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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2012

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

For the transition period from _____ to _____.

Commission File Number: 001-33609

SUCAMPO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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 o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

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 þ No o

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. o

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

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

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

The aggregate market value of the 11,514,311 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 $80.9 million.

As of March 7, 2013, there were outstanding 41,970,364 shares of the registrant's class A common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Proxy Statement for its 2013 Annual Meeting of Stockholders to be held on May 22, 2013, which Proxy Statement is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2012, 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 focused on innovative research, discovery, development and commercialization of proprietary drugs based on prostones and other novel drug technologies. The therapeutic potential of prostones was first discovered by our cofounder, Dr. Ryuji Ueno, and under his leadership we have pioneered the field of prostones. Prostones are naturally occurring fatty acid metabolites. Originally thought to be biologically inert, prostones have emerged as a promising compound class with unique physiological activities which can be targeted for the treatment of unmet or underserved medical needs.

We are focused on developing and/or commercializing prostone-based drugs to treat gastrointestinal, ophthalmic, neurologic, and oncology-based inflammatory disorders, and are also considering other potential therapeutic applications of our drug technologies.

We currently generate revenue mainly from product royalties, development milestone payments, clinical development activities and product sales. We expect to continue to incur significant expenses for the next several years as we continue our research and development activities, seek additional regulatory approvals and additional indications for AMITIZA® (lubiprostone), RESCULA® (unoprostone isopropyl) and other compounds, and commercialize our approved products (as discussed below) on a global basis.

To date, two prostone products have received marketing approval, AMITIZA and RESCULA, globally. A third prostone, cobiprostone, or SPI-8811, is in phase 1 clinical development for the target indication of prevention of oral mucositis, or OM, in 2013. Our orphan drug application for cobiprostone for OM has not been granted by the U.S. Food and Drug Administration, or FDA, because the FDA believes that anyone who has cancer and is at risk for developing OM would take the drug and thus the target population and estimate are larger than orphan drug status. Two additional prostones, SPI-017 and SPI-3608, have also been developed for human testing for the indication of management of pain caused by spinal stenosis, and SPI-017 is currently in a phase 2A trial that is expected to conclude by the fourth quarter of 2013.

Our operations are conducted through subsidiaries based in Japan, the U.S., Switzerland, the U.K. and Luxembourg. Our reportable geographic segments are Asia, the Americas and Europe and we evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors that depend on the growth of these subsidiaries. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other factors.

Drs. Ueno and Kuno are our controlling stockholders and are married to each other. Dr. Ueno is our Chief Executive Officer and Chairman of the Board of Directors. Dr. Kuno was a member of our Board of Directors and our executive advisor on international business development through September 30, 2012. Drs. Ryuji Ueno and Sachiko Kuno, together, directly or indirectly, own a majority of the stock of R-Tech Ueno, Ltd, or R-Tech, a pharmaceutical research, development and manufacturing company in Japan. R-Tech is responsible for the manufacture and supply of all of our drug products for commercial use and clinical development.

The Prostone Platform and Related Physiology

Prostones act locally to restore normal function in cells and tissues, and because they are quickly metabolized to an inactive form, their pharmacologic activity can be targeted to specific organs and tissues. Prostones possess a unique mechanism of action as highly potent and selective ion channel activators. Ion channels are integral parts of cell membranes that regulate the flow of specific ions into and out of cells. This regulation is key to the functioning of cells, such as metabolic processes and cell survival. As such, prostones are physiological mediators of the restoration of cellular homeostasis and tissue regeneration. There is also evidence that prostones have anti-inflammatory properties and can prevent cell death.

Our prostone-based compounds target the ClC-2 (chloride) and big potassium, or BK, ion channels. Because these ion channels play an important role in physiology, targeted dosing of prostones may have broad applicability in many disease states in different organ systems. We have developed synthetic analogs of the naturally occurring prostones, which have been optimized to be more potent, selective, and stable, thus enabling their use as drugs. These synthetic prostones are very selective for their molecular targets, and the approved prostone-based compounds are well-tolerated and generally safe.

We are the only company developing and commercializing prostone compounds on a global basis. We have established a broad patent estate of over 580 active issued patents based on our proprietary prostone technology.

Our Prostone Products, Approved and in Clinical Development

AMITIZA (lubiprostone)

Overview

AMITIZA was the first chloride channel activator approved by the FDA for the chronic treatment of chronic idiopathic constipation, or CIC, in adults of both genders and for irritable bowel syndrome, or IBS, with constipation, or IBS-C, in women aged 18 years and older with demonstrated safety and efficacy for use beyond 12 weeks.

AMITIZA was approved by the FDA in 2006 for chronic treatment for CIC in adults of both genders and in 2008 for chronic treatment for IBS-C in women aged 18 years and older. AMITIZA was also approved for chronic treatment of CIC in Switzerland in 2009, for chronic constipation, or CC, in Japan in the second quarter of 2012 and for CIC in the United Kingdom in the third quarter of 2012. In the third quarter of 2012, our supplemental new drug application, or sNDA, for AMITIZA for opioid-induced constipation, or OIC, was accepted by the FDA for priority review, with an initial Prescription Drug User Fee Act, or PDUFA, date of late January 2013. In November 2012, the FDA notified us that it had extended our PDUFA goal date by three months. The expected PDUFA date and FDA approval decision is late April 2013. More information on our priority review status are contained on pages under the heading “Opioid-Induced Constipation (OIC)”.

AMITIZA is well-tolerated and has a well-established profile for safety and efficacy. Since 2006, AMITIZA has been dispensed over 6 million times. Post marketing safety monitoring indicates that the safety profile 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. The most commonly reported adverse events in the clinical trials for CIC and IBS-C were nausea, diarrhea, abdominal pain and abdominal distension. AMITIZA users tend to be 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).

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 OIC will have to establish a safety profile prior to extensive first line use.

Overview of Current and Potential Indications for AMITIZA

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. CC 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 Treatments. Some patients suffering from occasional constipation may be treated with lifestyle modification, dietary changes and increased fluid and fiber intake, although there is very limited well-controlled clinical trial data in support of these alternatives in CIC or IBS-C patients. For patients who fail to respond to these approaches, physicians typically recommend laxatives, most of which are available over-the-counter (not prescription), or 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 nor is such use supported by long-term, well-controlled pivotal clinical trial data. Polyethylene glycol 3350, an osmotic, was approved in late 2008 for sale as an OTC treatment for CIC 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, tegaserod maleate, a 5-HT_4 serotonin-receptor agonist, was often prescribed. However, in March 2007, at the request of the FDA, tegaserod maleate was withdrawn from the U.S. market by Novartis based on a finding of an increased risk of serious cardiovascular adverse events associated with its use. Tegaserod maleate has subsequently been withdrawn from most international markets as well.

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. 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. Some OTC remedies pose significant issues of dependency, habituation and/or side effects. Finally, 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 December 2012, linaclotide, a guanylate cyclase-C (GC-C) agonist, was launched into the market by Ironwood Pharmaceuticals, Inc., or Ironwood. Linaclotide is a once-daily treatment approved for adult men and women with CIC or IBS-C. We believe that a new market entrant will increase awareness of prescription therapy for CIC and IBS-C and thus grow the overall market.

Market Opportunity. A meta-analysis published in *The American Journal of Gastroenterology* in September 2011 estimates that approximately 33.0 million people over 15 years of age in the U.S. suffer from chronic idiopathic constipation. 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.

In 2012, AMITIZA generated net sales of $271.9 million in the U.S., as reported to us by our partner, which increased by 20.1%. We believe AMITIZA, with a competitive marketing and sales campaign still has great potential for future growth in the U.S. given:

- CIC and IBS-C patients make up large, fundamentally under-served patient populations;
- Available epidemiology indicates that approximately 12-19% (37 million to 59 million) of people in the U.S. suffer from some form of constipation;
- The elderly population is more likely to suffer from CIC, and the growth of the elderly population is outpacing the growth of the general population growth;
- We estimate that over 12 million patients suffer from IBS-C;
- 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;
- There were 245 million courses of therapy dispensed or purchased for constipation or IBS-C, of which AMITIZA has a 1-2% share;
- 53% of AMITIZA patients are satisfied with their current treatment, versus only 27.5% of patients satisfied with OTC and similar store brands;
- AMITIZA had an average length of therapy per patient of approximately 155 days compared to approximately 132 days for tegaserod maleate;
- Recent studies have shown that acute high doses of PEGS can lead in rare cases to irreversible kidney damage, as demonstrated in bowel prep studies. With long-term exposure to PEGS, there is a signal for the development of hyperphosphatemia and possible kidney damage.
- Recent studies and a formal finding by the FDA 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, underscores 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; and
- In clinical trials and also as part of the AMITIZA labeling, AMITIZA has demonstrated symptom relief for CIC specifically relating to abdominal bloating, abdominal discomfort, stool consistency and straining as well as constipation severity ratings versus placebo. This labeling is different than that of the laxatives and also for linaclotide with respect to the CIC indication.

Irritable Bowel Syndrome with Constipation (IBS-C)

Disease Overview. IBS 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 IBS are commonly classified as having one of four forms: IBS-C, IBS with diarrhea, mixed-pattern IBS alternating between constipation and diarrhea, and unspecified irritable bowel syndrome. Currently, IBS in all its forms is considered to be one of the most common gastrointestinal disorders.

Current Treatments. 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. Until the approval of AMITIZA, tegaserod maleate was the only FDA approved drug indicated for the treatment of IBS-C before it was withdrawn in March 2007. As noted above, in December, 2012, linaclotide, a guanylate cyclase-C (GC-C) agonist, was launched into the market by Ironwood. We believe that a new market entrant will increase awareness of prescription therapy for IBS-C and thus grow the overall market.

Market Opportunity. According to a systematic review published in August 2002 in *The American College of Gastroenterology*, irritable bowel syndrome affects approximately 30 million people in the U.S. The same article states that IBS-C impacts approximately 5.0% of the adult population, or approximately 12 million patients in the U.S. According to *The American Journal of Gastroenterology Task Force* on IBS, there were approximately 3.6 million annual patient visits for IBS in 2009 in the U.S.

Opioid-Induced Constipation (OIC)

Disease Overview. There are over 200 million prescriptions for opioids in the U.S. and a substantial number of these are for patients with non-cancer pain. OIC occurs in approximately 4 million chronic non-cancer pain sufferers and it 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 OIC. These include inhibition of large intestine motility, decreased gastric emptying and hard stools. OIC is the predominant subset of opioid bowel dysfunction, or OBD. OIC 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 opioids cause. We believe that most OIC patients are currently under the care of physicians who would proactively seek treatment of OIC for their patients such that their patients may be compliant with the opioid treatments when less impacted by the side effect of OIC.

Current Treatments. AMITIZA is expected to be the first oral medicine approved for chronic use in OIC, which is a severe form of constipation affecting up to 80% of patients taking opioids. Current treatment options for OIC 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 OIC 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 approved methylnaltrexone bromide for OIC in patients with late-stage and advanced illness experiencing severe constipation. However, Methylnaltrexone bromide is available only as an injectable medication and is not recommended for patients with known or suspected intestinal obstructions. Common side effects of include abdominal pain, gas, nausea, dizziness and diarrhea.

Market Opportunity. In May 2011, *The American Journal of Gastroenterology* published an article estimating approximately 7 million American adults are on long-term opioid therapy for chronic non-cancer pain. Constipation is a recognized common side effect of opioid use, and estimates suggest that up to approximately 3 million patients in the U.S. suffer from OIC. While estimates of constipation vary across numerous studies, Kalso, et al. reported 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, with other reports suggesting an incidence rate of as high as 80.0% of opioid users.

Opioid drugs are known to increase absorption of electrolytes, including chloride, in the small intestine, resulting in the constipating effects of these analgesics. Clinical data suggests that AMITIZA, as a chloride channel activator, may directly counteract OIC without interfering with the analgesic benefits of opioids. As a result, we believe that AMITIZA, if approved for the treatment of 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 OIC. 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 OIC in adults using twice daily doses of 24 mcg each. The primary efficacy endpoint for these trials was the change from baseline in spontaneous bowel movement, or 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 and successfully settled a lawsuit against the contract research organization, or CRO, for its malperformance under the contract. A third confirmatory study, OBD1033, was conducted to further evaluate the safety and efficacy of AMITIZA in OIC patients and has been completed.

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 higher doses of methadone treatment regimens and who were randomized to receive lubiprostone showed a lower SBM response when compared to lubiprostone patients treated with other opioid medications.

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 conducted OBD1033, a phase 3 efficacy study, to submit an sNDA for the OIC indication. We initiated OBD1033 in December 2010 and completed in December 2011. In February 2012, we reported that 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 OBD0631 in which statistical significance (p=0.0226) was achieved for its primary endpoint and the accompanying long-term safety trial were presented to the FDA as part of an sNDA filing in July 2012 seeking approval of AMITIZA for OIC in patients with chronic, non-cancer pain. As per our agreement with Takeda Pharmaceutical Company Limited, or Takeda, approximately half of this third phase 3 study's expenses were funded by us.

In September 2012, the FDA granted priority review status to the AMITIZA sNDA for OIC, a designation reserved for drugs that offer either significant advances in treatment or provide a treatment where there is no existing adequate therapy. In November 2012, the FDA notified us that it had extended the PDUFA goal date for the FDA's priority review by three months from late January 2013 to late April 2013 because our November 16, 2012 submission of FDA-requested supportive analyses was designated as a major amendment to the initial application. No new clinical trials or studies were requested by the FDA.

Pediatric Constipation

Disease Overview. Constipation in children has similar characteristics to that of constipation in adults in that symptoms include infrequent bowel movements, hard stools, and painful passage of stools. Children may also experience fecal retention due to withholding. There is a tendency to avoid defecation and withhold bowel movements as a result of pain experienced from the passage of large stools. This withholding of bowel movements can result in episodes of fecal incontinence. Functional constipation occurs in all pediatric age groups, from newborns to young adults and its severity may vary from mild and short-lived to severe and chronic with fecal impaction. It is responsible for 3–5% of pediatric outpatient visits and 25.0% of pediatric gastroenterology consultations.

Current Treatment. Medical treatment is aimed at disimpaction of the impacted feces and restoration of regular bowel habits, which consist of passage of soft, normal stools without discomfort. The administration of laxatives is also used to achieve a normal bowel habit of passing a soft stool without pain. Even though the traditional treatment is well established and safe, for many patients it does not provide a satisfying improvement, prompting interest in other therapeutic strategies.

Market Opportunity. One systematic review conducted in 2006 showed a worldwide prevalence of childhood constipation in the general population ranging from 0.7% to 29.6%. Similar prevalence rates were reported for boys and girls. Childhood constipation continues beyond puberty in up to one third of the children followed up. Children aged 2 to 4 years seem to have a higher recurrence rate and a need for prolonged medication and support than younger infants. One follow-up study completed in 1986 has noted increased risk of persistent constipation in children who developed constipation early in infancy and who have a family history of constipation. Another follow-up study completed in 2003 assessing the clinical course of severe functional constipation in early childhood found that after initial success of treatment, a relapse occurred in 15.0% of the children within 3 years. Symptom duration of three months or less before referral was significantly correlated with better outcome.

Development Status. In 2013, we plan to initiate a phase 3 program in pediatric functional constipation. If these trials are successful, we would file for a fourth indication for AMITIZA for pediatric functional constipation.

Overview of Geographic Markets for AMITIZA

U.S. and Canada

In October 2004, we entered into a collaboration and license agreement, or Takeda Agreement, with 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. 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. More information on our agreements with Takeda and R-Tech are contained on pages under the heading "Takeda Collaboration".

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. Takeda currently promotes AMITIZA in the U.S. to office-based specialty and primary care physicians. Takeda reimburses us 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. 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. Since 2006 we have co-promoted AMITIZA through our specialty sales force, focusing on the institutional marketplace, including long-term care and veteran's affairs facilities. Beginning in 2013, we will no longer co-promote AMITIZA but have our specialty sales force focus on our other marketed product. We believe that Takeda's sales force will adequately cover the markets that our specialty sales force had covered. The reimbursement of co-promotion costs under the Supplemental Takeda Agreement expired on May 31, 2011. Co-promotion costs after May 31, 2011 were 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. After May 2011, we were reimbursed based on actual sales calls made presented to health care prescribers.

In November 2012, we received a supplement approval from the FDA that removed pregnancy "warnings and precautions" and clarified information regarding the use of AMITIZA by pregnant and/or nursing women. In addition, the FDA expanded the labeling text of the Mechanism of Action section in the prescribing information for AMITIZA. The following were the specific FDA-approved labeling changes:

- All pregnancy-related Warnings and Precautions (Section 5.1 of the label) have been removed. This includes deletion of the sentence: "Women who could become pregnant should have a negative pregnancy test prior to beginning therapy with AMITIZA and should be capable of complying with effective contraceptive measures."
- Section 8 of the product labeling, "use in Specific Populations," was updated to include additional animal data and a Clinical Consideration section, with the pregnancy category remaining unchanged.
- Previous labeling statements regarding the potential for serious adverse reactions in nursing infants have been removed. The revised label states that caution should be exercised when AMITIZA is administered to a nursing mother and advises "lactating women to monitor their human milk-fed infants for diarrhea while taking AMITIZA."
- The Mechanism of Action section (Section 12.1) of the label now reads as follows: "Lubiprostone is a locally acting chloride channel activator… activation of ClC-2 by lubiprostone has been shown to stimulate recovery of mucosal barrier function and **reduce intestinal permeability** (bolding added to indicate label addition) via the restoration of tight junction complexes in ex vivo studies of ischemic porcine intestine."

As stated above, we are currently pursuing FDA approval of a third gastrointestinal indication of AMITIZA for the treatment of OIC in patients with chronic, non-cancer pain and plan to also pursue a fourth indication for AMITIZA for pediatric functional constipation.

Japan

In February 2009, we entered into a license, commercialization and supply agreement, or the Abbott Agreement, with Abbott Japan Co. Ltd., or Abbott, for lubiprostone in Japan. 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 as well as supply.

As of December 31, 2012, we have received a total of $37.5 million in payments from Abbott, consisting of an upfront payment and clinical and regulatory milestone payments. We could receive additional milestone payments based on achieving other specified development and commercialization goals. We have retained the 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.

We received approval for AMITIZA for the treatment of CC excluding constipation caused by organic diseases, from the Ministry of Health, Labour and Welfare, or MHLW, in June 2012 and pricing approval in November 2012. In November 2012, we and Abbott announced the availability of AMITIZA in Japan for CC. AMITIZA is Japan's only prescription medicine for CC. More information on our collaboration with Abbott is found under the heading "Abbott Collaboration".

