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

## Form 10-K

(Mark 0	One)	
☑	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) O	F THE SECURITIES EXCHANGE ACT OF 1934
	For the fiscal year ended December 31, 2013	
0	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
		IACEUTICALS, INC. nt as specified in its charter)
	<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>30-0520478</b> (I.R.S. Employer Identification No.)
	4520 East-West Highway, 3rd Floor Bethesda, MD 20814 (Address of principal executive offices, including zip code)	<b>20814</b> (Zip Code)
		961-3400 elephone number)
	Securities registered pursu	ant 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
Inc	dicate by check mark if the registrant is a well-known seasoned issuer, as	defined in Rule 405 of the Securities Act. Yes o $\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $
	dicate by check mark if the registrant is not required to file reports pursuals o $\mathbb{Z}$	ant to Section 13 or Section 15(d) of the Act.
the pred		red to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 durin red to file such reports), and (2) has been subject to such filing requirements for the
be subr		and posted on its corporate Web site, if any, every Interactive Data File required t f this chapter) during the preceding 12 months (or for such shorter period that th
not be o		405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and wiformation statements incorporated by reference in Part III of this Form 10-K or an
definiti	ions of "large accelerated filer," "accelerated filer" and "smaller reporting	Non-accelerated filer o 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

The aggregate market value of the 12,753,602 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 \$83.9 million.

As of March 3, 2014, there were outstanding 43,998,430 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 2014 Annual Meeting of Stockholders to be held on May 9, 2014, which Proxy Statement is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2013, are incorporated by reference in Part III of this Annual Report on Form 10-



## Sucampo Pharmaceuticals, Inc.

## Form 10-K Table of Contents

		Page			
Part I					
Item 1.	<u>Business</u>				
Item 1A.	Risk Factors				
Item 1B.	<u>Unresolved Staff Comments</u>				
Item 2.	<u>Properties</u>				
Item 3.	<u>Legal Proceedings</u>				
Item 4.	Mine Safety Disclosures				
	Part II				
<u>Item 5.</u>	Markets for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities				
Item 6.	Selected Financial Data				
<u>Item 7.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations				
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk				
Item 8.	Financial Statements and Supplementary Data				
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure				
Item 9A.	Controls and Procedures				
Item 9B.	Other Information				
	Part III				
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>				
<u>Item 11.</u>	Executive Compensation				
<u>Item 12.</u>	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters				
<u>Item 13.</u>	Certain Relationships and Related Transactions, and Director Independence				
<u>Item 14.</u>	Principal Accounting Fees and Services				
Part IV					
<u>Item 15.</u>	Exhibits, Financial Statement Schedules				
<u>Signatures</u>					
<u>Index to Consolidated Financial Statements</u>					

#### 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 biopharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs based on ion channel activators known as prostones. The therapeutic potential of prostones was first discovered by our co-founder, Dr. Ryuji Ueno. Under his leadership we have pioneered the field of prostones. Prostones are naturally occurring fatty acid metabolites which were 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 we 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, commercialize our approved products (as discussed below) on a global basis and protect our intellectual property.

Our operations are conducted through subsidiaries based in Japan, the United States, Switzerland, the United Kingdom 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 segments. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other factors.

Dr. Ueno and Dr. Sachiko Kuno have direct or indirect interests in our controlling stockholder, S&R Technology Holding, LLC, and are married to each other. Dr. Ueno stepped down as our Chief Executive Officer, Chairman of the Board of Directors, and Board member effective March 3, 2014 and as Chief Scientific Officer effective March 31, 2014. Beginning April 1, 2014, he will be consulting for us as the Co-Founder, Chairman Emeritus and Scientific Advisor. Dr. Kuno was a member of our Board of Directors and our executive advisor on international business development through September 30, 2012. Drs. Ueno and 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.

Effective March 3, 2014, Daniel P. Getman, Ph.D. became Chairman of the Board of Directors and Peter Greenleaf joined us as our Chief Executive Officer and Board member.

## 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 critical for the functioning of 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 525 active issued patents based on our proprietary prostone technology.

## **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 United States and Canada under our collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, and in Japan under our collaboration and license agreement with Abbott Japan Co. Ltd., or Abbott. We hold all commercialization rights for unoprostone isopropyl globally except for Japan, Korea, Taiwan and the People's Republic of China, or R-Tech Territory.

Product/Product Candidate	<b>Target Indication</b>	<b>Development Phase</b>	Next Milestone					
Lubiprostone (AMITIZA ®)	Chronic idiopathic constipation (CIC) (adults of all ages)	Marketed in the U.S.	_					
		Marketed in Switzerland	_					
		Marketed in the U.K. Initiated mutual recognition process (MRP) for approval in other E.U. countries.	Will consider seeking approval for AMITIZA in other E.U. countries following the MRP					
	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					
	Opioid-induced constipation (OIC) in patients with chronic non-cancer pain	sNDA approved in U.S. in Q2 2013. MAA submitted in Switzerland and U.K. in Q1 2013	Discuss with MHRA regulatory options for obtaining OIC approval in the U.K					
	Chronic constipation	Marketed in Japan since Q4 2012						
	Liquid formulation	Phase 3 trial initiated	Complete phase 3 trial; analyze results and file NDA					
	Pediatric functional constipation	Pivotal phase 3 initiated	Complete phase 3 program and file sNDA					
Unoprostone Isopropyl (RESCULA ®)	Primary open angle glaucoma and ocular hypertension	Launched in the U.S. in Q1 2013						
	Glaucoma and ocular hypertension	_	Updated label and reauthorization in the E.U. and Switzerland					
	Retinitis pigmentosa	In phase 3 by development partner R-Tech Ueno. Orphan drug status obtained in the U.S. and E.U.	Meet with the U.S. and European regulators prior to the interim results of Japanese trial					
IV Ion Channel Activator	Lumbar spinal stenosis	Phase 2a completed	Initiate additional phase 2a trial					
PO Ion Channel Activator	Lumbar spinal stenosis	Phase 1a completed	Initiate phase 1b trial					
Cobiprostone	Oral mucositis	Phase 1b initiated	Complete phase 1b trial					

#### AMITIZA (lubiprostone)

AMITIZA is well-tolerated and has a well-established efficacy profile. Since 2006, AMITIZA has been dispensed over 8 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 chronic idiopathic constipation, or CIC, were nausea, diarrhea, headache, abdominal pain, abdominal distension, and flatulence; for irritable bowel syndrome with constipation, or IBS-C, were nausea, diarrhea, and abdominal pain; and for opioid-induced constipation, or OIC, were nausea and diarrhea. 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 CIC and IBS and one opioid antagonist for OIC were either removed from the market or had severely reduced labeling due to safety concerns. An important consideration in any medicine for chronic constipation is having an established safety profile. We believe new medicines indicated for chronic treatment of CIC, IBS or OIC will have to demonstrate a post-marketing safety profile prior to extensive first line use.

#### **United States**

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

In April 2013, we received approval for a supplemental new drug application, or sNDA, for AMITIZA at dosage strength of 24 micrograms twice daily as the first and only oral medication for the treatment of OIC, in adult patients with chronic, non-cancer pain.

We and Takeda jointly develop and Takeda commercializes AMITIZA for CIC, IBS-C and OIC in the United States and Canada under the Takeda Agreement. More information on our collaboration with Takeda is found under the heading "Takeda Collaboration."

#### Chronic Idiopathic Constipation (CIC)

Constipation is characterized by infrequent and difficult passage of stool and becomes chronic when a patient suffers specified symptoms for over 12 non-consecutive weeks within a 12-month period. Chronic constipation, or 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. 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 may recommend laxatives, most of which are available over-the-counter (not prescription), or OTC, for acute use. 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.

A meta-analysis published in *The American Journal of Gastroenterology* in September 2011 estimates that approximately 14% of adults over 15 years of age, or over 30 million people, in the United States, suffer from CIC. 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.

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

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. Like CIC, some patients suffering from IBS-C may be treated with dietary measures, such as increasing fiber and fluid intake, or, if these measures prove ineffective, laxatives are frequently used for the management of this condition, though they are not approved for IBS-C.

Opioid-Induced Constipation (OIC)

OIC is a common adverse effect of chronic opioid use affecting patients taking opioids. Binding of opioids to peripheral opioid receptors in the gastrointestinal tract results in absorption of electrolytes, such as chloride, and subsequent reduction in small intestinal fluid. In addition, activation of enteric opioid receptors results in abnormal gastrointestinal motility. Together, these processes result in OIC, which is characterized by infrequent and incomplete evacuation of stool, hard stool consistency, and straining associated with bowel movements.

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. Additionally, the standard prescription option for OIC is osmotic laxatives. 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. Opioid drugs are known to suppress firing of secretomotor neurons in the gut which reduces intestinal fluid secretion resulting in drier, harder stools. Lubiprostone bypasses the opioid effect to work locally in the gut to reestablish fluid secretion thus alleviating OIC. As a result, we believe that AMITIZA holds a competitive advantage over drugs that do not work through this mechanism of action, and to date is the only oral approved product for the treatment of non-cancer OIC.

There are more than 200 million prescriptions for opioid use in the United States annually, and a substantial number of these prescriptions are for non-cancer chronic pain. Market research indicates that there are approximately 2.5-4.5 million moderate to severe sufferers of OIC, and 40-80% of patients taking opioids chronically for non-cancer pain report constipation in the United States.

#### Japan

In Japan, AMITIZA was approved for the treatment of chronic constipation, or CC, excluding constipation caused by organic diseases, by the Ministry of Health, Labour and Welfare, or MHLW, in June 2012. On December 1, 2013, the two-week limitation on prescriptions, generally applied to all new approvals of products for the first year after NIH reimbursement price approval, was removed. AMITIZA is Japan's only prescription medicine for CC.

#### Chronic Constipation (CC)

According to MHLW epidemiology data, millions of people in Japan may live daily with the pain and discomfort of chronic constipation, yet not seek physician care. Medical attention could mean early diagnosis and effective, long-term treatment.

It is estimated that approximately 14.3% of the Japanese population, or over 18 million people, suffer from chronic constipation.

In Japan, AMITIZA is currently marketed under the Abbott Agreement. More information on our collaboration with Abbott is found under the heading "Abbott Collaboration".

#### Europe

In the United Kingdom, we received approval in September 2012 from the Medicines and Healthcare Products Regulatory Agency, or MHRA, for the use of AMITIZA to treat CIC, but in March 2014 we received notification from MHRA that the application for the OIC indication was not approved. We made AMITIZA available in the United Kingdom in the fourth quarter of 2013 and we are currently working to achieve National Institute for Health and Care Excellence endorsement for CIC.

In Switzerland, AMITIZA was approved to treat CIC in 2009. In 2012, we reached an agreement with the Bundesamt fur Gesundheit, or BAG, on a reimbursement price and limitations for AMITIZA in Switzerland, and began active marketing in the first quarter of 2013. In February 2014, we announced that the BAG revised several reimbursement limitations with which AMITIZA was first approved for reimbursement and inclusion in the Specialitätenliste, or SL, to allow all Swiss physicians to prescribe AMITIZA to patients who have failed previous treatments with at least two laxatives over a nine month period. The SL limitations that were revised are:

- · All Swiss physicians, not just gastroenterologists, may prescribe AMITIZA;
- · The change in the maximum treatment duration of AMITIZA increased from 12 to 52 weeks before a review is needed by a health insurance health care practitioner; and
- The BAG removed from AMITIZA's SL a group limitation pertaining to the number of AMITIZA packs that physicians can prescribe at one time.

We filed for the OIC indication in Switzerland in the first quarter of 2013, and in the United Kingdom in the second quarter of 2013. We were notified on March 7, 2014 that the MHRA did not approve the application for the OIC indication in the United Kingdom. We are considering the appropriate next steps with MHRA. We anticipate a decision in Switzerland in the first half of 2014. We are considering seeking approval for AMITIZA in other European Union countries following the Mutual Recognition Procedure, or MRP.

#### Chronic Idiopathic Constipation (CIC)

A meta-analysis published in *The American Journal of Gastroenterology* in September 2011 estimates that approximately 16% of adults over 15 years of age, or over 42 million people, in Northern Europe suffer from CIC.

A study published in *Alimentary Pharmacology and Therapeutics* in 2012 was conducted in ten European countries, including Switzerland, which demonstrated that approximately 28% of the participants suffering from constipation for at least 6 months were dissatisfied with their current treatment options using laxatives. As a result, approximately 83% of these patients are interested in seeking alternative methods to relieve their constipation. Additionally, patients in this study reported they want relief from all of their symptoms and to feel normal.

#### Other Global Markets

We and Takeda are currently exploring the commercialization of AMITIZA in Canada and we have met with Health Canada to discuss the best ways to proceed with AMITIZA registration in this market in the near future.

We continue to explore options to develop and commercialize lubiprostone in other geographic regions, inclusive of Latin America, Russia, the Middle East, the People's Republic of China and other Asian countries.

#### **RESCULA** (unoprostone isopropyl)

In the United States, a 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. 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 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.

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 effect 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 cardiovascular or pulmonary function in clinical studies, and minimal systemic absorption and exposure.

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 United States and Canada from R-Tech.

We began commercializing RESCULA in the United States in February 2013. In November 2013 we decided to eliminate our in-house sales force and deploy a contract sales force. Beginning in January 2014, we significantly decreased the amount of in-person sales calls for RESCULA by using a contract sales force to detail only current RESCULA prescribers. We also use a limited mix of inside sales and other promotional tactics, including digital, to reach the current non-prescriber base in an effort to increase prescribers and sales of RESCULA.

## **Our Other Clinical Development Programs**

#### Lubiprostone

## Liquid Formulation

In October 2013, we announced the initiation of a pivotal trial of a liquid formulation of lubiprostone 24mcg twice daily in adults with CIC. Upon reviewing the results of this trial, which we anticipate to end in the first half of 2014, we plan to file a new drug application for approval.

#### Pediatric Functional Constipation

Constipation in children has similar characteristics to that of constipation in adults in that symptoms include infrequent bowel movements, hard stools, large diameter stools and painful passage of stools. Rome III diagnostic criteria for childhood functional constipation dictate that such symptoms occur at least once per week for at least 2 months prior to diagnosis. 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. Ninety percent of pediatric constipation is functional constipation and it occurs in all age groups.

An analysis of longitudinal data in the United States showed a nearly 4-fold increase in rates of constipation over the last decade. Estimates of the prevalence rate of functional constipation in the pediatric population worldwide have varied greatly, from 4 to 37%. Only 50-70% of children with functional constipation demonstrate long-term improvement with the current treatments.

In December 2013, we announced the initiation of the pivotal phase 3 clinical program of AMITIZA in pediatric functional constipation. This is the first of a series of global, multicenter phase 3 studies to evaluate the efficacy, safety, and pharmacokinetics of AMITIZA capsules in patients  $\geq$  6 months through 17 years of age with pediatric functional constipation. We also plan to evaluate the long-term safety of AMITIZA in these populations through two open-label extension studies. One of the pediatric trials will also use the liquid formulation.

## **Unoprostone Isopropyl**

We continue to pursue additional intellectual property as well as further clinical development of unoprostone isopropyl. In clinical and preclinical studies, unoprostone isopropyl has increased ocular blood flow to the optic nerve and in the choroid; maintained visual field; delayed retinal degeneration induced by rhodopsin; inhibited topographic and blood changes in an ischemic optic nerve head; and lowered intraocular pressure. We believe that unoprostone isopropyl could potentially be effective in the treatment of other ocular diseases.

## Retinitis Pigmentosa

Retinitis pigmentosa, or RP, is a genetic disease characterized by progressive, irreversible vision loss and decreasing visual acuity. RP represents the most common hereditary cause of blindness in people from 20 to 60 years old. As RP progresses, daily life becomes increasingly difficult. Blindness from all causes is among the most significant injuries to a patient's quality of life and is a major driver of patient-based cost of care and lifestyle maintenance.

We have received orphan drug designation for unoprostone isopropyl from the FDA for the treatment of RP and from EMA. 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. In October 2013, we announced that R-Tech completed patient enrollment of the phase 3 clinical development for unoprostone isopropyl for RP. We have the rights to the clinical data for potential filing in Europe and the United States and will decide on our path forward assuming the Japanese trial is successful. Additionally, we are currently evaluating opportunities in other retinal diseases, such as age-related macular degeneration.

An article published in *Current Genomics* in 2011 estimates that approximately one in every 3,000 to 5,000 individuals, or over 170,000 people worldwide, suffers from RP.

## Intravenous (IV) and Oral (PO) Ion Channel Activators

## **Lumbar Spinal Stenosis**

We have both an IV ion channel activator and a PO ion channel activator in development for the treatment of lumbar spinal stenosis, or LSS. These compounds may also be investigated for other indications in the future. LSS is caused by degenerative change in the lumbar spine, and it 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, resulting in lower back pain, as well as pain, weakness, and numbness in the legs.

In the United States and Europe, there are no medications specifically approved for the pain associated with the treatment of lumbar spinal stenosis. Commonly used medications to address the symptoms 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 the improvement of subjective symptoms (pain and numbness of lower legs) and gait ability associated with acquired lumbar spinal canal stenosis (in patients with bilateral intermittent claudication showing normal SLR test result). Prostaglandins do not always achieve desired results, and while rare, severe side effects have been experienced with its use.

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.

In December 2013, we reported results of the treatment phase of our phase 2a, double-blind, placebo-controlled study of the IV version of our ion channel activator for LSS, that indicated statistically significant improvement in Visual Analog Scale pain. We plan to initiate an additional phase 2a in the second half of 2014 with a revised protocol and different patient group.

The PO ion channel activator for phase 1a clinical development results were reported in August 2013, and demonstrated that the compound is generally well-tolerated. We plan to initiate the next phase of clinical development in the first quarter of 2014.

#### Cobiprostone

## Oral Spray for Oral Mucositis

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 and/or treatment of oral mucositis, or OM. We are also investigating the potential for cobiprostone for oral administration in other disease areas.

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% 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 are at high risk of developing OM in the 89-100% range depending on if the radiation therapy is in combination with chemotherapy or altered fractionation RT. Additionally, patients being treated for hematopoietic stem cell transplant and other types of cancer are also at risk for developing oral mucositis.

OM current treatment includes basic oral care, cryotherapy, topical rinses such as lidocaine and carbomer and palifermin, a growth factor. There is currently no treatment available to address multiple aspects of this disease, consequently creating an unmet medical need.

There are approximately 5 million head and neck cancer patients globally, including approximately 350,000 in the United States. It is estimated that 80-90% of the United States population that receives radiotherapy and chemotherapy for head and neck cancer will experience some grade of oral mucositis during their treatment.

In August 2013, we reported results of our phase 1a trial for the oral spray formulation of cobiprostone that demonstrated the compound is to be generally well-tolerated in healthy volunteers. In October 2013, we initiated a phase 1b clinical development study, which is expected to conclude in the first half of 2014.

#### Takeda Collaboration

Under the Takeda Agreement, we and Takeda jointly develop and Takeda commercializes AMITIZA for gastrointestinal indications in the United States and Canada. We have limited co-promotion rights under the Takeda 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.

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 equally share all costs in excess of those amounts. With respect to any studies required to modify or expand the label for AMITIZA for the treatment of CIC, IBS-C or OIC, Takeda has agreed to fund 70% of the costs of such studies, and we have agreed to fund the remainder. Additionally, Takeda has agreed to fund 100% of the development costs for the liquid formulation of AMITIZA, and 70% of the development costs for the treatment of pediatric functional constipation. From inception of the Takeda Agreement to December 31, 2013, Takeda has reimbursed us an aggregate of \$114.7 million in research and development expenses.

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. In addition, Takeda is required to perform specified minimum number of professional product detail meetings with certain health care professionals throughout the term of the Takeda Agreement.

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 United States 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. In November, 2013, we announced that we would be exercising our co-promotion option and will begin co-promoting AMITIZA for OIC in adults with chronic, non-cancer pain in the first quarter of 2014.

Licensing Fees, Milestone Payments and Royalties. Takeda made an upfront payment of \$20.0 million in 2004, and has paid additional total development milestone payments of \$140.0 million through December 31, 2013, which includes a \$10.0 million milestone payment as a result of the commercial launch of the OIC indication in the second quarter of 2013. Takeda records all sales of AMITIZA in the United States and Canada and pays us a tiered royalty based on net sales of AMITIZA sold in the United States and Canada. There can be no assurances that we will receive additional development or commercial milestone payments under our Takeda Agreement.

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 not 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 Takeda Agreement.

*New Indications.* Takeda has a right of first refusal to obtain a license to develop and commercialize AMITIZA in the United States and Canada for any new indications outside of gastrointestinal indications that we may develop. We retain the rights to AMITIZA for all other therapeutic areas. We and Takeda are currently exploring the commercialization of AMITIZA in Canada and have met with Health Canada to discuss the best ways to proceed with AMITIZA registration in this market in the near future.

If one of our subsidiaries or licensees wishes to use certain proprietary data or information developed under the collaboration with Takeda outside the United States or Canada, for example in support of a regulatory filing in Europe or Asia, we are obligated to pay to Takeda 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, 2013, which includes 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.* With the commencement of product sales of AMITIZA in Japan in the fourth quarter of 2012, we now 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, and ion channel activators. As of December 31, 2013, these include a total of 47 U.S. patents, 39 U.S. patent applications, 20 European patents, 33 European patent applications, 32 Japanese patents and 27 Japanese patent applications. We license the rights to certain unoprostone patents from R-Tech. 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 25 issued U.S. patents, 10 issued European patents, and 16 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 23 issued U.S. patents, 10 issued European patents, and 17 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 ion channel activators consist of 8 issued U.S. patents, 5 issued European patents, and 7 issued Japanese 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 2021. The other U.S. patents and foreign patents expire between 2018 and 2032.

The patent rights relating to unoprostone isopropyl licensed from R-Tech consist of 6 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 2032. The other U.S. and foreign patents expire between 2016 and 2032.

We are actively seeking to augment our portfolio of compounds by focusing on the development of new chemical entities, or NCEs, such as cobiprostone, and ion channel activators, which have not previously received FDA approval. Upon approval by the FDA, NCEs are entitled to market exclusivity in the United States with respect to generic drug products for a period of five years from the date of FDA approval, even if the related patents have expired. 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 Pharmaceuticals, Inc. 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 ion channel activators 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, 2013. 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 United States 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.

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.

