, or result from or are suggested by any task assigned to Executive or any work performed by Executive for or on behalf of the Company or any of its Affiliates.

(d) "Invention" shall mean any apparatus, biological processes, cell line, chemical compound, creation, data, development, design, discovery, formula, idea, improvement, innovation, know-how, laboratory notebook, manuscript, process or technique, whether or not patentable or protectable by copyright, or other intellectual property in any form.

(e) "Predecessor" shall mean an entity, the major portion of the business and assets of which was acquired by another entity in a single transaction or in a series of related transactions.

(f) "Trade Secrets," as used in this Agreement, will be given its broadest possible interpretation under the law applicable to this Agreement.

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## 5.2 Nondisclosure and Nonuse

Executive acknowledges that prior to and during Executive's employment with the Company, Executive had and will have occasion to create, produce, obtain, gain access to or otherwise acquire, whether individually or jointly with others, Confidential Information. Accordingly, during the term of Executive's employment with the Company and at all times thereafter, Executive shall keep secret and shall not, except for the Company's benefit, disclose or otherwise make available to any person or entity or use, reproduce or commercialize, any Confidential Information, unless specifically authorized in advance by the Company in writing.

## 5.3 Other Confidentiality Obligations

Executive acknowledges that the Company may, from time to time, have agreements with other persons or entities or with the U.S. Government or governments of other countries, or agencies thereof, which impose confidentiality obligations or other restrictions on the Company. Executive hereby agrees to be bound by all such obligations and restrictions and shall take all actions necessary to discharge the obligations of the Company thereunder, including, without limitation, signing any confidentiality or other agreements required by such third parties.

## 5.4 Return of Confidential Information

At any time during Executive's employment with the Company, upon the Company's request, and in the event of Executive's termination of employment with the Company for any reason whatsoever, Executive shall immediately surrender and deliver to the Company all records, materials, notes, equipment, drawings, documents and data of any nature or medium, and all copies thereof, relating to any Confidential Information (collectively the "the Company Materials") which is in Executive's possession or under Executive's control. Executive shall not remove any of the Company Materials from the Company's business premises or deliver any of the Company Materials to any person or entity outside of the Company, except as required in connection with Executive's duties of employment. In the event of the termination of Executive's employment for any reason whatsoever, Executive shall promptly sign and deliver to the Company a Termination Certificate in the form of Exhibit B attached hereto.

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### 5.5 Confidential Information of Others

Executive represents that Executive's performance of all the terms of this Agreement and Executive's employment with the Company do not and will not breach any agreement to keep in confidence proprietary information, knowledge or data with regard to which Executive has obligations of confidentiality or nonuse, and Executive shall not disclose to the Company or cause the Company to use any such confidential proprietary information, knowledge or data belonging to any previous employer of Executive or other person. Executive represents that Executive has not brought and will not bring to the Company or use at the Company any confidential materials or documents of any former employer or other person that are not generally available to the public, unless express written authorization for their possession and use has been obtained from such former employer or other person. Executive agrees not to enter into any agreement, whether written or oral, that conflicts with these obligations.

### 5.6 Other Obligations

The terms of this Section 5 are in addition to, and not in lieu of, any statutory or other contractual or legal obligation to which Executive may be subject relating to the protection of Confidential Information.

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#### 5.7 Assignment of Confidential Information and Inventions; Works Made for Hire

Executive hereby assigns to the Company all right, title and interest in all intellectual property, including any patent applications, trade secrets, know how, copyrights, software, or trademarks associated with the Executive Work Product and Confidential Information. Executive hereby acknowledges and agrees that all Executive Work Product subject to copyright protection constitutes "work made for hire" under United States copyright laws (17 U.S.C. § 101) and is owned exclusively by the Company. To the extent that title to any Executive Work Product subject to copyright protection does not constitute a "work for hire," and to the extent title to any other Executive Work Product does not, by operation of law or otherwise, vest in the Company, all right, title, and interest therein, including, without limitation, all copyrights, patents and trade secrets, and all copyrightable or patentable subject matter, are hereby irrevocably assigned to the Company. Executive shall promptly disclose to the Company in writing all Executive Work Product. Executive shall, without any additional compensation, execute and deliver all documents or instruments and give the Company all assistance it requires to transfer all right, title, and interest in any Executive Work Product to the Company; to vest in the Company good, valid and marketable title to such Executive Work Product; to perfect, by registration or otherwise, trademark, copyright and patent protection of the Company with respect to such Executive Work Product; and otherwise to protect the Company's trade secret and proprietary interest in such Executive Work Product. Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agents and attorneys-in-fact to act for and on Executive's behalf, and to execute and file any documents and to do all other lawfully permitted acts to further the purposes of this Section 5.7 with the same legal force and effect as if executed by Executive.

