UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13	OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014	
o TRANSITION REPORT PURSUANT TO SECTIO	N 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period fromto	
	Commission File Number: 001-33609
CHCAMPO	
	PHARMACEUTICALS, INC. Exact name of registrant as specified in its charter)
Delaware	30-0520478
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
4520 East-West Highway, 3rd Floor	20814
Bethesda, MD 20814 (Address of principal executive offices,	(Zip Code)
including zip code)	
	(301) 961-3400
	(Registrant's telephone number)
Securities	registered pursuant to Section 12(b) of the Act:
Title of each class	Name of each exchange on which registered
Class A common stock, par value \$0.01	The NASDAQ Global Market
Securities regist	ered pursuant to Section 12(g) of the Exchange Act: None
Indicate by check mark if the registrant is a well-known seas	oned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☑
Indicate by check mark if the registrant is not required to file	reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No 🗵
	all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the nt was required to file such reports), and (2) has been subject to such filing requirements for the past 90
	l electronically and posted on its corporate Web site, if any, every Interactive Data File required to be 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant
	rsuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be xy or information statements incorporated by reference in Part III of this Form 10-K or any amendment
Indicate by check mark whether the registrant is a large a definitions of "large accelerated filer," "accelerated filer" and "sr	ccelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the naller reporting company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer o Accelerated filer ☑	Non-accelerated filer o Smaller reporting company o (Do not check if a smaller reporting company)
Indicate by check mark whether the registrant is a shell comp	oany (as defined in Rule 12b-2 of the Act). Yes o No ☑
	s A common stock held by non-affiliates of the registrant (based on the closing price of the registrant's most recently completed second fiscal quarter) was \$99.6 million.

DOCUMENTS INCORPORATED BY REFERENCE:

As of March 2, 2015, there were 44,900,719 shares of the registrant's class A common stock outstanding, par value \$0.01 per share.

Portions of the registrant's Proxy Statement for its 2015 Annual Meeting of Stockholders to be held on May 29, 2015, which Proxy Statement is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2014, are incorporated by reference in Part III of this Annual Report on Form 10-K.

Sucampo Pharmaceuticals, Inc.

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PART I

This Annual Report on Form 10-K, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding us and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "should," "could," "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, and development of proprietary drugs to treat gastrointestinal, ophthalmic, 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, product sales and clinical development activities. We expect to continue to incur significant expenses for the next several years as we continue our research and development activities, seek additional regulatory approvals and additional indications for our approved products and other compounds, seek global partnering opportunities for our approved products and compounds and seek strategic opportunities for non-prostone clinical candidates.

Our operations are conducted through subsidiaries based in Japan, the U.S., Switzerland and the U.K. 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.

Drs. Ryuji Ueno and Sachiko Kuno have direct or indirect interests in our controlling stockholder, S&R Technology Holdings, 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 18, 2014. Drs. Ueno and Kuno, together, directly or indirectly, own a majority of the stock of R-Tech Ueno, Ltd (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 (Board) and Peter Greenleaf joined us as our Chief Executive Officer and Board member. On December 10, 2014, John H. Johnson was appointed to the Board and the number of directors was increased from seven to eight members.

Our Clinical Development Focus

Our current pipeline is focused on prostone compounds. Prostones are naturally-occurring fatty acid metabolites which originally were thought to be biologically inactive and have now emerged as a promising compound class with physiological activities that can be targeted for the treatment of unmet or underserved medical needs. Prostones are believed to act locally to restore normal function in cells and tissues, and hence, their pharmacologic activity may be targeted to specific organs and tissues. They are believed to possess a mechanism of action as highly potent and selective ion channel activators based on in vitro studies and are physiological mediators that may have a role in the restoration of cellular homeostasis and tissue regeneration.

Our prostone-based compounds target the CIC-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 applicability in many disease states in different organ systems. We have developed synthetic analogs of the naturally occurring prostones, which have been developed 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.

Our Strategy

Our strategy is focused on becoming a leading biopharmaceutical company. We are built on the ongoing pursuit of scientific innovation and an unwavering passion for changing the lives of patients, their family members and their caregivers for the better. We are committed to harnessing the success of our history to maximize inmarket revenues, focus our clinical development efforts, and enhance our scientific capabilities.

After launching our new strategy in August 2014, we executed and accomplished the following key milestones to drive the achievement of that strategy.

Securing Our Foundation

In 2014, we made major gains to solidify our base business and focus our efforts on our core strengths in clinical development.

Strengthening the management team was a key priority, and throughout 2014, we added experienced industry leaders who have successful track records in leading and growing biopharmaceutical companies. The addition of such experienced biopharmaceutical executives equipped us with the depth of scientific leadership necessary to expedite our transformation and to execute on our priorities, including leveraging our strengths in drug development, securing and growing revenue from sales of AMITIZA® (lubiprostone), increasing our pace of current pipeline development and diversifying our portfolio through the acquisition of new science.

Partnerships are essential in driving the global growth of AMITIZA, and in 2014, we announced the following agreements, including global partnerships and resolution of generic litigation, designed to enhance mid- to long-term brand growth for the product:

- An exclusive license, development, commercialization and supply agreement (Global License Agreement) for lubiprostone with Takeda Pharmaceutical Company Limited (Takeda), where Takeda has the exclusive rights to further develop and commercialize AMITIZA in all global markets, except the U.S., Canada, Japan and the People's Republic of China;
- An amendment to the original existing collaboration and license agreement (North America Takeda Agreement) with Takeda covering the U.S. and Canada. The North America Takeda Agreement included various modifications to the original collaboration agreement, such as the extension of the current term, a change to the royalty percentage during the extension period, minimum commercial investment by Takeda during the current term and various governance changes, which would allow Takeda to have additional flexibility in commercializing our flagship product;
- Along with Takeda and R-Tech, we settled our patent litigation dispute in the U.S. with Anchen Pharmaceuticals, Inc. (Anchen), Par Pharmaceutical, Inc. (Par Pharmaceutical) and Par Pharmaceutical Companies, Inc. (Anchen and the Par Pharmaceuticals entities collectively, Par) with respect to AMITIZA pursuant to a settlement agreement and license agreement allowing us to maintain brand exclusivity during the current term of the North America Takeda Agreement and realize royalty revenue from 2021 to 2027 from generic or authorized generic sales by Par; and
- An exclusive global manufacturing and supply agreement with R-Tech for clinical and commercial supplies of AMITIZA in most global markets that provides for a lower cost of goods for the Global License Agreement.

Lastly, during 2014, we re-evaluated and accelerated our pipeline, focusing on clinical programs that we believe hold the most promise for patients, the highest likelihood for regulatory approval, and the strongest potential for commercial return. We accelerated a lifecycle management program of AMITIZA, made the decision to exit all direct manufacturing and selling of RESCULA, which provided low return for our shareholders, and resolved Par's generic challenge to RESCULA in early 2015. However, we will continue to explore the scientific properties of unoprostone isopropyl, the active pharmaceutical ingredient of RESCULA, and apply them to other programs in our pipeline.

Build The Growth Platform

The next element of our strategy is to advance our business through the diversification of our investor base, continue to strengthen our capability in clinical development, and to execute on our pipeline opportunities. Our key priority is to continue to advance our AMITIZA life cycle management programs. In addition, we will continue to optimize and explore our investment in our prostone programs such as cobiprostone for oral mucositis (OM) and non-erosive reflux disease (NERD) and unoprostone for retinitis pigmentosa (RP) and geographic atrophy (GA). We will also enrich our pipeline by acquiring new development-stage programs that complement our current therapeutic areas.

Transform the Business

Finally, through the launch of our AMITIZA lifecycle management programs and new pipeline compounds and the creation of a sustainable pipeline of drug candidates with near-term launch opportunities, we will seek transformative growth by launching additional products for new therapeutic areas, strengthening an already sizable revenue base, and creating a sustainable company that is built to last.

We have commenced an assessment of external programs that complement our existing product pipeline. We continue to seek opportunities for strategic partnerships to augment our existing pipeline and diversify our science. It is our vision to develop into a fully integrated, biopharmaceutical company centered on science and innovation and driven by the passionate and relentless efforts of our employees.

Our Competitive Strengths

Product Pipeline

The table below summarizes the development status of lubiprostone, unoprostone isopropyl and several other product candidates. We currently hold all of the commercialization rights to the compounds in our product pipeline, other than for commercialization of AMITIZA globally, which is covered by our agreements with Takeda and Abbott Japan Co. Ltd. (Abbott), and other than for unoprostone isopropyl, which is licensed to us by R-Tech outside of Japan, Korea, Taiwan and the People's Republic of China. Commercialization of each product candidate may be implemented after successful completion of clinical studies and approval from appropriate governmental agencies.