We also have a supply agreement with R-Tech for the supply of AMITIZA to Abbott under the Abbott Agreement and for supply for Europe, Middle East and Africa. These long-term agreements supply all Abbott's and our commercial supplies, including product samples, for AMITIZA for the Japan, Switzerland and UK markets. Like the Takeda arrangement, a 24-month rolling forecast of product and sample requirements is required for Japan and a 12-month rolling forecast is required for the Switzerland and UK markets and R-Tech is required to keep adequate levels of inventory in line with these forecasts. In the event that R-Tech cannot meet some or all of Abbott's or our demand, we do not have alternative manufacturing arrangements in place but R-Tech is required to keep commercially reasonable supplies on hand. R-Tech shall maintain a safety stock of active drug substance equal to six (6) months of forecast demand based on Abbott's most recent rolling forecast. R-Tech shall maintain a safety stock of additional materials to support the drug product manufacture and packaging equal to three (3) months of forecast demand based on Abbott's most recent rolling forecast. R-Tech and we are currently negotiating an exclusive manufacturing and supply agreement to take the place of the supply agreements for all territories other than Japan, US and Canada.

In 2009, we entered into an exclusive supply agreement with R-Tech for ten years to supply us with unoprostone isopropyl for the United States 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 ion channel activators, 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. R-Tech has decided to contract with NittoMedic in Japan for the manufacture of unoprostone isopropyl but NittoMedic's facility needed to be inspected by the FDA before it can manufacture unoprostone isopropyl. In light of this change in facility, we placed an order to sufficiently cover this supply period based on our forecasts for the launch of RESCULA in the United States and regulatory requirements in the E.U. R-Tech delivered that order to us in the first and second quarters of 2013. We filed a supplemental new drug application, or sNDA, in July 2013 for the new facility. The NittoMedic facility was inspected by the FDA in the fourth quarter of 2013. As a result of the inspection, FDA issued deficiencies to NittoMedic and a complete response letter to us with regard to the drug master file. NittoMedic has responded to the deficiencies and we have asked FDA to proceed with its review of the sNDA, which it has indicated it will do so. We are awaiting the

#### 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 United States, 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. initiated a double-blind, placebo-controlled, dose-ranging phase 2 clinical trial of linaclotide in Japanese adult patients with IBS-C but it was reportedly unsuccessful, 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 Shire 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 several European markets. Shire intends to develop prucalopride in the United States 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 muopioid receptor antagonists in patients taking opioids for chronic pain. Salix has appealed this complete response letter and the FDA will be convening an Advisory Committee meeting we believe 1H of 2014. 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). A fixed dose combination of oxycodone/naloxone (Targin®, Targinact®) is marketed by Mundipharma throughout Europe.
- · 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, and ion channel activators, 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 United States, 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.

#### **United States Government Regulation**

In the United States, 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 United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions most notably by the European Medicines Agency, 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 United States before we can commence clinical trials or marketing of the product in those countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country, and the time for approval 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 United States 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 United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party 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 United States continue to work towards significant legislation aimed to limit the growth of healthcare costs, including the cost of prescription drugs. Following the United States 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 United States government agencies designated to carry out the extensive requirements of the ACA. These regulatory actions have both positive and negative impacts on the United States 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 long term impacts on us. The provisions of the United States 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 United States 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 payers (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 United States, 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 United States Foreign Corrupt Practices Act which prohibits United States 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 United Kingdom 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. United States companies that conduct business in the United Kingdom 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 the United Kingdom, pharmaceutical companies set their own price and then National bodies (e.g. National Institute for Health and Care Excellence, or NICE), Scottish Medicines Consortium, or SMC), sub-National bodies (e.g. Greater Manchester Medicines Management Group, or GMMMG), London Procurement Partnership, or LPP), or Local bodies (e.g. Clinical Commissioning Groups, or CCGs), Health Boards, or HBs), will determine if a medicine is cost-effective. The National and sub-National bodies advise local bodies, which are greatly influenced by a NICE endorsement; however, ultimately the decision to pay for a medicine is made at a local level in the United Kingdom.

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 United Kingdom 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 7, 2014.

Name	Age	Position
Peter Greenleaf	44	Chief Executive Officer and member of the Board of Directors
Cary J. Claiborne	53	Chief Financial Officer
Ryuji Ueno, M.D., Ph.D., Ph.D.	60	Chief Scientific Officer, Co-Founder and Chairman Emeritus
Stanley G. Miele	50	President, Sucampo Pharma Americas, LLC and Senior Vice President of Sales and Marketing
Thomas J. Knapp	61	Executive Vice President, Chief Legal Officer and Corporate Secretary

Peter Greenleaf. Mr. Greenleaf is our Chief Executive Officer and member, Board of Directors, since March 2014. Prior to his leadership of our company, Mr. Greenleaf was CEO and Board member of Histogenics, a regenerative medicine company, from June 2013 through February 2014. From 2008 to June 2013, Mr. Greenleaf was employed by MedImmune LLC, the global biologics arm of AstraZeneca, where he most recently served as President. While at MedImmune, Mr. Greenleaf was instrumental in driving the expansion of MedImmune's pipeline into over 120 clinical and pre-clinical programs and the commercialization of its marketed products. Mr. Greenleaf also served as President of MedImmune Ventures from January 2010 to June 2013, a wholly owned venture capital fund within the AstraZeneca Group, where he led investment in emerging biopharmaceutical, medical device, and diagnostic companies. Prior to serving as President of MedImmune, Mr. Greenleaf was the Chief Commercial Officer of the company, responsible for its commercial, corporate development and strategy functions. Mr. Greenleaf has also held senior commercial roles at Centocor Biotech, Inc. (now Janssen Biotechnology, Johnson & Johnson) from 1998 to 2006 and prior to that Boehringer Mannheim G.m.b.H. (now Roche Holdings) from 1996 to 1998. Mr. Greenleaf currently chairs the Maryland Venture Fund Authority, whose vision is to oversee implementation of InvestMaryland, a public-private partnership to spur venture capital investment in the state. Mr. Greenleaf is also a member of the board of directors of the Biotechnology Industry Organization (BIO), where he also serves on the Governing Board of the Emerging Companies Section. Mr. Greenleaf's previous Board appointments include the University of Maryland Baltimore Foundation, Inc.; Rib-X Pharmaceuticals; LigoCyte Pharmaceuticals; and Corridor Pharmaceuticals. He received a Masters of Business Administration degree from St. Joseph's University and a Bachelor of Science degree from Western Connecticut State University.

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 and GE since 1982. Mr. Claiborne is also a member of the board of directors of MedicAlert Foundation, where he also serves as the chair of the Finance Committee. Mr. Claiborne graduated from Rutgers University where he earned a B.A., Business Administration and an MBA, in Finance, from Villanova University.

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, from September 2006 through March 2, 2014, 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, and served in that position until March 2014. 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.

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 our company 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.

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 3, 2014, we had 77 full-time employees, including 20 with doctoral or other advanced degrees. Of our workforce, 25 employees are engaged in research and development, 11 are engaged in sales and marketing and 41 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 2011, 2012 and 2013, 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 activities include the commercialization of RESCULA, AMITIZA income and costs associated with the Takeda collaboration. The segment recorded an income before taxes of \$21.0 million in 2013, compared to \$11.5 million in 2012, an increase of \$9.5 million, or 83.0%. This increase is primarily attributable to the receipt of the \$10.0 million milestone payment from Takeda in 2013 upon the first commercial sale of AMITIZA for OIC.

Our Europe segment activities include the commercialization of AMITIZA in Europe costs associated with pipeline development, intellectual property management and licensing activities. The segment recorded a loss before taxes of \$12.4 million in 2013, compared to a loss before taxes of \$15.9 million in 2012, a decrease of \$3.4 million, or 21.7%.

Our Asia segment activities include the commercialization of AMITIZA in Japan as a result of our collaboration with Abbott. The segment recorded an income before taxes of \$1.8 million in 2013, compared to \$12.2 million in 2012, a decrease of \$10.4 million, or 85.2%. This decrease is primarily attributable to the milestone payment received from Abbott in 2012.

(In thousands)	An	nericas	J	Europe	Asia	Cor	nsolidated
Year Ended December 31, 2013							
Total revenues	\$	73,637	\$	108	\$ 15,849	\$	89,594
Income (loss) before taxes		20,983		(12,425)	1,789		10,347
Identifiable assets		95,350		23,843	17,780		136,973
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

## **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 outstanding 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 outstanding common stock, class A common stock, 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 direct and indirect subsidiaries as of December 31, 2013:

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 United States 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 United States 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 products 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 commercialize 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 or effective;
- · our preclinical and clinical data is interpreted in different ways than we interpret that data;
- · we may be required to perform post-marketing clinical studies; or
- there may be changes in the approval policies or adoption of 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.

Our product, AMITIZA, faces competition from competitors' products like linaclotide, which, in addition to other factors, could in certain circumstances lead to a significant reduction in royalty revenues and product sales. Our other product, RESCULA, faces competition from other competitors' products, which, in addition to other factors, could lead to a significant reduction in product sales.

Our products, AMITIZA and RESCULA, face competition from competitors' products. Specifically, AMITIZA faces competition from linaclotide which was recently approved for two of the three indications that AMITIZA has been approved in the U.S and for IBS-C in certain European countries. Its manufacturer is seeking approval in other markets for IBS-C that we currently or intend to market AMITIZA. Linaclotide may be safer or more effectively marketed and sold than AMITIZA is by our partners or by ourselves. Similarly, RESCULA faces competition from other competitors' products which could be more effective, have better customer access or be 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 our products. As a result, if we fail 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 a predominantly research and development 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 from a predominately R&D 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 and RESCULA, and commercializing AMITIZA and RESCULA. Though we will continue to rely upon the collaboration agreement with Takeda and Abbott to commercialize AMITIZA in the United States and Japan, we may not be able to cause these third parties to effectively market and sell AMITIZA. 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 United States 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 United States, it could be difficult for us to access capital, to build the necessary infrastructure, to obtain and devote the resources necessary to successfully manage our commercialization efforts, to effectively market and sell our products, 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 United States 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, IBS-C and OIC, and successful commercialization of these indications within and outside the United States;
- · 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. The outstanding balance on the notes as of December 31, 2013 was \$33.7 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, 2013, we were compliant.

Although we have reported profit in 2013, we may not maintain operating profitability in the future, and this could force us to delay, reduce or abandon our commercialization efforts or product development programs.

Although we have reported net income in 2013, this was primarily attributable to increased product royalties and product sales under our agreements with Takeda and Abbott. We recorded a net income of \$6.4 million and \$4.8 million in 2013 and 2012, respectively. Our primary cost drivers result from expenses incurred in our research and development programs and from our commercialization, 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 United States 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 to 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 product royalty from AMITIZA;
- 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 at-the-market sales, public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we raise additional funds by at-the-market sales or 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 foreign political conditions and regulatory requirements and 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;
- $\cdot$   $\;$  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 unoprostone isopropyl, cobiprostone and ion channel activators, 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 United States for our products. These supplemental trials could be costly and could result in findings inconsistent with or contrary to our historic United States 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 United States, 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 United States 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 RESCULA. Inconsistent trial results could also lead to delays in obtaining marketing approval in the United States 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 replace our chief scientific officer and other key executives, we may not be able to successfully develop and commercialize our products.

We have been highly dependent on Dr. Ryuji Ueno, as 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 our company. Dr. Ueno will step down as our chief scientific officer to be a consultant for us in 2014. The loss of the services of Dr. Ueno as a full-time chief scientific officer and any of the scientific 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 consultant agreements and employment agreements with these executives and scientific persons, but these agreements are terminable by the consultants and employees on short or no notice at any time without penalty to the consultant or 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 and 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 ion channel activators 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 ion channel activators, 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 contracting with NittoMedic to manufacture RESCULA. In order to mitigate this risk, we had placed an order to sufficiently cover this supply period based on our forecasts. R-Tech delivered that order to us in the first quarter of 2013. However, the NittoMedic facility was required to be inspected by FDA. That inspection has resulted in NittoMedic receiving notice of deficiencies and us receiving a complete response letter for the sNDA. NittoMedic has responded to the FDA and we have asked the FDA to review the sNDa in light of the NittoMedic response. The FDA has indicated it will do so and we are awaiting FDA's decision.

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

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 United States regulations or similar regulatory requirements in force outside the United States. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products approved for sale. In addition, the FDA or other regulatory agencies outside the United States may at any time audit or inspect a manufacturing facility to ensure compliance with cGMP or similar regulations. Our failure, or the failure of R-Tech, R-Tech's subcontractors and suppliers or any other third-party manufacturer we use, to comply with applicable manufacturing regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates.

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

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

A key element of our business strategy is to collaborate where appropriate with third parties, particularly leading pharmaceutical companies, to 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 United States 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 contract research organizations, or 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 consultant to our company providing certain scientific and other services may 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 ion channel activators;
- a decision whether to engage R-Tech in the future to manufacture and supply compounds other than AMITIZA, RESCULA, cobiprostone and ion channel activators;
- 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, United Kingdom; SAG, based in Zug, Switzerland; and Ambrent Investments S.à r.l., based in Luxembourg. 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 United States and the other countries in which we and our affiliates operate. Transfer pricing regulations generally require that, for tax purposes, transactions between our subsidiaries and affiliates and us be priced on a basis that would be comparable to an arm's length transaction and that contemporaneous documentation be maintained to support the related party agreements. To the extent that United States or any foreign tax authorities disagree with our transfer pricing 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, 2013, 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 generic companies that an Abbreviated New Drug Application was filed, 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 adversely affected.

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 United States 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 United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor 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 United States 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 seeking 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 United States, may designate drugs that target relatively small patient populations as orphan drugs. We have received an orphan drug designation from the FDA for our product candidate cobiprostone for the treatment of disorders associated with cystic fibrosis. We have also received orphan drug designation for unoprostone Isopropyl from the FDA and EMA 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 United States, but this period may be interrupted if a sponsor of a competitive product that is otherwise the same drug for the same use can show that its drug is clinically superior to our orphan drug candidate. The European exclusivity period is ten years, but may be reduced to six years if a drug no longer meets the criteria for orphan drug designation, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified. In addition, European regulations establish that a competitor's marketing authorization for a similar product with the same indication may be granted if there is an insufficient supply of the product or if another applicant can establish that its product is safer, more effective or otherwise clinically superior. If a competitor obtains orphan drug exclusivity for a product objects with cobiprostone or unoprostone isopropyl 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 supe

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 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 scientific officer, and Dr. Sachiko Kuno, together through their direct or indirect interest in S&R Technology Holding, LLC beneficially own 26,190,255 shares of class A common stock, representing approximately 59.5% of the combined voting power of our outstanding common stock as of March 3, 2014. 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;
- $\cdot \quad \text{ the regulatory status of our product candidates;} \\$
- · the success of competitive products or technologies;
- · regulatory developments in the United States and foreign countries;

- · developments or disputes concerning patents or other proprietary rights;
- the ability of R-Tech to manufacture our products to commercial standards in sufficient quantities;
- · actual or anticipated fluctuations in our quarterly financial results;
- · variations in the financial results of companies that are perceived to be similar to us;
- · changes in the structure of healthcare payment systems;
- · market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations; and
- · general economic, industry and market conditions.

## 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.

We lease our Asian offices located in Tokyo and Osaka, Japan and European office, located in Zug, Switzerland, 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. Subsequently, we, along with R-Tech and Takeda, amended the lawsuit to add allegations in respect to an additional Notice Letter received from Anchen and Par which Notice Letter responded to an additional patent listed on the FDA's Orange Book. The parties have initiated written discovery and the District Court has entered a scheduling order. Depositions of the inventors and other fact witnesses will take place in the second and third quarter of 2014, with the trial starting in December 2014.

## 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, 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
March 31, 2013	\$ 6.54	\$ 4.77
June 30, 2013	\$ 10.04	\$ 6.14
September 30, 2013	\$ 7.00	\$ 5.62
December 31, 2013	\$ 9.47	\$ 6.09

As of March 3, 2014, we had 43,998,430shares of class A common stock outstanding held by 12 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 3, 2014, the closing price of our class A common stock was \$8.49.

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.

## **Issuer Purchases of Equity Securities.**

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.

During the fourth quarter ended December 31, 2013, we did not repurchase any of our equity securities. During the twelve months ended December 31, 2013, we repurchased 67,762 shares of our class A common stock under this program at a cost of \$336,000.

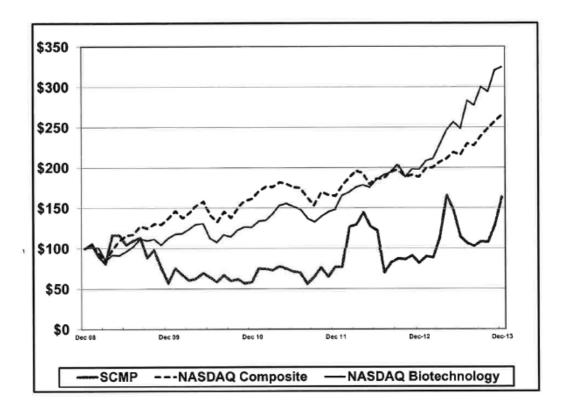
#### **Issuer Sales of Equity Securities**

As previously disclosed, on January 11, 2013, we entered into a sales agreement with Cantor Fitzgerald & Co., or Cantor Sales Agreement, which enables us to offer and sell shares of our class A common stock with aggregate class A common stock sales of up to \$20.0 million, from time to time through Cantor Fitzgerald & Co. as our sales agent. Sales of class A common stock under the Cantor Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Cantor Fitzgerald & Co. is entitled to receive a commission rate of 3.0% of gross sales in connection with the sale of our class A common stock sold on our behalf. From November 22, 2013 through December 31, 2013, we sold through the Cantor Sales Agreement an aggregate of 749,383 shares of our class A common stock, and received gross proceeds of approximately \$5.3 million, before deducting issuance expenses.

## **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 December 31, 2008, in each of (1) our class A common stock, (2) The NASDAQ Composite Index (United States and Foreign) and (3) the NASDAQ Biotechnology 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

The following derived consolidated financial data as of December 31, 2013 and 2012 and for the years ended December 31, 2013, 2012 and 2011 are from our audited Consolidated Financial Statements appearing elsewhere in this Annual Report. The following consolidated financial data as of December 31, 2011, 2010 and 2009 and for the years ended December 31, 2010 and 2009 are derived from audited Consolidated Financial Statements 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)		2013		2012		2011		2010		2009
Statement of operations data										
Revenues	\$	89,594	\$	81,487	\$	54,761	\$	61,870	\$	67,351
Costs and expenses:										
Cost of goods sold		12,402		3,030		-		-		-
Research and development		21,524		21,292		33,497		23,955		32,906
Settlement of legal dispute		-		-		(11,100)		-		-
General and administrative		25,413		30,157		41,270		27,867		15,000
Selling and marketing		21,059		18,691		8,783		10,201		10,030
Total costs and expenses		80,398		73,170		72,450		62,023		57,936
Income (loss) from operations		9,196		8,317		(17,689)		(153)		9,415
Total non-operating income (expense), net		1,151		(565)		(4,225)		(3,167)		446
Income (loss) before income taxes		10,347		7,752		(21,914)		(3,320)		9,861
Income tax benefit (provision)		(3,928)		(2,916)		4,608		565		(5,084)
Net income (loss)	\$	6,419	\$	4,836	\$	(17,306)	\$	(2,755)	\$	4,777
Basic net income (loss) per share	\$	0.15	\$	0.12	\$	(0.41)	\$	(0.07)	\$	0.11
Diluted net income (loss) per share	\$	0.15	\$	0.12	\$	(0.41)	\$	(0.07)	\$	0.11
Weighted average common shares outstanding - basic		41,716		41,660		41,839		41,848		41,844
Weighted average common shares outstanding - diluted		42,544		41,785		41,839		41,848		41,866
Per Share Data										
Income (loss) from operations-basic	\$	0.22	\$	0.20	\$	(0.42)	\$	(0.00)	\$	0.23
Income (loss) from operations-diluted	\$	0.22	\$	0.20	\$	(0.42)	\$	(0.00)	\$	0.22
Income (loss) from operations-diluted	\$	0.22	\$	0.20	\$	(0.42)	\$	(0.00)	\$	0.22

	December 31,								
(In thousands)	 2013		2012		2011		2010		2009
Balance sheet data:									
Cash and cash equivalents	\$ 44,102	\$	52,022	\$	50,662	\$	49,243	\$	61,420
Investments, current	16,003		6,035		24,452		54,524		72,434
Working capital	70,741		52,843		67,835		94,541		127,313
Total assets	136,973		127,796		157,569		149,273		180,005
Notes payable, current	26,892		19,129		20,400		19,522		-
Notes payable, non-current	25,828		33,722		39,227		44,439		-
Total liabilities	78,825		84,766		118,975		95,443		34,693
Retained earnings (accumulated deficit)	(27,681)		(34,100)		(38,936)		(21,630)		33,150
Total stockholders' equity	58,148		43,030		38,594		53,830		145,312

#### 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 biopharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs based on ion channel activators known as prostones. The therapeutic potential of prostones was first discovered by our co-founder, Dr. Ryuji Ueno. He initially found that that prostone production was high in early development, and postulated that prostones produced by 15-PGDH may play important roles as an endogenous local hormones in maturation and aging. Under his leadership we have pioneered the field of prostones. Prostones are naturally occurring fatty acid metabolites which were 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 have two approved products, AMITIZA® (lubiprostone) and RESCULA® (unoprostone isopropyl). Our strategic priorities are as follows: for AMITIZA, to increase sales in the United States, Japan and Europe, to expand into new indications, and to launch into new global markets; for RESCULA, to continue to commercialize the product to current prescribers in the United States, and to expand into new indications with unoprostone isopropyl; and to further develop our late-stage clinical development compounds.

First, in the United States, AMITIZA is being marketed and developed under a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, for gastrointestinal indications. In Japan, AMITIZA is being marketed under a collaboration agreement with Abbott Japan Co. Ltd., or Abbott. AMITIZA is also approved and currently being commercialized in the United Kingdom and Switzerland for chronic idiopathic constipation, or CIC. We have plans to file for approval in other European markets. Our priorities for AMITIZA are to increase sales of the product in markets where it is approved; to obtain approval of AMITIZA for other indications in certain European markets; to expand into new global markets; and to develop AMITIZA in a liquid formulation and for the pediatric market. We began clinical development for the liquid formulation and pediatric dosage in the second half of 2013.

Second, RESCULA received approval of a 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 United States on our own.

Third, a final priority for us is the development of our prostone-based pipeline. In 2013, we furthered our clinical development of three drug candidates: the intravenous and oral ion channel activators for lumbar spinal stenosis and cobiprostone for oral mucositis.

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 United States, Switzerland, the United Kingdom 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 segments. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other factors.