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### 5.8 Representations

Executive represents that, to the best of his or her knowledge, none of the Inventions will violate or infringe upon any right, patent, copyright, trademark or right of privacy, or constitute libel or slander against or violate any other rights of any person, firm or corporation, and that Executive will not knowingly create any Invention which causes any such violation.

### 5.9 Inventions, Intellectual Property and Equipment Not Transferred

Executive has set forth on Exhibit C attached hereto a complete list and brief description of all Inventions, intellectual property and equipment located at the Company which is owned directly or indirectly by Executive and which shall not be transferred to the Company pursuant to this Agreement. Except as so listed, Executive agrees that he or she will not assert any rights under any intellectual property as having been made or acquired by Executive prior to being employed by the Company. The Company may, at its discretion, require detailed disclosures and materials demonstrating ownership of the intellectual property so listed.

### 5.10 Exclusivity of Employment

During the Term, and without prior approval of the Board of Directors, Executive shall not directly or indirectly engage in any activity competitive with or adverse to the Company's business or welfare or render a material level of services of a business, professional or commercial nature to any other person or firm, whether for compensation or otherwise.

### 5.11 Covenant Not to Compete

Executive agrees to be bound and abide by the following covenant not to compete:

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(a) Term and Scope. During Executive's employment with the Company and for a period of twelve (12) months after the Term, Executive will not render to any Conflicting Organization (as hereinafter defined), services, directly or indirectly, anywhere in the world in connection with any Conflicting Product (as hereunder defined), except that Executive may accept employment with a Conflicting Organization whose business is diversified (and which has separate and distinct divisions) if Executive first certifies to the Company in writing that such prospective employer is a separate and distinct division of the Conflicting Organization and that Executive will not render services directly or indirectly in respect of any Conflicting Product. Such twelve (12) month time period shall be tolled during any period that Executive is engaged in activity in violation of this covenant.

(b) Judicial Construction. Executive and the Company agree that, if the period of time or the scope of this Covenant Not to Compete shall be adjudged unreasonably overbroad in any court proceeding, then the period of time and/or scope shall be modified accordingly, so that this covenant may be enforced with respect to such services or geographic areas and during such period of time as is judged by the court to be reasonable.

(c) Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

"Conflicting Product" means any product, method or process, system or service of any person or organization other than the Company that is the same as, similar to or interchangeable with any product, method or process, system or service that was provided or under development by the Company or any of its Affiliates at the time Executive's employment with the Company terminates, or about which Executive acquired any Confidential Information or developed any Executive Work Product.

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"Conflicting Organization" means any person or organization which is engaged in research on or development, production, marketing, licensing, selling or servicing of any Conflicting Product.

#### 5.12 Non-Solicitation

For a period of twelve (12) months after termination of employment with the Company for any reason, Executive shall not directly or indirectly solicit or hire, or assist any other person in soliciting or hiring, any person employed by the Company (as of the date of Executive's termination) or any person who, as of the date of Executive's termination, was in the process of being recruited by the Company, or induce any such employee to terminate his or her employment with the Company.

#### 5.13 Judicial Enforcement

In the event of a breach or violation of any provision of this Article 5 by Executive, the parties agree that, in addition to any other remedies it may have, the Company shall be entitled to equitable relief for specific performance, and Executive hereby agrees and acknowledges that the Company has no adequate remedy at law for the breach of the employment covenants contained herein.