Europe

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 the U.K., we received approval in September 2012 from the Medicines and Healthcare Products Regulatory Agency, or MHRA, for the use of AMITIZA to treat CIC, and are currently working to achieve National Institute for Clinical Excellence, or NICE, endorsement and launch in the U.K. in 2013. In Switzerland, AMITIZA was approved in 2009. In 2012 we reached an agreement with the Bundesamt fur Gesundheit, or BAG, on a reimbursement price for AMITIZA in Switzerland, and began active marketing in the first quarter of 2013. Since February 2012, AMITIZA has also been available through a Named Patient Program throughout the E.U., Iceland and Norway

We plan to commence the approval process in other E.U. countries for CIC via the Mutual Recognition Procedure, or MRP, in 2013. We filed for an OIC indication in Switzerland in February 2013 and plan to file in the U.K. during the first quarter 2013. If we receive approval in the U.K., we will seek approval in other E.U. countries following the MRP for OIC.

RESCULA (unoprostone isopropyl)

Overview

An sNDA for RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% for the lowering of intraocular pressure, or IOP, in patients with open-angle glaucoma or ocular hypertension was approved by the FDA in December, 2012, and we began commercializing the product in February 2013. According to the approved product labeling, RESCULA may be used as a first-line agent or concomitantly with other topical ophthalmic drug products to lower IOP. RESCULA is a BK channel activator, which is different from other IOP lowering agents.

RESCULA was originally approved by the FDA in 2000 for the 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 first launched in Japan in 1994, and since then over 53 million bottles have been shipped. . In April 2009, we acquired the commercialization rights to RESCULA for the U.S. and Canada from R-Tech.

RESCULA provides an alternate route for IOP reduction. It is believed to reduce elevated IOP by increasing the outflow of aqueous humor through the trabecular meshwork. The product may also have a local effect on BK channels and ClC-2 chloride channels. Unoprostone isopropyl is a member of our family of prostones and is a synthetic docosanoid. Complete details of the mechanism of action are unknown at this time. Other products for IOP lowering include prostaglandins, beta blockers, brimonidine tartrate ophthalmic solution and brinzolamide ophthalmic suspension.

RESCULA has been shown to be an effective medicine in lowering IOP in patients with open-angle glaucoma and ocular hypertension and has demonstrated an excellent systemic safety profile and an established ocular side effects profile. RESCULA provides efficacy throughout the day and over the long term. In pivotal trials at 6 months, RESCULA reduced mean IOP by ~3 to 4 mm Hg throughout the day (for 12 hours) with a flat diurnal curve (mean baseline IOP: 23 mm Hg). RESCULA had no deleterious effect on cardio vascular or pulmonary function in clinical studies, and minimal systemic absorption and exposure.

In April 2009, we acquired the development and commercialization rights to RESCULA for the U.S. and Canada from R-Tech for $3.5 million. Under this agreement, we hold the exclusive rights to commercialize RESCULA in the U.S. and Canada for its approved indication and all new indications developed by us. We also have the right to commercialize RESCULA in the U.S. and Canada for any additional indication developed by R-Tech or us.

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 U.S. 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.

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 U.S. within our licensed territories.

We continue to pursue additional intellectual property as well as further clinical development of RESCULA. In clinical and preclinical studies, RESCULA has increased ocular blood flow to the optic nerve and in the choroid; maintained visual field; delayed retinal degeneration induced by rhodoposin; 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. In September 2010, we received an Orphan Drug designation for unoprostone isopropyl from the FDA for the treatment of retinitis pigmentosa, or RP. In February 2013 we announced that the Japan Science and Technology Agency, or JST, adopted unoprostone isopropyl ophthalmic solution .15% in the Adaptable and Seamless Technology Transfer Program. As part of this program, R-Tech, our development partner, has signed an agreement for unoprostone isopropyl with the JST in which the Japanese government shall provide the majority of funding for phase 3 clinical development costs for unoprostone isopropyl for RP. We are co-developing unoprostone isopropyl with R-Tech and may file for FDA and EMA approval for the treatment of RP in the future assuming successful trials.

Our Other Development Programs

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

SPI-8811 (cobiprostone oral spray)

Overview. Cobiprostone, like AMITIZA, is an activator of the chloride ion channel, ClC-2, which is known to be present in gastrointestinal, liver and lung cells. Our most advanced area of development for cobiprostone is the prevention of OM. We are also investigating the potential for cobiprostone for oral administration in other disease areas.

Oral Mucositis Disease Overview. OM refers to the inflammation of oral mucosa resulting from chemotherapy, or CT, and or radiation therapy, or RT. OM, 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. OM is the primary dose limiting side effect that accounts for greater than 60.0% of the treatment interruptions. Other resulting outcomes of OM 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 OM in the 89.0%-100.0% range depending on if the radiation therapy is in combination with chemotherapy or altered fractionation RT. RT or CT 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 CTs have a higher incidence of grade 3-4 OM (e.g. Docetaxel/5FU – 66.0%).

Current Treatment. OM current treatment includes basic oral care, cryotherapy, topical rinses such as lidocaine and carbomer and palifermin, a growth factor. None of the above products have been completely successful in treating OM 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. It is estimated that 89.0%-100.0% of this population will develop oral mucositis. In addition there are >4M stage 3-4 cancer patients worldwide (>1m in U.S.) that are receiving high doses of CT or a combination of CT/RT that develop OM 1.0%-53.0% of the time.

Development Status. In 2012, we initiated a phase 1 trial of cobiprostone, designed to investigate the tolerability, safety, and pharmacokinetic profile of an oral spray formulation of SPI-8811 after its single oral cavity administration in Japanese healthy adult volunteers. In the first quarter of 2013, the trial concluded and cobiprostone was found to be well-tolerated up to 144 mcg, and no serious adverse events were observed.

SPI-017 (IV) and SPI-3608 (PO)

Overview. The target therapeutic goal for SPI-017 and SPI-3608 will be the management of symptoms associated with lumbar spinal stenosis.

Lumbar Spinal Stenosis Disease Overview. Lumbar spinal stenosis is caused by degenerative change in the lumbar spine, and is a very common disease observed in the growing aging population. It is the narrowing of the spinal canal that usually starts gradually and develops over a long period of time. As the spinal canal narrows, it can squeeze (compress) and irritate the nerve roots that branch out from the spinal cord, or it can squeeze and irritate the spinal cord itself.

Current Treatments. In the U.S. and Europe, there are no formally approved medications for lumbar spinal stenosis. Commonly used are NSAIDS, muscle relaxants, tricyclic antidepressants, short-term oral opioids, and membrane-stabilizing convulsants (such as carbamazepine), although all have potential side effects that may complicate their use. In Japan, limaprost alfadex, a prostaglandin analogue, is the only approved medication for lumbar spinal stenosis. Prostaglandins have been associated with a poor safety profile requiring careful, fractionated dosing.

Market Opportunity. It is estimated that about 400,000 Americans, most over the age of 60, may be suffering from the symptoms of lumbar spinal stenosis. There are as many as 1.2 million Americans with back and leg pain related to any type of spinal stenosis.

Development Status. In the first quarter of 2013, we initiated a phase 2A trial of SPI-017, and expect this trial to conclude in the fourth quarter of 2013. In the fourth quarter of 2012, we initiated a phase 1A/B program for SPI-3608, and expect it to conclude in the fourth quarter of 2013.

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. In the first quarter of 2013, we have decided to no longer support the development of the peptide compound. CuroNZ had started to evaluate the peptide compound for use in animal models of glaucoma and RP. Following the decision to discontinue, development provision has been made for the non-recovery of the loan.

In September 2011, we entered into a Loan Guarantee and Development Agreement, or Numab Agreement, with Numab AG, or Numab, of Wadenswil, Switzerland. Numab is considered a related party as a result of an ownership interest by one of our executive officers. Under the terms of the Numab Agreement, we will provide Numab with up to CHF 5.0 million, approximately $5.5 million as of the closing date, as collateral and will serve as guarantor for a loan to Numab from a third party. We 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 investigational new drug 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. In February 2012, we entered into a Master Lease Agreement, or Lease Agreement, with Numab whereby the maximum collateral of CHF 5.0 million is reduced by the purchase cost of any equipment leased to Numab. As of December 31, 2012, equipment with a purchase cost of CHF 544,000, approximately $595,000 as of the closing date, was leased to Numab thus reducing the maximum collateral and loan guarantee to CHF 4.5 million. Monthly rental payments are received under the terms of the lease. As of December 31, 2012, the collateral of CHF 3.5 million has been deposited by us and Numab has utilized CHF 3.0 million of its CHF 4.5 million loan. In the first quarter of 2013, Numab reported that it had met one of the success criteria for development of our named target, which this will result in us paying a success fee of CHF 3.0 million and will also reduce 90% of the loan guarantee. During 2012 in reviewing the amount outstanding of the loan, we recorded a liability of $1.2 million in collateral callable to meet a potential loan default by Numab. Following the reported success of our named target; the default provision has been released and full provision for the success fee has been made during 2012 as we considered it probable the success criteria would be met. The Company has decided to no longer pursue the further development of the target.

Product Pipeline

The table below summarizes the development status of lubiprostone, unoprostone isopropyl 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 Territory. Commercialization may be several years after successful completion of studies.

Product/Product Candidate	Target Indication	Development Phase	Next Milestone
AMITIZA ® (lubiprostone)	Chronic idiopathic constipation (CIC) (adults of all ages)	Marketed in the U.S.	——
		Marketed in Switzerland	——
		Marketing Authorization Application (MAA) approved for CIC in August 2012 in U.K.	Obtain NICE endorsement within the U.K.; Initiate mutual recognition process for approval in other E.U. countries
	Chronic constipation	Marketed in Japan since Q4 2012	——
	Opioid-induced constipation (OIC) in patients with chronic non-cancer pain	Phase 3 completed; sNDA accepted in U.S. for priority approval in Sept. 2012. MAA submitted in Switzerland in February 2013	sNDA approval (U.S.); MAA approval Switzerland; submission of MAA in U.K., MRP to get pan-European approval after U.K. approval
	Pediatric functional constipation	Phase 3 in U.S. and Europe	File sNDA for approval
	Irritable bowel syndrome with constipation (adult women) (IBS-C)	Marketed in the U.S.	Initiate phase 4 study on higher dosage and with additional male subjects
RESCULA ® (unoprostone isopropyl)	Primary open angle glaucoma and ocular hypertension	Approved in the U.S.	Launch in the U.S. in Q1 2013
	Glaucoma and ocular hypertension	——	Updated label and reauthorization in the E.U. and Switzerland
Cobiprostone (SPI-8811)	*Gastrointestinal* Oral mucositis	Phase 1: spray formulation	Complete Phase 1a: initiate phase 1b/2a trial
SPI-3608	Spinal stenosis	Initiate phase 1 trial	Complete phase 1 trial
SPI-017	Spinal stenosis	Phase 1 completed	Complete phase 2a study

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 our right to co-promote AMITIZA through a specialty sales force, focusing on the institutional market place, including long-term care and veteran's affairs 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 IBS-C; and reimbursement of certain stated amounts for our limited sales force deployed in the primary position to institutional customers.

In July of 2012, we announced that we received a final binding decision from the International Court of Arbitration, International Chamber of Commerce, or ICC, on our claims in our dispute with Takeda. The ICC did not agree with our claims and did not award any attorneys' fees or costs. The decision confirmed that the Takeda Agreement and all of its terms, rights and conditions for AMITIZA will remain in force until it expires in October 2020.

Development Costs. Takeda has agreed to fund all development costs, including regulatory-required studies, to a maximum of $50.0 million for each additional indication and $20.0 million for each additional 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 70.0% of the costs of such studies and we have agreed to fund the remainder. The development costs for AMITIZA for the treatment of pediatric functional constipation will be funded by Takeda up to 70.0%. From inception of the Takeda Agreement to December 31, 2012, Takeda paid an aggregate of $104.7 million in research and development reimbursement payments.

Commercialization Funding Commitment. Takeda is required to provide the funding levels necessary to fulfill its best effort obligations under the Takeda Agreement.

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 Takeda Agreement, we retain the right to co-promote AMITIZA for gastrointestinal indications. We retained the exclusive right to develop and commercialize lubiprostone 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, and reimbursement terms under the Takeda Agreement are based on actual sales representatives details presented to health care prescribers. Currently, we are not co-promoting AMITIZA.

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, 2012. 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 OIC 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. There can be no assurances that we will receive additional development or commercial milestone payments under our agreement with Takeda.

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 indications that we may develop. 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 certain subsidiaries or sub-licensees is set forth in the Takeda Agreement.

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 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 under certain conditions 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 $27.5 million through December 31, 2012, which includes a $5.0 million milestone payment as a result of submitting a marketing application for AMITIZA use in CIC to the Pharmaceutical and Medical Devices Agency, or PMDA, in September 2010 and a $15.0 million milestone payment as a result of the November 2012 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 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.

We hold the ownership rights to develop and commercialize lubiprostone and many other prostone compounds covered by patents and patent applications. In addition we hold licenses to develop and commercialize unoprostone isopropyl in certain territories. 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. As of December 31, 2012, these include a total of 37 U.S. patents, 37 U.S. patent applications, 19 European patents, 26 European patent applications, 23 Japanese patents and 28 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 26 issued U.S. patents, 12 issued European patents, and 14 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 21 issued U.S. patents, 15 issued European patents, and 9 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 2015 and 2029.

The patent rights relating to SPI-017 consist of 7 issued U.S. patents, 4 issued European patents and 7 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 2018 and 2029.

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 2018 and 2029.

The patent rights relating to unoprostone isopropyl licensed from R-Tech consist of 8 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 in 2018 and method of use in 2021. The other U.S. and foreign patents expire between 2013 and 2029.

We are actively seeking to augment our portfolio of compounds by focusing on the development of new chemical entities, or NCEs, such as 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. We are also engaged in lifecycle management strategies for our marketed products.

As a result of a notification of a patent challenge and generic drug application submission for AMITIZA, on February 8 2013, we announced that we, along with R-Tech and Takeda, filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Anchen Pharmaceuticals, Inc., or Anchen, and Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc., or Par. The lawsuit claims infringement of six patents that are listed in the FDA's Orange Book and that are scheduled to expire between 2020 and 2027.

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, 2012. 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 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 the sole supplier of lubiprostone to Takeda and to us. 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 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.

In 2009, we entered into an exclusive supply agreement with R-Tech for ten years to supply us with unoprostone isopropyl 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. In March 2012, R-Tech informed us that it was relocating its manufacturing facility to Sanda, Japan for unoprostone isopropyl beginning October 2012 and will not be able to manufacture and supply unoprostone isopropyl for up to 18 months. In the interim, R-Tech has designated another facility in Japan but such facility will need to be inspected by the FDA in 2013 before it can manufacture unoprostone isopropyl. In order to mitigate this risk, we 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. R-Tech delivered that order to us in the first quarter of 2013.

R-Tech operates a manufacturing facility near Sanda, Japan. The FDA inspected the site and concluded that it is compliant with current good manufacturing practices, or cGMP. R-Tech passed cGMP inspection from the FDA in July 2012 and by the Japanese Health Authority in February 2011.

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 RESCULA, as well as 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.

AMITIZA

Many patients are treated for CIC or IBS-C with competing OTC or prescription products, most of which are sold for occasional or infrequent constipation. In December 2012, linaclotide, a guanylin agonist dosed once a day 30 minutes before a meal, was approved for CIC and IBS-C. In the U.S., Ironwood and Forest Pharmaceuticals, Inc. are co- marketing linaclotide. In November 2012, linaclotide (co-marketed by Ironwood and Almirall, S.A.) was approved in Europe for IBS-C in adults. In Japan, Ironwood and Astellas Pharma US, Inc. have initiated a double-blind, placebo-controlled, dose-ranging phase 2 clinical trial of linaclotide in Japanese adult patients with IBS-C, and in China, Ironwood and AstraZeneca have a co-development and co-commercialization agreement for linaclotide.

Several companies also are working to develop new drugs and other therapies for CIC, IBS-C, and/or OIC. Some of these potential competitive drug products include:

- Plecanatide, a guanylate cyclase-C agonist, is being developed by Synergy Pharmaceuticals, Inc., or Synergy, which has completed a phase 2b/3 trial in CIC and is conducting a phase 2b study in IBS-C.
- Prucalopride is being developed and marketed by Movetis N.V. for the treatment of CC in adults in the E.U. Prucalopride received marketing approval in the E.U., Switzerland, Iceland, Liechtenstein and Norway for the symptomatic treatment of CC in women in whom laxatives fail to provide adequate relief. prucalopride was launched in Germany in January 2010, in the U.K. in March 2010 and in Belgium in September 2010. Movetis was acquired by Shire in September 2010, which intends to develop prucalopride in the U.S. for CC.
- SK Biopharmaceuticals commenced a phase 2 trial in 2012 to study YKP 10811, a 5-HT4 partial agonist, for CIC
- In July 2012, Ferring Pharmaceuticals acquired the global licensing rights (excluding Japan) for elobixibat, an IBAT (ileal bile acid transporter) from Albireo AB. Elobixibat will be entering phase 3 trials for CIC and phase 2B trials for IBS-C.
- Several products are in development for OIC. Seven of those products are mu-opioid receptor antagonists. Progenics Pharmaceuticals, Inc., or Progenics, received FDA approval of methylaltrexone in 2008 for the subcutaneous formulation of this drug in treating opioid bowel dysfunction in patients receiving palliative care. In July 2012, the FDA issued a complete response letter for Salix Pharmaceuticals, Inc., or Salix, and Progenics' Relistor subcutaneous injection for use in patients with chronic, non-cancer pain; Salix and Progenics are also developing an oral form of Relistor. Salix revealed that the complete response letter was due to a potential cardiovascular class effect related to opioid withdrawal associated with the chronic use of mu-opioid receptor antagonists in patients taking opioids for chronic pain. As a result, the FDA requested that Salix conduct a large, well-controlled, chronic administration trial to gain market approval for prucalopride subcutaneous and oral versions. Six other companies also have mu-opioid receptor antagonists in development: Nektar Therapeutics and AstraZeneca (naloxegol; phase 3 completed); Cubist Pharmaceuticals (bevenopran; phase 3 initiated); Theravance and GlaxoSmithKline (td-1211; phase 2b completed); S.L.A. Pharma (nalcol; phase 3 completed); and Cosmo Pharmaceuticals (CB-01-16; in phase 1).
- Shire is developing a 5-HT4 agonist which is currently in phase 3 for OIC.