# Our Prostone Products, Approved and in Clinical Development

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

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

## **United States**

In April 2013, we received approval for a supplemental new drug application, or sNDA, for AMITIZA at dosage strength of 24 micrograms twice daily as the first and only oral medication for the treatment of OIC in adult patients with chronic, non-cancer pain. Upon the first commercial sale of AMITIZA for OIC, we recognized a \$10.0 million milestone payment from Takeda as revenue, which we received in the second quarter of 2013. In November 2013, we announced that we are exercising our co-promotion option and will begin co-promoting AMITIZA for OIC in adults with chronic, non-cancer pain in the first quarter of 2014.

#### Japan

In Japan, AMITIZA is currently marketed under a license, commercialization and supply agreement, or the Abbott Agreement, with Abbott for the gastrointestinal indication of chronic constipation, or CC, excluding constipation caused by organic diseases. Abbott initiated commercial sales of AMITIZA in Japan for the treatment of CC in November 2012. AMITIZA is Japan's only prescription medicine for CC. On December 1, 2013, the two-week limitation on prescriptions, generally applied to all new approvals of products for the first year after reimbursement price approval, was removed.

#### Europe

We have retained full rights to develop and commercialize AMITIZA ourselves for the rest of the world's markets outside of the United States, Canada and Japan. In the United Kingdom, AMITIZA was approved for CIC in July 2012. We made AMITIZA available in the United Kingdom in the fourth quarter of 2013. We filed for the OIC indication in Switzerland in the first quarter of 2013, and we anticipate a decision in the first half of 2014. On March 7, 2014 MHRA notified us that the application for approval of the OIC indication in the United Kingdom was not approved, and we are considering the appropriate next steps with MHRA. We are also considering seeking approval for AMITIZA in other European Union countries following the Mutual Recognition Procedure, or MRP. We are currently working to achieve National Institute for Health and Care Excellence endorsement for CIC. In February 2012, we announced we are actively marketing AMITIZA in Switzerland. In February 2014, we announced that the BAG revised several limitations with which AMITIZA was first approved for reimbursement and inclusion in the specialitätenliste, or SL, to make it easier for all Swiss physicians to prescribe AMITIZA to patients who have failed previous treatments with at least two laxatives over a nine month period. The SL limitations that were revised are:

- · All Swiss physicians, not just gastroenterologists, are now allowed to prescribe AMITIZA;
- The change in the maximum treatment duration of AMITIZA increased from 12 to 52 weeks before a review is needed by a health insurance health care practitioner; and
- The BAG removed from AMITIZA's SL a group limitation pertaining to the number of AMITIZA packs that physicians can prescribe at one time.

#### Other Global Markets

We and Takeda are currently exploring the commercialization of AMITIZA in Canada and we have met with Health Canada to discuss the best ways to proceed with AMITIZA registration in this market in the near future.

We continue to explore options to develop and commercialize AMITIZA in other geographic regions, inclusive of Latin America, Russia, the Middle East and other Asian countries. In the People's Republic of China, we continue to evaluate development and potential commercialization of lubiprostone.

#### RESCULA (unoprostone isopropyl)

We began commercializing RESCULA in February 2013 in the United States. According to the United States 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 big potassium channel activator and has a different mechanism of action than other IOP lowering agents on the market.

We are also evaluating the opportunities in the European Union and other European countries to commercialize unoprostone isopropyl there. 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 successful trials.

During the third quarter of 2013, we recorded a \$4.5 million non-cash write-off of its RESCULA inventory to reflect anticipated excess quantities of dated product consisting of \$3.0 million of product for sale and \$1.5 million of sample inventory. The anticipated excess inventory was largely a result of the necessity to pre-order product in advance of FDA approval due to a planned change in manufacturing facility and lower than anticipated sales within the useful life of the dated product. Beginning in January 2014, we significantly decreased the amount of in-person sales calls for RESCULA by using a contract sales force to focus its detailing on current prescribers. We also use a limited mix of inside sales and other promotional tactics, including digital, to reach the current non-prescriber base in an effort to increase prescribers and sales of RESCULA.

# Our Other Clinical Development Programs

#### Lubiprostone

#### Liquid Formulation

In October 2013, we announced the initiation of a pivotal trial of a liquid formulation of lubiprostone 24mcg twice daily in adults with CIC. Upon reviewing the results of this trial, which we anticipate to end in the first half of 2014, we plan to file a new drug application for approval.

#### Pediatric Functional Constipation

In December 2013, we announced the initiation of the pivotal phase 3 clinical program for AMITIZA in pediatric functional constipation. This is the first of a series of global, multicenter phase 3 studies to evaluate the efficacy, safety, and pharmacokinetics of lubiprostone in patients aged  $\geq 6$  months through 17 years of age with pediatric functional constipation. The program will consist of two randomized, placebo-controlled, double-blinded studies and two long-term safety extension studies. One of the pediatric trials will also use the liquid formulation.

# **Unoprostone Isopropyl**

#### Retinitis Pigmentosa

In October 2013, we announced that our development partner, R-Tech, completed patient enrollment of a phase 3 clinical trial for unoprostone isopropyl for retinitis pigmentosa, or RP, in Japan. A substantial portion of the development costs for the program are being funded by the Japan Science and Technology Agency. We have the rights to the clinical data for potential filing in Europe and the United States, where unoprostone isopropyl has orphan drug designation, and will decide on our path forward assuming the Japanese trial is successful. Additionally, we are currently evaluating opportunities in other retinal diseases, such as age-related macular degeneration.

#### Intravenous (IV) and Oral (PO) Ion Channel Activators

#### Lumbar Spinal Stenosis

We have both an IV ion channel activator and a PO ion channel activator in development for the treatment of lumbar spinal stenosis, or LSS. In December 2013, we reported results of the treatment phase of our phase 2a, double-blind, placebo-controlled study of the IV version of our ion channel activator for LSS, that indicated statistically significant improvement in Visual Analog Scale pain. We plan to initiate an additional phase 2a in the second half of 2014. The PO ion channel activator for phase 1a clinical development results were reported in August 2013 and demonstrated to be generally well-tolerated. We plan to initiate the next phase of clinical development in the first quarter of 2014. Additionally, these compounds may be investigated for other indications.

### Cobiprostone

#### Oral spray for Oral Mucositis

Cobiprostone is in development for the target indication of prevention and/or treatment of oral mucositis, or OM. In August 2013, we reported results of our phase 1a trial for the oral spray formulation of cobiprostone that demonstrated the compound is to be generally well-tolerated in healthy volunteers. In October 2013, we initiated a phase 1b clinical development study, which is expected to conclude in the first half of 2014.

# 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)	T	Cash ecceived Through eember 31, 2013	Thi		ecognized fo d Decembe 2012		F fo	Accounts Receivable or the Year Ended ecember 31, 2013		Foreign Currency Effects	De	Amount eferred at cember 31, 2013
Collaboration revenue:									_			
Up-front payment associated with the Company's obligation to participate in joint committees	\$	846	\$	137	\$ 52	\$ 52	\$	-	\$	50	\$	555
Research and development revenue:												
Up-front payment - remainder	\$	9,154	\$	9,103	\$ 199	\$ -	\$	-	\$	(148)	\$	-
Development milestone payment		27,500		12,598	15,157	-		-		(255)		-
Total	\$	36,654	\$	21,701	\$ 15,356	\$ -	\$	-	\$	(403)	\$	-
Product sales revenue:	\$	19,017	\$	-	\$ 5,023	\$ 15,807	\$	2,076	\$	263	\$	

# 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;
- \$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; and
- \$10.0 million upon the commercial sale of AMITIZA for OIC in the second quarter of 2013.

# 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 United States 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, 2013, 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% of these expenses and we are responsible for 30%. Through December 31, 2013, 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%. As of December 31, 2013, we had incurred \$10.5 million of these expenses, 70% 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, 2013, we had incurred \$78.6 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, 2013, we have incurred \$4.5 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 \$61,000, \$3.6 million and \$3.4 million of co-promotion revenue reflecting these reimbursements for the years ended December 31, 2013, 2012 and 2011, respectively. In 2013, our sales force shifted away from selling AMITIZA, which was partially reimbursed by Takeda, to selling RESCULA. In November, 2013, we announced that we would be exercising our co-promotion option and will begin co-promoting AMITIZA for OIC in adults with chronic, non-cancer pain in the first quarter of 2014. Takeda will reimburse us under the Takeda Agreement for those product details made by our contract sales force of healthcare professionals.

#### **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 United States and Canada. The actual percentage depends on the level of net sales revenue attained each calendar year. All sales of AMITIZA in the United States and Canada, including those arranged by our specialty sales force, are made through Takeda. AMITIZA is currently marketed only in the United States and during the years ended December 31, 2013, 2012 and 2011 we recognized a total of \$52.1 million, \$50.7 million and \$41.5 million, respectively, as product royalty revenue.

#### **Commercialization Milestone Payments**

Our agreements also require Takeda to pay us up to an additional aggregate of \$50.0 million upon the achievement of specified targets for annual net sales revenue from AMITIZA in the United States and Canada. Sales of AMITIZA have not met these targets as of December 31, 2013.

#### 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:

R T	hrough	d gh Revenue Recognized for the				R for	eceivable r the Year Ended	De	Amount ferred at ember 31,		
í.		Thr					2013				2013
		_							<u>``</u>		
\$	2,375	\$	1,052	\$	147	\$	147	\$	-	\$	1,029
\$	17,624	\$	17,624	\$	-	\$	-	\$	-	\$	-
	140,000		130,000		-		10,000		-		-
	114,670		100,262		6,189		10,354		2,554		419
\$	272,294	\$	247,886	\$	6,189	\$	20,354	\$	2,554	\$	419
-											
\$	276,598	\$	188,631	\$	50,696	\$	52,100	\$	14,829	\$	-
\$	29,453	\$	25,816	\$	3,576	\$	61	\$	-	\$	-
	Dec	Received Through December 31, 2013  \$ 2,375  \$ 17,624   140,000  114,670   \$ 272,294  \$ 276,598	Received Through December 31, 2013  Thr  \$ 2,375 \$  \$ 17,624 \$ 140,000  114,670 \$ 272,294 \$  \$ 276,598 \$	Received Through December 31, 2013       Revenue Year E Through 2011         \$ 2,375       \$ 1,052         \$ 17,624       \$ 17,624         \$ 140,000       \$ 130,000         \$ 272,294       \$ 247,886         \$ 276,598       \$ 188,631	Received Through December 31, 2013       Revenue Reve	Received Through December 31, 2013       Revenue Recognized for Year Ended December 31         \$ 2,375       \$ 1,052       \$ 147         \$ 17,624       \$ 17,624       \$ - 140,000       - 130,000       - 140,000       - 140,000       - 100,262       6,189       - 189,631       - 188,631       \$ 50,696       - 189,696       - 188,631       - 1	Received Through December 31, 2013         Revenue Recognized for the Year Ended December 31 Through 2011           \$ 2,375         \$ 1,052         \$ 147         \$           \$ 17,624         \$ 17,624         \$ - \$         \$           \$ 140,000         \$ 130,000         \$ -         \$           \$ 272,294         \$ 247,886         \$ 6,189         \$           \$ 276,598         \$ 188,631         \$ 50,696         \$	Received Through December 31, 2013         Revenue Recognized for the Year Ended December 31, 2013           \$ 2,375         \$ 1,052         \$ 147         \$ 147           \$ 17,624         \$ 17,624         \$ - \$ - 140,000         130,000         - 100,000           \$ 272,294         \$ 247,886         \$ 6,189         \$ 20,354           \$ 276,598         \$ 188,631         \$ 50,696         \$ 52,100	Cash Received Through December 31, 2013       Revenue Recognized for the Year Ended December 31, 2013       December 31, 2012       December 31, 2013       December 31, 2013       December 31, 2013         \$ 2,375       \$ 1,052       \$ 147       \$ 147       \$ 147         \$ 17,624       \$ 17,624       \$ - \$ - \$ \$ 10,000       \$ 140,000       130,000       - 100,000         \$ 114,670       \$ 100,262       \$ 6,189       \$ 10,354       \$ 272,294       \$ 247,886       \$ 6,189       \$ 20,354       \$ \$ 20,354       \$ 20,354	Received Through December 31, 2013         Revenue Recognized for the Ended December 31, 2013 (1)           \$ 2,375         \$ 1,052         \$ 147         \$ 147         \$ - \$ 140,000         \$ 130,000         \$ - \$ 10,000         \$ - \$ 10,000         \$ 2,554         \$ 272,294         \$ 247,886         \$ 6,189         \$ 20,354         \$ 2,554         \$ 14,829	Cash Received Through December 31, 2013         Revenue Recognized for the Year Ended December 31, Decem

<sup>(1)</sup> 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 United States 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 ?V \$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, 2013 and 2012, respectively, which is recorded as contract revenue. During the years ended December 31, 2013, 2012 and 2011, we purchased clinical supplies from R-Tech of approximately \$827,000, \$1.4 million and \$72,000, 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 2013, 2012 or 2011. During the years ended December 31, 2013, 2012 and 2011, we purchased approximately zero, \$124,000 and \$125,000, respectively, of commercial supplies of lubiprostone from R-Tech in anticipation of a commercial launch in Europe.

Under the two-year, automatic renewal exclusive clinical manufacturing and supply agreement with R-Tech for cobiprostone and ion channel activators, no purchases were made for such clinical supplies during the years ended December 31, 2013, 2012 and 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, 2013, 2012 and 2011, we purchased approximately \$14.9 million, \$3.1 million and \$166,000, respectively, of commercial supplies of lubiprostone from R-Tech under this agreement. During the years ended December 31, 2013 and 2012, we purchased approximately \$673,000 and \$10,000, respectively, of clinical supplies from R-Tech under this agreement. There were no such clinical supplies purchased in 2011 from R-Tech under this agreement.

In April 2009, we entered into an agreement with R-Tech to acquire rights to RESCULA in the United States and Canada. Under the terms of the agreement, we hold the exclusive rights to commercialize RESCULA in the United States and Canada for its approved ophthalmic indication and any new indication developed by us. Under the terms of the agreement, 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 was paid to R-Tech in the first quarter of 2013 upon the re-launch of RESCULA for the treatment of glaucoma.

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, 2013, we made milestone payments to R-Tech of \$6.0 million, including \$3.0 million in the first quarter of 2012, which are 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, 2013, 2012, and 2011 of approximately \$194,000, \$466,000 and \$104,000, respectively.

In March 2012, R-Tech informed us that it was 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 designated another facility in Japan, but such facility would 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 United States. R-Tech commenced delivery of that order to us in the first and second quarters of 2013. Such facility has been inspected by the FDA in the fourth quarter of 2013, and the FDA issued a notice of deficiencies to contractor of the new facility. The FDA also issued a complete response letter to us concerning the drug master file. The new contractor has responded and we requested FDA to review the sNDA, which it has agreed to do. We are awaiting the decision of the FDA.

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

	Year Ended December 31,						
(In thousands)		2013		2012		2011	
Clinical supplies	\$	827	\$	1,450	\$	72	
Other research and development services		194		466		104	
Commercial supplies		14,902		3,288		155	
	\$	15,923	\$	5,204	\$	331	

#### **Critical Accounting Policies and Estimates**

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

We regard an accounting estimate or 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. However, we initiated new research and development studies after January 1, 2011, that are being reimbursed by Takeda and are treated as separate elements within the Takeda Agreement.

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 entered into prior to January 1, 2011, 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. 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.

For research and development deliverables agreed upon subsequent to January 1, 2011 which are reimbursable by Takeda at contractually predetermined percentages, we recognize revenue when the underlying research and development expenses are incurred, assuming all other revenue recognition criteria are met.

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.

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 consist of AMITIZA sales to Abbott in Japan and by us in Europe and RESCULA in the United States. 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 revenue from RESCULA product sales less deductions for estimated sales discounts and sales returns. We account for rebates to certain governmental agencies as a reduction of product sales. We allow customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. As a result, we estimate an accrual for product returns, which is recorded as a reduction of product sales. Given our limited history of selling RESCULA and the return period, we cannot reasonably estimate product returns from the wholesale distribution channel. Therefore, we are deferring the recognition of revenue until there is confirmation of pull-through sales to end-user customers. We will continue to defer recognition until the point at which we have obtained sufficient sales history to reasonably estimate returns from the wholesalers.

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. No material adjustments have been required for this accrued during the years ended December 31, 2013 and 2012.

#### 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, expiration dates of net operating loss carry-forwards, 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 United States 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, 2013, the total deferred charge is \$5.2 million after a net current year amortization expense of \$673,000.

As of December 31, 2013 and 2012, we had foreign net operating loss, or NOLs, carry forwards of \$11.9 million and \$21.0 million, respectively. Approximately \$7.0 million of the foreign NOL begin to expire in December 2019, and \$4.9 million of the foreign NOLs do not expire.

We followed the FASB's guidance for uncertainty in income taxes that requires the application of a "more likely than not" threshold to the recognition and derecognition of uncertain tax positions. If the recognition threshold is met, this guidance permits us to recognize a tax benefit measured at the largest amount of the tax benefit that, in our judgment, is more than 50.0% percent likely to be realized upon settlement.

We 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, 2013 mainly pertains to our interpretation of nexus in certain states related to certain revenue sources for state income tax purposes. The amount expected to reverse within the next twelve months as a result of prior period settlements with state tax authorities has been recorded as a current liability. Other than the expected settlement, 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, 2013 and December 31, 2012

#### Revenues

The following table summarizes our revenues for the years ended December 31, 2013 and 2012:

Year Ended					
	Decem	ber 31,			
	2013		2012		
\$	20,354	\$	21,545		
	52,100		50,696		
	16,425		5,037		
	61		3,576		
	654		633		
\$	89,594	\$	81,487		
	\$	Decem    2013   \$ 20,354   52,100   16,425   61   654	December 3 2013 \$ 20,354 \$ 52,100 16,425 61 654		

Total revenues were \$89.6 million in 2013 compared to \$81.5 million in 2012, an increase of \$8.1 million, or 9.9%.

#### Research and development revenue

Research and development revenue was \$20.4 million in 2013 compared to \$21.5 million in 2012, a decrease of \$1.2 million or 5.5%. The decrease was primarily due to the receipt of lower milestone payments in 2013 compared to 2012. In 2012 we received a \$15.0 million milestone payment from Abbott upon the first commercial sale of AMITIZA in Japan and in 2013 we received a \$10.0 million milestone payment from Takeda upon the first commercial sale of AMITIZA for OIC. Excluding the milestone payments, research and development revenue was \$10.4 million in 2013 compared to \$6.5 million in 2012, an increase of \$3.9 million or 58.2%, due primarily to lubiprostone studies of liquid formulation and pediatric dosage.

#### 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 2013, we recognized \$52.1 million of product royalty revenue compared to \$50.7 million in 2012, an increase of \$1.4 million or 2.8%. The increase was due to higher Takeda reported AMITIZA net sales that were primarily driven by higher prices.

#### Product sales revenue

Product sales revenue represents drug product net sales of AMITIZA in Japan and Switzerland and RESCULA in the United States. Product sales revenue in 2013 and 2012 was \$16.4 million and \$5.0 million, respectively, an increase of \$11.4 million or 226.1%. The increase was primarily due to the growth of product sales of AMITIZA in Japan, which commenced in the fourth quarter of 2012 and the commencement of product sales of RESCULA in the United States and AMITIZA in Switzerland during the first quarter of 2013

# Co-promotion revenue

Co-promotion revenue represents reimbursements by Takeda of a portion of our co-promotion costs for our specialty sales force. In 2013, we recognized \$61,000 of co-promotion revenue compared to \$3.6 million in 2012, a decrease of \$3.6 million, or 100%. The decrease in co-promotion revenue was the result of our sales force shifting away from selling AMITIZA, which was partially reimbursed by Takeda, to selling RESCULA.

# Cost of Goods Sold

Cost of goods sold relates to purchase and distribution costs of our products sold by us, including inventory write-offs for excess and obsolete inventory and amortization of marketing licenses. Cost of goods sold was \$12.4 million and \$3.0 million in 2013 and 2012, respectively, an increase of \$9.4 million, or 309.3%. The increase in cost of goods sold relates to increased drug product sales of AMITIZA in Japan and Switzerland, and RESCULA in the United States. Additionally, during the third quarter of 2013, we recorded a \$3.0 million write-off of RESCULA inventory to reflect anticipated excess quantities of dated product. The anticipated excess inventory was largely a result of the necessity to pre-order product in advance of FDA approval due to a planned manufacturer shutdown and lower than anticipated sales within the useful life of the dated product. In addition to initial sales falling below their forecast, in the fourth quarter of 2013 we decided to eliminate our in-house sales force and deploy a contract sales force to detail only current RESCULA prescribers at a much reduced level, which will further impact future sales of RESCULA.

# Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2013 and 2012:

		Year E Deceml	
(In thousands)		2013	2012
Direct costs:			
Lubiprostone	\$	10,644	\$ 8,311
Cobiprostone		1,269	2,019
Ion channel activator		2,738	581
Unoprostone isopropyl		1,060	2,819
Other		2,912	5,179
Total	_	18,623	18,909
Indirect costs		2,901	 2,383
Total	\$	21,524	\$ 21,292

Total research and development expenses in 2013 were \$21.5 million compared to \$21.3 million in 2012, an increase of \$232,000, or 1.1%. The increase in research and development expenses was primarily due to the higher costs associated with lubiprostone pediatric and liquid formulation, our clinical development of the lumbar spinal stenosis program, and higher indirect costs including regulatory fees; these increases were partially offset by lower costs associated with our development programs for cobiprostone and lubiprostone isopropyl and terminated Numab collaboration.

# General and Administrative Expenses

The following summarizes our general and administrative expenses for years ended December 31, 2013 and 2012:

Year Ended				
Decem	31,			
2013		2012		
\$ 8,307	\$	8,381		
7,377		12,621		
1,260		1,349		
2,474		1,991		
 5,995		5,815		
\$ 25,413	\$	30,157		
\$	<b>Decemb</b> 2013 \$ 8,307 7,377 1,260 2,474 5,995	December 3       2013     \$ 8,307     \$ 7,377       1,260     2,474       5,995     \$ 5,995		

General and administrative expenses were \$25.4 million in 2013 compared to \$30.2 million in 2012, a decrease of \$4.7 million, or 15.7%. The decrease in general and administrative expenses was primarily due to lower legal, consulting and other professional expenses as a result of the conclusion of certain legal matters in 2012, as well as expense reductions from 2013 productivity initiatives. These decreases were partially offset by an increase in pharmacovigilance (also known as drug safety) associated with the launch of AMITIZA in Japan.