Product/Product Candidate	Target Indication	Development Phase	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. Received mutual recognition procedure (MRP) recommendation for marketing authorization in select E.U. countries. Filed with Health Canada.	Obtain national marketing authorization from each country included in the MRP application. Obtain decision from Health Canada.
	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	Marketed in the U.S. and Switzerland. In the U.K., the application is under additional review with the MHRA. Filed with Health Canada.	Obtain decision from the U.K. Obtain decision from Health Canada.
	Chronic constipation	Marketed in Japan	
	New formulation	In non-clinical development	Initiate phase 3 trial
	Pediatric functional constipation (6 years - 17 years)	Pivotal and open label Phase 3 trials ongoing	Complete pivotal and open label phase 3 trials
	Pediatric functional constipation (6 months - 6 years)	New formulation in development	Initiate phase 3 program
Unoprostone Isopropyl	Retinitis pigmentosa	In phase 3 by development partner R-Tech Ueno. Orphan drug status obtained in the U.S. and E.U.	Receive interim data from R-Tech's phase 3 trial in Japan and make a go/no go decision for the U.S. and E.U. development.
	Geographic Atrophy	Pre-clinical	Initiate phase 1/2 (POC) trial
Cobiprostone	Oral mucositis	Phase 1b completed	Initiate phase 2 trial
	Non-erosive reflux disease (NERD)	Phase 2 initiated	Complete phase 2 trial

Our Prostone Products (Approved and in Clinical Development)

AMITIZA (lubiprostone)

AMITIZA is a CIC-2 chloride channel activator and is a highly differentiated product with the broadest label in the constipation market. AMITIZA has three indications that cover three distinct patient types: chronic idiopathic constipation (CIC), irritable bowel syndrome with constipation (IBS-C), and opioid-induced constipation (OIC), and it is well-tolerated and has an established safety profile. Since 2006, AMITIZA has been dispensed over 9 million times, and it is the only product currently on the market with a dual mechanism of action: AMITIZA increases intestinal fluid secretion, and it stimulates recovery of mucosal barrier function. AMITIZA users tend to be satisfied with their treatment and post marketing safety monitoring indicates that as seen in the clinical trials, AMITIZA is well-tolerated by patients. AMITIZA addresses a large market with significant unmet need as there are over 48 million total annual prescriptions in the prescription constipation market alone, with an additional \$800 million in annual sales in the over-the-counter constipation market. Market research demonstrates that patients are not satisfied with their current treatments, and the accelerating growth of AMITIZA well into its lifecycle is evidence of its value proposition for patients, physicians, and payers.

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 U.S. Food and Drug Administration (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 (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. In September 2014, we and Takeda launched a pilot direct-to-consumer advertising campaign for AMITIZA in select U.S. markets for adults with CIC which will run through the second half of 2015. In October 2014, we signed an amendment to the North America Takeda Agreement which, among other things, extended the term beyond December 2020, and during the extended term, we will share the annual net sales revenue with Takeda on branded AMITIZA sales. In addition, as of April 1, 2015, Takeda will no longer reimburse us for the product detailing of healthcare professionals or for promotional materials used by us.

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

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 (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) (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 U.S., 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 supplements.

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 reduction of secretion 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.

There are more than 200 million prescriptions for opioid use in the U.S. 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 U.S.

Japan

In June 2012, AMITIZA was approved for the treatment of chronic constipation (CC) excluding constipation caused by organic diseases, by the Ministry of Health, Labour and Welfare (MHLW). In December 2013, the two-week limitation on prescriptions, generally applied to all new approvals of products for the first year after U.S. National Institutes of Health (NIH) reimbursement price approval, was removed. AMITIZA is Japan's only prescription medicine for CC. On February 27, 2015, Abbott Laboratories, Inc. and Mylan, Inc. (Mylan), closed Mylan's purchase of Abbott's non-U.S. developed markets specialty and branded generics business which included the license, commercialization and supply agreement with us dated February 19, 2009 (Japan Abbott Agreement). We do not expect any significant changes in the commercialization of AMITIZA in Japan as a result of such transfer. Under the terms of the Japan Abbott Agreement, we received a commercial milestone payment of \$2.5 million during the third quarter of 2014 when annual net sales of AMITIZA in Japan exceeded ¥5.0 billion.

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 Japan Abbott Agreement. More information on our collaboration with Abbott is found under the heading "Abbott Collaboration".

Europe

In September 2012, we received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (U.K.) for the use of AMITIZA to treat CIC, and we made AMITIZA available in the U.K. in the fourth quarter of 2013. We subsequently filed for approval for the OIC indication, but in March 2014 we received notification from MHRA that the application for the OIC indication was not approved and after meeting MHRA have requested MHRA to review our application based on the concerns raised during the meeting. We currently await MHRA's decision on the OIC indication. In July 2014, the National Institute of Health and Care Excellence (NICE) published the technology appraisal guidance recommending the use of AMITIZA in the treatment of CIC and associated symptoms in adults who have failed laxatives. In January 2015, we successfully completed the European Mutual Recognition Procedure (MRP) for AMITIZA for the treatment of CIC in Austria, Belgium, Germany, Italy, Ireland, Luxembourg, Netherlands and Spain, resulting in a recommendation for marketing authorization in these markets. Ireland has notified us that it has approved AMITIZA for CIC.

In Switzerland, AMITIZA was approved to treat CIC in 2009. In 2012, we reached an agreement with the Bundesamt fur Gesundheit (BAG), the Federal Office of Public Health in Switzerland, 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 (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.

In Switzerland, AMITIZA was approved for the treatment of OIC in chronic, non-cancer adult patients in July 2014 by the Swissmedic, the Swiss Agency for Therapeutic Products.

Under the terms of the Global License Agreement, Takeda will request from the regulatory authorities that the market authorizations for U.K. and Switzerland be transferred to Takeda in the first half of 2015.

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

In August 2014, we signed an exclusive global manufacturing and supply agreement with R-Tech for clinical and commercial supplies of AMITIZA in most global markets. More information on our collaboration with R-Tech is found under the heading "Manufacturing."

In October 2014, we signed a Global License Agreement to develop and commercialize AMITIZA in all global markets except in the U.S., Canada, Japan and the People's Republic of China. More information on our collaboration with Takeda is found under the heading "AMITIZA Agreements."

In October 2014, we filed for regulatory approval of AMITIZA for the CIC and the OIC indications with Health Canada. We anticipate a decision in the second half of 2015.

RESCULA (unoprostone isopropyl)

In the U.S., a sNDA for RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% for the lowering of intraocular pressure (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 was originally approved by the FDA in 2000 for the lowering of IOP in open-angle glaucoma and ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP lowering medications. RESCULA first launched in Japan in 1994, and since then over 53 million bottles have been shipped. In April 2009, we acquired the commercialization rights to RESCULA for the U.S. and Canada from R-Tech.

In the fourth quarter of 2014, we ceased marketing RESCULA and in February 2015 we alerted physicians that after the March 2015 expiration date, there will be no product available.

Our Other Clinical Development Programs

Lubiprostone Lifecycle Management

New Formulation

It is estimated that approximately 40% of American adults have difficulty swallowing pills. Of those who have experienced difficulty swallowing pills, approximately 14% have delayed taking doses of their medication, 8% have skipped a dose and 4% have discontinued using their medication. In addition, the current formulation of pills is not amenable for administration to young children (6 months and older). We are developing a new formulation of lubiprostone both for adult and pediatric patients who are unable to tolerate capsules, or for naso-gastric tube fed patients. Takeda has agreed to fund 100% of the cost of this new formulation work and we expect to initiate a phase 3 trial in the second half of 2015.

Pediatric Functional Constipation

Constipation in children has similar characteristics to those of constipation in adults; symptoms include infrequent bowel movements, hard stools, large diameter stools and painful passage of stools. Children may also experience fecal retention due to withholding, since there is a tendency to avoid defecation and withhold bowel movements as a result of the pain experienced from the passage of large stools. This withholding of bowel movements can result in episodes of fecal incontinence. The 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. Furthermore, ninety percent of pediatric constipation is functional constipation and it occurs in all age groups.

An analysis of longitudinal data in the U.S. showed that over the last decade there has been a nearly 4-fold increase in rates of constipation. Nevertheless, the estimates of the prevalence rate of functional constipation in the pediatric population worldwide have varied greatly, from 4 to 37%. Regardless of this wide range of estimated prevalence, only 50-70% of children with functional constipation demonstrate long-term improvement with the current treatments, indicating a need for better 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 planned global, multicenter phase 3 studies to evaluate the efficacy, safety, and pharmacokinetics of lubiprostone in patients 6 months or older through 17 years of age with pediatric functional constipation. There are four planned phase 3 studies for our pediatric functional constipation development program, two of which are currently ongoing and are both testing the soft gelatin capsule formulation of lubiprostone in patients 6 to 17 years of age. The third planned phase 3 study, a 12-week, randomized, placebo-controlled trial, that was initiated in December 2013. The remaining planned phase 3 study, a follow-on, long-term safety extension study, was initiated in March 2014. We are also evaluating the timing of the initiation of the second pivotal trial in our phase 3 program for pediatric functional constipation in children aged 6 months to less than 6 years, which will require the new formulation.

Cobiprostone

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.

Oral Mucositis (OM)

A potential indication for cobiprostone is the prevention and/or treatment of OM.

OM refers to the serious inflammation of oral mucosa that results in patients that are undergoing chemotherapy (CT) and or radiation therapy (RT) and is the primary dose limiting adverse effect that accounts for greater than 60% of the treatment interruptions OM, 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 radiation or high-dose cancer therapy. Additional consequences of OM include weight loss, use of feeding tube, hospitalization and dysphagia. We are initially focusing on treating patients for head and neck cancer (HNC) that undergo RT. Most (89-100%) of these patients are at high risk of developing OM depending on whether the RT is in combination with CT or altered fractionation RT. Subsequently we may look at other patients who by virtue of their treatments, are at risk for developing OM which may be induced by CT of solid tumors or occur in patients being treated for hematopoietic stem cell transplant.