RESCULA

RESCULA faces many competitors which promote products 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 on the usage of prostaglandins as first line therapy. Other competitive products on the market which also have sales force presence and a focus within the ophthalmic market include travoprost, bimatoprost ophthalmic solution, brimonidine tartrate/timolol maleate ophthalmic solution, brinzolamide ophthalmic suspension, dorzolamide hydrochloride-timolol maleate ophthalmic solution , (dorzolamide hydrochloride ophthalmic solution, brimonidine tartrate ophthalmic solution and generic beta blockers. In February 2012, Merck & Co. Inc. received approval for tafluprost ophthalmic solution 0.0015%, a preservative-free prostaglandin analog ophthalmic solution, for reducing elevated IOP in patients with open-angle glaucoma, or OAG, or ocular hypertension. Prostaglandin analogues continue to have significant first line market share followed by generic beta blockers. Other products that are in development for POAG and ocular hypertension include the Rho Kinase inhibitors and Inoteks product which is an adenosine 1 agonist.

Product Candidates

We face similar competition from approved therapies and potential drug products for the diseases and conditions addressed by lubiprostone, unoprostone isopropyl, cobiprostone, SPI-017 and 3608, 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 investigational new drug, or IND, application 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 an NDA, to the FDA. The preparation of an NDA requires the expenditure of substantial funds and the commitment of substantial resources.

Failure 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 record-keeping 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, or EMA, 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 an MAA, either under a centralized, decentralized, or mutual recognition procedure, or MRP. 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 MRP 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, cGMP 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. 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, or FCPA, 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 FCPA 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, or the ACA, 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.

United States

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. Following the U.S. Supreme Court decision in June 2012 upholding the Patient Protection and Affordable Care Act there has been an increase in the pace of regulatory issuances by those U.S. government agencies designated to carry out the extensive requirements of the ACA. These regulatory actions have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA will ultimately affect the industry. 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.

Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law as the greater of 23.1% of the average manufacturer price, or AMP, or the difference between AMP and the best price available from us to any customer (with limited exceptions). The rebate amount must be adjusted upward if AMP increases more than inflation (measured by the Consumer Price Index - Urban). The adjustment can cause the rebate amount to exceed the minimum 23.1% rebate amount. The rebate amount is calculated each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare & Medicaid Services. The requirements for calculating AMP and best price are complex. We are required to report any revisions to AMP or best price previously reported within a certain period, which revisions could affect our rebate liability for prior quarters. In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the statute governing the Medicaid Drug Rebate Program provides for civil monetary penalties.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that do not need to be injected or otherwise administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The prescription drug plans negotiate pricing with manufacturers and may condition formulary placement on the availability of manufacturer discounts. Manufacturers, including us, are required to provide a 50% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

Our products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule, or FSS. FSS participation is required for our products to be covered and reimbursed by the Veterans Administration, or VA, Department of Defense, or DoD, Coast Guard, and Public Health Service, or PHS. Coverage under Medicaid, the Medicare Part B program and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the VA, DoD (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing equal to 76.0% of the non-federal average manufacturer price, or non-FAMP. An additional discount applies if non-FAMP increases more than inflation (measured by the Consumer Price Index - Urban). In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the governing statute provides for civil monetary penalties in addition to other penalties available to the government.

To maintain coverage of our products under the Medicaid Drug Rebate Program, we are required to extend discounts to certain purchasers under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

Regulation Pertaining to Sales and Marketing

We are subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws. Anti-kickback laws generally prohibit a prescription drug manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may be no regulations, guidance or court decisions that clarify how the laws apply to particular industry practices. There is therefore a possibility that our practices might be challenged under the anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and exclusion from federal health care programs (including Medicare and Medicaid). Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers or require disclosure to the government and public of such interactions. The laws include federal “sunshine” provisions enacted in 2010 as part of the comprehensive federal health care reform legislation. The sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments made to physicians and certain other healthcare practitioners or to teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain ambiguous requirements. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations. Outside the U.S., other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

Other Regulations

Foreign Anti-Corruption

We are subject to various federal and foreign laws that govern our international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act which prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

The laws to which we are subject also include the U.K. Bribery Act 2010 (Bribery Act) which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. U.S. companies that conduct business in the U.K. generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

Other Laws

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights may be subject to national or international antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

Europe

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), and
- Cost benefit analysis

Japan

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, 2013.

Name	Age	Position
Ryuji Ueno, M.D., Ph.D., Ph.D.	59	Chief Executive Officer, Chief Scientific Officer and Director, Chairman of the Board of Directors
Cary J. Claiborne	52	Chief Financial Officer
Stanley G. Miele	48	President, Sucampo Pharma Americas, LLC and Senior Vice President of Sales and Marketing
Gayle Dolecek	70	Executive Advisor, Research and Development Affairs and member of the Board of Directors
Thomas J. Knapp	60	Executive Vice President, Chief Legal Officer 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, or CEO, 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 our wholly-owned subsidiary, Sucampo AG, or 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 controlling stockholder of S&R Technology Holdings, LLC, or S&R, which owns a majority of our stock.

Cary J. Claiborne. Mr. Claiborne joined us March 2011 as Interim Chief Financial Officer until he was promoted to Chief Financial Officer, or CFO, 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 Vice President-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, LLC 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 FDA 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 in February 2010 as Senior Vice President General Counsel and Corporate Secretary until he was promoted to Executive Vice President, Chief Legal Officer and Corporate Secretary in March 2012. Prior to joining our company, he was Of Counsel at Exemplar Law Partners, LLC and a Partner and member at Knapp Law Firm beginning in 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, LLP, or Paul Hastings, 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 in Washington, D.C. from May 1996 to April 1998 and he served in various. in-house positions culminating with Labor Counsel at The Burlington Northern & Santa Fe Railway Company, in Chicago, Illinois and Fort Worth, Texas from September 1980 to December 1995. Mr. Knapp earned a B.A. in Political Science at University of Illinois-Urbana and a J.D. at Loyola University of Chicago School of Law.

Employees

As of March 7, 2013, we had 128 full-time employees, including 36 with doctoral or other advanced degrees. Of our workforce, 32 employees are engaged in research and development, 51 are engaged in sales and marketing and 45 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 2010, 2011 and 2012, see Item 7, "*Management Discussion and Analysis of Financial Condition and Results of Operations—Research and Development Expenses*".

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 growth 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 an income before taxes of $11.5 million in 2012, compared to a loss before taxes of $6.4 million in 2011. These results primarily reflect lower expenses associated with research and development and legal expenses as well as an increase in royalty revenues.

Our segment in Europe recorded a loss before taxes of $15.9 million in 2012, compared to a loss before taxes of $10.1 million in 2011.

Our segment in Asia recorded an income before taxes of $12.2 million in 2012, compared to a loss before taxes of $5.4 million in 2011. These results primarily reflect revenue recognized during the year ended December 31, 2012 from the milestone payment received from Abbott.

(In thousands)	Americas	Europe	Asia	Consolidated
Year Ended December 31, 2012				
Total revenues	$ 61,026	$ 30	$ 20,431	$ 81,487
Income (loss) before taxes	11,463	(15,861)	12,150	7,752
Identifiable assets	87,731	25,465	14,600	127,796
Year Ended December 31, 2011				
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
Year Ended December 31, 2010				
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

Our Class Capital Structure

On August 30, 2012, we announced that our majority stockholder and only holder of our class B common stock, S&R, had converted effective as of August 29, 2012, all of its 26,191,050 issued and outstanding shares of our class B common stock into shares of our class A common stock. S&R held all of our class B common stock. Class B common stock holders were entitled to ten votes per share while class A common stock holders were entitled to one vote per share. Our Articles of incorporation permit the holder of class B common stock to convert the shares of class B common stock into shares of class A common stock at any time and on a one-for-one basis. As a result of the conversion, there is now only a single class of our common stock, class A common stock, outstanding, totaling 41,970,364 shares as of March 7, 2013, each of which is entitled to one vote per share.

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, 2012:

Subsidiary	State or other jurisdiction of incorporation or organization
Sucampo Pharma Americas, LLC	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, 3rd Floor, 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 Securities 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

If we are unable to successfully commercialize and develop in a very competitive market, our business and results of operations will be materially adversely affected.

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 of marketing and promotional expenditures.

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, manufacture and commercial 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, we must submit, among other information, the results of preclinical and clinical studies on the new indication or product candidate to the applicable regulatory authorities. The number of preclinical and clinical studies that will be required for regulatory approval varies depending on the regulatory authority, 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 regulatory authority may find such data to be insufficient to support approval of the new indication or product. The regulatory authority can delay, limit or deny approval or clearance of a new indication or product candidate for many reasons, including:

- the new indication or product candidate is not safe and effective;
- our preclinical and clinical data is interpreted in different ways than we do;
- we may be required to perform post-marketing clinical studies; or
- there may be changes in the 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.

The Company's product, AMITIZA, face competition from a competitor's products, Linzess, which, in addition to other factors, could in certain circumstances lead to a significant reduction in royalty revenues. The Company's other product, RESCULA, faces competition from other competitor's products, which, in addition to other factors, could lead to a significant reduction in product sales.

The Company's products, AMITIZA and RESCULA, face competition from competitors' products. Specifically, AMITIZA faces competition from Linzess which was recently approved for the same indications that AMITIZA has been approved. Linzess may be safer or more effective or more effectively marketed and sold than AMITIZA. Similarly, RESCULA faces competition from other competitors' products which could be more effective, has better customer access or more effectively marketed and sold. Alternatively, in the case of generic competition, including the generic availability of competitors' branded products; they may be equally safe and effective products that are sold at a substantially lower price than the Company's products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial position and prospects.

We are transitioning from being a predominantly research and development company to being a fully integrated pharmaceutical company. As we build our own commercial capabilities we will continue to rely on certain third parties for the successful commercialization of some of our drug products. The success of these third parties as well as our own commercialization efforts will affect our ability to continue to develop new drug candidates. Our own commercial success will affect our ability to reduce our reliance on the performance of these third parties.

For most of our operating history, we have been a research and development company. As we move to a fully integrated pharmaceutical company, our operations will focus on organizing and staffing our company, building the necessary infrastructure to support commercialization, developing prostone technology, undertaking preclinical and clinical trials of our product candidates, pursuing the regulatory approval processes for additional indications for AMITIZA (lubiprostone) and RESCULA (unoprostone isopropyl), and commercializing AMITIZA and RESCULA. We will continue to rely upon the collaboration agreement with Takeda and Abbott to commercialize AMITIZA in the U.S. and Japan. While we are currently utilizing R-Tech to perform the manufacturing functions and rely on Takeda and Abbott to perform many of the sales and marketing functions with respect to the sale of AMITIZA in the in the U.S. and Japan, 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 lubiprostone and unoprostone isopropyl, and to pursue regulatory approvals for lubiprostone, unoprostone isopropyl and other products outside the U.S., it could be difficult for us to access capital, to build the necessary infrastructure, and to obtain and devote the resources necessary to successfully manage our commercialization efforts and to generate the assets to support commercialization of our products.

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, or ACA, was enacted in the United States. In 2012 the U.S. Supreme Court upheld the ACA. 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, many of which have 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 AMITIZA and RESCULA for the approved indications and other indications for which we are developing these drugs, 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 ourselves, Takeda and Abbott of AMITIZA, our commercialization of RESCULA, and our continued development of AMITIZA and RESCULA. The growth in sales of AMITIZA and RESCULA will depend on several factors, including the following:

- the best efforts of Takeda and Abbott to commercialize and maximize net sales revenue of AMITIZA;
- our ability to commercialize and maximize net sales revenue of AMITIZA and RESCULA;
- our ability to complete clinical trials and secure additional indications for lubiprostone;
- the ability of R-Tech, which has the exclusive right to manufacture and supply AMITIZA, or any substitute manufacturer to supply quantities of AMITIZA sufficient to meet market demand and at acceptable levels of quality and price;
- continued and growing acceptance of AMITIZA and RESCULA 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.;
- successful development and commercialization of RESCULA; and
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities for additional indications for AMITIZA and RESCULA.

We may generate growth through acquisitions and in-licensing and such strategy 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 for our existing products and 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 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 in December 2010 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. As of December 31, 2012, the Company was compliant.

Although we have reported profit in 2012, we may not maintain operating profitability in the future this could force us to delay, reduce or abandon our commercialization efforts or product development programs.

Although we have reported net income in 2012, this was primarily attributable to our development milestones and funding under our agreements with Takeda and Abbott. We recorded a net income of $4.7 million in 2012 and 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, and commercialize AMITIZA and RESCULA. 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, our 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 as well as our commercialization 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 much of our operations by payments received under our collaboration agreements with Takeda and Abbott and milestone and other payments from R-Tech. We believe that our existing cash and cash equivalents and internally generated funds that we anticipate from AMITIZA product sales will be sufficient to enable us to fund our operating expenses 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;
- the success of our commercialization efforts of AMITIZA and RESCULA; 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.

We are developing internationally and increasing our foreign operations; therefore, we have an increased exposure to fluctuations in foreign currency exchange rates.

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 our 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.

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 may perform additional clinical trials for other indications or in support of applications for regulatory marketing approval in jurisdictions outside the U.S. for our products. These supplemental trials could be costly and could result in findings inconsistent with or contrary to our historic U.S. clinical trials.

In the future, we may be required, or we may elect, to conduct additional clinical trials of AMITIZA or RESCULA to improve the current label or address regulatory authorities concerns about AMITIZA or RESCULA. 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. 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 AMITIZA, RESCULA, 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 and RESCULA to meet our commercial and clinical requirements throughout the world and we do not have an alternative source of supply for AMITIZA and RESCULA. We also do not have an alternative source of supply for cobiprostone or SPI-017, which R-Tech manufactures and supplies to us. If R-Tech is not able to supply AMITIZA, RESCULA 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 and RESCULA would be significantly impaired and our development programs could be seriously jeopardized. R-Tech has relocated its manufacturing facility for RESCULA beginning October 2012 and will not be able to manufacture and supply unoprostone isopropyl for up to 18 months. R-Tech has informed us that it is exploring other contract manufacturing facilities while it secures a replacement manufacturing facility. 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 co-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 co-development and commercialization of AMITIZA for gastrointestinal indications in the U.S. and Canada. While we have experienced significant difficulties with Takeda's performance under that agreement, we are working with Takeda to improve the performance of the commercialization activities under that agreement. We are also party to an agreement with Abbott for the development and commercialization 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 CROs, 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 CROs 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.

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 cGCP, 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 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, RESCULA, cobiprostone and SPI-017;
- a decision whether to engage R-Tech in the future to manufacture and supply compounds other than AMITIZA, RESCULA, cobiprostone and SPI-017;
- a decision whether to renegotiate the terms of our existing agreements with R-Tech or a strategic acquisition 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, Sucampo Pharma, Ltd., or SPL, based in Tokyo and Osaka, Japan; Sucampo Pharma Europe, Ltd., or SPE, based in Oxford, U.K.; 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, 2012, 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

As a result of receiving a notification from a generic company that an Abbreviated New Drug Application from generic companies, we have recently initiated a patent infringement lawsuit against those generic companies. 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 have recently been challenged for lubiprostone through the filing of an Abbreviated New Drug Application by generic companies and other licensed patents may be challenged, invalidated or circumvented, which could limit the term of patent protection for lubiprostone or our other products, diminish our ability to stop competitors from marketing related products, and materially adversely affect our business and results of operations. We filed a patent infringement lawsuit against the generic companies and if we are not successful in that lawsuit, we may not be able to stop the generic companies from entering the market. 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. 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 and foreign regulatory agencies have 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 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 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, one of whom is a member 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. Ryuji Ueno, our chief executive officer, chief scientific officer and a chairman, and Dr. Sachiko Kuno, together beneficially own 27,680,547 shares of class A common stock, representing approximately 66.0% 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 5.0 million 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 of the conversion of class B common stock to class A common stock in August 2012, the board of directors is now a staggered board. 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:

- as a result of the August 2012 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. Because of these provisions, the value of our common stock may be materially adversely affected.

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

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

On January 2, 2013, we received a first Notice Letter and on January 25, 2013, we received a second Notice Letter from Anchen and Par regarding their filing of an Abbreviated New Drug Application with the FDA to market a generic version of AMITIZA oral capsules, 8 mcg and 24 mcg. On February 8 2013, we announced that we, along with R-Tech and Takeda, filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Anchen and Par. The lawsuit claims infringement of six patents that are listed in the FDA's Orange Book and that are scheduled to expire between 2020 and 2027.

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, 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
March 31, 2012	$ 7.64	$ 4.25
June 30, 2012	$ 8.44	$ 6.73
September 30, 2012	$ 6.95	$ 3.88
December 31, 2012	$ 6.07	$ 4.48

As of March 7, 2013, we had 41,970,364 shares of class A common stock outstanding held by 10 stockholders of record. The number of holders of record of our class A common stock is not representative of the number of beneficial holders because many shares are held by depositories, brokers or nominees. As of March 7, 2013, the closing price of our class A common stock was $4.90.

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.

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" in our Proxy Statement.