# Selling and Marketing Expenses

The following summarizes our selling and marketing expenses for years ended December 31, 2013 and 2012:

	Year Ended					
	Decem	31,				
(In thousands)	2013		2012			
Salaries, benefits and related costs	\$ 6,735	\$	7,232			
Consulting and other professional expenses	4,599		4,220			
Stock option expense	191		349			
Sample expenses	2,556		-			
Other expenses	6,978		6,890			
Total	\$ 21,059	\$	18,691			

Selling and marketing expenses were \$21.1 million in 2013 compared to \$18.7 million in 2012, an increase of \$2.4 million, or 12.7%. The increase in selling and marketing expenses is primarily due to \$1.1 million for dispensing samples of RESCULA and a further non-cash write-off of anticipated excess samples of \$1.5 million.

#### Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the years ended December 31, 2013 and 2012:

	Year E Decemb		
(In thousands)	 2013	<i>Jei</i>	2012
Interest income	\$ 124	\$	179
Interest expense	(1,894)		(2,346)
Other income (expense), net	2,921		1,602
Total	\$ 1,151	\$	(565)

Interest income was \$124,000 in 2013 compared to \$179,000 in 2012, a decrease of \$55,000, or 30.7%. The decrease was primarily due to lower prevailing interest rates earned by our investments and lower cash balances.

Interest expense was \$1.9 million in 2013 compared to \$2.3 million in 2012, a decrease of \$452,000, or 19.3%. The decrease was primarily due to lower debt balance.

Other income was \$2.9 million in 2013 compared to \$1.6 million in 2012, an increase of \$1.3 million, or 82.3%. The increase in other income was primarily due to foreign exchange gains in the current period that are unrealized non-cash and that relate to amounts held within our Japan subsidiary.

#### **Income Taxes**

For the years ended December 31, 2013 and 2012, our consolidated effective income tax rate was 38.0% and 37.6%, respectively. For the years ended December 31, 2013 and 2012, we recorded a tax expense of \$3.9 and \$2.9 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 effective tax rate in 2013 is consistent with that of 2012 due to offsetting changes in the rate, attributable primarily to the change in the effective foreign and 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, 2013, the remaining valuation allowance against our deferred tax assets was \$1.8 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, 2012 and December 31, 2011

# Revenues

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

	Year Ended				
	Decem	31,			
(In thousands)	2012		2011		
Research and development revenue	\$ 21,545	\$	9,249		
Product royalty revenue	50,696		41,517		
Product sales revenue	5,037		-		
Co-promotion revenue	3,576		3,378		
Contract and collaboration revenue	633		617		
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 revenue represents reimbursements by Takeda of co-promotion costs for our specialty sales force. In 2012, we recognized \$3.6 million of co-promotion revenue compared to \$3.4 million in 2011, an increase of \$198,000 or 5.9%, 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

Product sales revenue represents sales of AMITIZA in Europe and Japan. Product sales revenue was \$5.0 million and nil in 2012 and 2011, respectively. This increase was due to the commencement of product sales of AMITIZA in Japan in the fourth quarter of 2012.

## Cost of Goods Sold

Cost of goods sold relates to purchase and distribution costs of AMITIZA in Europe and Japan. Cost of goods sold was \$3.0 million and nil in 2012 and 2011, respectively, an increase of \$3.0 million, or 100%. This increase was due to the commencement of product sales of AMITIZA in Japan in the fourth quarter of 2012.

#### Research and Development Expenses

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

		Year I Decem	
(In thousands)	201	2	2011
Direct costs:			
Lubiprostone	\$	3,311	\$ 23,998
Cobiprostone		2,019	520
Ion channel activator		581	611
Unoprostone isopropyl		2,819	2,961
Other		5,179	3,694
Total	1	3,909	31,784
Indirect costs		2,383	 1,713
Total	\$ 2	1,292	\$ 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:

	1	Teal Ellucu		
	De	December 31,		
(In thousands)	2012		2011	
Salaries, benefits and related costs	\$ 8,3	81 \$	6,670	
Legal, consulting and other professional expenses	12,6	21	27,225	
Stock option expense	1,3	49	964	
Pharmacovigilance	1,9	91	209	
Other expenses	5,8	15	6,202	
Total	\$ 30,1	.57	\$ 41,270	

Vear Ended

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 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:

	Ye	Year Ended			
	Dec	December 31,			
(In thousands)	2012		2011		
Interest income	\$ 1	79 \$	5 249		
Interest expense	(2,3	<b>1</b> 6)	(2,455)		
Other expense, net	1,6	)2	(2,019)		
Total	\$ (5	55) \$	(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.

## 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 activities include the commercialization of RESCULA, AMITIZA income and costs associated with the Takeda collaboration. The segment recorded an income before taxes of \$21.0 million in 2013, compared to \$11.5 million in 2012, an increase of \$9.5 million, or 83.0%. This increase is primarily attributable to the receipt of the \$10.0 million milestone payment from Takeda in 2013 upon the first commercial sale of AMITIZA for OIC. The 2012 income before taxes of \$11.5 million represents an increase of \$17.8 million, or 279.6%, over the 2011 loss before taxes of \$6.4 million. These results primarily reflect lower expenses associated with research and development and legal expenses, as well as an increase in royalty revenues.

Our Europe segment activities include the commercialization of AMITIZA in Europe, costs associated with pipeline development, intellectual property management and licensing activities. The segment recorded a loss before taxes of \$12.4 million in 2013, compared to a loss before taxes of \$15.9 million in 2012, a decrease of \$3.4 million, or 21.7%. The 2012 loss before taxes of \$15.9 million represents an increase of \$5.8 million, or 57.3%, over the 2011 loss before taxes of \$10.1 million.

Our Asia segment activities include the commercialization of AMITIZA in Japan as a result of our collaboration with Abbott. The segment recorded an income before taxes of \$1.8 million in 2013, compared to \$12.2 million in 2012, a decrease of \$10.4 million, or 85.2%. This decrease is primarily attributable to the milestone payment received from Abbott in 2012. The 2012 income before taxes of \$12.2 million represents an increase of \$17.6 million, or 323.2%, over the 2011 loss before taxes of \$5.4 million. These results primarily reflect revenue recognized during 2012 from the milestone payment received from Abbott.

(In thousands)	Americas		Americas Europe		Asia		Consolidated	
Year Ended December 31, 2013								
Total revenues	\$	73,637	\$	108	\$	15,849	\$	89,594
Income (loss) before taxes		20,983		(12,425)		1,789		10,347
Identifiable assets		95,350		23,843		17,780		136,973
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

# Liquidity and Capital Resources

#### Sources of Liquidity

We finance our operations principally from cash generated from revenues, cash and cash equivalents on hand, and to a lesser extent, from the issuance and sale of our class A common stock in "at-the-market" equity offerings through our Cantor Sales Agreement, and through the exercise of employee 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:

	Teal Ellucu			u
	December 31,			81,
(In thousands)		2013		2012
Cash and cash equivalents	\$	44,102	\$	52,022
Restricted cash, current		26,115		15,113
Restricted cash, non-current		2,471		3,832
Investments, current		16,003		6,035
Investments, non-current		7,219		14,408
Total	\$	95,910	\$	91,410

Vear Ended

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, 2013 and 2012, our restricted cash consisted primarily of the collateral pledged to support a loan with The Bank of Tokyo-Mitsubishi UFJ, Ltd., a loan agreement with The Mizuho Bank, Ltd., Numab's loan with Zurcher Kantonalbank and operating leases with certain financial institutions.

As of December 31, 2013, our short-term investments consisted of United States corporate commercial paper, municipal securities, certificates of deposit and variable rate demand notes which have short-term maturities of one year or less. Our non-current investments consisted of United States government securities, certificates of deposit and corporate bonds.

#### Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2013, 2012 and 2011:

	Year Ended December 31,			,		
(In thousands)		2013		2012		2011
Cash provided by (used in):						
Operating activities	\$	(5,418)	\$	12,000	\$	(19,991)
Investing activities		(13,881)		(589)		27,901
Financing activities		10,581		(8,446)		(8,081)
Effect of exchange rates		798		(1,605)		1,590
Net increase (decrease) in cash and cash equivalents	\$	(7,920)	\$	1,360	\$	1,419

#### Year ended December 31, 2013

Net cash used in operating activities was \$5.4 million for the year ended December 31, 2013. This reflected cash provided by net income of \$6.4 million, non-cash stock based compensation of \$1.7 million, depreciation and amortization of \$1.5 million, offset by non-cash unrealized currency translation gains of \$3.2 million, an increase in accounts receivable of \$4.0 million, and a decrease in both accrued expenses and deferred revenue of \$4.7 million and \$3.1 million, respectively.

Net cash used in investing activities of \$13.9 million for the year ended December 31, 2013 primarily reflected a \$10.8 million increase in restricted cash and a \$2.9 million increase in purchases of investments net of maturities.

Net cash provided by financing activities of \$10.6 million for the year ended December 31, 2013 primarily reflected proceeds of \$5.3 million from our "at-the-market" stock offering, and proceeds of \$2.3 million from the exercise of employee stock options.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for year ended December 31, 2013 was an increase of \$798,000.

# 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.

## **Commitments and Contractual Obligations**

As of December 31, 2013, our principal outstanding contractual obligations related to our loans and our contract research commitments. The following table summarizes these significant contractual obligations:

			Less than		Less than		Less than		Less than		1-3		3-5		More than	
(In thousands of U.S. dollars)	7	<b>Total</b>		1 year		years		years	5 ye	ars						
Loans	\$	52,720	\$	26,892	\$	16,848	\$	8,980	\$	-						
Interest on loans		3,379		1,380		1,706		293		-						
Operating lease commitments		3,589		1,273		2,177		139		-						
Contract research commitments		6,779		6,779		-		-		-						
Uncertain tax positions (1)		42		42		-		-								
	\$	66,509	\$	36,366	\$	20,731	\$	9,412	\$	-						

(1) As of December 31, 2013, we have recorded a total income tax liability for uncertain tax positions of approximately \$679,000, of which we expect to settle \$42,000 within the next twelve months, and the remaining \$637,000 in an unknown future period (see Note 14 below).

The table above does not include:

· 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 \$2.5 million. As of December 31, 2013 the potential amount of payments in the event of Numab's default was \$2.2 million (see Note 12 below).

## **Off-Balance Sheet Arrangements**

As of December 31, 2013, 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 January 11, 2013, we entered into a sales agreement with Cantor Fitzgerald & Co. (Cantor Sales Agreement), which enables us to offer and sell shares of our class A common stock with aggregate class A common stock sales of up to \$20.0 million, from time to time through Cantor Fitzgerald & Co. as our sales agent. Sales of class A common stock under the Cantor Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Cantor Fitzgerald & Co. is entitled to receive a commission rate of 3.0% of gross sales in connection with the sale of our class A common stock sold on our behalf. From November 22, 2013 through December 31, 2013, we sold through the Cantor Sales Agreement an aggregate of 749,383 shares of our class A common stock, and received gross proceeds of approximately \$5.3 million, before deducting issuance expenses.

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 United States;
- the launch and development of RESCULA in the United States;

- · development, regulatory and marketing efforts in Europe, Asia and other markets for lubiprostone;
- · development and regulatory activities for unoprostone isopropyl in the United States and Canada and other countries except Japan, Korea, Taiwan and the People's Republic of China;
- development, marketing and manufacturing activities at SAG;
- · activities to resolve our on-going legal matters;
- the costs involved in obtaining and maintaining proprietary protection for our products, technology and know-how, including litigation costs and the results of such litigation:
- · research and development activities for other prostone compounds, including cobiprostone, and other ion channel openers;
- · 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;
- the continuing purchase of shares of our class A common stock up to \$5.0 million pursuant to the repurchase program, which may be increased up to \$10.0 million as previously approved by our Board of Directors; and
- the payment of principal and interest under 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.

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 atthe-market sales, public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. At December 31, 2013, based upon our current business plan, we believe we have sufficient liquidity for the next 12 months.

#### **Effects of Foreign Currency**

We currently receive a portion of our revenue, incur a portion of our operating expenses, and have assets and liabilities in currencies other than the U.S. Dollar, the reporting currency for our Consolidated Financial Statements. 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 us to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, we are 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 United States GAAP to be reclassified in their entirety to net income, we are required to cross-reference to other disclosures required under United States GAAP that provide additional detail about those amounts. We adopted this update effective January 1, 2013, and such adoption did not have a material impact on our consolidated financial statements.

In July 2013, the FASB issued an Accounting Standards Update, or ASU, providing guidance on whether an uncertain tax position should be presented as a reduction to a deferred tax asset or as a separate liability. This guidance seeks to address diversity in practice. The adoption of this ASU amendment is not expected to have a material effect on our financial condition, results of operations or cash flows.

# 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 U.S. Dollar. We do not currently hedge our foreign currency transactions via derivative instruments.

#### 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, 2013.

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, 2013 and December 31, 2012, approximately 17.1% and 18.4%, 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, 2013. 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, 2013, 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, 2013 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 our company. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. 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* (1992). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2013.

The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Peter Greenleaf Chief Executive Officer (Principal Executive Officer) Cary J. Claiborne Chief Financial 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 outstanding 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 outstanding common stock, class A common stock, 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 2014 (Class II directors), 2015 (Class III directors), and 2016 (Class I 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 2014 Annual Meeting to be filed within 120 days after the fiscal year end of December 31, 2013, 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		D. 6
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	Amended and Restated Bylaws	Exhibit 3.3 to the Company's Current Report on Form 8-K (filed August 2, 2013)
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)
10.68^	Consulting Agreement, dated May 23, 2013, between the Company and Gayle Dolecek	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed May 31, 2013)
10.69^	Consulting Agreement, dated September 14, 2013, between the Company and Peter Lichtlen	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed September 17, 2013)
10.70^	Employment Agreement, dated February 10, 2014, between the Company and Peter Greenleaf	Included herewith
10.71^	Consulting Agreement, dated February 10, 2014, between the Company and Dr. Ryuji Ueno	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	Included herewith
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm	Included herewith
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith

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

^ Compensatory plan, contract or arrangement.

Oxley Act of 2002

† 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.

<sup>\*</sup> Confidential treatment has been granted for portions of this exhibit.

# **Signatures**

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

Sucampo Pharmaceuticals, Inc.

March 11, 2014 By: /s/ PETER GREENLEAF

Peter Greenleaf Chief Executive Officer (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/ PETER GREENLEAF Peter Greenleaf	Chief Executive Officer (Principal Executive Officer) Director	March 11, 2014
/s/ CARY J. CLAIBORNE Cary J. Claiborne	Chief Financial Officer (Principal Financial Officer)	March 11, 2014
/s/ ANDREW P. SMITH Andrew P. Smith	Principal Accounting Officer	March 11, 2014
/s/ WILLIAM L. ASHTON William L. Ashton	Director	March 11, 2014
/s/ ANTHONY C. CELESTE Anthony C. Celeste	Director	March 11, 2014
/s/ GAYLE R. DOLECEK Gayle R. Dolecek, P.D.	Director	March 11, 2014
/s/ DANIEL P. GETMAN Daniel P. Getman	Chairman of the Board	March 11, 2014
/s/ BARBARA A. MUNDER Barbara A. Munder	Director	March 11, 2014
/s/ MAUREEN E. O'CONNELL  Maureen E. O'Connell	Director	March 11, 2014
/s/ KEI S. TOLLIVER Kei S. Tolliver	Director	March 11, 2014

# SUCAMPO PHARMACEUTICALS, INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	<u>F-2</u>
Consolidated Balance Sheets as of December 31, 2013 and 2012	<u>F-3</u>
Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2013, 2012 and 2011	<u>F-4</u>
Consolidated Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2013, 2012 and 2011	<u>F-5</u>
Consolidated Statements of Cash Flows for the Years Ended December 31, 2013, 2012 and 2011	<u>F-6</u>
Notes to Consolidated Financial Statements	<u>F-7</u>

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, 2013 and December 31, 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 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, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, 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 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.

[PricewaterhouseCoopers LLP (signed)]
Baltimore, Maryland

March 7, 2014

# SUCAMPO PHARMACEUTICALS, INC.

# **Consolidated Balance Sheets**

(In thousands, except share data)

			ber 3	er 31,	
		2013		2012	
ASSETS:					
Current assets:					
Cash and cash equivalents	\$	44,102	\$	52,022	
Investments, current		16,003		6,035	
Product royalties receivable		14,829		14,175	
Unbilled accounts receivable		1		732	
Accounts receivable, net		5,407		1,360	
Prepaid and income taxes receivable		9		-	
Deferred tax assets, current		2,028		874	
Deferred charge, current		673		673	
Restricted cash, current		26,115		15,113	
Inventory		209		-	
Prepaid expenses and other current assets		3,977		1,930	
Total current assets		113,353		92,914	
Investments, non-current		7,219		14,408	
Property and equipment, net		1,156		1,540	
Intangible assets, net		6,438		7,415	
Deferred tax assets, non-current		1,212		1,654	
Deferred charge, non-current		4,540		5,213	
Restricted cash, non-current		2,471		3,832	
Other assets		584		820	
Total assets	\$	136,973	\$	127,796	
LIABILITIES AND STOCKHOLDERS' EQUITY:  Current liabilities:    Accounts payable	\$	7,614	\$	5,496	
Accrued expenses		5,682		10,595	
Deferred revenue, current		1,365		3,700	
Income tax payable		701		148	
Notes payable, current		26,892		19,129	
Other current liabilities		358		1,003	
Total current liabilities		42,612		40,071	
Notes payable, non-current		25,828		33,722	
Deferred revenue, non-current		6,169		7,093	
Deferred tax liability, non-current		2,066		2,627	
Other liabilities		2,150		1,253	
Total liabilities		78,825		84,766	
Commitments and contingencies (Notes 9 and 12)					
Stockholders' equity:					
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding a December 31, 2013 and 2012	İ	-			
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding a December 31, 2013 and 2012  Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2013 and 2012; 43,315,749 and 41,964,905 shares issued and outstanding at December 31, 2013 and 2012, respectively	i	432		420	
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding a December 31, 2013 and 2012  Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2013 and 2012; 43,315,749 and 41,964,905 shares issued and outstanding at December 31, 2013 and 2012, respectively  Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding at December 31, 2013 and 2012	i	-			
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding a December 31, 2013 and 2012  Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2013 and 2012; 43,315,749 and 41,964,905 shares issued and outstanding at December 31, 2013 and 2012, respectively  Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding at December 31, 2013 and 2012  Additional paid-in capital		- 72,109		- 62,521	
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding a December 31, 2013 and 2012  Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2013 and 2012; 43,315,749 and 41,964,905 shares issued and outstanding at December 31, 2013 and 2012, respectively  Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding at December 31, 2013 and 2012  Additional paid-in capital  Accumulated other comprehensive income		72,109 15,601		62,521 16,166	
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding a December 31, 2013 and 2012  Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2013 and 2012; 43,315,749 and 41,964,905 shares issued and outstanding at December 31, 2013 and 2012, respectively  Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding at December 31, 2013 and 2012  Additional paid-in capital  Accumulated other comprehensive income  Treasury stock, at cost; 524,792 and 457,030 shares		72,109 15,601 (2,313)		62,521 16,166 (1,977	
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2013 and 2012; 43,315,749 and 41,964,905 shares issued and outstanding at December 31, 2013 and 2012, respectively  Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding at December 31, 2013 and 2012  Additional paid-in capital  Accumulated other comprehensive income  Treasury stock, at cost; 524,792 and 457,030 shares  Accumulated deficit		72,109 15,601 (2,313) (27,681)		420 - 62,521 16,166 (1,977 (34,100	
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding a December 31, 2013 and 2012  Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2013 and 2012; 43,315,749 and 41,964,905 shares issued and outstanding at December 31, 2013 and 2012, respectively  Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding at December 31, 2013 and 2012  Additional paid-in capital  Accumulated other comprehensive income  Treasury stock, at cost; 524,792 and 457,030 shares		72,109 15,601 (2,313)		62,521 16,166 (1,977	

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)

	Yea	Year Ended December 31,		
	2013	2012	2011	
Revenues:				
Research and development revenue	\$ 20,35	4 \$ 21,545	\$ 9,249	
Product royalty revenue	52,10	50,696	41,517	
Product sales revenue	16,42	5,037	-	
Co-promotion revenue	6	1 3,576	3,378	
Contract and collaboration revenue	65-	4 633	617	
Total revenues	89,59	4 81,487	54,761	
Costs and expenses:				
Cost of goods sold	12,40	2 3,030	-	
Research and development	21,52			
Settlement of legal dispute	·		(11,100)	
General and administrative	25,41	30,157		
Selling and marketing	21,05	18,691	8,783	
Total costs and expenses	80,39	3 73,170	72,450	
Income (loss) from operations	9,19	6 <b>8,</b> 317	(17,689)	
Non-operating income (expense):	5,15	, 3,51,	(17,000)	
Interest income	12	4 179	249	
Interest expense	(1,89-			
Other income (expense), net	2,92			
Total non-operating income (expense), net	1,15			
Income (loss) before income taxes	10,34	7,752	(21,914)	
Income tax benefit (provision)	(3,92)			
Net income (loss)	\$ 6,41			
Tet meome (1966)	<del></del>		= (21,333)	
Net income (loss) per share:				
Basic net income (loss) per share	\$ 0.1	5 \$ 0.12		
Diluted net income (loss) per share	\$ 0.1 \$ 0.1	\$ 0.12 \$ 0.12	\$ (0.41)	
Weighted average common shares outstanding - basic	41,71		_	
Weighted average common shares outstanding - diluted	42,54	41,785	41,839	
Comprehensive income (loss):				
Net income (loss)	\$ 6,41	9 \$ 4,836	\$ (17,306)	
Other comprehensive income gain (loss):	Ψ 0,41.	, φ +,050	Ψ (17,500)	
Unrealized loss on investments, net of tax effect	the state of the s	2 36	(2)	
Foreign currency translation	(56			
Comprehensive income (loss)	\$ 5,85			

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		Class		Additional	Accumulated Other	_		Retained Earnings	Total
	Common Shares	Amount	Common Shares	Stock Amount	Paid-In Capital	Comprehensive Income (Loss)	Treasur Shares	y Stock Amount	(Accumulated Deficit)	Stockholders' Equity
Balance at December 31, 2010		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
Employee stock option expense	-	-	-	-	1,744	-	_	_		1,744
Stock issued upon exercise of					-					
stock options	597,836	5	-	-	2,332	-	_	-	_	2,337
Stock issued under employee										
stock purchase plan	3,625	-	-	-	25	-	-	-	-	25
Stock issued under "at-the-										
market" offering	749,383	7	-	-	5,274	-	_	-	-	5,281
Foreign currency translation	-	-	-	-	-	(567)	-	-	-	(567)
Unrealized loss on investments,										
net of tax effect	-	-	-	-	-	2	-	-	-	2
Windfall tax benefit from										
stock-based compensation	-	-	-	-	213	-	-	-	-	213
Treasury stock, at cost	-	-	-	-	-	-	67,762	(336)	-	(336)
Net income	-	_	-	-	-	-	-	_	6,419	6,419
Balance at December 31, 2013	43,315,749	432	-		72,109	15,601	524,792	(2,313)		58,148