There is a large unmet medical need in OM. Currently treatment is largely palliative and includes basic oral care, cryotherapy, topical rinses, such as lidocaine, and carbomer. In the U.S., there is currently no approved pharmaceutical treatment available to address OM. Palifermin, a growth factor, has been approved to treat OM in stem cell transplant patients who have undergone myelotoxic therapy. We have sought orphan drug status for OM in the E.U.

It is estimated that 3-5% of all cancers are HNC and annually, in the U.S., approximately 60,000 patients develop HNC and approximately 12,000 patients die from HNC. Half of the diagnosed patient have advanced stage disease and are treated with radiation. Worldwide, there are approximately 550,000 HNC cases annually.

In the first quarter of 2014, we completed our phase 1b trial that evaluated the safety and pharmacokinetics of an oral spray formulation of cobiprostone. The results of this phase 1b trial showed that cobiprostone was well-tolerated overall and revealed low systematic exposure. The next phase of clinical development, a phase 2a trial, is expected to begin at the end of the first half of 2015.

Non-Erosive Reflux Disease (NERD)

We are developing cobiprostone to treat non-erosive reflux disease for patients who have troublesome symptoms of gastro esophageal reflux disease (GERD), and have not had responded adequately to treatment with proton pump inhibitors (PPI).

NERD is a major subtype of GERD disease that is characterized macroscopically by the normal appearance of mucosa, but the NERD patients nevertheless have persistent symptoms of reflux disease Microscopically NERD appears to be characterized by dilated intercellular spaces which may allow access of acid to the receptors in the nerves that signal to the brain.

GERD affects 25% to 40% of the adult population of the United States to some degree at some point. About 20% of adults experience GERD weekly or daily. Not just adults are affected; even infants and children can have GERD. Furthermore, of these, 50-85% of patients with typical symptoms have no endoscopic (macroscopic) evidence of erosive esophagitis. These patients are considered to have NERD.

To date the medical treatment of NERD patients is primarily focused on the inhibition of gastric acid secretion with drugs such as PPIs. Although 40-60% of NERD patients do respond to PPIs, overall NERD patients have a substantially lower response to these agents than patients with erosive esophagitis, and consequently the NERD patients constitute the majority of cases of refractory heartburn.

Cobiprostone is a CIC-2 channel activator that stimulates and protects epithelial barrier function and thus should prevent access of acid to the sensory receptors. We have shown proof of concept for this in preclinical models and thus have begun a phase 2 program in NERD at the end of 2014.

Unoprostone Isopropyl

We continue to pursue further clinical development of unoprostone isopropyl. In clinical and preclinical studies, unoprostone isopropyl has increased ocular blood flow to the optic nerve and the choroid; maintained visual fields; delayed retinal degeneration induced by mutant rhodopsin; and lowered intraocular pressure. We believe that unoprostone isopropyl could potentially be effective in the treatment of other ocular diseases.

Retinitis Pigmentosa (RP)

RP is a group of inherited diseases that cause degeneration of the retina leading to progressive loss of sight. 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 of negative impacts to a patient's quality of life and is a major driver of patient-based cost of care and lifestyle maintenance. An article published in *Current Genomics* in 2011 estimated that approximately one in every 3,000 to 5,000 individuals worldwide suffers from RP.

We have received an orphan drug designation for unoprostone isopropyl for the treatment of RP from both the FDA and the European Medicines Agency (EMA). In the first half of 2015, we will obtain interim, one-year data from the two-year phase 3 study for RP in Japan, which is being conducted by R-Tech. We continue to work with clinical experts and regulators in the U.S. and Europe to determine a development plan for RP in these markets should results from Japan are supportive. Taken together, these efforts will provide us with the information needed to decide on the next steps in RP by mid-2015, with the aim to expand to a global program.

Geographic Atrophy (GA)

GA represents the advanced form of dry age-related macular degeneration (AMD). This is a disease of the elderly involving the retinal pigment epithelium (RPE) and the photoreceptor cells in the retina. The RPE at the back of the eye helps maintain the photoreceptor cells that are responsible for our vision. Degradation of the RPE leads to death of the photoreceptor cells, which then leads to the gradual loss of sight. This degeneration of the RPE and loss of photoreceptor cells are referred to as GA. It usually progresses slowly and spreads from around the center of the retina inward to the macula and fovea.

In the U.S., approximately 8 million people, typically 55 years or older, have monocular or binocular intermediate AMD or monocular advanced AMD. GA is responsible for approximately 20% of AMD-related legal blindness in North America. In Europe, approximately 1.2% of people older than 65 develop GA AMD, and this percentage increases with the increase of patient's age group.

Unoprostone activates BK channels, increases blood flow to support the RPE, and suppresses cell death of both the retinal cells and the RPE. A small trial to establish proof of activity has been carried out by clinical investigators in Japan, who showed that treatment with unoprostone for over one year delayed the spread of the atrophic area in patients with GA in comparison with the placebo control.

AMITIZA Collaboration Agreements

North America Takeda Agreement

In October 2004, we entered into an agreement with Takeda to develop and commercialize AMITIZA for gastrointestinal indications in the U.S. and Canada. The original agreement was amended on February 1, 2006 through a supplemental agreement, and in October 2014 we and Takeda and certain Takeda affiliates executed amendments to the agreement. Collectively, these are referred to as the North America Takeda Agreement. Under the terms of the North America Takeda Agreement (which expand past 2020 until Takeda terminates):

- · We receive royalty income from the sales of AMITIZA in the United and States and Canada from Takeda.
- \cdot There are several tiers ranging from 18%-26% with the royalty rate resetting every year.
- 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 new formulation of AMITIZA, and 70% of the development costs for the treatment of pediatric functional constipation.

- Takeda is required to provide a minimum annual commercial investment during the current term of the North America Takeda Agreement and may reduce it when a generic equivalent enters the market.
- · We retain the right to co-promote AMITIZA for gastrointestinal indications. In December 2014, as part of the amendments to the North America Takeda Agreement, we ceased our co-promoting activity.
- · We are eligible for additional commercial milestone payments contingent on the achievement of certain net sales revenue targets
- Our collaboration with Takeda is administered in part by four committees consisting of an equal number of representatives from both companies. In the case of a deadlock within the joint steering committee, our chief executive officer has the determining vote on matter 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.
- We and Takeda are currently exploring the commercialization of AMITIZA in Canada and we have filed for approval of CIC and OIC with Health Canada.

Takeda Global License Agreement

In October 2014, we entered into an exclusive global license agreement (Global License Agreement) with Takeda to develop and commercialize AMITIZA for gastrointestinal indications. The territories excluded from the Global License Agreement are Canada, the U.S., Japan and the People's Republic of China. Canada and the U.S. are covered by the North America Takeda Agreement and Japan is covered by the Japan Abbott Agreement. The agreement is effective until it expires on a country-by-country basis on the fourteenth anniversary of the date of first commercial sale in that country. Under the terms of the agreement:

- · We received an upfront payment of \$14.0 million from Takeda during October 2014.
- · We will recognize revenues from the product sales of AMITIZA to Takeda at a negotiated supply price.
- We are eligible for up to \$35.0 million in commercial milestone payments contingent on the achievement of certain net sales revenue targets.
- · We are responsible for the first \$6.0 million in development costs, and Takeda is responsible for all subsequent development activities and related costs.
- Takeda will request the regulatory authorities to transfer the market authorization for the U.K. and Switzerland in the first half of 2015, will become the marketing authorization holder for other countries upon regulatory approval and will be responsible for all commercialization and regulatory activities.

Japan Abbott Agreement

In February 2009, we entered into a license, commercialization and supply agreement with Abbott (Japan Abbott Agreement) to develop and commercialize AMITIZA for the treatment of CIC in Japan. Under the terms of the Japan Abbott Agreement (which continues until 2027):

- · We recognize revenues from the product sales of AMITIZA to Abbott at a negotiated supply price.
- 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. We are required to fund and complete all the development work including any additional clinical studies required to maintain regulatory approval in Japan. We own all the rights covered under the regulatory filings.
- Abbott is required to fund and undertake all commercialization efforts including pre-launch and post-launch marketing, promotion and distribution. Abbott is
 required to maintain the number of sales staff and the estimated level of annual net sales based on the commercialization plan approved by the joint
 commercialization and steering committee described below.
- · 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.
- · Our collaboration efforts under the Japan Abbott Agreement are administered by two committees consisting of an equal number of representatives from both parties.

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, methods of use, or a combination of these claims, and methods of manufacturing lubiprostone, cobiprostone, and ion channel activators. 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.

As of December 31, 2014, the patent rights relating to lubiprostone include compositions of matter, methods of use and methods of manufacturing including 16 patents listed in the U.S. Food and Drug Administration's (FDA) Orange Book. 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 expire between 2020 and 2027. Other foreign patents expire between 2020 and 2029.

The patent rights relating to cobiprostone include 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 2020 and 2027. The other U.S. and foreign patents/patent applications expire between 2020 and 2029.