During the three and twelve months ended December 31, 2012, we repurchased shares of our class A common stock pursuant to the stock repurchase program initially approved by our Board of Directors in December 2008 as follows:

Issuer Purchases of Equity Securities*

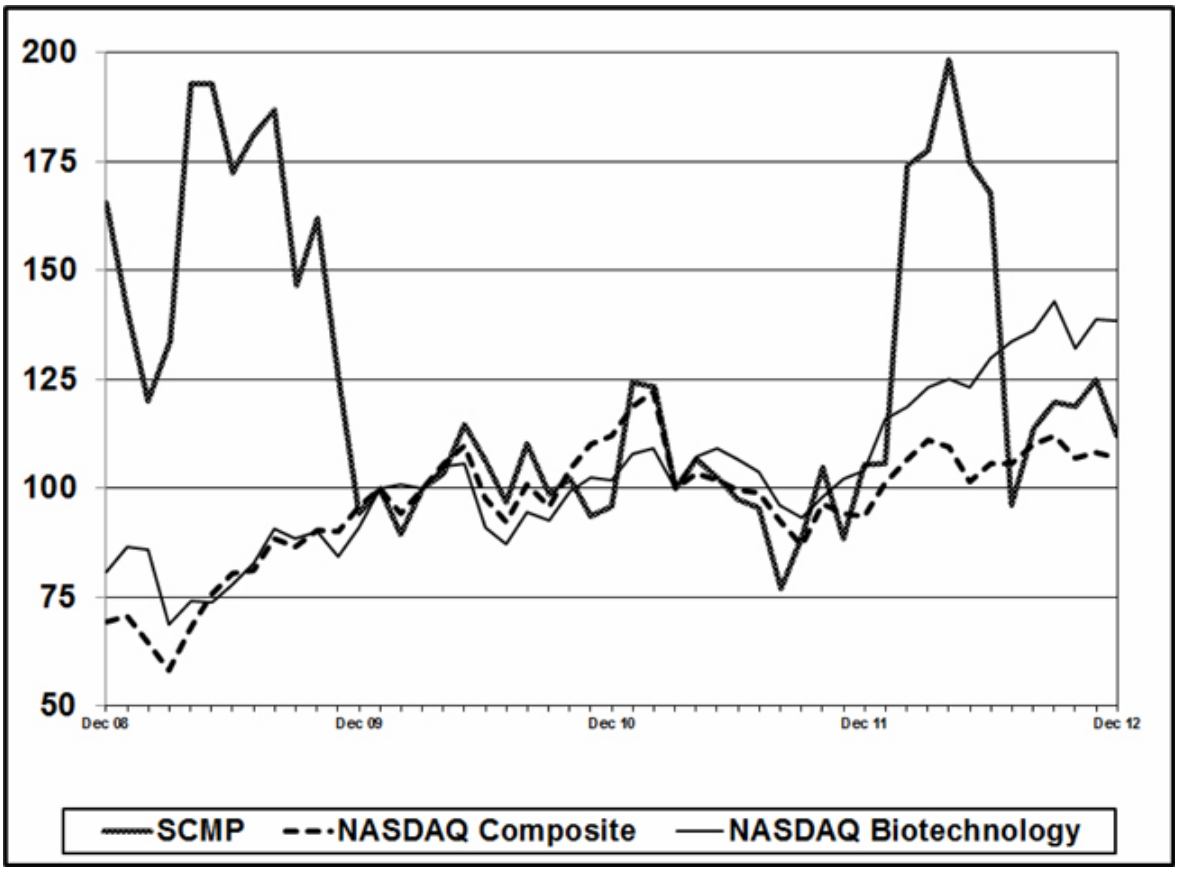
Period	**Total Number of Shares Purchased (a)**	**Average Price Paid per Share (b)**	**Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)**	**Maximum Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d)**
Month #1 (October 1, 2012 through October 31, 2012)	5,100	$ 4.70	5,100	24,146
Month #2 (November 1, 2012 through November 30, 2012)	74,069	$ 4.89	74,069	389,633
Month #3 (December 1, 2012 through December 31, 2012)	67,739	$ 4.87	67,739	721,487
Total	146,908	$ 4.28	146,908	721,487

*On December 11, 2008, we announced a stock repurchase program approved by our Board of Directors 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, we announced that 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 approved. On November 2, 2012, our Board of Directors authorized the increase of such amount of repurchase to up to an aggregate of $5.0 million. The stock repurchase program is expected to continue through the third quarter of 2013 unless extended or shortened. During the fourth quarter and twelve months ended December 31, 2012, we repurchased 146,908 and 270,043 shares, respectively, of our class A common stock under this program at a cost of $721,487 and $1,277,296, respectively. 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.

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, 2011, 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, 2011 and 2012 and for the years ended December 31, 2010, 2011 and 2012 from our audited Consolidated Financial Statements appearing elsewhere in this Annual Report. We have derived the following consolidated financial data as of December 31, 2008, 2009 and 2010 and for the years ended December 31, 2008 and 2009 from audited Consolidated Financial Statements, which are not included in this Annual Report. The information set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and related footnotes appearing elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
(In thousands, except per share data)	**2012**	**2011**	**2010**	**2009**	**2008**
Statement of operations data					
Revenues	$ 81,487	$ 54,761	$ 61,870	$ 67,351	$ 112,123
Cost of goods sold	3,030	-	-	-	-
Gross profit	78,457	54,761	61,870	67,351	112,123
Operating expenses:					
Research and development	21,292	33,497	23,955	32,906	46,181
Settlement of legal dispute	-	(11,100)	-	-	-
General and administrative	30,157	41,270	27,867	15,000	15,075
Selling and marketing	18,691	8,783	10,201	10,030	10,895
Total operating expenses	70,140	72,450	62,023	57,936	72,151
Income (loss) from operations	8,317	(17,689)	(153)	9,415	39,972
Total non-operating income (expense), net	(565)	(4,225)	(3,167)	446	466
Income (loss) before income taxes	7,752	(21,914)	(3,320)	9,861	40,438
Income tax benefit (provision)	(2,916)	4,608	565	(5,084)	(8,925)
Net income (loss)	$ 4,836	$ (17,306)	$ (2,755)	$ 4,777	$ 31,513
Basic net income (loss) per share	$ 0.12	$ (0.41)	$ (0.07)	$ 0.11	$ 0.75
Diluted net income (loss) per share	$ 0.12	$ (0.41)	$ (0.07)	$ 0.11	$ 0.75
Weighted average common shares outstanding - basic	41,660	41,839	41,848	41,844	41,787
Weighted average common shares outstanding - diluted	41,785	41,839	41,848	41,866	41,973

	December 31,				
(In thousands)	**2012**	**2011**	**2010**	**2009**	**2008**
Balance sheet data:					
Cash and cash equivalents	$ 52,022	$ 50,662	$ 49,243	$ 61,420	$ 93,704
Investments, current	6,035	24,452	54,524	72,434	42,750
Working capital	52,843	67,835	94,541	127,313	128,901
Total assets	127,796	157,569	149,273	180,005	182,354
Notes payable, current	19,129	20,400	19,522	-	-
Notes payable, non-current	33,722	39,227	44,439	-	-
Total liabilities	84,766	118,975	95,443	34,693	40,159
Retained earnings (accumulated deficit)	(34,100)	(38,936)	(21,630)	33,150	31,310
Total stockholders' equity	43,030	38,594	53,830	145,312	142,195

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 a global pharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs based on prostones and other novel drug technologies. Prostones are naturally occurring fatty acid metabolites.

We have two approved products, AMITIZA (lubiprostone) and RESCULA (unoprostone isopropyl). Our priorities are: for AMITIZA, to increase sales in the U.S., Japan and Europe, to expand into new indications, and to launch into new markets; for RESCULA, to successfully launch in the U.S., to expand into new indications, and launch into new markets; and to further develop our late-stage clinical development programs.

First, in the U.S., AMITIZA is being marketed and developed under a collaboration and license agreement with Takeda, for gastrointestinal indications. In Japan, AMITIZA is being marketed under a collaboration agreement with Abbott Japan. AMITIZA is also approved in the U.K. and Switzerland, with other filings within Europe under way; commercialization in Switzerland and the U.K. is underway. Our priorities for AMITIZA are to obtain approval of AMITIZA for OIC in the U.S. (priority review status; PDUFA of late April 2013) and certain European markets, as well as to develop AMITIZA in an oral formulation for the pediatric market.

Second, RESCULA received approval of an sNDA by the FDA in December 2012, and in the first quarter of 2013 we launched the product within the ophthalmology and optometry communities. This launch marks the first time we have commercialized a product in the U.S.

Third, a final priority for us is the development of our prostone-based pipeline. In 2012, we furthered our clinical development of three drug candidates: cobiprostone for OM, and SPI-017 and SPI-3608 for lumbar spinal stenosis.

We currently generate revenue mainly from product royalties, development milestone payments, clinical development activities and product sales. We expect to continue to incur significant expenses for the next several years as we continue our research and development activities, seek additional regulatory approvals for additional indications for AMITIZA, RESCULA and other compounds, and commercialize our approved products (as discussed below) on a global basis.

Our operations are conducted through subsidiaries based in Japan, the U.S., Switzerland, the U.K., and Luxembourg. 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 growth 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 are developing AMITIZA for OIC, for which we received FDA priority review. The PDUFA goal date is end of April 2013, extended from its original date of late January 2013. No new clinical trials or studies were requested by the FDA.

AMITIZA (lubiprostone) in Japan. We received approval of our NDA for AMITIZA for the treatment of CC excluding constipation caused by organic diseases, from the MHLW in June 2012, and pricing approval from the MHLW in November 2012. In November 2012, Abbott launched the product, which is Japan's only prescription medicine for CC, into the market. Based on initial sales, we believe that we will have a successful launch in Japan.

AMITIZA (lubiprostone) in other countries. We have retained full rights to develop and commercialize AMITIZA ourselves for the rest of the world's markets outside of the U.S., Canada and Japan. In the U.K., we received approval in September 2012 from the MHRA for the use of AMITIZA to treat CIC, and are currently working to achieve NICE endorsement, which we believe is important for commercialization in the U.K., and launch in the U.K. in 2013. In Switzerland, AMITIZA was approved in 2009 and has been made available through a Named Patient Program throughout the E.U., Switzerland, Iceland and Norway since February 2012. In 2012, we reached agreement with the BAG on a reimbursement price for AMITIZA in Switzerland, which was important in order to begin active marketing of the product, which commenced in the first quarter 2013.

We plan to commence the approval process in other E.U countries for CIC via the MRP in 2013. In the first quarter of 2013, we also filed for an OIC indication in the U.K and Switzerland. If we receive approval in the U.K., we will seek approval in other E.U. countries following the MRP for OIC.

RESCULA (unoprostone isopropyl). We began commercializing RESCULA in the U.S. for its approved indication in February 2013. We placed and received 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. We began marketing RESCULA to healthcare providers in early February 2013, and early sample request volume exceeded our expectations, demonstrating demand for the product.

We are also evaluating the opportunities to obtain an appropriate label in the E.U. and other European countries, and the timing of seeking reauthorization in those countries to commercialize unoprostone isopropyl. In addition, we are co-developing unoprostone isopropyl with R-Tech and may file for FDA and EMA approval for the treatment of RP in the future assuming the successful trials.

Cobiprostone. We are expected to conclude phase 1 clinical development for the target indication of the prevention of OM in 2013 Our orphan drug application for cobiprostone for OM is under review with the FDA because the FDA believes that anyone who has cancer and at risk for developing OM would take the drug and thus the target population and estimate are larger than orphan drug status.

Other. SPI-017 and SPI-3608, two additional prostone-based products, are also in clinical development for the indication of the management of pain caused by spinal stenosis, and SPI-017 is currently in a phase 2A trial that is expected to conclude by the fourth quarter of 2013.

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

Upfront Payment

Upon signing the Abbott Agreement in February 2009, we received a non-refundable upfront payment of $10.0 million.

Product Development Milestone Payments

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

- $7.5 million upon the initiation of the phase 3 clinical trial for lubiprostone for the treatment of CIC in Japanese patients in May 2009;
- $5.0 million as a result of submission of a marketing application to the PMDA for AMITIZA at dosage strength of 24 micrograms for the indication of CIC in October 2010; and
- $15.0 million as a result of first commercial sale of AMITIZA at dosage strength of 24 micrograms in Japanese adults in November 2012.

There can be no assurances that we will receive additional development or commercial milestone payments under our agreement with Abbott.

Product Revenue

We 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 Received Through December 31, 2012	Revenue Recognized for the Year Ended December 31, Through 2010	2011	2012	Accounts Receivable for the Year Ended December 31, 2012	Foreign Currency Effects	Amount Deferred at December 31, 2012
Collaboration revenue:							
Up-front payment associated with the Company's obligation to participate in joint committees	$ 846	$ 85	$ 52	$ 52	$ -	$ (68)	$ 725
Research and development revenue:							
Up-front payment - remainder	$ 9,154	$ 8,583	$ 520	$ 199	$ -	$ (148)	$ -
Development milestone payment	27,500	11,901	697	15,157	-	(255)	$ -
Total	$ 36,654	$ 20,484	$ 1,217	$ 15,356	$ -	$ (403)	$ -
Product sales revenue:	$ 4,924	$ -	$ -	$ 5,023	$ 99	$ -	$ -

Financial Terms of our License and Collaboration Agreement with Takeda

Upfront Payment

Upon signing the Takeda Agreement in October 2004, 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 upon the filing of the sNDA 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 sale of AMITIZA for OIC or other additional indication.

Research and Development Cost-Sharing for AMITIZA

Our Takeda Agreement and Supplemental Takeda Agreement 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, 2012, the related aggregate research and development expense incurred was $45.8 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, 2012, we had incurred $2.4 million of these expenses, of which we were reimbursed approximately $1.6 million by Takeda.
- The expense of ongoing and future clinical development of AMITIZA for the treatment of pediatric functional constipation will be borne by Takeda up to 70.0%. As of December 31, 2012, we had incurred $1.9 million of these expenses, 70.0% 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 OIC. Through December 31, 2012, we had incurred $76.9 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. Through December 31, 2012, we have incurred $1.6 million of expenses to date relating to liquid formulation.

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 $3.6 million, $3.4 million and $4.4 million of co-promotion revenue reflecting these reimbursements for the years ended December 31, 2012, 2011 and 2010, respectively. For 2013, we will not be reimbursed any co-promotion expenses as our sales force will not be promoting AMITIZA, and will instead be promoting RESCULA.

Takeda also agreed to reimburse us for all of the costs we incur in connection with specified miscellaneous marketing activities related to the promotion of AMITIZA.

Product Royalty Revenue

Takeda is obligated to pay us a sliding royalty rate based on a percentage of the net sales revenue from the sale of AMITIZA in the U.S. and Canada. The actual percentage depends on the level of net sales revenue attained each calendar year. All sales of AMITIZA in the U.S. and Canada, including those arranged by our specialty sales force, are made through Takeda. AMITIZA is currently marketed only in the U.S. and during the years ended December 31, 2012, 2011 and 2010 we recognized a total of $50.7 million, $41.5 million and $40.3 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, 2012.

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, 2012	Revenue Recognized for the Year Ended December 31,			Accounts Receivable for the Year Ended December 31, 2012 (1)	Amount Deferred at December 31, 2012
		Through 2010	2011	2012		
Collaboration revenue:						
Up-front payment associated with the Company's obligation to participate in joint committees	$ 2,375	$ 905	$ 147	$ 147	$ -	$ 1,176
Research and development revenue:						
Up-front payment - remainder	$ 17,624	$ 17,624	$ -	$ -	$ -	$ -
Development milestones	130,000	130,000	-	-	-	-
Reimbursement of research and development expenses	104,653	92,230	8,032	6,189	2,047	249
Total	$ 252,277	$ 239,854	$ 8,032	$ 6,189	$ 2,047	$ 249
Product royalty revenue	$ 225,152	$ 147,114	$ 41,517	$ 50,696	$ 14,175	$ -
Co-promotion revenue	$ 28,613	$ 22,438	$ 3,378	$ 3,576	$ 779	$ -

(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 total cash receipts of $6.0 million 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, 2012 and 2011, respectively, which is recorded as contract revenue. During the years ended December 31, 2012, 2011 and 2010, we purchased clinical supplies from R-Tech of approximately $1.4 million, $72,000 and $344,000, 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 2012, 2011 or 2010. During the years ended December 31, 2012, 2011 and 2010, we purchased approximately $124,000, $125,000 and $110,000, respectively, of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch in Europe.

Under the two-year exclusive clinical manufacturing and supply agreement with R-Tech for cobiprostone and SPI-017 and during the year ended December 31, 2010, we purchased from R-Tech approximately $48,000 of clinical supplies under the terms of this agreement. There were no such clinical supplies purchases in 2012 or 2011.

We entered into an exclusive supply arrangement 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, 2012, 2011 and 2010, we purchased approximately $3.1 million, $166,000 and $267,000, respectively, of commercial supplies of lubiprostone from R-Tech under this agreement. During the year ended December 31, 2012, we purchased approximately $10,000 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 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 re-launch of RESCULA for the treatment of glaucoma, which occurred in February 2013, and will be paid in the first quarter of 2013.

Under the terms of the 2011 agreement, we may be required to pay up to $100.0 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. Through December 31, 2012, we made milestone payments to R-Tech of $6.0 million, including $3.0 million in the first quarter of 2012, which is reflected in other non-current assets in the accompanying Consolidated Balance Sheets.

We have also made purchases for other research and development services during the years ended December 31, 2012, 2011, and 2010 of approximately $466,000, $104,000 and $69,000, respectively.

In March 2012, R-Tech has informed us that it is relocating its manufacturing facility for unoprostone isopropyl beginning October 2012 and will not be able to manufacture and supply unoprostone isopropyl for up to 18 months. R-Tech has designated another facility in Japan but such facility will need to be inspected by the FDA in 2013 before it can manufacture unoprostone isopropyl. In order to mitigate this risk, we placed an order of approximately $5.3 million to cover this supply period based on our forecasts for the launch of RESCULA in the U.S. R-Tech commenced delivery of that order to us in the first quarter of 2013.

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

	Year Ended December 31,		
(In thousands)	**2012**	**2011**	**2010**
Clinical supplies	$ 1,450	$ 72	$ 392
Other research and development services	466	104	69
Commercial supplies	3,288	155	376
	$ 5,204	$ 331	$ 837

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 assumptions 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, product royalties and product sales.

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.

In October 2009, the FASB issued new revenue recognition standards for arrangements with multiple deliverables, which were effective for us as of January 1, 2011. These standards address the determination of the unit(s) of accounting for multiple-element arrangements and how the arrangement's consideration should be allocated to each unit of accounting. An item can generally be considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of us. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on vendor-specific objective evidence, or VSOE, if available; third-party evidence, if VSOE is unavailable; and estimated selling prices if neither VSOE nor third-party evidence is available. The new accounting standards were adopted by us on a prospective basis on January 1, 2011. We did not enter into any new multiple-element arrangements or materially modify any existing arrangements during 2011. The adoption of these standards did not have a material effect on our consolidated results of operations, financial position or liquidity.

Where agreements include contingent milestones we evaluate whether each milestone is substantive. Milestones are considered substantive if all of the following conditions are met: (1) it is commensurate with either our performance to meet the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the our performance to achieve the milestone, (2) it relates solely to past performance, and (3) the value of the milestone is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement. Where milestones are not considered substantive their treatment is based on either a time-based or proportional performance model.

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. The milestone recognized and received in 2012 was considered a substantive milestone.

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.

Product sales predominately consist of AMITIZA sales to Abbott in Japan. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to product and associated risk of loss have passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured. We do not record sales deductions and returns for sales of AMITIZA to Abbott due to the absence of discounts and rebates and no right of return under the contract with Abbott.