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 3				
		2013		2012		2011
Cash flows from operating activities:						
Net income (loss)	\$	6,419	\$	4,836	\$	(17,306)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:						
Depreciation and amortization		1,488		1,488		1,308
Loss on disposal of property and equipment		-		-		12
Deferred tax provision (benefit)		(1,678)		(23,026)		26,228
Deferred charge		673		23,922		(29,808)
Stock-based compensation		1,744		2,233		1,370
Amortization of premiums on investments		110		67		651
Notes payable paid-in-kind interest		-		2,024		2,288
Unrealized currency translations (gains) losses		(3,232)		(1,300)		-
Changes in operating assets and liabilities:						
Accounts receivable		(4,047)		3,256		(3,885)
Unbilled accounts receivable		732		1,303		(939)
Product royalties receivable		(654)		(3,380)		(280)
Inventory		(163)		87		(127)
Prepaid and income taxes receivable and payable, net		560		2,998		(2,173)
Accounts payable		2,242		(1,453)		2,872
Accrued expenses		(4,685)		15		523
Deferred revenue		(3,126)		(95)		(1,940)
Accrued interest payable		(32)		-		
Other assets and liabilities, net		(1,769)		(975)		1,215
Net cash provided by (used in) operating activities		(5,418)		12,000		(19,991)
Cash flows from investing activities:						
Purchases of investments		(10,127)		(23,609)		(20,598)
Proceeds from the sales of investments		755		750		7,380
Maturities of investments		6,485		27,790		46,665
Purchases of property and equipment		(168)		(439)		(284)
Proceeds from disposals of property and equipment		-		-		25
Issuance of notes receivable		-		-		(100)
Purchases of intangible assets		-		(3,000)		(3,000)
Purchase of other investing activities		-		(432)		-
Change in restricted cash		(10,826)		(1,649)		(2,187)
Net cash provided by (used in) investing activities		(13,881)		(589)		27,901
Cash flows from financing activities:						
Proceeds from notes payable		10,600		-		-
Repayment of notes payable		(7,539)		(7,500)		(7,500)
Proceeds from exercise of stock options		2,337		311		106
Proceeds from employee stock purchase plan		25		20		13
Proceeds from "at-the market" stock issuance		5,281		(4.055)		(500)
Purchase of treasury stock		(336)		(1,277)		(700)
Windfall tax benefit from stock-based compensation		213		-		-
Net cash provided by (used in) financing activities		10,581		(8,446)		(8,081)
Effect of exchange rates on cash and cash equivalents		798		(1,605)		1,590
Net increase (decrease) in cash and cash equivalents		(7,920)		1,360		1,419
Cash and cash equivalents at beginning of period		52,022		50,662		49,243
Cash and cash equivalents at end of period	\$	44,102	\$	52,022	\$	50,662
Supplemental cash flow disclosures:						
Cash paid for interest	\$	156	\$	157	\$	171
Tax refunds received	\$	103	\$	3,658	\$	245
	_					
Tax payments made	\$	4,939	\$	3,665	\$	1,476
Supplemental disclosure of non-cash investing and financing activities:						
Purchase of intangible assets included in accrued expenses	\$	-	\$	-	\$	3,000

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 ion channel activators known as prostones. The therapeutic potential of prostones was first discovered by the Company's cofounder, Dr. Ryuji Ueno. Dr. Ueno initially found that that prostone production was high in early development, and postulated that prostones produced by 15-PGDH may play important roles as an endogenous local hormones in maturation and aging. Under his leadership the Company has pioneered the field of prostones. Prostones are naturally occurring fatty acid metabolites which 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 critical for the functioning of 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 (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. 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, is in phase 1b clinical development for the target indication of prevention and/or treatment of oral mucositis, or OM. In April 2013, the Company received approval for a supplemental new drug application, or sNDA, for AMITIZA at dosage strength of 24 micrograms twice daily as the first and only oral medication for the treatment of opioid-induced constipation, or OIC, in adult patients with chronic, non-cancer pain. Additionally, in December 2013, the Company announced the initiation of the pivotal phase 3 clinical program of AMITIZA in pediatric functional constipation. This is the first of a series of global, multicenter phase 3 studies to evaluate the efficacy, safety, and pharmacokinetics of AMITIZA capsules in patients ≥ 6 months through 17 years of age with pediatric functional constipation. The Company also plans to evaluate the long-term safety of AMITIZA in these populations through two open-label extension studies. One of the pediatric trials will also use the liquid formulation. Lastly, two ion channel activators, in both the intravenous, or IV, and oral, or PO, forms, are in clinical development for the treatment of lumbar spinal stenosis, or LSS. In December 2013, the Company reported results of the treatment phase of the phase 2a, double-blind, placebo-controlled study of the IV version of the Company's ion channel activator for LSS, that indicated statistically significant improvement in Visual Analog Scale pain. The Company plans to initiate an additional phase 2a in the second half of 2014. The PO ion channel activator for phase 1a clinical development results were reported in August 2013 and demonstrated to be generally well-tolerated. The Company plans to initiate the next phase of clinical development in the first quarter of 2014. Additionally, these compounds may be investigated for other indications.

AMITIZA is being marketed in the United States for three 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, irritable bowel syndrome with constipation, or IBS-C, in adult women and opioid-induced constipation, or OIC, in adults,. 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 primarily responsible for commercialization of AMITIZA in the United States and Canada. The Company and Takeda initiated commercial sales of AMITIZA in the United States for the treatment of CIC, in April 2006, for the treatment of IBS-C in May 2008 and for the treat of OIC in May 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 and pricing approval in November 2012. In November 2012, the Company and Abbott announced the availability of AMITIZA in Japan for CC. In early December 2013, the two-week limitation on prescriptions, generally applied to all new approvals of products for the first year after reimbursement price approval, was removed. AMITIZA is Japan's only prescription medicine for CC.

In the United Kingdom, 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. The Company has made AMITIZA available in the United Kingdom in the fourth quarter of 2013 and is currently working to achieve National Institute for Health and Care Excellence endorsement for CIC. In Switzerland, AMITIZA was approved in 2009. In 2012, the Company 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 European Union, Iceland and Norway. In February 2014, the Company announced that the BAG revised several reimbursement limitations with which AMITIZA was first approved for reimbursement and inclusion in the Specialitätenliste, or SL, to allow all Swiss physicians to prescribe AMITIZA to patients who have failed previous treatments with at least two laxatives over a nine month period.

The Company filed for the OIC indication in Switzerland in the first quarter of 2013, and anticipates a decision in the first half of 2014. On March 7, 2014, MHRA notified the Company that the application for approval of the OIC indication in the United Kingdom was not approved. The Company is considering the appropriate next steps with MHRA. The Company is considering seeking approval for AMITIZA in other European Union countries following the Mutual Recognition Procedure, or MRP.

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. A 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 an agreement in 2011 with Numab AG, or Numab, to obtain access to their proprietary technology for the discovery of high-affinity antibodies against certain selected targets. In October 2013, Numab and the Company entered into a termination arrangement which will result in continued development by Numab. After successful development by Numab and an agreement with a third party investor, Numab and the Company will enter into a license agreement on commercially reasonable terms.

## Basis of Presentation

The accompanying Consolidated Financial Statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America, 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, United Kingdom, 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.

Revision to Previously Issued Financial Statements

The Company has revised the December 31, 2012 consolidated statements of operations and comprehensive income to correct an error in the improper presentation of gross profit. As a result of this revision, gross profit will be removed as a sub-total and cost of goods sold will be disclosed as an operating cost under the heading "Costs and expenses". Gross profit was presented on the consolidated statements of operations and comprehensive income beginning in the period ended December 31, 2012 and for periods ended March 31, June 30 and September 30, 2013. The revision has no impact on income from operations or net income and was determined to not be material to any previously issued financial statements. Accordingly, the Company will revise previously reported interim periods in future filings. The following revision has been made to the previously reported December 31, 2012 balances:

	Presentation as of December 31, 2012						
(In thousands)		Previously Reported		Revision djustment	As Revised		
				<u>-</u>	_		
Gross profit	\$	78,457	\$	(78,457)	\$	-	
Total costs and expenses		(70,140)		(3,030)		(73,170)	

## 2. Summary of Significant Accounting Policies

## Cash and Cash Equivalents

For the purpose of the Consolidated Balance Sheets and Consolidated Statements of Cash Flows, cash equivalents include all highly liquid investments with a maturity of 90 days or less at the time of purchase.

## Restricted Cash

Restricted cash primarily represents collateral pledged to support a loan agreement with The Bank of Tokyo-Mitsubishi UFJ, Ltd. (the Tokyo-Mitsubishi Bank); a loan agreement with The Mizuho Bank, Ltd. (the Mizuho Bank); a loan agreement between Numab AG (Numab) and Zurcher Kantonalbank, which the Company serves as guarantor; and operating leases with certain financial institutions. Restricted cash totaled approximately \$28.6 million and \$18.9 million at December 31, 2013 and 2012, respectively.

## **Current and Non-Current Investments**

Current and non-current investments consist primarily of United States government agency securities, certificates of deposit, corporate bonds, municipal securities and variable rate demand notes, and are classified as current or non-current based on their maturity dates. The Company classifies all 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, 2013 and 2012, approximately \$16.4 million, or 17.1%, and \$16.8 million, or 18.4%, respectively, of the Company's cash, cash equivalents, restricted cash and investments were issued or insured by the United States government or United States 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 Takeda, an unrelated party, accounted for 81.3%, 74.4% and 96.9%, of the Company's total revenues for the years ended December 31, 2013, 2012 and 2011, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 88.2% and 98.0% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at December 31, 2013 and 2012. Revenues from another unrelated party, Abbott, accounted for 17.6%, 19.3% and 2.3% of the Company's total revenues for the years ended December 31, 2013, 2012 and 2011. The Company depends significantly upon 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 Ueno, Ltd, or R-Tech, to provide the Company 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 (see Note 10).

## Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments approximate their fair values based on their short maturities, independent valuations or internal assessments. The Company's financial instruments include cash and cash equivalents, restricted cash, current and non-current investments, receivables, accounts payable and accrued expenses. The carrying amounts of the notes payable at December 31, 2013 and 2012 were less than the estimated fair values (see Note 11.) The Company's debt is subject to the fair value disclosure requirements as discussed in Note 4 below, and is classified as a Level 2 security.

#### Accounts Receivable and Unbilled Accounts Receivable

Accounts receivable primarily represent amounts due under the Takeda and Abbott Agreements. Unbilled accounts receivable consist of research and development expenses that are reimbursable by Takeda, but as of the balance sheet date have not been billed to Takeda. The Company recorded an allowance for doubtful accounts of approximately \$440,000 and \$280,000 at December 31, 2013 and 2012, respectively, related to certain disputed Takeda invoices.

## **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.

#### Inventory

Inventory is stated at cost or market, whichever is lower. Cost is determined on a first-in, first-out basis. Inventory is reviewed periodically for potential excess, dated or obsolete status. The Company's management evaluates the carrying value of inventory on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the prices the Company expects to obtain for products in their respective markets compared to historical costs, and the remaining shelf life of goods on hand.

## **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 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 Evaluation for 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, 2013, 2012 or 2011 because there have been no indicators of impairment during those years.

## Revenue Recognition

The Company's revenues are derived primarily from product royalties, development milestone payments, clinical development activities and product sales.

## Research and Development Revenue

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 12 below.

Where agreements include contingent milestones the Company evaluates 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 agreed upon prior to January 1, 2011 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 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.

For research and development deliverables agreed upon subsequent to January 1, 2011 which are reimbursable by Takeda at contractually predetermined percentages, the Company recognizes revenue when the underlying research and development expenses are incurred, assuming all other revenue recognition criteria are met.

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.

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

#### **Product Royalty Revenue**

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

#### **Product Sales Revenue**

AMITIZA product sales consist of AMITIZA sales to Abbott in Japan and by the Company in Europe. Revenue from AMITIZA product sales is recognized when persuasive evidence of an arrangement exists, delivery has occurred, title to product and associated risk of loss have passed to the customer, the price is fixed or determinable, and collection from the customer is reasonably assured. The Company did not record sales deductions and returns for sales of AMITIZA due to the absence of discounts and rebates and the lack of right of return.

RESCULA product sales consist of RESCULA sales in the United States. The Company recognizes revenue from RESCULA product sales less deductions for estimated sales discounts and sales returns. Revenue from product sales of RESCULA is recognized when persuasive evidence of an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. As a result, the Company estimates an accrual for product returns, which is recorded as a reduction of product sales. Given the Company's limited history of selling RESCULA and the return period, the Company cannot reasonably estimate product returns from the wholesale distribution channel. Therefore, the Company is deferring the recognition of revenue until there is confirmation of pull-through sales to end-user customers. The Company will continue to defer recognition until the point at which the Company has obtained sufficient sales history to reasonably estimate returns from the wholesalers. The Company's three largest wholesale customers accounted for 96.2% of its RESCULA product sales for the year ended December 31, 2013.

## Co-promotion Revenue

Co-promotion revenue relates to a limited reimbursement of co-promotion costs based on details to healthcare prescribers.

## **Contract and Collaboration Revenue**

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

The Company considers its participation in joint committees under its 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 the Abbott Agreement and, as such, records revenue on a gross basis in the Condensed Consolidated Statements of Comprehensive Income (Loss).

## **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, 2013 and 2012, total deferred revenue was approximately \$7.5 million and \$10.8 million, respectively.

Total deferred revenue consists of the following as of:

	December 31,						
(In thousands)		2013		2012			
Deferred revenue, current	\$	1,365	\$	3,700			
Deferred revenue, non-current		6,169		7,093			
	\$	7,534	\$	10,793			
Deferred revenue to related parties, included in total deferred revenue:							
Deferred revenue to related parties, current	\$	477	\$	479			
Deferred revenue to related parties, non-current		4,925		5,386			
Total	\$	5,402	\$	5,865			

## Cost of Goods Sold

Cost of goods sold relates to purchase and distribution costs of the products sold by the Company, including inventory write-offs for excess and obsolete inventory and amortization of marketing licenses.

## 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. No material adjustments have been required for this accrual during the years ended December 31, 2013 and 2012.

## **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, 2013 were as follows:

	Year	r Ended Decembe	er 31,
	2013	2012	2011
Expected volatility	65% - 75%	62% - 64%	55% - 64%
Risk-free interest rate	1.23% - 1.40%	0.76% - 1.60%	1.30% - 3.30%
Expected term (in years)	5.50 - 6.25	5.50 - 6.25	2.10 - 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 United States 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, 2013 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, 2013, 2012 and 2011, 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, 2013 was as follows:

	Year Ended December 31,						
(In thousands)		2013		2012		2011	
Research and development expense	\$	293	\$	535	\$	234	
General and administrative expense		1,260		1,349		964	
Selling and marketing expense		191		349		172	
Total		1,744		2,233		1,370	
Employee stock-based compensation expense per basic and diluted share of common stock	\$	0.04	\$	0.05	\$	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 United States 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 United States 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, 2013 and 2012, the total deferred charge is \$5.2 million and \$5.9 million after a net current year amortization expense of \$673,000 and \$77,000, respectively.

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 \$679,000 and \$1.1 million, including interest, for uncertain tax positions as of December 31, 2013 and 2012, respectively. As of December 31, 2013, \$42,000 and \$637,000 are reflected as other current liabilities and other liabilities, respectively, in the accompanying Consolidated Balance Sheets. As of December 31, 2012, \$660,000 and \$471,000 are reflected as other current liabilities and other liabilities, respectively, 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, 2013 and 2012 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 party interest in foreign jurisdictions. During the twelve months ended December 31, 2013, the liability for income taxes has decreased approximately \$452,000. This decrease in the liability is related primarily to settlement of prior periods with state tax authorities, offset by a net increase related to current year activity in the United States 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 settle prior periods with state tax authorities; therefore, the amount of \$42,000 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 2010, 2011, 2012 and 2013 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 Americas, 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 United States GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under United States GAAP to be reclassified in their entirety to net income, the Company is required to cross-reference to other disclosures required under United States GAAP that provide additional detail about those amounts. The Company adopted this update effective January 1, 2013, and such adoption did not have a material impact on the Company's consolidated financial statements.

In July 2013, the FASB issued an Accounting Standards Update, or ASU, providing guidance on whether an uncertain tax position should be presented as a reduction to a deferred tax asset or as a separate liability. This guidance seeks to address diversity in practice. The adoption of this ASU amendment is not expected to have a material effect on the Company's financial condition, results of operations or cash flows.

## 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, 2013, is shown below:

(in thousands, except per share data)	2013 2012			2012	2011		
Basic net income (loss) per share:							
Net income (loss)	\$	6,419	\$	4,836	\$	(17,306)	
Weighted average class A and B common shares outstanding		41,716		41,660		41,839	
Basic net income (loss) per share	\$	0.15	\$	0.12	\$	(0.41)	
Diluted net income (loss) per share:							
Net income (loss)	\$	6,419	\$	4,836	\$	(17,306)	
Weighted average class A and B common shares outstanding for diluted net income per share		41,716		41,660		41,839	
Assumed exercise of stock options under the treasury stock method		828		125		-	
		42,544		41,785	_	41,839	
Diluted net income (loss) per share	\$	0.15	\$	0.12	\$	(0.41)	

The potentially dilutive securities used in the calculations of diluted net income per share at December 31, 2013, 2012 and 2011 are as follows:

	I	December 31,					
(In thousands)	2013	2012	2011				
Employee stock options	2,129	2,811	-				
Non-employee stock options	410	450	-				

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, 2013, 2012 and 2011:

	D		
(In thousands)	2013	2012	2011
Employee stock options	530	596	3,595
Non-employee stock options	-	-	450

## 4. Current and Non-Current Investments

At December 31, 2013 and 2012, current and non-current investments consisted of the following securities:

	December 31, 2013									
			Unrealized		Unrealized					
(In thousands)	Cost		Gains		ins Losses		Fai	air Value		
Current:										
U.S. government securities	\$	1,000	\$	-	\$	-	\$	1,000		
U.S. government agencies		9,048		3		-		9,051		
Certificates of deposits		3,500		-		-		3,500		
Corporate bonds		752		-		-		752		
Municipal securities		1,700		-		-		1,700		
Total	\$	16,000	\$	3	\$	-	\$	16,003		
Non-current:										
U.S. government agencies	\$	4,212	\$	-	\$	(3)	\$	4,209		
Certificates of deposits	\$	2,500					\$	2,500		
Corporate bonds		511		-		(1)		510		
Total	\$	7,223	\$	-	\$	(4)	\$	7,219		
	December 31, 2012									

	December 31, 2012								
			Unrealized		Unrealized				
(In thousands)		Cost		Gains	Losses		Fair Valu		
Current:									
U.S. commercial paper	\$	2,499	\$	-	\$	-	\$	2,499	
U.S. government securities		251		-		-		251	
Corporate bonds		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	

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:

<u>Level 1</u>: quoted prices in active markets for identical assets or liabilities;

<u>Level 2</u>: 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	Measure	ments	at Reporting	g Dat	te U	sıng
	Quoted Pr	ices						_
	in Activ	e	Signific	ant				
	Markets	for	Other		Significan	nt		
	<b>Identical</b>		Observable		Unobservabl			
December 31, 2013	Assets	Assets		ts	Inputs			
(In thousands)	(Level 1	.)	(Level	2)	(Level 3)			Total
U.S. government securities	\$	-	\$ 1	,000	\$	-	\$	1,000
U.S. government agencies		-	13	,260		-		13,260
U.S. commercial paper		-	6	,449		-		6,449
Municipal securities		-	1	,700		-		1,700
Certificates of deposits		-	6	,000		-		6,000
Corporate bonds		-	5	,533		-		5,533
Money market funds	5,	955		-		_		5,955
Total assets measured at fair value	\$ 5,	955	\$ 33	,942	\$	_	\$	39,897

	Fair Value Measurements at Reporting Date Using								
	Quoted Prices in Active Markets for Identical	Significant Other Observable	Significant Unobservable						
December 31, 2012	Assets	Inputs	Inputs						
(In thousands)	(Level 1)	(Level 2)	(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	<u>-</u>	2,785	<u>-</u>	2,785					
Total assets measured at fair value	\$ 16,274	\$ 29,952	\$ -	\$ 46,226					

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:

Decemb	<b>er 3</b> 1	l,
 2013		2012
\$ 2,607	\$	2,598
480		434
1,444		1,478
 4,531		4,510
(3,375)		(2,970)
\$ 1,156	\$	1,540
¢	2013 \$ 2,607 480 1,444 4,531 (3,375)	\$ 2,607 \$ 480 1,444 4,531 (3,375)

Depreciation expense for the years ended December 31, 2013, 2012 and 2011 was approximately \$512,000, \$542,000 and \$591,000, respectively.

The leasehold improvements as of December 31, 2013 and 2012 are 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 license all patents and other intellectual property rights related to RESCULA for its FDA approved indication and any new indications for unoprostone isopropyl in the United States and Canada. A 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 and milestone payments of \$3.5 million and may be required to pay up to \$5.0 million in additional milestone payments based on the achievement of specified development and commercialization goals. The Company allocated the acquisition cost between an intangible asset of \$3.4 million and a non-current prepaid inventory of \$85,000. The \$3.4 million intangible asset is included in other non-current assets in the accompanying Condensed Consolidated Balance Sheets as of December 31, 2013 and 2012. The non-current prepaid inventory of \$85,000 was written-off during the year ended December 31, 2013. Upon the February 2013 RESCULA re-launch, a \$500,000 milestone payment was paid to R-Tech in May 2013. The cost is being 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, 2013, 2012 and 2011. The annual amortization expense will be approximately \$341,000 through April 2019. The unamortized amount included in intangible assets was \$1.8 million and \$2.1 million at December 31, 2013 and 2012, respectively

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.

Pursuant to the 2011 R-Tech Agreement, the Company has made payments to R-Tech of \$6.0 million, which is reflected in other non-current assets in the accompanying Condensed 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 R-Tech 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, 2013, 2012 and 2011, respectively. The annual amortization expense will be approximately \$613,000 through March 2021. The unamortized amount included in intangible assets was \$4.4 million and \$4.9 million at December 31, 2013 and 2012, respectively.