The patent rights relating to ion channel activators include compositions of matter, methods of use, pharmaceutical formulations and other claims. The U.S. patents/patent applications relating to compositions of matter expire in 2021 or 2032. The other U.S. and foreign patents/patent applications expire between 2018 and 2035.

The patent rights relating to unoprostone isopropyl include our patents/patent applications as well as the patents/patent applications licensed from R-Tech. The U.S. patents relating to compositions of matter expire between 2018 and 2033 and method of use in 2031. The other U.S. and foreign patents/patent applications expire between 2016 and 2035.

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 U.S. with respect to generic drug products for a period of five years from the date of FDA approval, even if the related patents have expired. We are also engaged in lifecycle management strategies for our marketed products.

In October 2014, we, along with R-Tech and Takeda, settled a patent infringement lawsuit against Par by entering into a settlement and license agreement with Par. The agreement provides that we will grant Par a license for a generic or authorized generic version of AMITIZA on January 1, 2021 and split the gross profits with Par on the sales of Par's product or the authorized generic product. In the event Par decides to distribute an authorized generic product, we will supply Par at a negotiated supply price. The term of the agreement expires in 2027.

In January 2015, we also resolved the patent challenge and generic drug application submission for RESCULA filed by Par on December 22, 2014 through an agreement for a license to Par for a generic or authorized generic version of RESCULA under certain events that allows a generic version of RESCULA to enter the market prior to 2021. In the event we do grant a license, we will split the profits with Par and if Par chooses to distribute an authorized generic product, we will supply the product at a negotiated supply price. The term of the agreement expires in 2021.

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. 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.

In August 2014, the Company entered into an exclusive global manufacturing and supply agreement with R-Tech for ten years with an automatic renewal of ten more years unless the parties terminate the agreement. The Company granted R-Tech the exclusive right to manufacture and supply lubiprostone to meet its commercial and clinical requirements globally. This agreement supercedes previous manufacturing and supply agreements for lubiprostone.

Competition

Many patients are treated for CIC, IBS-C or OIC with competing OTC or prescription products, most of which are sold for occasional or infrequent constipation. In December 2012, linaclotide, a guanylin peptide that is an agonist of the guanylyl cyclase receptor GC-C, that is dosed once a day 30 minutes before a meal, was approved for CIC and IBS-C. In the U.S., Ironwood and Forest Pharmaceuticals, Inc. are co-marketing linaclotide. In November 2012, linaclotide (co-marketed by Ironwood and Almirall, S.A.) was approved in Europe for IBS-C in adults. In Japan, Ironwood and Astellas Pharma US, Inc. 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. In September 2014, Naloxegol was approved by the FDA as a once-daily oral peripherally-acting mu-opioid receptor antagonist medication for the treatment of OIC, in adult patients with chronic, non-cancer pain. AstraZeneca plans to launch the product in the first half of 2015.

AMITIZA

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 (Synergy) which has completed a phase 2b trial in CIC and the
 two phase 3 trials for CIC will conclude in the first half of 2015. The first of two IBS-C phase 3 studies will complete in the first half of 2015 and the second
 study will be initiated in the second half of 2015.
- 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 U.S. for CC.
- SK Biopharmaceuticals commenced a phase 2 trial in 2012 to study YKP 10811, a 5-HT4 partial agonist, for CIC.
- · In July 2012, Ferring Pharmaceuticals acquired the global licensing rights (excluding Japan) for elobixibat; an IBAT (ileal bile acid transporter) from Albireo AB. Elobixibat will be entering phase 3 trials for CIC and phase 2B trials for IBS-C.
- Several products are in development for OIC. Seven of those products are mu-opioid receptor antagonists. Progenics Pharmaceuticals, Inc. received FDA approval of methylnaltrexone in 2008 for the subcutaneous formulation of this drug in treating opioid bowel dysfunction in patients receiving palliative care. The product has since been licensed to Salix Pharmaceuticals, Inc. In September 2014 the same formulation was approved by the FDA for chronic non cancer OIC patients. Six other companies/partnerships also have mu-opioid receptor antagonists in development: Nektar Therapeutics and AstraZeneca (naloxegol; phase 3 studies completed and approved in the U.S. and the E.U. for the indication of OIC to be launched in the U.S. by Astra Zeneca by the end of the first quarter of 2015, and currently being launched in the E.U.); Cubist Pharmaceuticals (bevenopran; phase 3 initiated); Theravance and GlaxoSmithKline (td-1211; phase 2b completed); S.L.A. Pharma (nalcol; phase 3 completed); Cosmo Pharmaceuticals (CB-01-16; in phase 1); and Mundipharma (fixed dose combination of oxycodone/naloxone (Targin®, Targinact®) marketed throughout Europe).
- · Shire plc is developing a 5-HT4 agonist which is currently in phase 3 for OIC.

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 U.S., at the federal, state and local level, and in other countries extensively regulate the research, development, testing, approval, manufacturing, labeling, post-approval monitoring and reporting, packaging, promotion, storage, advertising, distribution, marketing and export and import of pharmaceutical products such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, as amended, and implements 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 application with the FDA. In addition, there are three phases of human testing following Good Clinical Practices (GCP) guidelines:

- Phase 1 consists of safety tests with human clinical evaluations, generally in normal, healthy volunteers;
- Phase 2 programs expand safety tests and measure efficacy along with dose finding evaluations and are conducted in volunteers with a particular disease condition that the drug is designed to treat; and
- Phase 3 programs are greatly expanded clinical trials to determine the effectiveness of the drug at a particular dosage level in the affected patient population.

The data from these clinical tests are combined with data regarding chemistry, manufacturing and animal pharmacology and toxicology, and is then submitted in the form of a new drug application (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 our business.

The FDA extensively regulates all aspects of manufacturing quality under its current good manufacturing practice (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 U.S., we are subject to a variety of regulations in other jurisdictions most notably by the Health Canada in Canada, European Medicines Agency (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 approval by the comparable regulatory authorities of countries outside the U.S. before we can commence clinical trials or marketing of the product in those countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country, and the time for approval is country dependent and may be longer or shorter than that required by the FDA.

Canada

In Canada the new drug approval process parallels that in the U.S., after which it was modelled. The process is divided into four phases: preclinical studies, clinical trials, new drug submission and marketing. Health Canada regulates the clinical trials and grants market authorization based on an assessment of the safety, efficacy and quality of drug products. In addition to approval of new drugs, the federal government also regulates drug pricing through the Patented Medicines Prices Review Board (PMPRB).

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 (MRP). The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes and optional for those which are innovative, provides for the grant of a single marketing authorization that is valid for all E.U. member states. The decentralized procedure provides for a member state, known as the reference member state, to assess an application, with one or more concerned, member states subsequently approving that assessment. The MRP provides approval in one country and then allows for a request from subsequent countries to mutually recognize the original country's approval. The E.U. also governs among other areas, the authorization and conduct of clinical trials, the marketing authorization process for medical products, manufacturing and import activities, and post-authorization activities including pharmacovigilance. The E.U. has established regulations on pediatric medicines which impose certain obligations on pharmaceutical companies with respect to the investigation of their products in children.

Japan

In Japan, pre-marketing approval and clinical studies are required for all pharmaceutical products. The regulatory requirements for pharmaceuticals in Japan have in the past been so lengthy and costly that it has been cost-prohibitive for many pharmaceutical companies. Historically, Japan has required that pivotal clinical data submitted in support of a new drug application be performed on Japanese patients. Recently, however, as a part of the global drug harmonization process, Japan has signaled a willingness to accept U.S. or E.U. patient data when submitted along with a bridging study, which demonstrates that Japanese and non-Japanese subjects react comparably to the product. This approach, which is executed on a case-by-case basis, may reduce the time required for approval and introduction of new products into the Japanese market. To obtain manufacturing/marketing approval, we must submit an application for approval to the MHLW with results of nonclinical and clinical studies to show the quality, efficacy and safety of a new drug. A data compliance review, GCP on-site inspection, cGMP audit and detailed data review are undertaken by the PMDA. The application is then discussed by the committees of the Pharmaceutical Affairs and Food Sanitation Council (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 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 False Claims 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 (FCPA), 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 (ACA), which among other things changes access to healthcare products and services; creates new fees for the pharmaceutical and medical device industries; changes rebates and prices for health care products and services; and requires additional reporting and disclosure.

If our operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation, or if interpretations of the foregoing change, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations.

Pharmaceutical Pricing and Reimbursement

In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers. Third-party payers include government health administrative authorities, managed care providers, pharmacy benefit managers, private health insurers and other organizations. These third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our products may not be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

United States

Federal, state and local governments in the U.S. continue to work towards significant legislation aimed to limit the growth of healthcare costs, including the cost of prescription drugs. Following the U.S. Supreme Court decision in June 2012 upholding the Patient Protection and Affordable Care Act there has been an increase in the pace of regulatory issuances by those U.S. government agencies designated to carry out the extensive requirements of the ACA. These regulatory actions have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA will ultimately affect the industry. This legislation has both current and long term impacts on us. The provisions of the U.S. Healthcare Reform Act are effective on various dates over the next several years.