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 CROs 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. 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, we 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. As of December 31, 2012, the total deferred charge is $5.9 million after a net current year amortization expense of $77,000.

As of December 31, 2012 and 2011, we had foreign net operating loss, or NOLs, carry forwards of $21.0 million and $16.4 million, respectively. Approximately $10.9 million of the foreign NOL begin to expire in December 2019, and $10.1 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 de-recognition 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 recognize interest and penalties accrued related to uncertain tax positions as a component of the income tax provision. The liability for uncertain tax positions as of December 31, 2012 mainly pertains to our interpretation of nexus in certain states related to certain revenue sources for state income tax purposes. We expect to file income tax returns in 2013 in several states where we have recorded a liability for uncertain tax positions as of December 31, 2012. Therefore, the amount expected to reverse within the next twelve months has been recorded as a current liability. Other than the expected settlement with various state tax authorities, no other uncertain tax positions have been identified 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 and 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, 2012 and December 31, 2011

Revenues

The following table summarizes our revenues for the years ended December 31, 2012 and 2011:

	Year Ended December 31,	
(In thousands)	**2012**	**2011**
Research and development revenue	$ 21,545	$ 9,249
Product royalty revenue	50,696	41,517
Co-promotion revenue	3,576	3,378
Contract and collaboration revenue	633	617
Product sales revenue	5,037	-
Total	$ 81,487	$ 54,761

Total revenues were $81.5 million in 2012 compared to $54.8 million in 2011, an increase of $26.7 million, or 48.8%.

Research and development revenue

Research and development revenue was $21.5 million in 2012 compared to $9.2 million in 2011, an increase of $12.3 million or 132.9%. The increase was primarily due to the receipt of the $15.0 million milestone from Abbott upon the first commercial sale of AMITIZA at dosage strength of 24 micrograms in Japanese adults.

Product royalty revenue

Product royalty revenue represents royalty revenue earned on net sales of AMITIZA in the United States, as reported to us by our partner, Takeda. In 2012, we recognized $50.7 million of product royalty revenue compared to $41.5 million in 2011, an increase of $9.2 million or 22.1%. The increase was primarily due to higher price and volume of AMITIZA net sales.

Co-promotion revenue

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force. In 2012, we recognized $3.6 million of co-promotion revenues compared to $3.4 million in 2011, an increase of $198,000, as a result of a change in the method of reimbursement following the ending of the applicable provision in the Supplemental Takeda Agreement.

Product sales revenue and cost of goods sold

Product sales revenue and cost of goods sold represents sales of AMITIZA in Europe and Japan. In 2012, we recognized $5.0 million of product sales revenue and $3.0 million of cost of goods sold compared to nil in 2011, respectively.

Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2012 and 2011:

	Year Ended December 31,	
(In thousands)	**2012**	**2011**
Direct costs:		
Lubiprostone	$ 8,311	$ 23,998
Cobiprostone	2,019	520
SPI-017	581	611
Unoprostone isoproypl	2,819	2,961
Other	5,179	3,694
Total	18,909	31,784
Indirect costs	2,383	1,713
Total	$ 21,292	$ 33,497

Total research and development expenses in 2012 were $21.3 million compared to $33.5 million in 2011, a decrease of $12.2 million, or 36.4%. The decrease was primarily due to higher expenses in 2011 associated with the completion of the phase 3 OIC trial for AMITIZA.

General and Administrative Expenses

The following summarizes our general and administrative expenses for years ended December 31, 2012 and 2011:

	Year Ended December 31,	
(In thousands)	**2012**	**2011**
Salaries, benefits and related costs	$ 8,381	$ 6,670
Legal, consulting and other professional expenses	12,621	27,225
Stock option expense	1,349	964
Other expenses	7,806	6,411
Total	$ 30,157	$ 41,270

General and administrative expenses were $30.2 million in 2012 compared to $41.3 million in 2011, a decrease of $11.1 million, or 26.9%. The decrease in legal, consulting and other professional expenses relates primarily to lower costs incurred following the conclusion of certain legal matters, including our concluded disputes with Takeda and a CRO. The increase in other expenses primarily relates to higher costs incurred in connection with corporate marketing and branding and staff organizations to support business growth.

Selling and Marketing Expenses

The following summarizes our selling and marketing expenses for years ended December 31, 2012 and 2011:

	Year Ended December 31,	
(In thousands)	**2012**	**2011**
Salaries, benefits and related costs	$ 7,232	$ 5,701
Consulting and other professional expenses	4,220	9
Stock option expense	349	172
Other expenses	6,890	2,901
Total	$ 18,691	$ 8,783

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 $18.7 million in 2012 compared to $8.8 million in 2011, an increase of $9.9 million, or 112.8%. The increase in consulting and other professional expenses and other expenses relates primarily to some non-recurring pre-commercialization planning activities for AMITIZA, and commercialization and launch costs for RESCULA. Part of the ongoing 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, 2012 and 2011:

	Year Ended December 31,	
(In thousands)	**2012**	**2011**
Interest income	$ 179	$ 249
Interest expense	(2,346)	(2,455)
Other income (expense), net	1,602	(2,019)
Total	$ (565)	$ (4,225)

Interest income was $179,000 in 2012 compared to $249,000 in 2011, a decrease of $70,000, or 28.1%. The decrease was primarily due to lower prevailing interest rates earned by our investments and lower cash balances.

Interest expense was $2.3 million in 2012 compared to $2.5 million in 2011, a decrease of $109,000, or 4.4%. The decrease was primarily due to lower debt balance.

Other income was $1.6 million in 2012 compared to other expense of $2.0 million in 2011, an increase of $3.6 million. The majority of the increase relates to foreign exchange losses in the prior year that are unrealized, non-cash and that relate to amounts held within subsidiaries.

Income Taxes

For the years ended December 31, 2012 and 2011, our consolidated effective income tax rate was 37.6% and 21.0%, respectively. For the years ended December 31, 2012 and 2011, we recorded a tax expense of $2.9 million and a tax benefit of $4.6 million, respectively. The tax expense for the year ended December 31, 2012 includes a benefit of approximately $1.9 million related to the reassessment of the partial internal transfer of intellectual property. The change in our effective tax rate in 2012 from 2011 was attributable primarily to the change in the effective state tax rate, impact of the intellectual property transfer, 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, 2012, the remaining valuation allowance against our deferred tax assets was $4.1 million and related 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, 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	$ 54,761	$ 61,870

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 awaited 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, as reported to us by our partner, Takeda. 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%. The increase was primarily due to higher price and volume of AMITIZA net sales.

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	31,784	21,649
Indirect costs	1,713	2,306
Total	$ 33,497	$ 23,955

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 OIC 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 expenses are reimbursed and included as revenue, as described in the accounting policies and 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:

	Year Ended December 31,	
(In thousands)	**2011**	**2010**
Salaries, benefits and related costs	$ 6,670	$ 5,567
Legal, consulting and other professional expenses	27,225	15,337
Stock option expense	964	-
Other expenses	6,411	6,963
Total	$ 41,270	$ 27,867

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 on-going 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

The following summarizes our selling and marketing expenses for years ended December 31, 2011 and 2010:

	Year Ended December 31,	
(In thousands)	**2011**	**2010**
Salaries, benefits and related costs	$ 5,701	$ 5,489
Consulting and other professional expenses	9	748
Stock option expense	172	280
Other expenses	2,901	3,684
Total	$ 8,783	$ 10,201

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:

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

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 our 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.

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 growth 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 an income before taxes of $11.5 million in 2012, compared to a loss before taxes of $6.4 million in 2011. These results primarily reflect lower expenses associated with research and development and legal expenses as well as an increase in royalty revenues.

Our segment in Europe recorded a loss before taxes of $15.9 million in 2012, compared to a loss before taxes of $10.1 million in 2011.

Our segment in Asia recorded an income before taxes of $12.2 million in 2012, compared to a loss before taxes of $5.4 million in 2011. These results primarily reflect revenue recognized during the year ended December 31, 2012 from the milestone payment received from Abbott.

(In thousands)	**Americas**	**Europe**	**Asia**	**Consolidated**
Year Ended December 31, 2012				
Total revenues	$ 61,026	$ 30	$ 20,431	$ 81,487
Income (loss) before taxes	11,463	(15,861)	12,150	7,752
Identifiable assets	87,731	25,465	14,600	127,796
Year Ended December 31, 2011				
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
Year Ended December 31, 2010				
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

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, 2012	2011
Cash and cash equivalents	$ 52,022	$ 50,662
Restricted cash, current	15,113	15,113
Restricted cash, non-current	3,832	2,129
Investments, current	6,035	24,452
Investments, non-current	14,408	998
Total	$ 91,410	$ 93,354

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, 2012 and 2011, our restricted cash consisted primarily of the collateral pledged to support a loan with The Bank of Tokyo-Mitsubishi UFJ, Ltd., Numab's loan with Zurcher Kantonalbank and operating leases with certain financial institutions.

As of December 31, 2012, our short-term investments consisted of U.S. corporate commercial paper, municipal securities, certificates of deposits and variable rate demand notes which have short-term maturities of one year or less. Our non-current investments consisted of U.S. government securities, certificates of deposits and corporate bonds.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2012, 2011 and 2010:

(In thousands)	Year Ended December 31, 2012	2011	2010
Cash provided by (used in):			
Operating activities	$ 12,000	$ (19,991)	$ (3,350)
Investing activities	(589)	27,901	(11,856)
Financing activities	(8,446)	(8,081)	(1,635)
Effect of exchange rates	(1,605)	1,590	4,664
Net increase (decrease) in cash and cash equivalents	$ 1,360	$ 1,419	$ (12,177)

Year ended December 31, 2012

Net cash provided by operating activities was $12.0 million for the year ended December 31, 2012. This reflected a net income of $4.8 million, non-cash interest expense of $2.0 million, non-cash stock based compensation of $2.2 million, depreciation and amortization of $1.5 million and changes in other operating assets and liabilities.

Net cash used in investing activities of $589,000 for the year ended December 31, 2012 primarily reflected our purchases of investments, intangible assets and an increase in restricted cash, offset in part by our proceeds from the sales and maturities of investments.

Net cash used in financing activities of $8.4 million for the year ended December 31, 2012 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, 2012 was a decrease of $1.6 million.

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.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for year ended December 31, 2010 was an increase of $4.7 million.

Commitments and Contingencies

As of December 31, 2012, 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 for the indicated year as of:

(In thousands of U.S. dollars)	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Loans	$ 19,129	$ 7,873	$ 8,234	$ 8,611	$ 9,005	$ 52,852
Interest on loans	1,750	1,411	1,057	687	301	5,206
Operating lease commitments	1,275	1,068	1,052	1,084	139	4,618
Purchase commitments*	5,355	-	-	-	-	5,355
Contract research commitments	3,469	36	15	-	-	3,520
	$ 30,978	$ 10,388	$ 10,358	$ 10,382	$ 9,445	$ 71,551

*We had an outstanding purchase order commitment of approximately $5.3 million with R-Tech (see Note 10 below).

The above table does not include:

- Our share of research and development costs for AMITIZA for the treatment of OIC, which will not be reimbursed by Takeda. We share equally with Takeda research and development expenses in excess of $50.0 million.
- 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, 2012 the potential amount of payments in the event of Numab's default was $3.8 million (see Note 10 below).

Off-Balance Sheet Arrangements

As of December 31, 2012, 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

On December 11, 2008, we announced a stock repurchase program approved by the Board of Directors 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, we announced that our Board of Directors authorized the repurchase of up to an aggregate of $2.0 million of its Class A common stock out of the $10.0 million approved. On November 2, 2012, our Board of Directors authorized the increase of such amount of repurchase up to an aggregate of $5.0 million. During 2011, we repurchased 186,987 shares of our class A common stock under this program at a cost of $700,000. During 2012, we repurchased 270,043 shares of our class A common stock under this program at a cost of $1.3 million. All shares of class A common stock purchased in 2012 were purchased in August, September, October, November and December.

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

- our share of the on-going development program of AMITIZA in the U.S.;
- the launch and growth of RESCULA 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, SPI-3608 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 $5.0 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 of Directors; and
- the satisfaction of the conditions of our loan note obligations.

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

- the 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.

As of December 31, 2012, we have sufficient liquidity for the next 12 months. 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.

Effects of Foreign Currency

We currently incur a portion of our operating expenses in Switzerland, Japan and the 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 February 2013, the FASB issued an accounting update on Comprehensive Income-Topic 220: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income, which requires the Company to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, the Company is required to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, the Company is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. This update will be effective for public companies during the interim and annual periods beginning after December 15, 2012. The Company does not expect that the adoption of this guidance will have a material impact on the Company's consolidated financial statements.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

Foreign Currency Exchange Rate 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 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, 2012.

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, 2012 and December 31, 2011, approximately 18.4% and 16.7%, 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 Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2012. 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, 2012, 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 SEC, 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 Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (defined in Rules 13a-15(f) or 15d-15(f) 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, 2012. 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, 2012.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2012 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.	Cary J. Claiborne
Chief Executive Officer, Chief Scientific Officer and Chairman of the Board of Directors	*Chief Financial Officer*
(Principal Executive Officer)	*(Principal Financial Officer)*

ITEM 9B. OTHER INFORMATION

Conversion of Class B common stock

On August 30, 2012, we announced that our majority stockholder and only holder of our class B common stock, S&R had converted effective as of August 29, 2012, all of its 26,191,050 issued and outstanding shares of our class B common stock into shares of our class A common stock. S&R held all of our class B common stock. Class B common stock holders were entitled to ten votes per share while class A common stock holders were entitled to one vote per share. Our Articles of incorporation permit the holder of class B common stock to convert the shares of class B common stock into shares of class A common stock at any time and on a one-for-one basis. As a result of the conversion, there is now only a single class of our common stock, class A common stock, outstanding, totaling 41,970,364 shares as of March 7, 2013, each of which is entitled to one vote per share.

Board Classification

In accordance with our Articles of Incorporation, upon the date of the conversion of the class B common stock to class A common stock our Board of Directors was automatically divided into three classes. All directors within a class have the same three-year term of office. The class terms expire at successive annual stockholder meetings so that each year a class of directors is elected. The current terms of director classes expire in 2013 (Class I directors), 2014 (Class II directors), and 2015 (Class III directors).

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 2013 Annual Meeting to be filed within 120 days after the fiscal year end of December 31, 2012, 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” in our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information regarding certain relationships and related transactions is incorporated by reference to the information provided under the heading “Related Party Transactions” in our Proxy Statement. The information regarding director independence is incorporated by reference to the information provided under the heading “Corporate Governance Principles and Board Matters, Board Structure and Committee Composition – Board Determination of Independence.”

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” in our Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(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.

Exhibit Number	Description	Reference
2.1	Agreement and Plan of Reorganization, dated as of December 29, 2008, by and among the Company, Sucamp Pharma Holdings, Inc. and Sucampo MS, Inc.	Exhibit 2.1 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^	Amended and Restated 2001 Stock Incentive Plan	Exhibit 10.1 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.2^	Amended and Restated 2006 Stock Incentive Plan	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (filed November 14, 2007)
10.3^	2006 Employee Stock Purchase Plan	Exhibit 10.3 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.4^	Form of Incentive Stock Option Agreement for 2006 Stock Incentive Plan	Exhibit 10.4 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.5^	Form of Nonstatutory Stock Option Agreement for 2006 Stock Incentive Plan	Exhibit 10.5 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.6^	Form of Restricted Stock Agreement for 2006 Stock Incentive Plan	Exhibit 10.6 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)

10.7^	Non-employee Director Compensation Summary	Exhibit 10.7 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.8^	Employment Agreement, dated June 16, 2006, between the Company and Ryuji Ueno	Exhibit 10.9 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.9^	Form of Executive Employment Agreement	Exhibit 10.10 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.10	Indemnification Agreement, dated May 26, 2004, between the Company and Sachiko Kuno	Exhibit 10.11 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.11	Indemnification Agreement, dated May 26, 2004, between the Company and Ryuji Ueno	Exhibit 10.12 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.12	Indemnification Agreement, dated May 26, 2004, between the Company and Michael Jeffries	Exhibit 10.13 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.13	Indemnification Agreement, dated May 26, 2004, between the Company and Hidetoshi Mine	Exhibit 10.14 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.14	Form of Investor Rights Agreement	Exhibit 10.16 to Registration Statement No. 333-135133, (filed June 19, 2006)
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 Quarterly 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 Annual 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 Annual 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 Quarterly 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	Exhibit 10.58 to the Company's Annual Report on Form 10-K (filed March 15, 2012)
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 Quarterly 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	Exhibit 10.60 to the Company's Annual Report on Form 10-K (filed March 15, 2012)
10.61	Master Lease Agreement, effective as of January 31, 2012, between Sucampo AG and Numab AG	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (filed May 10, 2012)
10.62^	Employment Agreement, effective as of December 31, 2012, between the Company and Ryuji Ueno	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.63^	Employment Agreement, effective as of December 31, 2012, between the Company and Gayle Dolecek	Exhibit 99.2 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.64^	Employment Agreement, effective as of December 31, 2012, between the Company and Cary J. Claiborne	Exhibit 99.3 to the Company's Current Report on Form 8-K (filed January 7, 2013)

10.65^	Employment Agreement, effective as of December 31, 2012, between the Company and Stanley G. Miele	Exhibit 99.4 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.66^	Employment Agreement, effective as of December 31, 2012, between the Company and Thomas J. Knapp	Exhibit 99.5 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.67^	Form of Indemnification Agreement, dated December 31, 2012, between the Company and each of Ryuji Ueno, Gayle Dolecek, Cary J. Claiborne, Stanley G. Miele and Thomas J. Knapp	Exhibit 99.6 to the Company's Current Report on Form 8-K (filed January 7, 2013)
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 18, 2013

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

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

Signature	Title	Date
/s/ RYUJI UENO Ryuji Ueno, M.D., Ph.D., Ph.D.	Chief Executive Officer (Principal Executive Officer), Chief Scientific Officer and Chairman	March 18, 2013
/s/ CARY J. CLAIBORNE Cary J. Claiborne	Chief Financial Officer (Principal Financial Officer)	March 18, 2013
/s/ ANDREW P. SMITH Andrew P. Smith	Principal Accounting Officer	March 18, 2013
/s/ WILLIAM L. ASHTON William L. Ashton	Director	March 18, 2013
/s/ ANTHONY C. CELESTE Anthony C. Celeste	Director	March 18, 2013
/s/ GAYLE R. DOLECEK Gayle R. Dolecek, P.D.	Director	March 18, 2013
/s/ DANIEL P. GETMAN Daniel P. Getman	Director	March 18, 2013
/s/ BARBARA A. MUNDER Barbara A. Munder	Director	March 18, 2013
/s/ MAUREEN E. O'CONNELL Maureen E. O'Connell	Director	March 18, 2013