The Company reviews intangible assets for impairment when events or changes in circumstances indicate that the carrying value of its intangible assets may not be recoverable. An impairment in the carrying value of an intangible asset is recognized whenever anticipated future undiscounted cash flows from an intangible asset are estimated to be less than its carrying value. There have been no impairment charges recorded during the years ended December 31, 2013, 2012 or 2011 because there have been no indicators of impairment during those years. If the Company's actual results, or the plans and estimates used in future impairment analyses, are lower than the original estimates used to assess the recoverability of these assets, the Company could incur future impairment charges.

## 7. Accrued Expenses

Accrued expenses consist of the following:

		1,		
(In thousands)	·	2013		2012
Research and development costs	\$	1,775	\$	6,662
Employee compensation		2,531		1,219
Selling and marketing costs		584		487
Legal service fees		14		830
RESCULA milestones		-		500
Other accrued expenses		778		897
Total	\$	5,682	\$	10,595

#### 8. Other Liabilities

Other liabilities consist of the following:

		Decem	ber 3	31,
(In thousands)	2	2013		2012
Japan consumption tax payable	\$	917	\$	-
Deferred leasehold incentive		255		373
Deferred rent expense		341		408
Other liabilities		637		472
Total	\$	2,150	\$	1,253

## 9. Commitments and Contingencies

## **Operating Leases**

The Company leases office space in the United States, Switzerland, and Japan, under operating leases through 2017. At December 31, 2013, total future minimum, non-cancelable lease payments under operating leases are as follows:

	Dece	ember 31,
(In thousands of U.S. dollars)		2013
2014	\$	1,273
2015		1,093
2016		1,084
2017		139
2018		-
Total minimum lease payments	\$	3,589

Rent expense for all operating leases was \$1.3 million, \$1.6 million and \$1.6 million for the years ended December 31, 2013, 2012 and 2011, 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 2016 under these agreements as of December 31, 2013 were approximately \$6.8 million.

The maximum contingent liability under the Numab Agreement (see Note 12 below) in the event that Numab defaults under its loan with Zurcher Kantonalbank is \$2.5 million. As of December 31, 2013, the potential amount of payments in the event of Numab's default is \$2.2 million.

## 10. Related Party Transactions

## R-Tech Ueno, Ltd.

On March 7, 2003, the Company entered into an exclusive supply agreement with R-Tech. This agreement grants R-Tech the exclusive right to manufacture and supply RUG-015, a prostone compound, and lubiprostone in the United States and Canada, and in consideration for such right R-Tech agreed to pay the Company as follows: \$1.0 million upon execution of the agreement, \$2.0 million upon commencement of the first phase 2 lubiprostone trial, \$3.0 million 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, or Board, approved the Company's decision to discontinue the development of RUG-015. In addition to the Company's Board, 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, 2013, 2012 and 2011, which is recorded as contract revenue. During the years ended December 31, 2013, 2012 and 2011, the Company purchased from R-Tech approximately \$827,000, \$1.4 million, and \$72,000, respectively, of clinical supplies under the terms of this agreement. Commercial supplies of AMITIZA in the United States are subject to a three-party agreement among the Company, 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. The Company amended this agreement in 2013 to reduce the per-capsule cost of the supply of lubiprostone. 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 became available in the United Kingdom beginning in the fourth quarter of 2013, the \$2.0 million deferral has been recorded as both current and non-current deferred revenue as of December 31, 2013, and as non-current deferred revenue as of December 31, 2012. In 2014 the Company will begin to ratably recognize this deferred revenue into income. During the years ended December 31, 2013, and 2011, the Company purchased approximately zero, \$124,000 and \$125,000, 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 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 2013, 2012 or 2011.

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 ion channel activators. 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 renew for additional two year terms. There were no clinical supplies purchased under the terms of this agreement during the years ended December 31, 2013, 2012 and 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, 2013, 2012 and 2011, the Company purchased approximately \$14.9 million, \$3.1 million and \$166,000, respectively, of commercial supplies of lubiprostone from R-Tech under this agreement. During the years ended December 31, 2013 and 2012, the Company purchased approximately \$673,000 and \$10,000, respectively, of clinical supplies from R-Tech under this agreement. There were no such clinical supplies purchases in 2011 from R-Tech under this agreement.

The Company has also made purchases for other research and development services during the years ended December 31, 2013, 2012, and 2011 of approximately \$194,000, \$466,000 and \$104,000, respectively.

In 2009 and 2011, the Company entered into two agreements with R-Tech to license 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, 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)	 2013		2012		2011	
Clinical supplies	\$ 827	\$	1,450	\$	72	
Other research and development services	194		466		104	
Commercial supplies	14,902		3,288		155	
	\$ 15,923	\$	5,204	\$	331	

	Yea	Year Ended December				
(In thousands)		2013		2012		
Deferred revenue, current	\$	477	\$	479		
Deferred revenue, non-current		4,925		5,386		
	\$	5,402	\$	5,865		

In March 2012, R-Tech advised the Company that it would relocate its manufacturing facility for unoprostone isopropyl in October 2012, and would not be able to manufacture and supply unoprostone isopropyl for up to 18 months. R-Tech has decided to contract with NittoMedic in Japan for the manufacture of unoprostone isopropyl but NittoMedic's facility needed to be inspected by the FDA before it can manufacture unoprostone isopropyl. In light of this change in facility, the Company placed an order of \$5.6 million of unoprostone isopropyl to cover this supply period based on the Company's forecasts for the launch of RESCULA in the United States. R-Tech delivered \$5.6 million of that order to the Company in the first and second quarters of 2013. This inventory was substantially written-off as discussed in Note 2 above. The Company filed a supplemental new drug application, or sNDA, in July 2013 for the new facility. The NittoMedic facility was inspected by the FDA in the fourth quarter of 2013. As a result of the inspection, FDA issued deficiencies to NittoMedic and a complete response letter to us with regard to the drug master file. NittoMedic has responded to the deficiencies and we have asked the FDA to proceed with its review of the sNDA, which it has indicated it will do so. The Company is awaiting the decision by the FDA.

In addition, R-Tech has a 30-year lease with Ueno Fine Chemicals Industry, LTD., or Ueno Fine Chemical, for the land upon which R-Tech's manufacturing facility that produces lubiprostone is located. There are approximately 20 years remaining on the lease and R-Tech's manufacturing facility is on the campus of Ueno Fine Chemical. R-Tech and Ueno Fine Chemical are in litigation in Japan over the terms of the lease including whether or not the lease should be terminated. However, based on information from R-Tech, the Company does not believe that the dispute will adversely affect the supply of lubiprostone.

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 are also controlling stockholders of the Company. Dr. Ueno was the Company's Chief Executive Officer and Chairman of the Board and member through March 3, 2014, and is our Chief Scientific Officer, Co-Founder and Chairman Emeritus. On March 31, 2014, Dr. Ueno will step down as Chief Scientific Officer and will become Scientific Advisor.

## 11. Notes Payable

In November 2010, the Company entered into a \(\frac{\text{\$\text{\$1,000,000,000}}\), approximating \(\frac{\text{\$11.6}}\) 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 and the Bank. The loan was renewed in November 2013. Borrowings may be used to finance research and development activities, for working capital needs and for the general corporate purposes of the Company. 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, 2013 was 1.22%. The outstanding loan balances included in the accompanying Consolidated Balance Sheets were \(\frac{\text{\$9.5}}{\text{\$9.5}}\) million and \(\frac{\text{\$11.6}}{\text{{\$million}}}\) as of December 31, 2013 and 2012, respectively. 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 \(\frac{\text{\$14.9}}{\text{{\$million}}}\) 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, 2013 and 2012. Due to the short-term maturity of the facility, the Company estimated that the carrying value approximated the fair value at December 31, 2013 and 2012.

In March 2013, the Company entered into a ¥1,000,000,000, approximating \$10.6 million as of the closing date, secured term loan agreement with the Mizuho Bank. The loan agreement provides for the extension of credit for the period of one year, which can be renewed annually upon the agreement of the Company and the Mizuho Bank. Borrowings may be used to finance research and development activities, for working capital needs and for the general corporate purposes of the Company. The loan bears annual interest based on the three-month TIBOR plus 0.25% and is reset quarterly. The interest rate at December 31, 2013 was 0.47%. The outstanding loan balance included in the accompanying Condensed Consolidated Balance Sheets was \$9.5 million as of December 31, 2013. 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 100% of the initial balance throughout the term of the loan. The Company deposited \$11.0 million with the Mizuho Bank and the deposit bears annual interest of 0.30%, which is recorded as restricted cash, current in the accompanying Condensed Consolidated Balance Sheets as of December 31, 2013. Due to the short-term maturity of the agreement, the Company estimated that the carrying value approximated the fair value at December 31, 2013.

## Subordinated Unsecured Promissory Notes

In connection with the SAG acquisition in 2010, the Company 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, 2013 is 4.3%.

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, through December 1, 2012, all accrued and unpaid interest was not paid in cash, but rather added to the principal balance of the notes. Interest paid-in-kind was nil, \$2.2 million and \$2.3 million for the three years ended December 31, 2013, 2012 and 2011, respectively.

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:

Fair Value			Carryin	g Va	Value	
December 31,			Year Ended December			
	2013		2013		2012	
\$	19,008	\$	19,008	\$	11,600	
	34,889		33,712		41,251	
\$	53,897	\$	52,720	\$	52,851	
		\$	26,892	\$	19,129	
			25,828		33,722	
		\$	52,720	\$	52,851	
	Dec	December 31, 2013 \$ 19,008 34,889	December 31,     Yes       2013     \$ 19,008       \$ 19,008     \$ 34,889       \$ 53,897     \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	December 31,         Year Ended I           2013         2013           \$ 19,008         \$ 19,008           34,889         33,712           \$ 53,897         \$ 52,720           \$ 26,892         25,828	December 31,         Year Ended December 32013           \$ 19,008         \$ 19,008           \$ 34,889         \$ 33,712           \$ 53,897         \$ 52,720           \$ 26,892         \$ 25,828	

The Company's debt is subject to the fair value disclosure requirements as discussed in Note 4 above, and is classified as a Level 2 security.

## 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 completed all development activities in the fourth quarter of 2012. 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.

As of December 31, 2013, the Company has received a total of \$37.5 million in up-front and development milestone payments under the Abbott Agreement, consisting of a \$15.0 million development milestone payment received in December 2012 for the first commercial sale of AMITIZA, as well as \$10.0 million and \$12.5 million in up-front and development milestone payments, respectively, received 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 following table summarizes the cash streams and related revenue recognized or deferred under the Abbott Agreement for the year ended December 31, 2013:

	R T	Cash eceived hrough ember 31,		Year E		cognized fo		,	the	Accounts eceivable for e Year Ended ecember 31,		Foreign Currency	De	Amount eferred at cember 31,
(In thousands)		2013	Thr	ough 2011	_	2012	_	2013	_	2013	_	Effects		2013
Collaboration revenue:														
Up-front payment associated with the Company's obligation to participate in joint committees	\$	846	\$	137	\$	52	\$	52	\$		\$	50	\$	555
Research and development revenue:														
Up-front payment - remainder	\$	9,154	\$	9,103	\$	199	\$	-	\$	-	\$	(148)	\$	_
Development milestone payment		27,500		12,598		15,157		-		-		(255)		-
Total	\$	36,654	\$	21,701	\$	15,356	\$	-	\$	-	\$	(403)	\$	-
Product sales revenue:	\$	19,017	\$	_	\$	5,023	\$	15,807	\$	2,076	\$	263	\$	_

## 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 \$160.0 million in upfront and development milestone payments through December 31, 2013 under the Takeda Agreement, including a \$10.0 million development milestone received in the second quarter of 2013 for the first commercial sale of AMITIZA for OIC. Subject to development and acceptance of future indications, 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 for the year ended December 31, 2013:

	Cash Received Through December 31,		Received Through Revenue Recognized for the December 31, Year Ended December 31,						Accounts Receivable for the Year Ended December 31,		Dec	mount ferred at ember 31,
(In thousands)		2013	Thro	ough 2011		2012		2013		2013 (1)		2013
Collaboration revenue:												
Up-front payment associated with the Company's obligation to participate in joint committees	\$	2,375	\$	1,052	\$	147	\$	147	\$	-	\$	1,029
Research and development revenue:												
Up-front payment - remainder	\$	17,624	\$	17,624	\$	-	\$	-	\$	-	\$	-
Development milestones		140,000		130,000		-		10,000		-		-
Reimbursement of research and development expenses		114,670		100,262		6,189		10,354		2,554		419
Total	\$	272,294	\$	247,886	\$	6,189	\$	20,354	\$	2,554	\$	419
Product royalty revenue	\$	276,598	\$	188,631	\$	50,696	\$	52,100	\$	14,829	\$	-
Co-promotion revenue	\$	29,453	\$	25,816	\$	3,576	\$	61	\$	-	\$	-

#### (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, 2013, 2012 and 2011, 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, 2013 and 2012 was approximately \$1.0 million and \$1.2 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 \$52.1 million, \$50.7 million and \$41.5 million for the years ended December 31, 2013, 2012 and 2011, respectively. This revenue is recorded as product royalty revenue in the Consolidated Statements of Operations and Comprehensive Income (Loss).

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

The Company initially deferred the residual amount of the \$20.0 million upfront payment totaling approximately \$17.6 million, development milestone payments received totaling \$50.0 million, and reimbursement of the initial \$30.0 million of research and development costs for the development of AMITIZA for CIC and IBS-C indications. These deferred amounts were applied towards the unit of accounting that combines the participation in the joint development committee and the development of CIC and IBS-C and was recognized over the performance period of developing the CIC and IBS-C NDA submissions. The Company completed the development of the CIC and IBS-C in June 2007 and filed a sNDA for IBS-C. This was the culmination of the performance period. In June 2007, the Company also recognized as revenue, in full, \$30.0 million from Takeda upon the filing of the sNDA for AMITIZA to treat IBS-C. The Company received a \$50.0 million development milestone from Takeda as a result of the FDA's approval on April 29, 2008 of the sNDA for IBS-C in women aged 18 years and older and recognized the payment as research and development revenue during the year ended December 31, 2008.

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

- The Company is obligated to perform studies in connection with changes to labeling for CIC. Takeda is obligated to fund 70% of the labeling studies and the Company is obligated to fund the remaining 30%. There is no defined performance period, but the performance period will not exceed the term of the Takeda Agreement.
- The Company 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 a sNDA for the OBD indication. In February 2012, the Company announced that lubiprostone met the primary endpoint in a phase 3 clinical trial for the treatment of OBD in patients with chronic, non-cancer pain, excluding those taking methadone.
- The Company is obligated to perform all development work necessary for phase 4 studies, for which Takeda is obligated to fund all development work. There is no defined performance period, but the performance period will not exceed the term of the Supplemental 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, 2013, 2012 and 2011, the Company recognized approximately \$10.4 million, \$4.4 million and \$8.0 million related to these three deliverables as research and development revenue in the Consolidated Statements of Operations and Comprehensive Income (Loss), respectively.

In 2011, the Joint Commercialization Committee (JCC) granted approval to begin studies for a liquid formulation. In addition, in 2012, the JCC granted approval for studies for a pediatric dosage. These additional deliverables are considered separate units of accounting and the Company recognizes revenue from Takeda reimbursements for these deliverables when earned.

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 \$61,000, \$3.6 million and \$3.4 million of revenues for the years ended December 31, 2013, 2012 and 2011, 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

In September 2011, the Company entered into a Loan Guarantee and Development Agreement, or the Numab Agreement, with Numab. Until September 2013, Numab was considered a related party as a result of an ownership interest in Numab by one of the Company's former executive officers, who resigned in September 2013. Under the terms of the Numab Agreement, the Company would provide Numab with up to CHF 5.0 million as collateral and would serve as guarantor for a loan to Numab from a third party, Zurcher Kantonalbank. Following the payment of the first success fee during the first quarter of 2013, this amount was reduced to CHF 2.2 million, or approximately \$2.5 million as of December 31, 2013.

As of December 31, 2013, the collateral of CHF 2.2 million has been deposited by the Company and Numab has utilized CHF 2.0 million of its loan facility, or approximately \$2.2 million. During 2012, the Company considered it probable that the success criteria for the first target would be met and made full provision for the success fee. This fee was paid during the first quarter of 2013. In the first quarter of 2013, the Company decided to no longer pursue further development of the target. In October 2013, Numab and the Company entered into a termination arrangement which may result in continued development by Numab. After successful development by Numab and an agreement with a third party investor, Numab and the Company will enter into a license agreement on commercially reasonable terms. At December 31, 2013 and 2012, the Company has a recorded liability of \$663,000 and nil, respectively, in collateral callable to meet a potential loan default by Numab.

## 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 43,998,430 shares as of March 3, 2014, each of which is entitled to one vote per share.

## **Cantor Sales Agreement**

On January 11, 2013, the Company entered into a sales agreement with Cantor Fitzgerald & Co., or the Cantor Sales Agreement, which enables the Company to offer and sell shares of the Company's class A common stock with an aggregate sales price of up to \$20.0 million, from time to time through Cantor Fitzgerald & Co. as our sales agent. Sales of class A common stock under the Cantor Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Cantor Fitzgerald & Co. is entitled to receive a commission rate of 3.0% of gross sales in connection with the sale of the Company's class A common stock sold on the Company's behalf. From November 22, 2013 through December 31, 2013, the Company had sold through the Cantor Sales Agreement an aggregate of 749,383 shares of the Company's class A common stock, and received gross proceeds of approximately \$5.3 million, before deducting issuance expenses. The Company does not make repurchases under the stock repurchase program when it is making at-the-market equity offerings.

## Treasury Stock

On December 11, 2008, the Company announced a stock repurchase program under which the Company is authorized to purchase up to \$10.0 million of its class A common stock from time to time in open-market transactions. On September 8, 2011, the Company's Board 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 on December 9, 2008. On November 2, 2012, the Board authorized the increase of such amount of repurchase to up to an aggregate of \$5.0 million. In 2013 and 2012, the Company repurchased 67,762 shares and 270,043 shares of its class A common stock under this program at a cost of \$336,000 and \$1.3 million, respectively. All shares of class A common stock purchased in 2013 were purchased in January, February and March. In 2012 all shares were purchased in August, September, October, November and December. These shares are not retired and are recorded at cost.

## Stock Option Plans

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 Company's Board administers the 2001 Incentive Plan and has sole discretion to grant options. On September 1, 2003, the Board amended the 2001 Incentive Plan to allow for a maximum of 8,500,000 shares of class A common stock to be issued under all awards, including incentive stock options under the 2001 Incentive Plan. In 2006, the Board determined no further options would be granted under this plan.

In August 2005, the Board granted 510,000 stock options to non-employees under the 2001 Incentive Plan. These non-employee stock options vested immediately and have a weighted average exercise price per share of \$5.85. At December 31, 2013 and 2012, there were 410,000 and 450,000 options outstanding and exercisable with a remaining contractual life of 1.33 and 2.33 years, respectively.

On June 5, 2006, the Board approved a 2006 Stock Incentive Plan, or the 2006 Incentive Plan, which has been amended and restated, and reserved 8,500,000 shares of class A common stock for issuance under this plan. At December 31, 2013, a total of 5,986,937 shares were available for future grants under this 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 on the date of grant. The options generally vest over four years and have a ten-year contractual term.

On October 18, 2007, the Board 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 may determine. The Board 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, 2012 and 2013 pursuant to the "evergreen" provision, would be zero.

On October 7, 2009, the Board 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 amended the 2006 Incentive Plan for its non-employee directors, to increase the approved annual stock option grants to non-employee directors to 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, 2013 under the Company's 2001 Incentive Plan is presented below.

		Weighted	Weighted	
		Average	Average	
		Exercise	Remaining	
		Price Per	Contractual	Aggregate
	Shares	Share	Term (Years)	<b>Intrinsic Value</b>
Options outstanding, December 31, 2012	156,400	\$ 10.00		
Options expired	(10,200)	10.00		
Options outstanding, December 31, 2013	146,200	10.00	2.34	\$ -
Options exercisable, December 31, 2013	146,200	10.00	2.34	\$ -

A summary of the employee stock option activity for the year ended December 31, 2013 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, 2012	3,251,493	\$ 4.83		
Options granted	204,250	7.36		
Options exercised	(557,836)	4.43		
Options forfeited	(334,879)	5.36		
Options expired	(49,965)	6.61		
Options outstanding, December 31, 2013	2,513,063	5.03	7.34	\$ 11,346,066
Options exercisable, December 31, 2013	1,143,912	5.41	6.97	\$ 4,919,233

A summary of the non-employee stock option activity for the year ended December 31, 2013 under the Company's 2001 Stock Incentive Plan is presented below:

		Weighted Average Exercise Price Per	Weighted Average Remaining Contractual	Aggregate
	Shares	Share	Term (Years)	Intrinsic Value
Options outstanding, December 31, 2012	450,000	\$ 5.85		
Options exercised	(40,000)	5.85		
Options outstanding, December 31, 2013	410,000	5.85	1.31	\$ 1,455,500
Options exercisable, December 31, 2013	410,000	5.85	1.31	\$ 1,455,500

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 under its 2006 Incentive Plan. 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 2013 or 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 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, 2013, 2012 and 2011 were \$7.36, \$6.30 and \$1.81, respectively. As of December 31, 2013, approximately \$1.1 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 1.65 years. When an option is exercised, the Company issues a new share of class A common stock.

## **Employee Stock Purchase Plan**

On June 5, 2006, the Board 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 3,625 and 3,550 shares of common stock were purchased under the ESPP during the years ended December 31, 2013 and 2012, respectively. The Company received approximately \$24,000, \$20,000 and \$13,000 upon purchase of shares under the ESPP for the years ended December 31, 2013, 2012 and 2011, respectively.

## Tax Benefits

As of December 31, 2013, the balance of the Company's additional paid-in capital pool related to tax windfall benefits from the stock option exercises was \$213,000.

The Company applies a with-and-without approach in determining its intra-period allocation of tax expense or benefit attributable to stock based compensation deductions. Since the Company does not have any net operating loss carry-forwards in the U.S., the tax benefit reduces income taxes payable in the current year and is therefore recorded to additional paid-in-capital.