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

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

Our products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for our products to be covered and reimbursed by the Veterans Administration (VA) Department of Defense, (DoD), Coast Guard, and Public Health Service (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 U.S., other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

Other Regulations

Foreign Anti-Corruption

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

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

Other Laws

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

Canada

The purpose of the PMPRB is to ensure that prices of patented and non-patented medicines are not excessive so it monitors and reports prices of non-patented drugs and publishes annual reports on the prices using international median prices as a benchmark. The PMPRB does not set drug prices, analyze relative cost effectiveness or value of new drugs or take an active role in formulary listing and reimbursement pricing as these responsibilities are assumed either by the provinces and territories. In order to determine whether the price for a given drug is "excessive", new drugs are labelled in one of three categories: Category 1 refers to line extensions of existing medicines. The price of a Category 1 drug is presumed excessive if it does not bear a reasonable relationship to the price of other medicines of the same strength sold by the patentee; Category 2 refers to breakthrough or substantial improvements over existing drugs. The price of a Category 2 drug is presumed excessive if it exceeds the prices of all the medicines in the same therapeutic class or the median of the prices in seven countries (France, Germany, Italy, Sweden, Switzerland, the U.S.). Category 3 refers to new chemical entities offering moderate, little or no therapeutic improvement. The price of a Category 3 drug is presumed excessive if it exceeds the prices of all the medicines in the same therapeutic class. The PMPRB also monitors the price of existing drugs, which is considered excessive if it exceeds the increase in the general Canadian Consumer Price Index. When manufacturers set the price of a patented medicine too high, the PMPRB first attempts to have the manufacturer reduce the price voluntarily. Barring this, it can hold a public hearing into the price following which it can order the manufacturer to reduce the price, withdraw the manufacturer's market authorization, or impose a fine equal to or double the amount of the excessive increase in price.

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 U.K., pharmaceutical companies set their own price, and then national bodies (e.g., NICE and Scottish Medicines Consortium), sub-national bodies (e.g., Greater Manchester Medicines Management Group and London Procurement Partnership), or local bodies (e.g., Clinical Commissioning Groups and Health Boards) 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 U.K.

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 SL. 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 (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 SL. After EAK's evaluation of a drug, BAG and EAK decide on the maximum price in the market. The criteria used are:

- · Internal comparison with reimbursed and non-reimbursed therapeutic equivalents,
- External cross country comparison (reference countries: Denmark, Germany, the U.K. and the Netherlands), and
- · Cost benefit analysis

Japan

In Japan, pricing is established utilizing various information including reference prices from other international markets. However, the MHLW biannually reviews the pharmaceutical prices of individual products. In the past, these reviews have resulted in price reductions. We expect similar price reviews in the future, in line with the government's previously announced plan for controlling health care costs. It is not possible to predict the outcome of these reviews, and it is possible that Japanese authorities will again reduce drug reimbursement rates, which could adversely affect the reimbursement levels for our products or product candidates.

Employees

As of March 2, 2015, we had 80 full-time employees, including 34 with doctoral or other advanced degrees. Of our workforce, 26 employees are engaged in research and development, and 54 are engaged in business development, legal, finance, administration and sales and marketing. 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 2012, 2013 and 2014, see Item 7, "Management Discussion and Analysis of Financial Condition and Results of Operations—Research and Development Expenses".

Financial Information About Geographic Areas

Consolidated revenues by geographic area where derived are as follows:

		Years Ended December 31,			
(In thousands)	2014		2013		2012
United States	\$	74,688	73,637	\$	61,026
Japan		32,128	15,849		20,431
Rest of the world		8,634	108		30
Total revenues	\$ 1	15,450	89,594	\$	81,487

Total revenues generated outside the U.S. were \$40.8 million, \$16.0 million and \$20.5 million in the years ended December 31, 2014, 2013 and 2012, respectively.

Property and equipment, net by geographic area where located is as follows:

	December 31,				
(In thousands)		2014		2013	2012
United States	\$	566	\$	869	\$ 1,276
Japan		114		175	228
Rest of the world		83		112	36
Total property and equipment, net	\$	763	\$	1,156	\$ 1,540

Our Class Capital Structure

We have two classes of common stock authorized; class A common stock and class B common stock. In 2012, our majority stockholder and only holder of our class B common stock converted all of its outstanding shares of our class B common stock into shares of our class A common stock. We are not authorized to issue additional shares of class B common stock except in limited circumstances. 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

We were incorporated under the laws of Delaware in December 1996.

The following is a list of our direct and indirect subsidiaries as of December 31, 2014:

Subsidiary	State or other jurisdiction of incorporation or organization				
Sucampo Pharma Americas, LLC	Delaware				
Sucampo LLC	Delaware				
Sucampo AG	Switzerland				
Sucampo Pharma, LLC	Japan				
Sucampo Pharma Europe Ltd.	United Kingdom				

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 U.S. Securities and Exchange Commission (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 (Exchange Act), 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 continue successful commercialization of AMITIZA for the approved indications and other indications or dosage forms for which we are developing this drug, or experience significant delays in doing so, our ability to generate royalty and product-based revenues and achieve profitability will be jeopardized.

Our business currently depends entirely on the successful commercialization of our first product, lubiprostone. Lubiprostone was launched in the U.S. in 2006, under the brand name AMITIZA. AMITIZA is currently marketed in the U.S., U.K., Switzerland and Japan for various indications. We have a limited history of generating global revenues from the sale of lubiprostone. Our ability to meet expectations with respect to global sales of lubiprostone and revenues from such sales, and to attain profitability and maintain positive cash flow from the lubiprostone business, in the time periods we anticipate, or at all, will depend on a number of factors, including the following:

- our and our partners' ability to continue to build, and to maintain, market acceptance for lubiprostone among healthcare professionals and patients in the U.S., and to gain such market acceptance in the countries where lubiprostone is approved, or may in the future receive approval;
- the best efforts of Takeda and Abbott to commercialize and maximize net sales revenue of AMITIZA;
- the degree to which both physicians and patients determine that the safety and side effect profiles of lubiprostone are manageable, and that the benefits of lubiprostone outweigh the risks;
- the current and future prevalence of CIC, IBS-C or CC;
- the willingness of insurance companies, managed care organizations, other private payers, and government entities that provide reimbursement for medical costs in the U.S. to continue to provide reimbursement for lubiprostone at the prices at which we offer lubiprostone without imposing any additional major hurdles to access or other significant restrictions or limitations, and the ability and willingness of patients to commit to any co-pay amounts for lubiprostone applicable under their insurance coverage;
- our commercial partners' ability to obtain pricing approval and/or reimbursement required for selling lubiprostone in the major countries of the E.U., Japan and in other countries in which we may receive approval to market lubiprostone on a timely basis and at price levels that are acceptable to us without the applicable government agencies or other payers in such countries imposing onerous caps, rebate, risk sharing or other requirements which effectively and significantly lower the reimbursement rates for lubiprostone;
- the extent of the likely negative impact of the introduction of new competitive products on sales of lubiprostone;
- · our ability to gain regulatory approval of lubiprostone outside the countries in which we have already received approval without restrictions that are substantially more onerous or manufacturing specifications that are more difficult to consistently achieve than those imposed in the U.S. and E.U.;
- our ability to accurately forecast revenues from sales of lubiprostone and the metrics that impact revenues, such as prescription rate, short-term and long-term drop-out rate, conversion rate, reimbursement and pricing; the timing and availability of named patient sales and the impact of future competition;
- our ability to successfully gain approval of a dosage form of lubiprostone for pediatric functional constipation, and to generate revenues from sales of the dosage form for pediatric functional constipation, if approved;
- successful completion of clinical trials of AMITIZA for the treatment of other constipation-related gastrointestinal indications beyond CIC, IBS-C and OIC as
 well as other dosage forms other than the 24 mcg and 8 mcg soft gelatin capsule, and successful commercialization of these indications and dosage forms
 within and outside the U. S.;
- the ability of R-Tech, which has the exclusive right to manufacture and supply AMITIZA, or any substitute manufacture to manufacture sufficient bulk quantities of active pharmaceutical ingredient (API) and sufficient quantities of each dosage strength and dosage form of lubiprostone to meet demand;
- · our ability to hire and retain key personnel necessary to optimize the lubiprostone business; and
- · our and our partners' ability to continue to execute effectively on our commercial launch plan and other key activities related to lubiprostone in the U.S., and to launch lubiprostone successfully in those key markets outside the U.S. in which we receive pricing and reimbursement approval, and the level of cost required to conduct such activities.

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

As a general matter, 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 investments in research and development, marketing and promotion.

Our product, AMITIZA, faces 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. We also face competition from naloxegol which was recently approved for OIC in the U.S. and E.U. and will be marketed in the first quarter of 2015 in the US and is currently being launched in the E.U. Competitor products such as linaclotide and naloxegol may be more effective or more effectively marketed and sold than AMITIZA is by our partners or by us. 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.

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 approval for 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 U.S. 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, applicable regulatory authorities 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 product is not safe or effective either generally or for a new indication;
- · 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.

We continue to rely on third parties for the successful commercialization of some of our drug products. The success of these third parties will affect our ability to continue to develop new drug candidates.