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## Article 6. Miscellaneous

### 6.1 Notices

All notices or other communications which are required or permitted hereunder shall be deemed to be sufficient if contained in a written instrument given by personal delivery, air courier or registered or certified mail, postage prepaid, return receipt requested, addressed to such party at the address set forth below or such other address as may thereafter be designated in a written notice from such party to the other party:

To Company:                Sucampo Pharmaceuticals, Inc.  
                                  4520 East West Highway, Third Floor  
                                  Bethesda, Maryland 20814  
                                  Attention: Chief Executive Officer

To Executive:             Cary Claiborne  
                                  3056 Seneca Chief Trail  
                                  Ellicott City, Maryland 21042

All such notices, advances and communications shall be deemed to have been delivered and received (i) in the case of personal delivery, on the date of such delivery, (ii) in the case of air courier, on the business day after the date when sent and (iii) in the case of mailing, on the third business day following such mailing.

### 6.2 Headings

The headings of the articles and sections of this Agreement are inserted for convenience only and shall not be deemed a part of or affect the construction or interpretation of any provision hereof.

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### 6.3 Modifications; Waiver

No modification of any provision of this Agreement or waiver of any right or remedy herein provided shall be effective for any purpose unless specifically set forth in a writing signed by the party to be bound thereby. No waiver of any right or remedy in respect of any occurrence or event on one occasion shall be deemed a waiver of such right or remedy in respect of such occurrence or event on any other occasion.

### 6.4 Entire Agreement

This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, the offer letter between Executive and the Company dated October 18, 2011.

### 6.5 Severability

Any provision of this Agreement that may be prohibited by, or unlawful or unenforceable under, any applicable law of any jurisdiction shall, as to such jurisdiction, be ineffective without affecting any other provision hereof. To the full extent, however, that the provisions of such applicable law may be waived, they are hereby waived, to the end that this Agreement be deemed to be a valid and binding agreement enforceable in accordance with its terms.

### 6.6 Controlling Law

This Agreement has been entered into by the parties in the State of Maryland and shall be continued and enforced in accordance with the laws of Maryland.

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#### 6.7 Arbitration

Any controversy, claim, or breach arising out of or relating to this Agreement or the breach thereof shall be settled by arbitration in the State of Maryland in accordance with the rules of the American Arbitration Association for commercial disputes and the judgment upon the award rendered shall be entered by consent in any court having jurisdiction thereof; provided, however, that this provision shall not preclude the Company from seeking injunctive or similar relief from the courts to enforce its rights under the Employment Covenants set forth in Article 5 of this Agreement. It is understood and agreed that, in the event the Company gives notice to Executive of termination for Cause and it should be finally determined in a subsequent arbitration that Executive's termination was not for Cause as defined in this Agreement, then the remedy awarded to Executive shall be limited to such compensation and benefits as Executive would have received in the event of Executive's termination other than for Cause at the same time as the original termination.

#### 6.8 Assignments

Subject to obtaining Executive's prior approval, which shall not be unreasonably withheld or delayed, the Company shall have the right to assign this Agreement and to delegate all rights, duties and obligations hereunder to any entity that controls the Company, that the Company controls or that may be the result of the merger, consolidation, acquisition or reorganization of the Company and another entity. Executive agrees that this Agreement is personal to Executive and Executive's rights and interest hereunder may not be assigned, nor may Executive's obligations and duties hereunder be delegated (except as to delegation in the normal course of operation of the Company), and any attempted assignment or delegation in violation of this provision shall be void.

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6.9 Read and Understood

Executive has read this Agreement carefully and understands each of its terms and conditions. Executive has sought independent legal counsel of Executive's choice to the extent Executive deemed such advice necessary in connection with the review and execution of this Agreement.

**IN WITNESS WHEREOF**, the parties have executed this Agreement as of the date first indicated above.

**SUCAMPO PHARMACEUTICALS, INC.**

By: \_\_\_\_\_  
Dr. Ryuji Ueno, Chairman, Chief  
Executive Officer and Chief Scientific Officer

\_\_\_\_\_  
Cary Claiborne

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-147420) of Sucampo Pharmaceuticals, Inc. of our report dated March 15, 2012 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland  
March 15, 2012

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**CERTIFICATION OF PRINCIPAL EXECUTIVE 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 15, 2012

/s/ RYUJI UENO

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, Cary J. Claiborne, 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 15, 2012

/s/ CARY J. CLAIBORNE

Cary J. Claiborne  
(Principal Financial 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, 2011 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2012

/s/ RYUJI UENO

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, 2011 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2012

/s/ CARY J. CLAIBORNE

Cary J. Claiborne

(Principal Financial Officer)

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