## 14. Income Taxes

Income (loss) before income taxes is as follows:

	Year Ending December 31,						
	 2013 2012			2011			
U.S.	\$ 9,175	\$	8,580	\$	(9,670)		
Foreign	1,172		(828)		(12,244)		
	\$ \$ 10,347 \$ 7,752		7,752	\$	(21,914)		

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

	Year	Ended December	er 31,
(In thousands)	2013	2012	2011
Current tax provision (benefit):			
U.S. Federal	\$ 5,198	\$ 1,431	\$ (597)
U.S. State	1,008	658	(194)
Foreign	(582)	51	550
Total current tax provision (benefit)	5,624	2,140	(241)
Deferred provision (benefit):			
U.S. Federal	(1,783)	1,248	(1,369)
U.S. State	(279)	(193)	385
Foreign	366	(279)	(3,383)
Total deferred provision (benefit)	(1,696)	776	(4,367)
Total income tax provision (benefit)	\$ 3,928	\$ 2,916	\$ (4,608)

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

	Deceml	ber 31	l <b>,</b>
	 2013		2012
(In thousands)	 		
Deferred tax assets:			
Foreign net operating loss carry-forwards	\$ 2,538	\$	5,132
State net operating loss carry-forwards	38		100
Deferred revenue	2,143		2,431
Accrued expenses	1,637		1,316
Tax benefits on stock options	2,378		1,832
Inventory	1,243		-
Other	 220		388
Gross deferred tax assets	10,197		11,199
Deferred tax liabilities:			
Property and equipment	(202)		(272)
Intangibles	(7,070)		(6,884)
Gross deferred tax liabilities	(7,272)		(7,156)
Less: valuation allowance	(1,751)		(4,142)
Net deferred tax assets (liabilities)	\$ 1,174	\$	(99)

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:

	Year Eı	31,	
(In thousands)	2013	2012	2011
Federal tax provision (benefit)	35.0%	34.0%	34.0%
State taxes, net of federal tax benefit	5.2%	7.5%	0.4%
General business credits	0.0%	-0.5%	1.6%
Changes in valuation allowance	-22.3%	-3.7%	-3.7%
Nondeductible expenses	1.3%	1.7%	-0.2%
Stock based compensation	-2.9%	12.7%	-1.9%
Impact of intangible transfer	7.7%	-18.6%	-4.7%
Impact of uncertain tax positions	-0.1%	-4.2%	-0.2%
Adjustment to deferred tax asset	11.8%	-10.4%	0.1%
Impact of foreign operations	1.8%	6.4%	-4.6%
Change in tax rates	0.6%	12.4%	-0.1%
Changes in other tax matters	-0.1%	0.3%	0.4%
	38.0%	37.6%	21.1%

At December 31, 2013 and 2012, the Company had foreign net operating loss carry-forwards of \$11.9 million and \$21.0 million, respectively. Approximately \$7.0 million of the foreign NOLs begin to expire in December 2019, and \$4.9 million of the foreign NOLs do not expire. As of December 31, 2013 and 2012, the Company had no NOLs in the United States.

As of December 31, 2013 and 2012, the Company had a valuation allowance on its deferred tax assets of \$1.8 million and \$4.1 million, respectively. The net decrease in the valuation allowance of \$2.4 million 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, as well as the reversal of all deferred tax assets of Ambrent due to its anticipated liquidation in early 2014. 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 United States 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 United States 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, 2013, the total deferred charge is \$5.2 million after a net current year amortization expense of \$673,000.

The valuation allowance at December 31, 2013 and 2012 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, 2013, 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 \$679,000 and \$1.1 million, including interest for uncertain tax positions as of December 31, 2013 and 2012, respectively. The Company expects to settle prior periods with state tax authorities; therefore, the amount of \$42,000 expected to reverse within the next twelve months has been reflected as other current liabilities and the remaining \$637,000 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, 2013 and 2012 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,					,
	2	013		2012		2011
Balance at January 1	\$	979	\$	1,226	\$	1,245
Increases for tax positions taken during prior periods		4		207		22
Decreases in unrecognized tax benefits related to settlements with taxing authorities		(467)		(536)		(71)
Increases for tax positions taken during current period		34		82		30
Balance at December 31	\$	550	\$	979	\$	1,226

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision. During 2013, 2012 and 2011, the Company recorded approximately \$22,000, \$42,000 and \$69,000, 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 2010, 2011, 2012 and 2013 remain open and subject to examination in the major tax jurisdictions in which tax returns are filed. The tax years 2009-2011 are currently under examination by the U.S. tax authorities. Management does not believe that the result of such examination will have a material impact on the financial statements.

## 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		ope Asia		Cor	solidated				
Year Ended December 31, 2013												
Research and development revenue	\$	20,354	\$	-	\$	-	\$	20,354				
Product royalty revenue		52,100		-		-		52,100				
Product sales revenue		556		62		15,807		16,425				
Co-promotion revenue		61		-		-		61				
Contract and collaboration revenue		566		46		42		654				
Total revenues		73,637		108		15,849		89,594				
Cost of goods sold		3,588		15		8,799		12,402				
Research and development expenses		11,090		5,445		4,989		21,524				
Depreciation and amortization		736		716		36		1,488				
Other operating expenses		35,911		5,900		3,173		44,984				
Income (loss) from operations		22,312		(11,968)		(1,148)		9,196				
Interest income		112		11		1		124				
Interest expense		(1,427)		(302)		(165)		(1,894)				
Other non-operating expense, net		(14)		(166)		3,101		2,921				
Income (loss) before income taxes	\$	20,983	\$	(12,425)	\$	1,789	\$	10,347				
Capital expenditures	\$	40	\$	105	\$	23	\$	168				

(In thousands)	Α	mericas	]	Europe	Asia C		Consolidated	
Year Ended December 31, 2012								
Research and development revenue	\$	6,189	\$	-	\$ 15,356	\$	21,545	
Product royalty revenue		50,696		-	-		50,696	
Product sales revenue		-		14	5,023		5,037	
Co-promotion revenue		3,576		-	-		3,576	
Contract and collaboration revenue		565		16	52		633	
Total revenues		61,026		30	20,431		81,487	
Cost of goods sold		98		9	2,923		3,030	
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	\$	3,470	\$ -	\$	3,871	
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	
As of December 31, 2013								
Property and equipment, net	\$	869	\$	112	\$ 175	\$	1,156	
Identifiable assets, net of intercompany loans and investments	\$	95,350	\$	23,843	\$ 17,780	\$	136,973	
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	

## 16. Quarterly Financial Data (unaudited)

(In thousands, except per share data)

Total revenues	\$	24,490	\$	21,163	\$	27,023	\$	16,919
Income (loss) from operations	\$	2,679	\$	(1,044)	\$	10,169	\$	(2,608)
Net income (loss)	\$	2,153	\$	1,291	\$	6,119	\$	(3,145)
Net income (loss) per share:								
Basic	\$	0.05	\$	0.03	\$	0.15	\$	(80.0)
Diluted	\$	0.05	\$	0.03	\$	0.14	\$	(80.0)
Diluted	<u> </u>		<u> </u>					()
Diluted	=		· <del></del>	2012 Quarte	ers E		<u> </u>	(1111)
(In thousands, except per share data)	Dec	ember 31					M	arch 31
	Dec \$			2012 Quarte		Ended	M \$	
(In thousands, except per share data)	Dec \$	ember 31		2012 Quarte tember 30	\$	Ended June 30	\$	arch 31

2013 Quarters Ended

(0.14)

(0.14)

June 30

(0.02)

(0.02)

September 30

March 31

(0.05)

(0.05)

December 31

0.33

0.32

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.

## 17. Subsequent Events

Net income (loss) per share:

Basic

Diluted

On February 10, 2014, the Company announced that Peter Greenleaf will join the Company as Chief Executive Officer, or CEO, and a member of the Board on March 3, 2014. Dr. Ryuji Ueno will step down as CEO and member and Chairman of the Board on March 3, 2014, and as Chief Scientific Officer on March 31, 2014. Dr. Daniel P. Getman will become Chairman of the Board on March 3, 2014.

The dissolution of Ambrent Investments, S.à r.l., or Ambrent, which began in the fourth quarter of 2013, is expected to be completed in the first quarter of 2014. Any remaining assets or liabilities of Ambrent will be transferred to Sucampo LLC.

On March 6, 2014, the Company was advised by Gayle R. Dolecek, P.D. that he will not stand for re-election as a member of the Board at the annual shareholder meeting on May 9, 2014, but will continue as a consultant of the Company under his existing consulting agreement. Dr. Dolecek's departure is not the result of any disagreement with the Company or the Board on any matter relating to the Company's operations, policies or practices. The Nominating and Corporate Governance Committee of the Board will begin a search to fill the vacancy created by Dr. Dolecek's departure.

On March 7, 2014, MHRA notified the Company that the application for Type II variation to update the summary of product characteristics to include the additional therapeutic indication of the treatment of opioid-induced constipation and associated signs and symptoms in adults with chronic, non-cancer pain in the UK was not approved and we are considering the appropriate next steps with MHRA.

## Schedule II - Valuation and Qualifying Accounts

	Balance	ing	Additions Charged to Costs and	1	n 1			Balan	
(In thousands)	of Yea	ar	Expenses	_	Dear	uctions		End of	Year
Allowance for doubtful accounts:									
2011	\$	-	\$	-	\$	-		\$	-
2012	\$	-	\$ 28	) (a)	\$	-		\$	280
2013	\$	280	\$ 16	) (a)	\$	-		\$	440
Valuation allowance for deferred tax assets:									
2011	\$ 9,	,658	\$ 93	2 (b)	\$	(6,123)	(b)	\$	4,467
2012	\$ 4,	,467	\$ 1,07	3 (c)	\$	(1,398)	(c)	\$	4,142
2013	\$ 4,	,142	\$	-	\$	(2,391)	(d)	\$	1,751

- (a) In 2013 and 2012, the increase in allowance for doubtful accounts is primarily associated with certain disputed Takeda invoices.
- (b) In 2011, the net decrease in the valuation allowance of \$5.2 million was due primarily to the recognition of gains in local tax jurisdictions on the transfer of certain intellectual property to SAG as well as the partial release of valuation allowances in certain jurisdictions that management believes the deferred tax assets are more likely than not to be utilized.
- (c) 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.
- (d) In 2013, the net decrease in valuation allowance of \$2.4 million 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, as well as the reversal of all deferred tax assets of Ambrent for anticipated liquidation.

## 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	Amended and Restated Bylaws	Exhibit 3.3 to the Company's Current Report on Form 8-K (filed August 2, 2013)
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)
	II-1	

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)
	П 2	

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)
10.68^	Consulting Agreement, dated May 23, 2013, between the Company and Gayle Dolecek	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed May 31, 2013)
10.69^	Consulting Agreement, dated September 14, 2013, between the Company and Peter Lichtlen	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed September 17, 2013)
10.70^	Employment Agreement, dated February 10, 2014, between the Company and Peter Greenleaf	Included herewith
10.71^	Consulting Agreement, dated February 10, 2014, between the Company and Dr. Ryuji Ueno	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	Included herewith
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm	Included herewith
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith

- 32.1 Certification of the Principal Executive Officer pursuant to 18 U.S.C. Included herewith Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of the Principal Financial Officer pursuant to 18 U.S.C. Included herewith Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- ^ Compensatory plan, contract or arrangement.
- \* Confidential treatment has been granted for portions of this exhibit.

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

Confidential

Peter Greenleaf Employment Agreement February 10, 2014 FINAL

# EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), dated as of February 10, 2014, is hereby entered into in the State of Maryland by and between SUCAMPO PHARMACEUTICALS, INC., a Delaware corporation (the "Company"), and PETER GREENLEAF ("Executive").

WHEREAS, the Board of Directors ("Board") of the Company desires to hire Executive as the Chief Executive Officer of the Company;

WHEREAS, Executive desires to be employed as the Chief Executive Officer of the Company;

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

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

WHEREAS, in light of the foregoing, the Company desires to employ Executive as the Chief Executive Officer as of March 3, 2014 (the "Effective Date") and Executive desires to be employed on such date.

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

# Article 1. Employment Agreement

# 1.1 Employment and Duties

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

vacation, sickness, disability, or other leaves to which Executive is entitled). Executive will perform all of Executive's responsibilities in compliance with all applicable laws and will ensure that the operations that Executive manages are in compliance with all applicable laws.

# Article 2. Employment Term

# 2.1 <u>Term</u>

The term of Executive's employment hereunder (the "Term") shall be deemed to commence on March 3, 2014 and shall end on January 31, 2017, unless sooner terminated as hereinafter provided; provided, however, that the Term shall be automatically renewed and extended for an additional period of one (1) year on each anniversary date of this Agreement unless either party gives a Notice of Termination (as defined below) to the other party at least sixty (60) days prior to such expiration date.

# 2.2 <u>Survival on Merger or Acquisition</u>

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

# Article 3. Compensation and Benefits

# 3.1 <u>Compensation</u>

(a) <u>Base Salary</u>. The Company shall pay Executive a salary at an annual rate that is not less than Five Hundred and Twenty-Five Thousand and 00/100 dollars (\$525,000.00), to be paid in bi-weekly installments, in arrears (the "Base Salary"). After 2014, the Base Salary will be reviewed by the Compensation Committee of the Board of Directors ("Compensation Committee") at least annually, and the Committee's recommendation shall be reviewed and approved by the Board of Directors. The Base Salary may, in the sole discretion of the Board of Directors, be increased, but not decreased (unless either mutually agreed by Executive and the Company, or established as part of across-the-board salary reductions that apply equally to all similarly situated officers as a percentage reduction in their salaries).

# (b) Stock Compensation.

(i) Awards. On the Effective Date, the Company shall grant Executive, on the terms and conditions set forth in the Incentive Stock Option Agreement attached hereto as Exhibit A and generally described herein, the right and option to purchase, in whole or in part, 600,000 shares of the Company's common stock at the option exercise price as defined in the Incentive Stock Option Agreement in effect on the grant date, which will be the Effective Date of this Agreement and which will vest ratably over a 4 year period. In addition, provided the Executive completes a Board approved strategic plan and assessment of the Company within 6 months of the Effective Date, the Company shall grant Executive, on the terms and conditions set forth in the Incentive Stock Option Agreement attached hereto as Exhibit B and generally described herein, the right and option to purchase, in whole or in part, an additional 200,000 shares of the Company's common stock to vest ratably when the average trading price of such common stock on the Nasdaq Global Market over any thirty (30) consecutive trading days equals or exceeds \$16 per share prior to the end of the 4 year performance period. Further, beginning in 2015 and at least annually for the Term of this Agreement, the Executive shall be eligible for an annual equity award consistent with a new long-term stock incentive program under the Amended and Restated 2006 Stock Incentive Plan ("Plan") subject to the recommendation of the Compensation Committee and approved by the Board. It is intended that such a long-term stock incentive program would provide the Executive with an annual equity award equivalent to at least \$500,000 in fair market value on the grant date as defined in the Incentive Stock Option Agreement. Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discret

(ii) <u>Effect of Termination of Employment</u>. As more fully set forth in the Executive's Incentive Stock Option Agreement and generally described herein, in the event that, during the Term, (1) the Company terminates Executive's

employment by not renewing this Agreement or without Cause, any unvested stock options that have a duration vesting condition as defined in the Incentive Stock Option Agreement (such terms shall govern in the event of any conflict with this Agreement) shall immediately vest to the extent such unvested stock options would have vested in the twelve (12) months from the Date of Termination; or (2) if the Company is acquired or is the non-surviving party in a merger, or the Company sells all or substantially all of its assets, and the Executive is terminated without cause or terminates his employment for Good Reason, as those terms and conditions are defined in the Incentive Stock Option Agreement (such terms shall govern in the event of a conflict with this Agreement), any unvested stock options under the Plan shall immediately vest and may be exercised only to the extent the performance targets have been achieved or would be achieved by such acquisition, merger or sale in accordance with the terms of the Plan and the Executive's Incentive Stock Option Agreement, which in the event of a conflict with this Agreement controls.

- (c) Bonuses. Executive shall be eligible to receive an annual cash bonus award targeted at 60% of annual Base Salary in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified from time to time. Any cash bonus awarded for the calendar year 2014 shall be prorated based on the number of months of employment in 2014. The annual cash bonus may be increased up to 84% of annual Base Salary based on Executive exceeding performance objectives established and approved by the Board. Recommendations concerning the decision to make a cash bonus award and the amount of any cash bonus award are entirely discretionary and shall be made by the Compensation Committee of the Board.
- (d) Taxes. Executive acknowledges and agrees that Executive shall be solely responsible for the satisfaction of any applicable taxes that may arise pursuant to this Agreement (including taxes arising under Code Section 409A (regarding deferred compensation) or 4999 (regarding golden parachute excise taxes), and that neither the Company nor any of its employees, officers, directors, or agents shall have any obligation whatsoever to pay such taxes or to otherwise indemnify or hold Executive harmless from any or all of such taxes. For purposes of Section 409A, the right to a series of installment payments under this Agreement shall be

treated as a right to a series of separate payments. All compensation due to Executive shall be paid subject to withholding by the Company to ensure compliance with all applicable laws and regulations.

(e) <u>Vacation</u>. Executive shall be entitled to receive 4 weeks of paid vacation prorated for 2014 and 5 weeks of paid vacation beginning in 2015 for the remainder of the Term of the Agreement.

# 3.2 Participation in Benefit Plans

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

# 3.3 Expenses

The Company will pay or reimburse Executive for all reasonable and necessary out-of pocket expenses incurred by Executive in the performance of Executive's duties under this Agreement. Executive shall provide to the Company detailed and accurate records of such expenses for which payment or reimbursement is sought, and Company payments shall be in accordance with the regular policies and procedures maintained by the Company from time to time, and all reimbursements due under this Agreement shall be separately requested and paid not later than one year after Executive incurs the underlying expense.

# 3.4 <u>Professional Organizations</u>

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

# 3.5 Parking

During the Term and where Executive uses an automobile to commute to work, the Company shall either provide parking for Executive's automobile at the Company's expense or reimburse Executive for such expense.

# Article 4. Termination of Employment

# 4.1 Definitions

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

- (a) "Benefit Period" shall mean (i) the twelve (12) month period commencing on the Date of Termination which occurs in connection with a termination of employment described in the first sentence of Section 4.4(a)(i) or (ii) or the twenty-four (24) month period commencing on the Date of Termination which occurs in connection with a termination of employment described in the first sentence of Section 4.4(a)(ii), or a period ending when Executive becomes eligible for group medical benefits coverage from another source, whichever is shorter.
  - (b) "Cause" shall mean any of the following:
    - (i) the gross neglect or willful failure or refusal of Executive to perform Executive's duties hereunder (other than as a result of Executive's death or Disability);
    - (ii) perpetration of an intentional and knowing fraud against or affecting the Company or any customer, supplier, client, agent or employee thereof:
    - (iii) any willful or intentional act that could reasonably be expected to injure the reputation, financial condition, business or business relationships of the Company or Executive's reputation or business relationships;
    - (iv) conviction (including conviction on a *nolo contendere* plea) of a felony or any crime involving fraud, dishonesty or moral turpitude;
    - (v) the material breach by Executive of this Agreement (including, without limitation, the Employment Covenants set forth in Article 5 of this Agreement); or

- (vi) the failure or continued refusal to carry out the directives of Executive's supervisor or the Board that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; provided, however, that Cause shall not exist if such refusal arises from Executive's reasonable, good faith belief that such failure or refusal is required by law.
- (c) "<u>Date of Termination</u>" shall mean the date specified in the Notice of Termination (as hereinafter defined) (except in the case of Executive's death, in which case the Date of Termination shall be the date of death); <u>provided</u>, however, that if Executive's employment is terminated by the Company other than for Cause, the date specified in the Notice of Termination shall be at least thirty (30) days from the date the Notice of Termination is given to Executive.
- (d) "Notice of Termination" shall mean a written notice from the Company to Executive that indicates Section 2 or the specific provision of Section 4 of this Agreement relied upon as the reason for such termination or nonrenewal, the Date of Termination, and, in the case of termination or non-renewal by the Company for Cause, in reasonable detail, the facts and circumstances claimed to provide a basis for termination or nonrenewal.
  - (e) "<u>Good Reason</u>" shall mean:
    - (i) Company effects a material diminution of Executive's position, authority or duties;
    - (ii) any requirement that Executive, without his/her consent, move his/her regular office to a location more than fifty (50) miles from Company's executive offices;
    - (iii) the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
    - (iv) any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive

determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within thirty (30) days, and Executive resigns within sixty (60) days thereafter. If any of these conditions is not met, Executive shall not have a Good Reason to terminate Executive's employment.

# (f) "Change in Control" shall mean:

- (i) the acquisition by any person of beneficial ownership of fifty percent (50%) or more of the outstanding shares of the Company's voting securities; or
- (ii) the Company is the non-surviving party in a merger; or
- (iii) the Company sells all or substantially all of its assets; provided, however, that no "Change in Control" shall be deemed to have occurred merely as the result of a refinancing by the Company or as a result of the Company's insolvency or the appointment of a conservator; or
- (iv) the Board of the Company, in its sole and absolute discretion, determines that there has been a sufficient change in the share ownership or ownership of the voting power of the Company's voting securities to constitute a change of effective ownership or control of the Company.

# 4.2 <u>Termination Upon Death or Disability</u>

This Agreement and Executive's employment hereunder, shall terminate automatically and without the necessity of any action on the part of the Company upon the death of Executive. In addition, except as prohibited by applicable law, the Company may terminate Executive's employment on account of Disability, as defined in this subparagraph. "Disability" shall mean a physical or mental illness, injury, or condition that prevents Executive from performing some or all of the essential functions of Executive's job for a period of at least ninety (90) consecutive calendar days, or one-hundred and twenty (120) calendar days whether consecutive or not, during any one (1) year period, as certified by an independent physician competent to assess the condition at issue, and which cannot be reasonably accommodated without undue hardship on the Company.