For most of our operating history, we have been a research and development company. As we move to expand our management, organizational and operational capabilities, expand our global partnerships, develop our diversified product pipeline, acquire non-prostone clinical candidates, and enhance our capital structure, our operations will focus on organizing and staffing our company, building the necessary infrastructure to support these capabilities, developing the pipeline and non-prostone technologies which we may acquire, undertaking preclinical and clinical trials of our product candidates, and pursuing the regulatory approval processes for additional indications for AMITIZA. Though we will continue to rely upon Takeda and Abbott to commercialize AMITIZA in most of the world, 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 exclusive manufacturing functions and rely on Takeda and Abbott to perform the sales and marketing functions with respect to the sale of AMITIZA, we may nevertheless encounter unforeseen expenses, difficulties, complications and delays as Takeda obtains regulatory approvals and establishes the commercial markets for AMITIZA in the rest of the world. As we continue to develop and seek regulatory approval of additional product candidates and additional indications for lubiprostone, unoprostone isopropyl, cobiprostone, and ion channel activators within and outside the U.S., it could be difficult for us to access capital, to build the necessary infrastructure, to obtain and devote the resources necessary to obtain and develop product candidates, to effectively sell our products, and to provide resources to support commercialization of our products.

We are subject to on-going obligations to monitor the safety of our products and product candidates. Any failure to meet these obligations could adversely affect our ability to generate revenue.

Safety problems or signals can arise as our products are marketed and our product candidates are evaluated in clinical trials. With our collaborators, we are required to continuously collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. If regulatory agencies determine that we or our collaborators have not complied with the applicable reporting or other pharmacovigilance requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including monetary fines, marketing authorization withdrawal and other penalties.

We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

The use of lubiprostone or any other product candidate in clinical trials and the sale of AMITIZA or any other product candidate for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers or others selling or otherwise coming into contact with our product and product candidates. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- · decreased demand for lubiprostone or any other product candidate for which we obtain marketing approval;
- · impairment of our business reputation and exposure to adverse publicity;
- increased warnings on product labels;
- withdrawal of clinical trial participants;
- costs as a result of related litigation;
- · distraction of management's attention from our primary business;
- · substantial monetary awards to patients or other claimants;
- · loss of revenue; and
- · the inability to successfully commercialize lubiprostone or any other product candidate for which we obtain marketing approval.

We have obtained product liability insurance coverage for both our clinical trials and our commercial exposures. However, our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects or warnings found to be inadequate. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. A product liability claim or series of claims brought against us could cause our stock price to decline and, if the claim is successful and judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Recent federal legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, and other negative pricing trends could limit our ability to generate revenues.

In March 2010, the Patient Protection and Affordable Care Act, or the ACA, was enacted in the U.S. In 2012, the U.S. Supreme Court upheld the ACA. This legislation may have both immediate and long-term impacts on us. A number of the provisions of legislation 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.

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval.

In the U.S., the European Union, and other potentially significant markets for our product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

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.

The acquisition of Sucampo AG (SAG), in December 2010 resulted in the issuance of two subordinated unsecured promissory notes in the aggregate amount of approximately \$51.9 million to Ueno Trust and Kuno Trust. As of December 31, 2014, the outstanding balance on the notes was \$25.8 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, 2014, we were compliant.

Risks Related to Our Commercial Operations

We have a relatively short history of profitability. 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.

We have recorded net income since 2012. However, 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 and develop non-prostone products and compounds, seek regulatory approvals for additional indications and additional territories for AMITIZA and for other drug candidates, and protect the patents of our prostone products from generic challenges. Regulatory changes and changes in market conditions, including the generic competition, 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 and selling, general and administrative 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 development programs.

We have continued to finance much of our operations by payments received under our collaboration agreements with Takeda and Abbott. We believe that our existing cash and cash equivalents and internally generated funds that we anticipate from AMITIZA royalty revenues and product sales will be sufficient to enable us to fund our current operating expenses but not for all of our future research and development programs. Our future funding requirements, however, will depend on many factors, including:

actual levels of product royalty and product sales from AMITIZA

- 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 the commercialization efforts of AMITIZA; 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 licensing our products globally; 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 seek global opportunities for our products and to develop candidates internationally in the future. Such opportunities and development will inherently subject us to a number of risks and uncertainties, including:

- · changes in international regulatory and compliance requirements that could restrict our ability to develop, market and sell our products;
- political and economic instability;
- · diminished protection of intellectual property in some countries outside of the U.S.;
- · trade protection measures and import or export licensing requirements;
- · difficulty in staffing and managing international operations;
- · differing labor regulations and business practices;
- · potentially negative consequences from changes in or interpretations of tax laws;
- · changes in international medical reimbursement policies and programs;
- · financial risks such as longer payment cycles, difficulty collecting accounts receivable and exposure to fluctuations in foreign currency exchange rates; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' and service providers' activities that
 may fall within the purview of the FCPA or similar foreign laws such as the UK Bribery Act.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations. These or other similar risks could adversely affect our revenue and profitability. As we develop internationally, our exposure to these factors will increase.

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 our pipeline and non-prostone compounds will be impaired, which may jeopardize our business.

Before obtaining regulatory approval for the sale of our product candidates from our pipeline and from non-prostone acquisitions, 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 had anticipated;
- · 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:
- · many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, site selection, 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;
- 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; and
- if we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing or if the results of these trials or tests are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for our product candidates, not be able to obtain marketing approval, or obtain approval for indications that are not as broad as those for which we apply.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

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

In the future, we may be required, or we may elect, to conduct additional clinical trials of AMITIZA to improve the current label or address regulatory authorities concerns about AMITIZA. In addition, if we seek marketing approval from regulatory authorities in jurisdictions outside the U.S., they may require us to perform additional clinical trials that would be costly and difficult to know if there will be successful outcomes and to submit data from supplemental clinical trials in addition to data from the clinical trials that supported our U.S. filings with the FDA. Any requirements to conduct supplemental trials would add to the cost of developing our product candidates. Additional or supplemental trials could also produce findings that are inconsistent with the trial results we have previously submitted to the FDA, in which case we would be obligated to report those findings to the FDA. This could result in new restrictions on the existing marketing approval for AMITIZA or could force us to stop selling AMITIZA. Inconsistent trial results could also lead to delays in obtaining marketing approval in the U.S. for other indications for AMITIZA or for other product candidates 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.

Our agreements with makers of generic AMITIZA products are subject to government scrutiny in the U.S.

We are and have been involved in patent litigations that have resulted or may result in settlement agreements. We have filed our settlement and license agreements with Par and will file any future settlement agreements with the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice for review. The FTC has, in the past, brought actions against some brand and generic companies that have entered into such agreements alleging violations of antitrust laws in connection therewith.

We may receive civil investigative demands from the FTC that requires us to provide the FTC information and documents relating to various settlement and other agreements with makers of generic AMITIZA products following patent infringement claims and litigation, and other efforts principally regarding AMITIZA. If the FTC believes that these or other agreements or efforts violates antitrust laws, it could challenge us through an administrative or judicial proceeding, which could result in the imposition of monetary and/or injunctive relief, including the invalidation of agreements, any of which could have a material adverse effect on our results of operations and financial condition. In addition, any such litigation could be protracted, requiring a substantial commitment of our management's time and cash expenditures over multiple years.

Risks Related to Our Dependence on Third Parties, Including Related Parties

We have no manufacturing capabilities and are dependent upon R-Tech to manufacture and supply us with our product and product candidates. If R-Tech does not manufacture AMITIZA or our other product candidates in sufficient quantities, at acceptable quality levels and at acceptable cost and if we are unable to identify a suitable replacement manufacturer, our sales of AMITIZA and our further clinical development and commercialization of other products could be delayed, prevented or impaired.

We do not own or operate manufacturing facilities and have little experience in manufacturing pharmaceutical products. We currently rely, and expect to continue to rely, exclusively on R-Tech to supply AMITIZA, unoprostone, 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 to meet our commercial and clinical requirements throughout the world. We do not have an alternative source of supply for AMITIZA, unoprostone, cobiprostone or ion channel activators. If R-Tech is not able to supply AMITIZA or these other compounds on a timely basis, in sufficient quantities and at acceptable levels of quality and price, and if we are unable to identify an alternate manufacturer to perform these functions on acceptable terms, sales of AMITIZA would be significantly impaired, and our development programs could be seriously jeopardized.

The risks of relying solely on R-Tech for the manufacture of our products include:

- we rely solely on R-Tech for quality assurance and their continued compliance with regulations relating to the manufacture of pharmaceuticals;
- R-Tech's manufacturing capacity may not be sufficient to produce commercial quantities of our product, or to keep up with subsequent increases in the
 quantities necessary to meet potentially growing demand;
- R-Tech may not have access to the capital necessary to expand its manufacturing facilities in response to our needs;
- · Given that the know-how and trade secrets of the manufacturing process for prostones are owned by R-Tech, if R-Tech were to cease conducting business, if its operations were to be interrupted, or we elect to contract with another manufacturer to supply us, it would be difficult and time consuming for us to find an alternate supplier and the change would need to be submitted to and approved by the FDA and/or foreign regulatory agencies;
- · R-Tech relies on numerous sub-contractors to fulfill its manufacturing obligations, and any difficulty or disruption at one of these sub-contractors could jeopardize R-Tech's ability to produce AMITIZA or our other products;
- 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 API used in the manufacture of prostones. R-Tech could experience delays in production should it become necessary to switch its source of supply for the API to another supplier or to manufacture the API itself. R-Tech has subcontracted with a single contract manufacturer to encapsulate the bulk form AMITIZA supplied by R-Tech into soft gelatin capsules and another manufacturer to package the final product for distribution in the U.S. If these subcontractors experience 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 an alternative 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/or foreign regulatory agencies, and any change in the party packaging the product would need to be submitted to and reviewed by the FDA and/or foreign regulatory agencies, which could increase the time required to replace these subcontractors 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, our ability to expand globally 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 fail to comply with the FDA's cGMP regulations or other governmental regulations. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products approved for sale. In addition, the FDA or other regulatory agencies outside the U.S. may at any time audit or inspect a manufacturing facility to ensure compliance with cGMP or similar regulations. Our failure, or the failure of R-Tech, R-Tech's subcontractors and suppliers or any other third-party manufacturer we use, to comply with applicable manufacturing regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates.