SUCAMPO PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

In our opinion, the consolidated financial statements listed in the index appearing under Item 15 (a) (1) present fairly, in all material respects, the financial position of Sucampo Pharmaceuticals, Inc. and its subsidiaries at December 31, 2012 and December 31, 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 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, 2012, 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 Annual 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 18, 2013

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

	December 31,	
	2012	**2011**
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 52,022	$ 50,662
Investments, current	6,035	24,452
Product royalties receivable	14,175	10,795
Unbilled accounts receivable	732	2,036
Accounts receivable, net	1,360	4,616
Prepaid and income taxes receivable	-	2,845
Deferred tax assets, current	874	163
Deferred charge, current	673	3,057
Restricted cash, current	15,113	15,113
Prepaid expenses and other current assets	1,930	1,177
Total current assets	92,914	114,916
Investments, non-current	14,408	998
Property and equipment, net	1,540	1,669
Intangible assets, net	7,415	8,364
Deferred tax assets, non-current	1,654	2,089
Deferred charge, non-current	5,213	26,751
Restricted cash, non-current	3,832	2,129
Other assets	820	653
Total assets	$ 127,796	$ 157,569
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 5,496	$ 6,978
Accrued expenses	10,595	13,648
Deferred revenue, current	3,700	3,888
Deferred tax liability, current	-	2,167
Income tax payable	148	-
Notes payable, current	19,129	20,400
Other current liabilities	1,003	-
Total current liabilities	40,071	47,081
Notes payable, non-current	33,722	39,227
Deferred revenue, non-current	7,093	7,045
Deferred tax liability, non-current	2,627	23,019
Other liabilities	1,253	2,603
Total liabilities	84,766	118,975
Commitments and contingencies (Notes 10 and 13)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 5,000,000 shares authorized at December 31, 2012 and 2011; no shares issued and outstanding at December 31, 2012 and 2011	-	-
Class A common stock, $0.01 par value; 270,000,000 shares authorized at December 31, 2012 and 2011; 41,964,905 and 15,690,780 shares issued and outstanding at December 31, 2012 and 2011, respectively	420	157
Class B common stock, $0.01 par value; 0 and 75,000,000 shares authorized at December 31, 2012 and 2011; 0 and 26,191,050 shares issued and outstanding at December 31, 2012 and 2011, respectively	-	262
Additional paid-in capital	62,521	59,957
Accumulated other comprehensive income	16,166	17,854
Treasury stock, at cost; 457,030 and 186,987 shares	(1,977)	(700)
Accumulated deficit	(34,100)	(38,936)
Total stockholders' equity	43,030	38,594
Total liabilities and stockholders' equity	$ 127,796	$ 157,569

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,		
	2012	**2011**	**2010**
Revenues:			
Research and development revenue	$ 21,545	$ 9,249	$ 16,540
Product royalty revenue	50,696	41,517	40,300
Co-promotion revenue	3,576	3,378	4,417
Contract and collaboration revenue	633	617	613
Product sales revenue	5,037	-	-
Total revenues	81,487	54,761	61,870
Cost of goods sold	3,030	-	-
Gross profit	78,457	54,761	61,870
Operating expenses:			
Research and development	21,292	33,497	23,955
Settlement of legal dispute	-	(11,100)	-
General and administrative	30,157	41,270	27,867
Selling and marketing	18,691	8,783	10,201
Total operating expenses	70,140	72,450	62,023
Income (loss) from operations	8,317	(17,689)	(153)
Non-operating income (expense):			
Interest income	179	249	608
Interest expense	(2,346)	(2,455)	(75)
Other income (expense), net	1,602	(2,019)	(3,700)
Total non-operating income (expense), net	(565)	(4,225)	(3,167)
Income (loss) before income taxes	7,752	(21,914)	(3,320)
Income tax benefit (provision)	(2,916)	4,608	565
Net income (loss)	$ 4,836	$ (17,306)	$ (2,755)
Net income (loss) per share:			
Basic net income (loss) per share	$ 0.12	$ (0.41)	$ (0.07)
Diluted net income (loss) per share	$ 0.12	$ (0.41)	$ (0.07)
Weighted average common shares outstanding - basic	41,660	41,839	41,848
Weighted average common shares outstanding - diluted	41,785	41,839	41,848
Comprehensive income (loss):			
Net income (loss)	$ 4,836	$ (17,306)	$ (2,755)
Other comprehensive income gain (loss):			
Unrealized loss on investments, net of tax effect	36	(2)	(18)
Foreign currency translation	(1,724)	1,282	3,745
Comprehensive income (loss)	$ 3,148	$ (16,026)	$ 972

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	Accumulated Other Comprehensive	Treasury Stock		Retained Earnings (Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Shares	Amount	Deficit)	Equity
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	15,690,780	157	26,191,050	262	59,957	17,854	186,987	(700)	(38,936)	38,594
Conversion of shares	26,191,050	262	(26,191,050)	(262)	-	-	-	-	-	-
Employee stock option expense	-	-	-	-	2,233	-	-	-	-	2,233
Stock issued upon exercise of stock options	79,525	1	-	-	311	-	-	-	-	312
Stock issued under employee stock purchase plan	3,550	-	-	-	20	-	-	-	-	20
Foreign currency translation	-	-	-	-	-	(1,724)	-	-	-	(1,724)
Unrealized loss on investments, net of tax effect	-	-	-	-	-	36	-	-	-	36
Treasury stock, at cost	-	-	-	-	-	-	270,043	(1,277)	-	(1,277)
Net income	-	-	-	-	-	-	-	-	4,836	4,836
Balance at December 31, 2012	41,964,905	$ 420	-	$ -	$ 62,521	$ 16,166	457,030	$ (1,977)	$ (34,100)	$ 43,030

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,		
	2012	**2011**	**2010**
Cash flows from operating activities:			
Net income (loss)	$ 4,836	$ (17,306)	$ (2,755)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,488	1,308	964
Loss on disposal of property and equipment	-	12	1
Deferred tax provision (benefit)	(23,026)	26,228	(99)
Deferred charge	23,922	(29,808)	-
Stock-based compensation	2,233	1,370	1,260
Amortization of premiums on investments	67	651	1,617
Notes payable paid-in-kind interest	2,024	2,288	-
Gain on trading securities	-	-	(1,086)
Loss on settlement rights on auction rate securities	-	-	1,086
Unrealized currency translations (gains) losses	(1,300)	-	-
Changes in operating assets and liabilities:			
Accounts receivable	3,256	(3,885)	(218)
Unbilled accounts receivable	1,303	(939)	(453)
Product royalties receivable	(3,380)	(280)	507
Inventory	87	(127)	-
Prepaid and income taxes receivable and payable, net	2,998	(2,173)	(2,689)
Accounts payable	(1,453)	2,872	893
Accrued expenses	15	523	3,329
Deferred revenue	(95)	(1,940)	(6,525)
Other assets and liabilities, net	(975)	1,215	818
Net cash provided by (used in) operating activities	12,000	(19,991)	(3,350)
Cash flows from investing activities:			
Purchases of investments	(23,609)	(20,598)	(84,857)
Proceeds from the sales of investments	750	7,380	25,855
Maturities of investments	27,790	46,665	90,492
Purchases of property and equipment	(439)	(284)	(333)
Proceeds from disposals of property and equipment	-	25	5
Issuance of notes receivable	-	(100)	-
Purchases of intangible assets	(3,000)	(3,000)	-
Purchase of other investing activities	(432)	-	-
Acquisition of SAG	-	-	(28,118)
Restricted cash	(1,649)	(2,187)	(14,900)
Net cash provided by (used in) investing activities	(589)	27,901	(11,856)
Cash flows from financing activities:			
Proceeds from notes payable	-	-	12,079
Repayment of notes payable	(7,500)	(7,500)	-
Proceeds from exercise of stock options	311	106	-
Purchase of treasury stock	(1,277)	(700)	-
Proceeds from employee stock purchase plan	20	13	14
Dividend payments	-	-	(13,728)
Net cash used in financing activities	(8,446)	(8,081)	(1,635)
Effect of exchange rates on cash and cash equivalents	(1,605)	1,590	4,664
Net increase (decrease) in cash and cash equivalents	1,360	1,419	(12,177)
Cash and cash equivalents at beginning of period	50,662	49,243	61,420
Cash and cash equivalents at end of period	$ 52,022	$ 50,662	$ 49,243
Supplemental cash flow disclosures:			
Cash paid for interest	$ 157	$ 171	$ 2
Tax refunds received	$ 3,658	$ 245	$ 126
Tax payments made	$ 3,665	$ 1,476	$ 2,683
Supplemental disclosure of non-cash investing and financing activities:			
Purchase of intangible assets included in accrued expenses	$ -	$ 3,000	$ -
Loan notes issued for acquisition of SAG	$ -	$ -	$ 51,882

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 biopharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs based on prostones and other novel drug technologies. The therapeutic potential of prostones was first discovered by the Company's cofounder, Dr. Ryuji Ueno, and under his leadership the Company has pioneered the field of prostones. Prostones are naturally occurring fatty acid metabolites. Originally thought to be biologically inert, prostones have emerged as a promising compound class with unique physiological activities which can be targeted for the treatment of unmet or underserved medical needs.

Prostones act locally to restore normal function in cells and tissues, and because they are quickly metabolized to an inactive form, their pharmacologic activity can be targeted to specific organs and tissues. Prostones possess a unique mechanism of action as highly potent and selective ion channel activators. Ion channels are integral parts of cell membranes that regulate the flow of specific ions into and out of cells. This regulation is key to the functioning of cells, such as metabolic processes and cell survival. As such, prostones are physiological mediators of the restoration of cellular homeostasis and tissue regeneration. There is also evidence that prostones have anti-inflammatory properties and can prevent cell death.

The Company's prostone-based compounds target the ClC-2 and big potassium, or BK, ion channels. Because these ion channels play an important role in physiology, targeted dosing of prostones may have broad applicability in many disease states in different organ systems. The Company has developed synthetic analogs of the naturally occurring prostones, which have been optimized to be more potent, selective, and stable, thus enabling their use as drugs. Prostones are very selective for their molecular targets, and the approved prostone-based compounds are well-tolerated and generally safe.

The Company is focused on developing prostones to treat gastrointestinal, ophthalmic, neurologic, and oncology-based inflammatory disorders, and is also considering other potential therapeutic applications of the Company's drug technologies.

The Company currently generates revenue mainly from product royalties, development milestone payments, clinical development activities and product sales. The Company expects to continue to incur significant expenses for the next several years as the Company continues its research and development activities, seeks regulatory approvals and additional indications for AMITIZA® (lubiprostone), RESCULA® (unoprostone isopropyl) and other compounds, and commercializes the Company's approved products on a global basis.

To date, two prostone products have received marketing approval, AMITIZA and RESCULA, globally. A third prostone, cobiprostone, or SPI-8811, is in phase 1 clinical development for the target indication of prevention of oral mucositis, or OM, in 2013. The Company's orphan drug application for cobiprostone for OM has not been granted by the U.S. Food and Drug Administration, or FDA, because the FDA believes that anyone who has cancer and is at risk for developing OM would take the drug and thus the target population and estimate are larger than orphan drug status. Two additional prostones, SPI-017 and SPI-3608, have also been developed for human testing for the indication of management of pain caused by spinal stenosis, and SPI-017 is currently in a phase 2A trial that is expected to conclude by the fourth quarter of 2013.

AMITIZA is being marketed in the U.S. for two gastrointestinal indications under the October 2004 collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda Agreement. These indications are chronic idiopathic constipation, or CIC, in adults and irritable bowel syndrome with constipation, or IBS-C, in adult women. Takeda also holds marketing rights to AMITIZA in Canada, but has not yet commercialized it there. The Company is primarily responsible for clinical development activities under the Takeda Agreement while Takeda is responsible for commercialization of AMITIZA in the U.S. and Canada. 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. In July 2012, the Company filed a supplemental new drug application, or sNDA, with the FDA seeking priority review of a new, third indication for the use of AMITIZA in the treatment of opioid-induced constipation, or OIC. The sNDA was accepted for priority review, with an initial Prescription Drug User Fee Act, or PDFUA, date of late January 2013. In November 2012, the FDA notified us that it had extended the Company's PDUFA goal date by three months. The expected PDUFA and FDA approval decision date is late April 2013.

In Japan, lubiprostone is being developed and marketed under a license, commercialization and supply agreement, or the Abbott Agreement, with Abbott Japan Co. Ltd., or Abbott, for the treatment of chronic idiopathic constipation, or CIC, in Japan. The Company received approval of its new drug application, or NDA, for AMITIZA for the treatment of chronic constipation, or CC, excluding constipation caused by organic diseases, from the Ministry of Health, Labour and Welfare in June 2012. In November 2012, the Company and Abbott announced the availability of AMITIZA in Japan for CC.

In the U.K., the Company received approval in September 2012 from the Medicines and Healthcare products Regulatory Agency, or MHRA, for the use of AMITIZA to treat CIC, and is currently working to achieve National Institute for Health and Clinical Excellence endorsement and launch in the U.K. in 2013. In Switzerland, AMITIZA was approved in 2009 and has been made available through a Named Patient Program throughout the E.U., Switzerland, Iceland and Norway since February 2012. In 2012, the Company reached agreement with the Bundesamt fur Gesundheit on a reimbursement price for AMITIZA in Switzerland, and began active marketing in the first quarter of 2013.

The Company plans to commence the approval process in other E.U countries for CIC via the Mutual Recognition Procedure, or MRP, in 2013. In the first quarter of 2013, the Company also filed for an OIC indication in the U.K and Switzerland. If the Company receives approval in the U.K., the Company will seek approval in other E.U. countries following the MRP for OIC.

The Company holds license agreements for RESCULA in the United States and Canada and the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China. An sNDA for RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% for the lowering of intraocular pressure, or IOP, in patients with open-angle glaucoma or ocular hypertension was approved by the FDA in December 2012 and the Company began commercializing the product in February 2013. According to the approved product labeling, RESCULA may be used as a first-line agent or concomitantly with other topical ophthalmic drug products to lower intraocular pressure. RESCULA is a BK channel activator, which is different from other IOP lowering agents.

In other areas of development, the Company entered into agreements in 2011 with CuroNZ of New Zealand, which may augment the Company's ophthalmic development opportunities. In the first quarter of 2013, the Company has decided to no longer support the development of the peptide compound CuroNZ had started to evaluate the peptide compound for use in animal models of glaucoma and RP. Additionally, in 2011, and the Company entered into an agreement with Numab AG, or Numab of Switzerland, to obtain access to their proprietary technology for the discovery of high-affinity antibodies against certain selected targets.

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, and the rules and regulations of the Securities and Exchange Commission, or SEC. The Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiaries: Sucampo AG, or SAG, based in Zug, Switzerland, in which the company conducts certain worldwide and European operations; Sucampo Pharma, Ltd., or SPL, based in Tokyo and Osaka, Japan, in which the Company conducts its Asian operations; Sucampo Pharma Americas LLC, or SPA, based in Bethesda, Maryland, in which the Company conducts operations in North and South America; Sucampo Pharma Europe, Ltd., or 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 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 $18.9 million and $17.2 million at December 31, 2012 and December 31, 2011, respectively. Restricted cash represents cash required to be deposited with financial institutions in connection with a loan agreement with The Bank of Tokyo-Mitsubishi UFJ, Ltd. (see Note 11 below), the Numab Agreement (see Note 12 below) and operating leases.

Current and Non-Current Investments

Current and non-current investments consist primarily of U.S. government agency's securities, corporate bonds, mutual funds and variable rate demand notes. 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 as available for sale securities and reports unrealized gains or losses, net of related tax effects, in other comprehensive income.

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, 2012 and 2011, approximately $16.8 million, or 18.4%, and $15.6 million, or 16.7%, 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 74.4%, 96.9% and 81.4%, of the Company's total revenues for the years ended December 31, 2012, 2011 and 2010, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 98.0% and 100.0% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at December 31, 2012 and 2011. Revenues from another unrelated party, Abbott, accounted for 19.3%, 2.3% and 18.0% of the Company's total revenues for the years ended December 31, 2012, 2011 and 2010. 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 10).

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, restricted cash, current and non-current investments, bank loan, 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 notes payable at December 31, 2012 was less than the estimated fair value and at December 31, 2011 approximated its fair value. The Company's debt is subject to the fair value disclosure requirements as discussed in Note 4 below and is considered a Level 2 security.

Accounts Receivable and Unbilled Accounts Receivable

Accounts receivable represent mainly amounts due under the Takeda Agreement and the Abbott Agreement (Note 12). Unbilled accounts receivable represent the research and development expenses that are reimbursable by Takeda but have not been billed to Takeda as of the balance sheet date. The Company recorded an allowance for doubtful accounts at December 31, 2012 of approximately $280,000 related to certain disputed Takeda invoices. No allowance was recorded in 2011.

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, 2012, 2011 or 2010 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, product sales 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.

In October 2009, the FASB issued new revenue recognition standards for arrangements with multiple deliverables, which were effective for the Company as of January 1, 2011. These standards address the determination of the unit(s) of accounting for multiple-element arrangements and how the arrangement's consideration should be allocated to each unit of accounting. An item can generally be considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on VSOE if available; third-party evidence, if VSOE is unavailable; and estimated selling prices if neither VSOE nor third-party evidence is available. The new accounting standards were adopted by the Company on a prospective basis on January 1, 2011. The Company did not enter into any new multiple-element arrangements or materially modify any existing arrangements during 2011. The adoption of these standards did not have a material effect on the Company's consolidated results of operations, financial position or liquidity.

Where agreements include contingent milestones we evaluate whether each milestone is substantive. Milestones are considered substantive if all of the following conditions are met: (1) it is commensurate with either our performance to meet the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the our performance to achieve the milestone, (2) it relates solely to past performance, and (3) the value of the milestone is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement. Where milestones are not considered substantive their treatment is based on either a time-based or proportional performance model.

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 a supplemental agreement, or 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).

Product Sales Revenue

Product sales predominately consist of AMITIZA sales to Abbott in Japan. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to product and associated risk of loss have passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured. The Company did not record sales deductions and returns for sales of AMITIZA to Abbott due to the absence of discounts and rebates and no right of return under the contract with Abbott.