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

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

# 4.4 <u>Compensation Upon Termination</u>

# (a) Severance.

In the event the Company terminates Executive's employment without Cause; pursuant to Section 4.2 due to the disability of Executive, or elects not to renew this Agreement under circumstances where Executive is willing and able to execute a new agreement providing terms and conditions substantially similar to those in this Agreement, Executive shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement of any COBRA continuation premium payments made by Executive for the Benefit Period, and (iii) a lump sum severance payment equal to twelve (12) months of Executive's then current annual Base Salary and the current target bonus percentage of the current annual Base Salary to be made not later than sixty (60) days following Executive's Date of Termination; provided, however that each of the benefits provided under clauses (ii) and (iii) hereof are absolutely contingent on Executive's execution of the Release (as provided in Section 4.4(c) below) without any revocation having occurred. Notwithstanding the foregoing, the Company shall, to the extent necessary and only to the extent necessary, modify the timing of delivery of severance benefits to Executive if the Company reasonably determines that the timing would subject the severance benefits to any additional tax or interest assessed under Section 409A of the Internal Revenue Code. In such event, the payments will be made as soon as practicable without causing the severance benefits to trigger such additional tax or interest under Section 409A of the Internal Revenue Code. If any amounts that become due under Section 4.4 constitute "nonqualified deferred compensation" within the meaning of Section 409A, payment of such amounts shall not commence until Executive incurs a "separation from service" within the meaning of

Treasury Regulation Section 1.409A-l(h). If, at the time of Executive's separation from service, Executive is a "specified employee" (under Internal Revenue Code Section 409A), any benefit as to which Section 409A penalties could be assessed that becomes payable to Executive on account of Executive's "separation from service" (including any amounts payable pursuant to the preceding sentence) shall be paid, without interest thereon, on the date six months and one day after such separation from service. In no event shall Executive be entitled to the continuation of any compensation, bonuses or benefits provided hereunder, or any other payments following the Date of Termination, other than Base Salary earned through such Date of Termination and any other benefits payable under Section 4.4(a).

(b) <u>Change in Control</u>. In the event that Executive is terminated other than for "Cause" or terminates for Good Reason within twelve (12) months following the occurrence of a "Change in Control" of the Company or terminates because this Agreement is not assumed by the successor corporation (or affiliate thereto) as the result of a Change in Control,

Executive shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement of any COBRA continuation premium payments made by Executive for the Benefit Period, and (iii) a lump sum severance payment equal to twenty-four (24) months of Executive's then current annual Base Salary and the current target bonus percentage of the current annual Base Salary (the "Change in Control Severance Payment") to be made not later than sixty (60) days following Executive's Date of Termination; provided, however that each of the benefits provided under clauses (ii) and (iii) hereof are absolutely contingent on Executive's execution of the Release (as provided in Section 4.4(c) below) without any revocation having occurred. In the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 2800 and 4999 of the Internal Revenue Code of 1986, as amended (the "Code"). If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code, with any such reduction being made last with respect to benefits that are not exempt from Code §409A.

(c) Release. Anything to the contrary contained herein notwithstanding, as a condition to Executive receiving severance benefits to be paid pursuant to this Section 4.4, Executive shall execute and deliver to the Company a general release in the form attached hereto as Exhibit C not later than forty-five (45) days after Executive's Date of Termination. The Company shall have no obligation to provide any severance benefits to Executive until it has received the general release from Executive within the time specified in the preceding sentence, and any revocation or rescission period applicable to the Release shall have expired without revocation or rescission.

# **Article 5. Employment Covenants**

#### 5.1 Definitions

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

- (a) "Affiliate" shall mean a person or entity that directly or indirectly through one or more intermediaries, controls or is controlled by, or under common control with another person or entity, including current and former directors and officers of such an entity.
- (b) "Confidential Information" shall mean all confidential and proprietary information of the Company, its Predecessors and Affiliates, whether in written, oral, electronic or other form, including but not limited to trade secrets; technical, scientific or business information; processes; works of authorship; Inventions; discoveries; developments; systems; chemical compounds; computer programs; code; algorithms; formulae; methods; ideas; test data; know how; functional and technical specifications; designs; drawings; passwords; analyses; business plans; information regarding actual or demonstrably anticipated business, research or development; marketing, sales and pricing strategies; and information regarding the Company's current and prospective consultants, customers, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii) Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to

the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.

- (c) "Executive Work Product" shall mean all Confidential Information and Inventions conceived of, created, developed or prepared by Executive (whether individually or jointly with others) before or during Executive's employment with the Company, during or outside of working hours, which relate in any manner to the actual or demonstrably anticipated business, research or development of the Company, or result from or are suggested by any task assigned to Executive or any work performed by Executive for or on behalf of the Company or any of its Affiliates.
- (d) "Invention" shall mean any apparatus, biological processes, cell line, chemical compound, creation, data, development, design, discovery, formula, idea, improvement, innovation, know-how, laboratory notebook, manuscript, process or technique, whether or not patentable or protectable by copyright, or other intellectual property in any form.
- (e) "Predecessor" shall mean an entity, the major portion of the business and assets of which was acquired by another entity in a single transaction or in a series of related transactions.
  - (f) "Trade Secrets" as used in this Agreement, will be given its broadest possible interpretation under the law applicable to this Agreement.

# 5.2 <u>Nondisclosure and Nonuse</u>

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

# 5.3 Other Confidentiality Obligations

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

# 5.4 Return of Confidential Information

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

# 5.5 <u>Confidential Information of Others</u>

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

# 5.6 Other Obligations

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

# 5.7 <u>Assignment of Confidential Information and Inventions; Works Made for Hire</u>

Executive hereby assigns to the Company all right, title and interest in all intellectual property, including any patent applications, trade secrets, know how, copyrights, software, or trademarks associated with the Executive Work Product and Confidential Information. Executive hereby acknowledges and agrees that all Executive Work Product subject to copyright protection constitutes "work made for hire" under United States copyright laws (17 U.S.C. §101) and is owned exclusively by the Company. To the extent that title to any Executive Work Product subject to copyright protection does not constitute a "work for hire," and to the extent title to any other Executive Work Product does not, by operation of law or otherwise, vest in the Company, all right, title, and interest therein, including, without limitation, all copyrights, patents and trade secrets, and all copyrightable or patentable subject matter, are hereby irrevocably assigned to the Company. Executive shall promptly disclose to the Company in writing all Executive Work

Product. Executive shall, without any additional compensation, execute and deliver all documents or instruments and give the Company all assistance it requires to transfer all right, title, and interest in any Executive Work Product to the Company; to vest in the Company good, valid and marketable title to such Executive Work Product; to perfect, by registration or otherwise, trademark, copyright and patent protection of the Company with respect to such Executive Work Product; and otherwise to protect the Company's trade secret and proprietary interest in such Executive Work Product. Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agents and attorneys-in-fact to act for and on Executive's behalf, and to execute and file any documents and to do all other lawfully permitted acts to further the purposes of this Section 5.7 with the same legal force and effect as if executed by Executive.

# 5.8 Representations

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

# 5.9 <u>Inventions, Intellectual Property and Equipment Not Transferred</u>

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

# 5.10 Exclusivity of Employment

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

# 5.11 Covenant Not to Compete

Executive acknowledges that his services to the Company involve a unique level of trust, of skills, and of access to Confidential Information and other business and strategic insights about the Company, and accordingly Executive agrees to be bound and abide by the following covenant not to compete:

- (a) <u>Term and Scope</u>. During Executive's employment with the Company and for a period of twelve (12) months after the Term, Executive will not render to any Conflicting Organization (as hereinafter defined), services, directly or indirectly, anywhere in the world in connection with any Conflicting Product (as hereunder defined), except that Executive may accept employment with a Conflicting Organization whose business is diversified (and which has separate and distinct divisions) if Executive first certifies to the Company in writing that such prospective employer is a separate and distinct division of the Conflicting Organization and that Executive will not render services directly or indirectly in respect of any Conflicting Product. Such twelve (12) month time period shall be tolled during any period that Executive is engaged in activity in violation of this covenant.
- (b) <u>Judicial Construction</u>. Executive and the Company agree that, if the period of time or the scope of this Covenant Not to Compete shall be adjudged unreasonably overbroad in any court proceeding, then the period of time and/or scope shall be modified accordingly, so that this covenant may be enforced with respect to such services or geographic areas and during such period of time as is judged by the court to be reasonable.
  - (c) <u>Definitions</u>. For purposes of this Agreement, the following terms shall have the following meanings:
    - (i) "Conflicting Product" means any product, method or process, system or service of any person or organization other than the Company that is the same as, similar to or interchangeable with any product, method or process, system or service that was provided or under development by the Company or any of its Affiliates at the time Executive's employment with the Company terminates, or about which Executive acquired any Confidential Information or developed any Executive Work Product.

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

# 5.12 Non-Solicitation

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

# 5.13 <u>Judicial Enforcement</u>

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

# Article 6. Miscellaneous

# 6.1 <u>Notices</u>

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

To Company: Sucampo Pharmaceuticals, Inc.

4520 East West Highway, Third Floor

Bethesda, Maryland 20814 Attention: Human Resources Copy to: Corporate Secretary

Peter Greenleaf Employment Agreement February 10, 2014 FINAL

To Executive: Peter Greenleaf

7307 Burdette Court Bethesda, MD 20817

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

#### 6.2 Headings

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

# 6.3 <u>Modifications; Waiver</u>

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

# 6.4 Entire Agreement

This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other prior agreements, understandings, representations and warranties, written and oral, heretofore made with respect thereto.

# 6.5 <u>Severability</u>

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

# 6.6 <u>Controlling Law</u>

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

# 6.7 <u>Arbitration</u>

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

# 6.8 Assignments

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

# 6.9 Read and Understood

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

# 6.10 <u>Counterparts</u>

This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original and both of which, taken together shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signature.

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

Sucampo Pnarmaceuticais, inc.	Executive	
/s/ Dr. Ryuji Ueno	/s/ Peter Greenleaf	
Dr. Ryuji Ueno, Chairman of the Board,	Peter Greenleaf	
Chief Executive Officer and		
Chief Scientific Officer		
/s/ Anthony Celeste		
Anthony Celeste, Lead Director of the		
Board of Directors		

Ryuji Ueno, MD, Ph.D., Ph.D. 24687 Yacht Club St. Michaels, MD 21663 February 10, 2014

Dear Dr. Ueno,

This letter agreement (this "Agreement") sets forth the terms and conditions whereby you agree to provide certain services (as described below) to Sucampo AG, with offices located at Baarerstrasse 22, 6300 Zug, Switzerland (the "SAG" or "Company").

#### 1. Services

1.1 The Company hereby engages you, and you hereby accept such engagement, as an independent contractor to provide certain services on the terms and conditions set forth in this Agreement (the "Services"). Your title during the Term of this Agreement shall be Co-Founder, Chairman Emeritus and Scientific Advisor. Principal contact for you during the Term of this Agreement shall be the Chief Executive Officer. The Services are set forth as Exhibit A to this Agreement. The Company shall not control the manner or means by which you perform the Services.

# 2. Term

The "**Term**" of this Agreement shall commence on April 1, 2014, and shall continue until March 31, 2015, unless earlier terminated in accordance with paragraph 10. The Term shall automatically renew for successive one (1) year periods, unless either party provides sixty (60) days advance written notice of its intention not to renew.

#### 3. Fees and Expenses

- 3.1 As full compensation for the Services for the initial Term of this Agreement and any subsequent Term unless the parties agree otherwise, the Company shall pay you \$50,000 monthly (the "Fees"). You shall submit monthly invoices to Company listing the services provided the previous month.
- 3.2 In the event of travel or other expenses pre-approved in writing by the Company, please follow the guidelines outlined in Exhibit B. Exceptions to the costs outlined in Exhibit B (such as more expensive accommodations or meals) should be documented with approval from the Company.
- 3.3 The Company shall pay all approved expenses and undisputed Fees within thirty (30) days after the Company's receipt of an invoice submitted by you to the Company at ap@sucampo.com.

#### 4. RELATIONSHIP OF THE PARTIES

4.1 You are an independent contractor of the Company, and this Agreement shall not be construed to create any association, partnership, joint venture, employee or agency relationship between you and the Company for any purpose. You have no authority (and shall not hold yourself out as having authority) to bind the Company and you shall not make any agreements or representations on the Company's behalf without the Company's prior written consent.

Confidential 1 Ryuji Ueno

4.2 Without limiting paragraph 4.1, you will not be eligible under this Agreement to participate in any vacation, group medical or life insurance, disability, profit sharing or retirement benefits or any other fringe benefits or benefit plans offered by the Company to its employees, and the Company will not be responsible for withholding or paying any income, payroll, Social Security or other federal, state or local taxes, making any insurance contributions, including unemployment or disability, or obtaining worker's compensation insurance on your behalf. You shall be responsible for, and shall indemnify the Company against, all such taxes or contributions, including penalties and interest. Any persons employed by you in connection with the performance of the Services shall be your employees and you shall be fully responsible for them.

# 5. Intellectual Property Rights

- The Company is and shall be, the sole and exclusive owner of all right, title and interest throughout the world in and to all the results and proceeds of the Services performed under this Agreement, including but not limited to the deliverables produced under this engagement letter (collectively, the Deliverables), including all patents, copyrights, trademarks, trade secrets and other intellectual property rights (collectively Intellectual Property Rights) therein. You agree that the Deliverables are hereby deemed a "work made for hire" as defined in 17 U.S.C. § 101 for the Company. If, for any reason, any of the Deliverables do not constitute a "work made for hire," you hereby irrevocably assign to the Company, in each case without additional consideration, all right, title and interest throughout the world in and to the Deliverables, including all Intellectual Property Rights therein.
- 5.2 Any assignment of copyrights under this Agreement includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as "moral rights" (collectively, **Moral Rights**). You hereby irrevocably waive, to the extent permitted by applicable law, any and all claims you may now or hereafter have in any jurisdiction to any Moral Rights with respect to the Deliverables.
- Upon the reasonable request of the Company, you shall promptly take such further actions, including execution and delivery of all appropriate instruments of conveyance, as may be necessary to assist the Company to prosecute, register, perfect, record or enforce its rights in any Deliverables. In the event the Company is unable, after reasonable effort, to obtain your signature on any such documents, you hereby irrevocably designate and appoint the Company as your agent and attorney-in-fact, to act for and on your behalf solely to execute and file any such application or other document and do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights or other intellectual property protected related to the Deliverables with the same legal force and effect as if you had executed them. You agree that this power of attorney is coupled with an interest.
- 5.4 Notwithstanding paragraph 5.1, to the extent that any of your pre-existing materials are contained in the Deliverables, you retain ownership of such pre-existing materials and hereby grant to the Company an irrevocable, worldwide, unlimited, royalty-free license to use, publish, reproduce, display, distribute copies of, and prepare derivative works based upon, such pre-existing materials and derivative works thereof. The Company may assign, transfer and sublicense such rights to others without your approval.

Confidential 2 Ryuji Ueno

- 5.5 Except for such pre-existing materials, you have no right or license to use, publish, reproduce, prepare derivative works based upon, distribute, perform, or display any Deliverables. You have no right or license to use the Company's trademarks, service marks, trade names, trade names, logos, symbols or brand names.
- 5.6 If applicable, you shall require each of your employees to execute written agreements securing for the Company the rights provided for in this paragraph 5 prior to such employee providing any Services under this Agreement.

# 6. Confidentiality

- Your work, all communications regarding this matter, whether in writing or oral, and all materials and other information provided to you by Sucampo and/or any counsel for Sucampo, should remain strictly confidential. In the course of providing Services, you acknowledge that you will have access to information that is treated as confidential and proprietary by the Company, including, without limitation, any trade secrets, technology, information pertaining to business operations and strategies, customers, pricing, and marketing, marketing, finances, sourcing, personnel or operations of the Company, its affiliates or their suppliers or customers, in each case whether spoken, printed, electronic or in any other form or medium (collectively, the Confidential Information). Any Confidential Information that you develop in connection with the Services, including but not limited to any Deliverables, shall be subject to the terms and conditions of this paragraph. You agree to treat all Confidential Information as strictly confidential, not to disclose Confidential Information or permit it to be disclosed, in whole or part, to any third party without the prior written consent of the Company in each instance, and not to use any Confidential Information for any purpose except as required in the performance of the Services. You shall notify the Company immediately in the event you become aware of any loss or disclosure of any Confidential Information.
- 6.2 Confidential Information shall not include information that:
  - (a) is or becomes generally available to the public other than through your breach of this Agreement;
  - (b) is communicated to you by a third party that had no confidentiality obligations with respect to such information; or
  - (c) is required to be disclosed by law, including without limitation, pursuant to the terms of a court order; provided that you have given the Company prior notice of such disclosure and an opportunity to contest such disclosure.

# 7. Representations and Warranties

- 7.1 You represent and warrant to the Company that:
  - (a) you have the right to enter into this Agreement, to grant the rights granted herein and to perform fully all of your obligations in this Agreement;
  - (b) your entering into this Agreement with the Company and your performance of the Services do not and will not conflict with or result in any breach or default under any other agreement to which you are subject;

Confidential 3 Ryuji Ueno

- (c) you have the required skill, experience and qualifications to perform the Services, you shall perform the Services in a professional and workmanlike manner in accordance with best industry standards for similar services and you shall devote sufficient resources to ensure that the Services are performed in a timely and reliable manner;
- (d) you shall perform the Services in compliance with all applicable federal, state and local laws and regulations and Company compliance policies;
- (e) the Company will receive good and valid title to all Deliverables, free and clear of all encumbrances and liens of any kind;
- (f) all Deliverables are and shall be your original work (except for material in the public domain or provided by the Company) and, to the best of your knowledge, do not and will not violate or infringe upon the intellectual property right or any other right whatsoever of any person, firm, corporation or other entity.
- 7.2 The Company hereby represents and warrants to you that:
  - (a) it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder; and
  - (b) the execution of this Agreement by its representative whose signature is set forth at the end hereof has been duly authorized by all necessary corporate action.

#### 8. Indemnification

Sucampo agrees to indemnify and hold harmless you from any losses, claims, damages, judgments, costs or other liabilities or expense (including reasonable legal fees) incurred in connection with any claim, action or proceeding brought by a third-party as a result of this engagement, to the extent permitted by applicable law. You shall promptly notify Sucampo of any claim, action or proceeding filed or threatened against you by any third-party in respect of which indemnification may be sought hereunder. You shall obtain the written consent of Sucampo prior to settling any such claim, action or proceeding in respect of which indemnification may be sought hereunder.

# 9. Non-Solicitation

You agree that during the Term of this Agreement and for a period of twelve (12) months following the termination or expiration of this Agreement, you shall not make any solicitation to employ the Company's personnel without written consent of the Company to be given or withheld in the Company's sole discretion.

# 10. Termination

- 10.1 a) The Company may terminate this Agreement without cause upon thirty (30) days written notice to you. In the event of termination pursuant to this paragraph 10.1(a), the Company shall pay you on a proportional basis any Fees then due and payable for any Services completed up to and including the date of such termination.
  - b) You may terminate this Agreement without cause upon thirty (30) days written notice to the Company. In the event of termination pursuant to this paragraph 10.1(b), the Company shall pay you on a proportional basis any Fees then due and payable for any Services completed up to and including the date of such termination.

Confidential 4 Ryuji Ueno

- 10.2 The Company may terminate this Agreement, effective upon written notice to you, in the event that you materially breach this Agreement;
- 10.3 Upon expiration or termination of this Agreement for any reason, or at any other time upon the Company's written request, you shall within five (5) days after such expiration or termination:
  - (a) deliver to the Company all Deliverables (whether complete or incomplete) and all hardware, software, tools, equipment or other materials provided for your use by the Company;
  - (b) deliver to the Company all tangible documents and materials (and any copies) containing, reflecting, incorporating or based on the Confidential Information;
  - (c) permanently erase all of the Confidential Information from your computer systems; and
  - (d) certify in writing to the Company that you have complied with the requirements of this paragraph.
- 10.4 The terms and conditions of this paragraph 10.4 and paragraph 4, paragraph 5, paragraph 6, paragraph 7, paragraph 8, paragraph 10.3, paragraph 11, paragraph 12 and paragraph 13 shall survive the expiration or termination of this Agreement.

#### 11. Assignment

You shall not assign any rights, or delegate or subcontract any obligations, under this Agreement without the Company's prior written consent. Any assignment in violation of the foregoing shall be deemed null and void. The Company may freely assign its rights and obligations under this Agreement at any time. Subject to the limits on assignment stated above, this Agreement will inure to the benefit of, be binding upon, and be enforceable against, each of the parties hereto and their respective successors and assigns.

# 12. MISCELLANEOUS

- 12.1 You shall not export, directly or indirectly, any technical data acquired from the Company, or any products utilizing any such data, to any country in violation of any applicable export laws or regulations.
- All notices, requests, consents, claims, demands, waivers and other communications hereunder (each, a **Notice**) shall be in writing and addressed to the parties at the addresses set forth on the first page of this Agreement (or to such other address that may be designated by the receiving party from time to time in accordance with this section). All Notices shall be delivered by personal delivery, nationally recognized overnight courier (with all fees pre-paid), facsimile or e-mail of a PDF document (with confirmation of transmission) or certified or registered mail (in each case, return receipt requested, postage prepaid). Except as otherwise provided in this Agreement, a Notice is effective only if (a) the receiving party has received the Notice and (b) the party giving the Notice has complied with the requirements of this Section.

Confidential 5 Ryuji Ueno

- 12.3 This Agreement, together with any other documents incorporated herein by reference and related exhibits and schedules, constitutes the sole and entire agreement of the parties to this Agreement with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter.
- 12.4 This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each party hereto, and any of the terms thereof may be waived, only by a written document signed by each party to this Agreement or, in the case of waiver, by the party or parties waiving compliance.
- 12.5 This Agreement shall be governed by and construed in accordance with the internal laws of the State of Maryland without giving effect to any choice or conflict of law provision or rule.
- 12.6 If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.
- 12.7 This Agreement may be executed in multiple counterparts and by facsimile signature, each of which shall be deemed an original and all of which together shall constitute one instrument.

If this letter accurately sets forth our understanding, kindly execute the enclosed copy of this letter and return it to the undersigned.

Very truly yours,

SUCAMPO AG

BY: /s/ *Thomas J. Knapp*Name: Thomas J. Knapp
Title: Director & Secretary

ACCEPTED AND AGREED: RYUJI UENO, M.D., PH.D., PH.D.

By: /s/ Ryuji Ueno, M.D., PH.D., PH.D.

Date:

Confidential 6 Ryuji Ueno

# SUBSIDIARIES OF COMPANY

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

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-147420) of Sucampo Pharmaceuticals, Inc of our report dated March 11, 2014 relating to the financial statements, financial statement schedules and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP Baltimore, Maryland March 11, 2014

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

# I, Peter Greenleaf, 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 11, 2014

/s/ PETER GREENLEAF
Peter Greenleaf
Chief Executive Officer
(Principal Executive Officer)

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

#### I, Cary J. Claiborne, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of Sucampo Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(F)) for the registrant and have:
  - (a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the 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 11, 2014 /s/ CARY J. CLAIBORNE

Cary J. Claiborne (Principal Financial Officer)

# 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, 2013 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 11, 2014

/s/ PETER GREENLEAF
Peter Greenleaf
Chief Executive Officer
(Principal Executive Officer)

# 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, 2013 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 11, 2014

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