If it were to become necessary for us to replace R-Tech as contract manufacturer, we would compete with other companies for access to appropriate manufacturing facilities. Any such change would need to be submitted to and approved by the FDA and/or foreign regulatory agencies before commercial activities of AMITIZA or any other product could resume. 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 the North America Takeda Agreement for the co-development and commercialization of AMITIZA for gastrointestinal indications in the U.S. and Canada. In October 2014, we entered into the Takeda Amendment to amend the North America Takeda Agreement to, among other things, extend the term and providing that, during such extended term, Takeda and we will split the annual net sales revenue of the branded AMITIZA products. Also in October 2014, we and Takeda entered into the Global License Agreement for AMITIZA whereby Takeda will become the marketing authorization holder and will be responsible for all development, commercialization and regulatory activities other than in Canada, the U.S., Japan and the People's Republic of China.

We are also party to the Japan Abbott Agreement for the development and commercialization of AMITIZA in Japan. On February 27, 2015, Abbott Laboratories, Inc. and Mylan, Inc. (Mylan) closed Mylan's purchase of Abbott's non-U.S. developed markets specialty and branded generics business, which includes the Japan Abbott Agreement. Though we do not expect the commercialization of AMITIZA in Japan to be adversely affected, if Mylan does not devote the resources and effort to the commercialization of AMITIZA, our profitability could be affected. We have no commercial experience collaborating with Mylan, and consequently the compatibility of our two companies is unknown.

The success of our collaboration arrangements will depend heavily on the efforts and activities of Takeda, Abbott, and its successor under our agreement, Mylan. The risks that we face in connection with these collaborations 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 their 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;
- we may become involved in disputes with our collaborators regarding operations, strategies, intellectual property or financial matters;
- 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 global clinical trials for our product candidates. We rely on third parties, such as contract research organizations (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 and foreign regulatory agencies require 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 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, unoprostone, cobiprostone and ion channel activators:
- a decision whether to engage R-Tech in the future to manufacture and supply compounds other than AMITIZA, unoprostone, 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 three foreign subsidiaries, Sucampo Pharma, LLC, based in Tokyo and Osaka, Japan; Sucampo Pharma Europe, Ltd., based in Oxford, U.K.; and SAG, based in Zug, Switzerland. We expect to operate through a consolidated organizational structure and we expect to enter into commercial transactions with some of these entities or future subsidiaries on an ongoing basis. As a result of these transactions, we will be subject to complex transfer pricing and other tax regulations in both the U.S. and the other countries in which we and our affiliates operate. Transfer pricing regulations generally require that, for tax purposes, transactions between our subsidiaries and affiliates and us be priced on a basis that would be comparable to an arm's length transaction and that contemporaneous documentation be maintained to support the related party agreements. To the extent that U.S. or any foreign tax authorities disagree with our transfer pricing or other policies, we could become subject to significant tax liabilities and penalties related to prior, existing and future related party agreements. As of December 31, 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

We have received notifications from generic companies that they have filed Abbreviated New Drug Applications (ANDA) with the FDA against our products. In response, we initiated patent infringement lawsuits against those generic companies which are ongoing as to certain of these companies and settled as to others. 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 in the U.S. for AMITIZA (lubiprostone) by Par and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's) and for RESCULA (unoprostone isopropyl) by Par Pharmaceutical through the filing of ANDAs by those generic companies with the FDA. Other licensed patents may be challenged, invalidated or circumvented, which could limit the term of patent protection for lubiprostone, unoprostone isopropyl or our other products, diminish our ability to stop competitors from marketing related products, and materially adversely affect our business and results of operations. In response to the filed ANDAs, we filed patent infringement lawsuits regarding AMITIZA against Par and Dr. Reddy's. In October 2014, we resolved our patent litigation with Par in the U.S. related to our AMITIZA (lubiprostone) 8 mcg and 24 mcg soft gelatin capsule products in which we and R-Tech granted Par a non-exclusive license to market Par's generic version of lubiprostone 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule in the U.S. for the indications approved for AMITIA beginning January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par will split with us the gross profits of the licensed products sold during the term of the agreement, which continues until each of our related patents has expired. In the event Par elects to launch an authorized generic form of lubiprostone, we agree to supply Par under the terms of a manufacturing and supply agreement at a negotiated price.

In November 2014, we, R-Tech Ueno, Ltd., Takeda, and certain affiliates of Takeda filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Dr. Reddy's. The lawsuit claims infringement of the same 7 patents listed in the FDA's Orange Book involved in the Par lawsuit, with the latest expiring in 2027. Under the Hatch-Waxman Act, as a result of the patent infringement lawsuit, final FDA approval of Dr. Reddy's ANDA will be stayed up to 30 months from the date of receipt of the notice letter.

In February 2015, we and R-Tech executed a stipulation and license agreement (Stipulation Agreement) with Par Pharmaceutical for RESCULA (unoprostone isopropyl) ophthalmic solution 0.15% indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Subject to the terms of the Stipulation Agreement, we and R-Tech are obligated to grant Par Pharmaceutical, prior to the expiration of the latest expiring patent relating to RESCULA, a non-exclusive license to market Par Pharmaceutical's generic version or authorized generic of unoprostone isopropyl ophthalmic solution 0.15% indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension product in the U.S. Under such license, Par Pharmaceutical will split with us the gross profits of the generic or authorized generic version sold during the term of the Stipulation Agreement, which continues until the last of our patents relating to RESCULA have expired. In the event Par Pharmaceutical elects to so launch an authorized generic form of unoprostone isopropyl, we will supply Par Pharmaceutical under the terms of a manufacturing and supply agreement at a negotiated price.

We have certain patents on our products that expire in the near future. We may not be able to use other existing patents or patent applications to successfully protect our products from generic competition. In addition, changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of R-Tech's patents and our intellectual property or narrow the scope of the protection provided by these patents. Accordingly, we cannot determine the degree of future protection for our proprietary rights in the patents and patent applications. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, a related patent may expire or may remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Patents may not afford us protection against competitors with similar technology. Because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor R-Tech can be certain whether a judicial court will uphold the validity of a patent.

If our patent position does not adequately protect our product and product candidates, others could compete against us more directly, which would harm our business, possibly materially.

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 2020 and 2027. The other U.S. and foreign patents expire between 2020 and 2029.

Our commercial success with respect to lubiprostone will depend significantly on our ability to protect our existing patent position with respect to lubiprostone as well as our ability to obtain and maintain adequate protection of other intellectual property for our technologies, product candidates and any future products in the U.S. and other countries.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- · we or our licensors were the first to make the inventions covered by each of our pending patent applications;
- · we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications or those we have licensed will result in issued patents;
- · any of our patents or those we have licensed will be valid or enforceable;
- any patents issued to us or our licensors and collaborators will provide a basis for any additional commercially viable products, will provide us with any
 competitive advantages or will not be challenged by third parties;
- · we will develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others will not have an adverse effect on our business.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product and any product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. There could be issued patents of which we are not aware that our products or product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that our products or product candidates or the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents.

Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- · the patentability of our inventions relating to our product or any product candidates; and
- the enforceability, validity or scope of protection offered by our patents relating to our product or any product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion.

In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- · incur substantial monetary damages;
- encounter significant delays in bringing our product candidates to market; and
- · be precluded from manufacturing or selling our product candidates.

In such event, our business could be adversely affected, possibly materially.

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 and outside the U.S. 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 license arrangements, we or our partner 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 U.S., may designate drugs that target relatively small patient populations as orphan drugs. We have received an orphan drug designation from the FDA for cobiprostone for the treatment of disorders associated with cystic fibrosis, and for unoprostone Isopropyl from the FDA and the EMA for the treatment of retinitis pigmentosa. We have sought orphan drug designation from EMA for cobiprostone for the treatment of oral mucositis and we may seek such status with additional product candidates. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity. The exclusivity applies only to the indication for which the drug has been designated and approved. The applicable exclusivity period is seven years in the U.S., but this period may be interrupted if a sponsor of a competitive product that is otherwise the same drug for the same use can show that its drug is clinically superior to our orphan drug candidate. The European exclusivity period is ten years, but may be reduced to six years if a drug no longer meets the criteria for orphan drug designation, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified. Even if we obtain orphan drug exclusivity for cobiprostone or unoprostone isopropyl for these indications, we may not be able to maintain it if a competitor with a product that is otherwise the same drug can establish that its product is clinically superior.