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, 2012 and 2011, total deferred revenue was approximately $10.8 million and $10.9 million, respectively.

Total deferred revenue consists of the following as of:

	December 31,	
(In thousands)	**2012**	**2011**
Deferred revenue, current	$ 3,700	$ 3,888
Deferred revenue, non-current	7,093	7,045
	$ 10,793	$ 10,933
Deferred revenue to related parties, included in total deferred revenue:		
Deferred revenue to related parties, current	$ 479	$ 433
Deferred revenue to related parties, non-current	5,386	5,063
Total	$ 5,865	$ 5,496

Cost of Goods Sold

Cost of goods sold relates to sales and distribution of the Company's products sold by the Company.

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 and promote RESCULA, 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 stock options granted for the three years ended December 31, 2012 were as follows:

	Year Ended December 31,		
	2012	**2011**	**2010**
Expected volatility	62% - 64%	55% - 64%	51% - 63%
Risk-free interest rate	0.76% - 1.60%	1.30% - 3.30%	1.89% - 3.24%
Expected term (in years)	5.50 - 6.25	2.10 - 6.25	5.00 - 6.25
Expected dividend yield	0%	0%	0%

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

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

Expected Term: The Company elected to use the "simplified" method to calculate its expected term of share-based awards. Under this method, the expected term is the weighted average of the vesting term and the contractual term. 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 31, 2012 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, 2012, 2011 and 2010, the estimated forfeiture rate ranged from 10.0% to 14.0%.

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, 2012 was as follows:

(In thousands)	Year Ended December 31, 2012	2011	2010
Research and development expense	$ 535	$ 234	$ 252
General and administrative expense	1,349	964	729
Selling and marketing expense	349	172	279
Total	2,233	1,370	1,260
Employee stock-based compensation expense per basic and diluted share of common stock	$ 0.05	$ 0.03	$ 0.03

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 carry-forwards. 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, or NOL, carry-forwards that can be utilized in the future to offset taxable income.

In September 2011, the Company internally transferred certain intellectual property and licenses from the Company's subsidiaries, including the U.S. based subsidiary, 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 is being amortized over ten years. Following the decision of the International Court of Arbitration of the International Chamber of Commerce on the Takeda Agreement in July 2012, the Company determined that the internal transfer of the intellectual property was only partially complete and is continuing to evaluate whether the U.S. rights related to AMITIZA will transfer to SAG in the future. This resulted in a reassessment of the deferred charge, deferred tax liability and the mix of profits and losses earned in each jurisdiction. For the year ended December 31, 2012, the Company recorded a benefit of approximately $1.9 million related to the partial reversal of the internal transfer and reduced the deferred charge and deferred tax liability by approximately, $23.8 million and $24.1 million respectively. As of December 31, 2012, the total deferred charge is $5.9 million after a net current year amortization expense of $77,000.

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 de-recognition 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% likely to be realized upon settlement.

The Company has recorded an income tax liability of approximately $1.1 million and $1.5 million, including interest, for uncertain tax positions as of December 31, 2012 and 2011, respectively. As of December 31, 2012 and 2011, $660,000 and $471,000 are reflected as other current liabilities and other liabilities, respectively, in the accompanying Consolidated Balance Sheets. As of December 31, 2011, $1.5 million was reflected as other liabilities in the accompanying Consolidated Balance Sheets. These amounts represent 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, 2012 and 2011 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. During the twelve months ended December 31, 2012, the liability for income taxes has decreased approximately $350,000. This decrease in the liability is related primarily to settlement of a tax audit in Japan, offset by a net increase related to current year activity in the U.S. including settlements with tax authorities and revisions to prior year estimates.

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision. The Company expects to file income tax returns as of December 31, 2012; the Company has recorded a liability for uncertain tax positions. Therefore, the amount of $660,000 expected to reverse within the next twelve months has been recorded as a current liability. Other than the expected settlement of tax liabilities, no additional uncertain tax positions have been identified 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. In addition, future changes in the unrecognized tax benefits would have an effect on the effective tax rate when recognized.

Currently tax years 2009, 2010, 2011 and 2012 remain open and subject to examination in the major tax jurisdictions in which tax returns are filed.

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 results from this process are included in accumulated other comprehensive income in the stockholders' equity section of the balance sheet.

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

Other Comprehensive Income

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

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

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 February 2013, the FASB issued an accounting update on Comprehensive Income-Topic 220: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income, which requires the Company to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, the Company is required to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, the Company is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. This update will be effective for public companies during the interim and annual periods beginning after December 15, 2012. The Company does not expect that the adoption of this guidance will have a material impact on the Company's consolidated financial statements.

3. Net Income (Loss) per Share

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

The computation of net income (loss) per share for the three years ended December 31, 2012, is shown below:

	December 31,		
(in thousands, except per share data)	**2012**	**2011**	**2010**
Basic net income (loss) per share:			
Net income (loss)	$ 4,836	$ (17,306)	$ (2,755)
Weighted average class A and B common shares outstanding	41,660	41,839	41,848
Basic net income (loss) per share	$ 0.12	$ (0.41)	$ (0.07)
Diluted net income (loss) per share:			
Net income (loss)	$ 4,836	$ (17,306)	$ (2,755)
Weighted average class A and B common shares outstanding for diluted net income per share	41,660	41,839	41,848
Assumed exercise of stock options under the treasury stock method	125	-	-
	41,785	41,839	41,848
Diluted net income (loss) per share	$ 0.12	$ (0.41)	$ (0.07)

For the years listed above, the potentially dilutive securities used in the calculations of diluted net income per share as of December 31, 2012, 2011 and 2010 are as follows:

	December 31,		
(In thousands)	**2012**	**2011**	**2010**
Employee stock options	2,811	-	-
Non-employee stock options	450	-	-

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, 2012, 2011 and 2010:

	December 31,		
(In thousands)	**2012**	**2011**	**2010**
Employee stock options	596	3,595	1,554
Non-employee stock options	-	450	450

4. Current and Non-Current Investments

At December 31, 2012 and 2011, current and non-current investments consisted of the following securities:

	December 31, 2012			
(In thousands)	**Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Current:				
U.S. commercial paper	$ 2,499	$ -	$ -	$ 2,499
Municipal securities	251	-	-	251
Certificates of deposits	500	-	-	500
Variable rate demand notes	2,785	-	-	2,785
Total	$ 6,035	$ -	$ -	$ 6,035
Non-current:				
U.S. government securities	$ 10,131	$ 2	$ (3)	$ 10,130
Certificates of deposits	3,000	-	-	3,000
Corporate bonds	1,281	-	(3)	1,278
Total	$ 14,412	$ 2	$ (6)	$ 14,408

	December 31, 2011			
(In thousands)	**Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Current:				
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	$ 24,444	$ 11	$ (3)	$ 24,452
Non-current:				
U.S. government securities	$ 1,000	$ -	$ (2)	$ 998
Total	$ 1,000	$ -	$ (2)	$ 998

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 the Company 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			
December 31, 2012 (In thousands)	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
U.S. government securities	$ -	$ 10,130	$ -	$ 10,130
U.S. commercial paper	-	5,998	-	5,998
Municipal securities	-	1,253	-	1,253
Certificates of deposits	-	3,500	-	3,500
Corporate bonds	-	6,286	-	6,286
Money market funds	16,274	-	-	16,274
Variable rate demand notes	-	2,785	-	2,785
Total assets measured at fair value	$ 16,274	$ 29,952	$ -	$ 46,226

	Fair Value Measurements at Reporting Date Using			
December 31, 2011 (In thousands)	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
U.S. 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

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.

5. Property and Equipment

Property and equipment consists of the following as of:

(In thousands)	December 31, 2012	December 31, 2011
Computer and office machines	$ 2,598	$ 2,181
Furniture and fixtures	434	438
Leasehold improvements	1,478	1,495
Total cost	4,510	4,114
Less: accumulated depreciation	(2,970)	(2,445)
Total	$ 1,540	$ 1,669

Depreciation expense for the years ended December 31, 2012, 2011 and 2010 was approximately $542,000, $591,000 and $604,000, respectively.

The leasehold improvements as of December 31, 2012 are related to tenant improvements to the Company's headquarters in Bethesda, Maryland.

6. Intangible Assets

In April 2009, the Company entered into an agreement with R-Tech, or the 2009 R-Tech Agreement, 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. An sNDA for RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension was approved by the FDA in December 2012 and the Company began commercializing the product in February, 2013. According to the approved product labeling, RESCULA may be used as a first-line agent or concomitantly with other topical ophthalmic drug products to lower intraocular pressure. RESCULA is a BK, or Big Potassium, channel activator, which is different from other IOP lowering agents.

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. The Company 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, 2012, both of which are reflected in other non-current assets in the accompanying Consolidated Balance Sheets. The cost is amortized over the 10-year life of the 2009 R-Tech Agreement, which the Company believes approximates the useful life of the underlying rights and data. Amortization expense was approximately $341,000 for each of the years ended December 31, 2012 and 2011 and 2010. The annual amortization expense will be approximately $341,000 through April 2019.

On March 22, 2011, the Company entered into a license agreement with R-Tech for unoprostone isopropyl, or the 2011 R-Tech Agreement, 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. The Company is now evaluating the opportunities to obtain an appropriate label in the E.U. and other European countries, and the timing of seeking reauthorization in those countries to commercialize unoprostone isopropyl.

The Company has made payments to R-Tech of $6.0 million, which is reflected in other non-current assets in the accompanying Consolidated Balance Sheets, and may be required to pay up to $100.0 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The Company 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 the Company believes approximates the useful life of the underlying rights and data. Amortization expense was approximately $613,000 for each of the years ended December 31, 2012 and 2011 and 2010, respectively. The annual amortization expense will be approximately $613,000 through March 2021.

7. Accrued Expenses

Accrued expenses consist of the following as of:

(In thousands)	December 31, 2012	December 31, 2011
Research and development costs	$ 6,662	$ 5,622
Employee compensation	1,219	1,607
Selling and marketing costs	487	76
Legal service fees	830	1,955
RESCULA milestones	500	3,500
Other accrued expenses	897	888
Total	$ 10,595	$ 13,648

8. Other Liabilities

Other liabilities consist of the following as of:

(In thousands)	December 31, 2012	December 31, 2011
Deferred leasehold incentive	$ 373	$ 609
Deferred rent expense	408	514
Other liabilities	472	1,480
Total	$ 1,253	$ 2,603

9. Commitments and Contingencies

Operating Leases

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

(In thousands of U.S. dollars)	December 31, 2012
2013	$ 1,275
2014	1,068
2015	1,052
2016	1,084
2017	139
Total minimum lease payments	$ 4,618

Rent expense for all operating leases was $1.6 million, $1.6 million and $1.3 million for the years ended December 31, 2012, 2011 and 2010, 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 2015 under these agreements as of December 31, 2012 were approximately $3.5 million.

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, 2012 the potential amount of payments in the event of Numab's default was $3.8 million (see Note 10 below).

We had an outstanding purchase order commitment of approximately $5.3 million with R-Tech (see Note 10 below).

10. Related Party Transactions

R-Tech Ueno, Ltd.

On March 7, 2003, the Company entered into an exclusive supply agreement with R-Tech. This agreement grants R-Tech the exclusive right to manufacture and supply RUG-015, a prostone compound, and lubiprostone in the U.S. and Canada, and in consideration for such right R-Tech agreed to pay the Company as follows: $1.0 million upon execution of the agreement, $2.0 million upon commencement of the first phase 2 lubiprostone trial, $3.0 million upon commencement of the 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, 2012, 2011 and 2010, which is recorded as contract revenue. During the years ended December 31, 2012, 2011 and 2010, the Company purchased from R-Tech approximately $1.4 million, $72,000, and $344,000, 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.

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 commercialized throughout Europe, the $2.0 million has been recorded as non-current deferred revenue as of December 31, 2012 and 2011. During the years ended December 31, 2012, 2011 and 2010, the Company purchased approximately $124,000, $125,000 and $110,000, respectively, of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch in Europe.

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 2012, 2011 or 2010.

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 year ended December 31, 2010, the Company purchased from R-Tech $48,000 of clinical supplies under the terms of this agreement. There were no clinical supplies purchased in 2012 or 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 $500,000 in milestone payments for the regulatory approval of lubiprostone in Japan. R-Tech is obligated to pay $250,000 upon the commercial launch in Japan, which occurred in November 2012. The $250,000 will be amortized over the life of the agreement. 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, 2012, 2011 and 2010, the Company purchased approximately $3.1 million, $166,000 and $267,000, respectively, of commercial supplies of lubiprostone from R-Tech under this agreement. During the year ended December 31, 2012, the Company purchased approximately $10,000 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.

We have also made purchases for other research and development services during the years ended December 31, 2012, 2011, and 2010 of approximately $466,000, $104,000 and $69,000, respectively.

In 2009 and 2011, the Company entered into two agreements with R-Tech to acquire rights to RESCULA globally except the R-Tech Territory. Under the terms of the agreements, the Company holds the exclusive rights to commercialize RESCULA for its approved indication and any new indication developed by the Company, and has the right of first refusal to commercialize 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 and R-Tech is exclusively responsible for the supply of RESCULA to the Company. The terms of these agreements are described in Note 6 above.

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

	Year Ended December 31,		
(In thousands)	**2012**	**2011**	**2010**
Clinical supplies	$ 1,450	$ 72	$ 392
Other research and development services	466	104	69
Commercial supplies	3,288	155	376
	$ 5,204	$ 331	$ 837

	Year Ended December 31,	
(In thousands)	**2012**	**2011**
Deferred revenue, current	$ 479	$ 433
Deferred revenue, non-current	5,386	5,063
	$ 5,865	$ 5,496

R-Tech has informed the Company that it is relocating its manufacturing facility for unoprostone isopropyl beginning October 2012 and will not be able to manufacture and supply unoprostone isopropyl for up to 18 months. R-Tech has designated another facility in Japan but such facility will need to be inspected by the FDA in 2013 before it can manufacture unoprostone isopropyl. In order to mitigate this risk, the Company placed an order of $5.3 million to cover this supply period based on Company forecasts for the launch of RESCULA in the U.S., R-Tech commenced delivery of that order to the Company in the first quarter of 2013

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.

Numab AG

In September 2011, the Company entered into a Loan Guarantee and Development Agreement, or Numab Agreement, with Numab AG, or Numab, of Wadenswil, Switzerland. Numab is considered a related party as a result of an ownership interest by one of our executive officers. Under the terms of the Numab Agreement the Company will provide Numab with up to CHF 5.0 million, approximately $5.5 million as of the closing date, 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 investigational new drug 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. In February 2012, the Company entered into a Master Lease Agreement, or Lease Agreement, with Numab whereby the maximum collateral of CHF 5.0 million is reduced by the purchase cost of any equipment leased to Numab. As of December 31, 2012, equipment with a purchase cost of CHF 544,000, approximately $595,000, as of the closing date, was leased to Numab thus reducing the maximum collateral and loan guarantee to CHF 4.5 million. Monthly rental payments are received under the terms of the lease. As of December 31, 2012, the collateral of CHF 3.5 million has been deposited by the Company and Numab has utilized CHF 3.0 million of its CHF 4.5 million loan. In the first quarter of 2013, Numab reported that it had met one of the success criteria for development of our named target; this will result in the Company paying a success fee of CHF 3.0 million and will also reduce 90% of the loan guarantee. During 2012 in reviewing the amount outstanding of the loan, the Company recorded a liability of $1.2 million in collateral callable to meet a potential loan default by Numab. Following the reported success of the Company's named target, the default provision has been released and full provision for the success fee has been made during 2012 as we considered it probable the success criteria would be met. The Company has decided to no longer pursue the further development of the target. Numab and the Company will begin discussions in light of this decision.

11. Notes Payable

In November 2010, SPL entered into a ¥1,000,000,000, approximating $11.6 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. The loan was renewed in November 2012. 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 at December 31, 2012 was 1.31%. The outstanding loan balances included in the accompanying Consolidated Balance Sheets were $11.6 million and $12.9 million as of December 31, 2012 and 2011, respectively. 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 0.25%, which is recorded as restricted cash, current in the accompanying Consolidated Balance Sheets as of December 31, 2012 and 2011. Following the loan renewal in November 2012, and due to the short-term maturity of the facility, the Company estimated that the carrying value approximated the fair value at December 31, 2012.

Subordinated Unsecured Promissory Notes

In connection with the SAG acquisition 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 $25.9 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, 2012 is 4.5%.

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. In November 2012, Ambrent made the second principal payment of $7.5 million. Interest paid-in kind was $2.2 million for the year ended December 31, 2012.

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

Due to changes in LIBOR rates the Company has estimated the fair value of the notes payable and this is shown in the table below.

Notes payable at their carrying amount and fair value consist of the following:

(In thousands)	Fair Value December 31, 2012	Carrying Value Year Ended December 31, 2012	2011
Loan agreement, The Bank of Tokyo-Mitsubishi UFJ, Ltd	$ 11,600	$ 11,600	$ 12,900
Promissory notes, Sellers of SAG	42,072	41,251	46,727
	$ 53,672	$ 52,851	$ 59,627
Notes payable, current		$ 19,129	$ 20,400
Notes payable, non-current		33,722	39,227
		$ 52,851	$ 59,627

12. 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 oversees 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 $37.5 million in up-front and development milestone payments under this agreement, including a $15.0 million development milestone payment, received in December 2012, for the first commercial sale of AMITIZA at dosage strength of 24 micrograms in Japanese adults, as well as $10.0 million and $12.5 million in up-front and development milestone payments, respectively, in 2009. Under the Abbott Agreement the Company could receive additional milestone payments based on achieving other specified development and commercialization goals 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, unless the Company determines that the milestone is substantive where is recognized when due and collection can be reasonably assured. The Company determined that the milestone due on first commercial sale was a substantive milestone. The following table summarizes the cash streams and related revenue recognized or deferred for this agreement:

(In thousands)	Cash Received Through December 31, 2012	Revenue Recognized for the Year Ended December 31, Through 2010	2011	2012	Accounts Receivable for the Year Ended December 31, 2012	Foreign Currency Effects	Amount Deferred at December 31, 2012
Collaboration revenue:							
Up-front payment associated with the Company's obligation to participate in joint committees	$ 846	$ 85	$ 52	$ 52	$ -	$ (68)	$ 725
Research and development revenue:							
Up-front payment - remainder	$ 9,154	$ 8,583	$ 520	$ 199	$ -	$ (148)	$ -
Development milestone payment	27,500	11,901	697	15,157	-	(255)	$ -
Total	$ 36,654	$ 20,484	$ 1,217	$ 15,356	$ -	$ (403)	$ -
Product sales revenue:	$ 4,924	$ -	$ -	$ 5,023	$ 99	$ -	$ -

Takeda collaboration and license agreement

In October 2004, the Company entered into the 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, 2012 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, 2012	Revenue Recognized for the Year Ended December 31,			Accounts Receivable for the Year Ended December 31, 2012 (1)	Amount Deferred at December 31, 2012
		Through 2010	2011	2012		
Collaboration revenue:						
Up-front payment associated with the Company's obligation to participate in joint committees	$ 2,375	$ 905	$ 147	$ 147	$ -	$ 1,176
Research and development revenue:						
Up-front payment - remainder	$ 17,624	$ 17,624	$ -	$ -	$ -	$ -
Development milestones	130,000	130,000	-	-	-	-
Reimbursement of research and development expenses	104,653	92,230	8,032	6,189	2,047	249
Total	$ 252,277	$ 239,854	$ 8,032	$ 6,189	$ 2,047	$ 249
Product royalty revenue	$ 225,152	$ 147,114	$ 41,517	$ 50,696	$ 14,175	$ -
Co-promotion revenue	$ 28,613	$ 22,438	$ 3,378	$ 3,576	$ 779	$ -

(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, 2012, 2011 and 2010, 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, 2012 and 2011 was approximately $1.2 million and $1.3 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 $50.7 million, $41.5 million and $40.3 million for the years ended December 31, 2012, 2011 and 2010, 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 an 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 OIC. 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 an 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 Takeda 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, 2012, 2011 and 2010, the Company recognized approximately $4.4 million, $8.0 million and $5.5 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.

The reimbursement of co-promotion costs under the Supplemental Takeda Agreement expired on May 31, 2011. Co-promotion costs after May 31, 2011 were 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. After May 2011, the Company was reimbursed on actual details presented to health care prescribers. The Company has recognized approximately $3.6 million, $3.4 million and $4.4 million of revenues for the years ended December 31, 2012, 2011 and 2010, 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.

Numab AG

On September 8, 2011, the Company entered into the Numab Agreement with Numab, under which the Company will have access to Numab's proprietary technology for the discovery of high-affinity antibodies against certain selected targets. The Company will be responsible for clinical development and will have exclusive commercial rights to any biologic products successfully developed and commercialized in the course of the collaboration. The Company has agreed to provide Numab with up to CHF 5.0 million as collateral for a loan to Numab from a third party. The Company 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. The Company has decided to no longer pursue the further development of the target. Numab and the Company will begin discussions in light of this decision. See Note 10 above.

13. Stockholders' Equity

Capital Structure

On August 30, 2012, the Company announced that its majority stockholder and only holder of its class B common stock, S&R Technology Holdings, LLC, or S&R, had converted effective as of August 29, 2012, all of its 26,191,050 issued and outstanding shares of the Company's class B common stock into shares of the Company's class A common stock. S&R held all of the Company's class B common stock. Class B common stock holders were entitled to ten votes per share while class A common stock holders were entitled to one vote per share. The Company's Articles of Incorporation permit the holder of class B common stock to convert the shares of class B common stock into shares of class A common stock at any time and on a one-for-one basis. As a result of the conversion, there is now only a single class of common stock, class A common stock, outstanding, totaling 41,970,364 shares as of March 7, 2013, each of which is entitled to one vote per share.

Treasury Stock

On December 11, 2008, the Company announced a stock repurchase program under which the Company is authorized to purchase up to $10,000,000 million of its 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. On November 2, 2012, the Board of Directors authorized the increase of such amount of repurchase to up to an aggregate of $5.0 million. In 2011, the Company repurchased 186,987 shares of its class A common stock under this program at a cost of $700,042. In 2012, the Company repurchased 270,043 shares of its class A common stock under this program at a cost of $1.3 million. All shares of class A common stock purchased in 2012 were purchased in August, September, October, November and December. These shares are not retired and are recorded at cost. The Company did not repurchase any of our equity securities in 2010.

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 8.5 million 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, 2012, a total of 5,248,507 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, 2012 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, 2011	190,400	$ 10.00		
Options expired	(34,000)	10.00		
Options outstanding, December 31, 2012	156,400	10.00	3.33	$ -
Options exercisable, December 31, 2012	156,400	10.00	3.33	$ -

A summary of the employee stock option activity for the year ended December 31, 2012 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, 2011	3,402,380	$ 4.75		
Options granted	502,750	6.30		
Options exercised	(79,525)	3.92		
Options forfeited	(432,506)	4.51		
Options expired	(141,606)	9.75		
Options outstanding, December 31, 2012	3,251,493	4.83	8.26	$ 1,820,758
Options exercisable, December 31, 2012	1,243,479	5.05	7.70	$ 743,057

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. No market condition options were granted during 2012.

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.

The weighted average grant date fair value of options granted during the years ended December 31, 2012, 2011 and 2010 were $6.30, $1.81 and $2.05, respectively. As of December 31, 2012, approximately $2.3 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards are expected to be recognized over a weighted average period of 2.48 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, 2012 and 2011, 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 2.33 and 3.33 years, respectively, as of both December 31, 2012 and 2011.

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 3,550 and 3,363 shares of common stock were purchased under the ESPP during the years ended December 31, 2012 and 2011, respectively. The Company received approximately $20,000, $13,000 and $14,000 upon purchase of shares under the ESPP for the years ended December 31, 2012, 2011 and 2010, 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.

14. Income Taxes

Income (loss) before income taxes is as follows:

	Year Ending December 31,		
	2012	**2011**	**2010**
U.S.	$ 8,580	$ (9,670)	$ (3,819)
Foreign	(828)	(12,244)	499
	$ 7,752	$ (21,914)	$ (3,320)

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

	Year Ended December 31,		
(In thousands)	**2012**	**2011**	**2010**
Current tax provision (benefit):			
U.S. Federal	$ 1,431	$ (597)	$ (1,063)
U.S. State	658	(194)	128
Foreign	51	550	469
Total current tax provision (benefit)	2,140	(241)	(466)
Deferred provision (benefit):			
U.S. Federal	1,248	(1,369)	(44)
U.S. State	(193)	385	(56)
Foreign	(279)	(3,383)	1
Total deferred provision (benefit)	776	(4,367)	(99)
Total income tax provision (benefit)	$ 2,916	$ (4,608)	$ (565)

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

	December 31,	
	2012	**2011**
(In thousands)		
Deferred tax assets:		
Foreign net operating loss carry-forwards	$ 5,132	$ 5,638
U.S. net operating loss carry-forwards	100	903
Deferred revenue	2,431	2,547
Accrued expenses	1,316	1,043
Tax benefits on stock options	1,832	1,960
Other	388	869
Gross deferred tax assets	11,199	12,960
Deferred tax liabilities:		
Property and equipment	(272)	(339)
Intangibles	(6,884)	(30,918)
Accrued expenses	-	(3)
Other	-	(167)
Gross deferred tax liabilities	(7,156)	(31,427)
Less: valuation allowance	(4,142)	(4,467)
Net deferred tax liabilities	$ (99)	$ (22,934)

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, 2012	2011	2010
Federal tax provision (benefit)	34.0%	34.0%	34.0%
State taxes, net of federal tax benefit	7.5%	0.4%	3.7%
General business credits	-0.5%	1.6%	18.5%
Changes in valuation allowance	-3.7%	-3.7%	-11.8%
Nondeductible expenses	1.7%	-0.2%	4.0%
Acquisition costs	0.0%	0.0%	-9.4%
Stock based compensation	12.7%	-1.9%	-4.2%
Impact of intagible transfer	-18.6%	-4.7%	0.0%
Impact of uncertain tax positions	-4.2%	-0.2%	-1.4%
Adjustment to deferred tax asset	-10.4%	0.1%	-27.9%
Impact of foreign operations	6.4%	-4.6%	19.1%
Change in tax rates	12.4%	-0.1%	-6.0%
Changes in other tax matters	0.3%	0.4%	-1.5%
	37.6%	21.1%	17.0%

At December 31, 2012 and 2011, the Company had foreign net operating loss carry-forwards of $21.0 million and $16.4 million, respectively. Approximately $10.9 million of the foreign NOLs begin to expire in December 2019, and $10.1 million of the foreign NOLs do not expire. As of December 31, 2012 and 2011, the Company had no U.S. NOLs. The U.S. had research and development credits of approximately nil and $472,000, as of December 31, 2012 and 2011, respectively.

As of December 31, 2012 and 2011, the Company had a valuation allowance on its deferred tax assets of $4.1 million and $4.5 million, respectively. The net decrease in the valuation allowance of $325,000 was due to 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.

In September 2011, the Company internally transferred certain intellectual property and licenses from the Company's subsidiaries, including the U.S. based subsidiary, 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 is being amortized over ten years. Following the decision of the International Court of Arbitration of the International Chamber of Commerce on the Takeda Agreement in July 2012, the Company determined that the internal transfer of the intellectual property was only partially complete and is continuing to evaluate whether the U.S. rights related to AMITIZA will transfer to SAG in the future. This resulted in a reassessment of the deferred charge, deferred tax liability and the mix of profits and losses earned in each jurisdiction. For the year ended December 31, 2012, the Company recorded a benefit of approximately $1.9 million related to the partial reversal of the internal transfer and reduced the deferred charge and deferred tax liability by approximately, $23.8 million and $24.1 million respectively. As of December 31, 2012, the total deferred charge is $5.9 million after a net current year amortization expense of $77,000.

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, future forecasts of taxable income and expiration periods of NOL carry forwards amongst other items in determining whether a full or partial release of a valuation allowance is warranted. The valuation allowance at December 31, 2012 and 2011 relates to deferred tax assets in the foreign jurisdictions. A partial valuation allowance was maintained on the deferred tax assets of the Company's subsidiary in Japan based on management's estimate of the NOL carry-forwards that will expire unused. 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. As of December 31, 2012, the Company does not expect to reverse any of the valuation allowance in the next twelve months.

The Company has recorded a total income tax liability of approximately $1.1 million and $1.5 million, including interest for uncertain tax positions as of December 31, 2012 and 2011, respectively. The Company expects to file income tax returns in 2013 in several states where we have recorded a liability for uncertain tax positions as of December 31, 2012. Therefore, the amount of $660,000 expected to reverse within the next twelve months has been reflected as other current liabilities and the remaining $471,000 has been recorded as other liabilities in the accompanying Consolidated Balance Sheets. 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, 2012 and 2011 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,		
	2012	2011	2010
Balance at January 1	$ 1,226	$ 1,245	$ 1,200
Increases for tax positions taken during prior periods	207	22	3
Decreases in unrecognized tax benefits related to settlements with taxing authorities	(536)	(71)	-
Increases for tax positions taken during current period	82	30	42
Balance at December 31	$ 979	$ 1,226	$ 1,245

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision. During 2012, 2011 and 2010, the Company recorded approximately $42,000 $69,000 and $75,000, respectively, of interest related to uncertain tax positions. Other than the decrease related to the settlement of state income liabilities, no additional uncertain tax positions have been identified 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 have an impact on the effective tax rate.

Currently tax years 2009, 2010, 2011 and 2012 remain open and subject to examination in the major tax jurisdictions in which tax returns are filed.

15. 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, product sales 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
Year Ended December 31, 2012				
Research and development revenue	$ 6,189	$ -	$ 15,356	$ 21,545
Product royalty revenue	50,696	-	-	50,696
Co-promotion revenue	3,576	-	-	3,576
Contract and collaboration revenue	565	16	52	633
Product sales revenue	-	14	5,023	5,037
Total revenues	61,026	30	20,431	81,487
Cost of goods sold	98	9	2,923	3,030
Gross profit	60,928	21	17,508	78,457
Research and development expenses	7,809	9,571	3,912	21,292
Depreciation and amortization	484	964	40	1,488
Other operating expenses	41,410	2,993	2,957	47,360
Income (loss) from operations	11,225	(13,507)	10,599	8,317
Interest income	161	16	2	179
Interest expense	-	(2,183)	(163)	(2,346)
Other non-operating expense, net	77	(187)	1,712	1,602
Income (loss) before income taxes	$ 11,463	$ (15,861)	$ 12,150	$ 7,752
Capital expenditures	$ 401	$ 3,038	$ -	$ 3,439

(In thousands)	Americas	Europe	Asia	Consolidated
Year Ended December 31, 2011				
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	791	474	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
Year Ended December 31, 2010				
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
As of December 31, 2012				
Property and equipment, net	$ 1,276	$ 36	$ 228	$ 1,540
Identifiable assets, net of intercompany loans and investments	$ 87,731	$ 25,465	$ 14,600	$ 127,796
As of December 31, 2011				
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

16. Quarterly Financial Data (unaudited)

(In thousands, except per share data)	2012 Quarters Ended December 31	September 30	June 30	March 31
Total revenues	$ 34,862	$ 15,496	$ 16,683	$ 14,446
Income (loss) from operations	$ 12,966	$ (1,653)	$ (2,674)	$ (322)
Net income (loss)	$ 13,532	$ (5,949)	$ (819)	$ (1,928)
Net income (loss) per share:				
Basic	$ 0.33	$ (0.14)	$ (0.02)	$ (0.05)
Diluted	$ 0.32	$ (0.14)	$ (0.02)	$ (0.05)

(In thousands, except per share data)	2011 Quarters Ended December 31	September 30	June 30	March 31
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)

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
Allowance for doubtful accounts:				
2010	$ -	$ -	$ -	$ -
2011	$ -	$ -	$ -	$ -
2012	$ -	$ 280(a)	$ -	$ 280
Valuation allowance for deferred tax assets:				
2010	$ 8,584	$ 1,074(b)	$ -	$ 9,658
2011	$ 9,658	$ 932(c)	$ (6,123)(c)	$ 4,467
2012	$ 4,467	$ 1,073(d)	$ (1,398)(d)	$ 4,142

(a) In 2012, the increase in allowance for doubtful accounts is primarily associated to certain disputed Takeda invoices.

(b) In 2010, the increase in valuation allowance is primarily associated with certain foreign net operating losses. This increase in the valuation allowance was based on management's assessment that, due to changing business conditions and the limitation of tax planning strategies, the Company was not likely to fully realize these deferred tax assets.

(c) In 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.

(d) In 2012, the net decrease in valuation allowance of $325,000 was due primarily to the release of the valuation allowance 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, dated as of December 29, 2008, by and among the Company, Sucamp Pharma Holdings, Inc. and Sucampo MS, Inc.	Exhibit 2.1 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^	Amended and Restated 2001 Stock Incentive Plan	Exhibit 10.1 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.2^	Amended and Restated 2006 Stock Incentive Plan	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (filed November 14, 2007)
10.3^	2006 Employee Stock Purchase Plan	Exhibit 10.3 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.4^	Form of Incentive Stock Option Agreement for 2006 Stock Incentive Plan	Exhibit 10.4 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.5^	Form of Nonstatutory Stock Option Agreement for 2006 Stock Incentive Plan	Exhibit 10.5 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.6^	Form of Restricted Stock Agreement for 2006 Stock Incentive Plan	Exhibit 10.6 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
10.7^	Non-employee Director Compensation Summary	Exhibit 10.7 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)

10.8^	Employment Agreement, dated June 16, 2006, between the Company and Ryuji Ueno	Exhibit 10.9 to Registration Statement No. 333-135133, Amendment No. 1 (filed August 11, 2006)
10.9^	Form of Executive Employment Agreement	Exhibit 10.10 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.10	Indemnification Agreement, dated May 26, 2004, between the Company and Sachiko Kuno	Exhibit 10.11 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.11	Indemnification Agreement, dated May 26, 2004, between the Company and Ryuji Ueno	Exhibit 10.12 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.12	Indemnification Agreement, dated May 26, 2004, between the Company and Michael Jeffries	Exhibit 10.13 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.13	Indemnification Agreement, dated May 26, 2004, between the Company and Hidetoshi Mine	Exhibit 10.14 to Registration Statement No. 333-135133, (filed June 19, 2006)
10.14	Form of Investor Rights Agreement	Exhibit 10.16 to Registration Statement No. 333-135133, (filed June 19, 2006)
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 Quarterly 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 Annual 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 Annual 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 Quarterly 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	Exhibit 10.58 to the Company's Annual Report on Form 10-K (filed March 15, 2012)
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 Quarterly 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	Exhibit 10.60 to the Company's Annual Report on Form 10-K (filed March 15, 2012)
10.61	Master Lease Agreement, effective as of January 31, 2012, between Sucampo AG and Numab AG	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (filed May 10, 2012)

10.62^	Employment Agreement, effective as of December 31, 2012, between the Company and Ryuji Ueno	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.63^	Employment Agreement, effective as of December 31, 2012, between the Company and Gayle Dolecek	Exhibit 99.2 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.64^	Employment Agreement, effective as of December 31, 2012, between the Company and Cary J. Claiborne	Exhibit 99.3 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.65^	Employment Agreement, effective as of December 31, 2012, between the Company and Stanley G. Miele	Exhibit 99.4 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.66^	Employment Agreement, effective as of December 31, 2012, between the Company and Thomas J. Knapp	Exhibit 99.5 to the Company's Current Report on Form 8-K (filed January 7, 2013)
10.67^	Form of Indemnification Agreement, dated December 31, 2012, between the Company and each of Ryuji Ueno, Gayle Dolecek, Cary J. Claiborne, Stanley G. Miele and Thomas J. Knapp	Exhibit 99.6 to the Company's Current Report on Form 8-K (filed January 7, 2013)
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.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-147420) and Form S-3 (No. 333- 185635) of Sucampo Pharmaceuticals, Inc. of our report dated March 15, 2013 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, 2013

EXHIBIT 31.1

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 registrants fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2013

/s/ RYUJI UENO
Ryuji Ueno, M.D., Ph.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, 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 registrants fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2013

/s/ CARY J. CLAIBORNE
Cary J. Claiborne
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Sucampo Pharmaceuticals, Inc. (the "Company") certifies to the best of his knowledge that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2012 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 18, 2013

/s/ RYUJI UENO
Ryuji Ueno, M.D., Ph.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Sucampo Pharmaceuticals, Inc. (the "Company") certifies to the best of his knowledge that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2012 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 18, 2013

/s/ CARY J. CLAIBORNE
Cary J. Claiborne
(Principal Financial Officer)