We must comply with federal, state and foreign laws, regulations, and other rules relating to the health care business, and, if we are unable to fully comply with such laws, regulations and other rules, we could face substantial penalties.

We are or will be directly or indirectly through our collaborators, 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 collaborators 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, we do not control our collaborators, including their compliance activities and if our collaborators 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.

We only have regulatory approval for commercial distribution and reimbursement of lubiprostone in a limited number of countries, and may not receive regulatory approval in other countries.

We are currently permitted to market lubiprostone in only a limited number of countries on a commercial basis. To obtain marketing approval in other countries, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, pricing, promotion and distribution of the product. Approval procedures vary among countries, and can involve additional product testing and additional administrative review periods. For example, we and Takeda are currently exploring the commercialization of AMITIZA in Canada. We may not be successful in obtaining such approval.

In addition, regulatory authorities in countries outside the U.S. and E.U. are increasingly requiring risk management plans and post-marketing commitments which may be more onerous than those required in the U.S. and E.U. The time required to obtain approval in other countries may differ from that required to obtain FDA approval or marketing authorization from the E.U. In particular, in many countries outside the U.S., including most E.U. countries and Canada, a product must receive pricing and reimbursement approval before it can be commercialized broadly. This can result in substantial delays in such countries, and the price that is ultimately approved may be lower than the price for which we expect to offer, or would be willing to offer, lubiprostone in such countries, and may impact pricing in other countries. Marketing and pricing and reimbursement approval in one country does not ensure such approvals in another. Failure to obtain the approvals necessary to commercialize lubiprostone in other countries at reimbursement levels that are acceptable to us or any delay or setback in obtaining such approvals would impair our partners' ability to develop foreign markets for lubiprostone.

Risks Related to Our Class A Common Stock

Our majority stockholders and their affiliates maintain the ability to have significant control over matters submitted to stockholders for approval, which could result in actions of which you or other stockholders do not approve.

As of March 2, 2015, our founders, Dr. Ryuji Ueno and Dr. Sachiko Kuno, together through their direct or indirect interest in S&R Technology Holding, LLC, held 25,675,255 shares of class A common stock, representing approximately 57.2% of our outstanding class A common stock. Therefore, until such time that the selling stockholders further dispose of additional shares of class A common stock, this concentration of ownership and voting power could influence all matters requiring stockholder approval and 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 our stockholders. For example, our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock. The Board of Directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our class A common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents contain other provisions that could have an anti-takeover effect, including:

- · only one of our three classes of directors will be elected each year;
- stockholders are not entitled to remove directors other than by a 75.0% vote and for cause;
- · stockholders are not permitted to take actions by written consent;
- · stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our class A common stock. These provisions may also prevent changes in our management.

$Our\ class\ A\ common\ stock\ is\ thinly\ traded\ and\ our\ stock\ price\ is\ volatile;\ investors\ in\ our\ class\ A\ common\ stock\ could\ incur\ substantial\ losses.$

The public trading market for our class A common stock is characterized by small trading volumes and a highly volatile stock price. The stock market in general and the market for pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market and industry factors might seriously harm the market price of our class A common stock, regardless of our operating performance. 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 (lubiprostone) or other approved products, if any, to achieve commercial success;
- · results of clinical trials of our product candidates or those of our competitors;
- · the regulatory status of our product candidates;
- · the success of competitive products or technologies;
- · regulatory developments in the U.S. and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- the ability of our third party suppliers and manufacturers to perform;
- · 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 and other regulatory developments;
- 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.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

We do not anticipate paying dividends on our capital stock.

We do not intend to pay dividends on our capital stock in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our capital stock, which is uncertain and unpredictable. There is no guarantee that our capital stock will appreciate in value or even maintain the price at which you purchased your shares.

Substantial future sales of our class A common stock in the public market may depress our stock price and make it difficult for you to recover the full value of your investment in our class A common stock.

As of March 2, 2015, we had 44,900,719 shares of class A common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. The market price of our class A common stock may decline if our class A common stockholders sell a large number of shares of our class A common stock in the public market, or the market perceives that such sales may occur. In addition, as of March 2, 2015, we had 4,005,494 outstanding options to purchase an aggregate of 4,005,494 shares of our class A common stock. If these options are exercised and the shares issued upon exercise are sold, the market price of our securities may also decline. These factors also could impair our ability to raise needed capital by depressing the price at which we could sell our securities.

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 February 8 2013, we, along with R-Tech and Takeda, filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par, which we subsequently amended. The lawsuit claimed infringement of seven patents that are listed in the FDA's Orange Book and that are scheduled to expire between 2020 and 2027. On October 9, 2014, we, along with R-Tech, Takeda and certain affiliates of Takeda executed a settlement and license agreement with Par that resolved our patent litigation with Par related to AMITIZA (lubiprostone) 8 mcg and 24 mcg soft gelatin capsule products. On December 1, 2014, the District Court entered a consent judgment and permanent injunction against Par, including their officers, agents, servants, employees and attorneys, enjoining them from manufacturing, using, offering to sell or selling within the U.S., or importing into the U.S., any generic capsule product containing 8 mcg and/or 24 mcg of lubiprostone per capsule that is the subject of ANDA No. 201442 until January 1, 2021 or at such earlier date as may be permitted by such settlement and license agreement.

On October 3, 2014, we received a Paragraph IV certification notice letter regarding an ANDA submitted to FDA by Dr. Reddy's, requesting approval to market, sell, and use a generic version of the 8 mcg and 24 mcg soft gelatin capsule products. In its notice letter, Dr. Reddy's alleges that U.S. Patent Nos. 6,414,016; 6,583,174; 7,064,148; 7,417,067; 8,026,393; 8,071,613; 8,088,934; 8,097,649; 8,114,890; 8,338,639; 8,748,481; 8,779,187; 7,795,312; 8,097,653; and 8,389,542, which cover compositions, formulations and methods of using AMITIZA, are invalid, unenforceable and/or will not be infringed by Dr. Reddy's manufacture, use or sale of the product described in its ANDA. The latest of such patents expires in 2027. On November 12, 2014, we, R-Tech, Takeda, and certain affiliates of Takeda filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Dr. Reddy's related to the ANDA previously filed by Dr. Reddy's and described above. The lawsuit claims infringement of 7 patents that are listed in the FDA's Orange Book, with the latest expiring in 2027. Under the Hatch-Waxman Act, as a result of the patent infringement lawsuit, final FDA approval of Dr. Reddy's ANDA will be stayed up to 30 months from the date of receipt of the notice letter. On January 26, 2015, Dr. Reddy's filed an answer and counterclaim to our complaint.

On December 22, 2014, we received a Paragraph IV certification notice letter regarding an ANDA submitted to the FDA by Par Pharmaceutical requesting approval to market, sell, and use a generic version of the RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% product approved for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. In its notice letter, Par Pharmaceutical alleges that U.S. Patent Nos. 6,458,836 and 6,770,675, which cover compositions, formulations and methods of using RESCULA, are invalid and/or will not be infringed by Par Pharmaceutical's manufacture, use or sale of the product described in its ANDA. The latest of such patents expires in 2021. On February 5, 2015, the day on which the Hatch-Waxman lawsuit was to be filed, we and R-Tech executed the Stipulation Agreement with Par Pharmaceutical for RESCULA (unoprostone isopropyl) ophthalmic solution 0.15% indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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, 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
March 31, 2014	\$ 10.81	\$ 6.60
June 30, 2014	\$ 7.44	\$ 6.65
September 30, 2014	\$ 7.29	\$ 5.90
December 31, 2014	\$ 14.28	\$ 6.36

As of March 2, 2015, we had 44,900,719 shares of class A common stock outstanding held by 13 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 2, 2015, the closing price of our class A common stock was \$13.60.

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 for our 2015 Annual Meeting of Shareholders.

Issuer Purchases of Equity Securities

In December 2008, our Board of Directors approved a stock repurchase program to purchase up to \$10.0 million of our class A common stock from time to time in open-market transactions. In 2012, our Board of Directors authorized the repurchase of up to an aggregate of \$5.0 million of our class A common stock out of the \$10.0 million approved. During the three months and twelve months ended December 31, 2014, we did not repurchase any of our class A common stock.

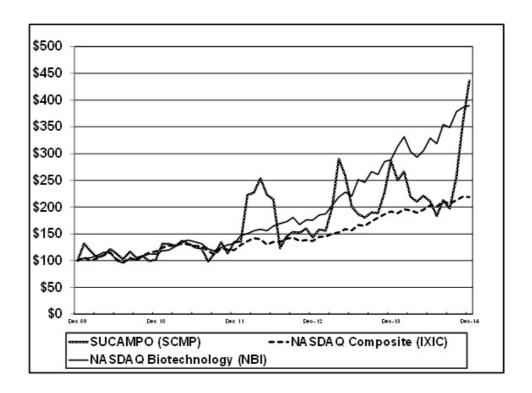
Issuer Sales of Equity Securities

In January 2013, we entered into a sales agreement with Cantor Fitzgerald & Co. (Cantor Sales Agreement), which enables us to offer and sell up to an aggregate of \$20.0 million of shares of our class A common stock through Cantor Fitzgerald & Co. as our sales agent. Sales of our class A common stock under the Cantor Sales Agreement are sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (Securities Act). Cantor Fitzgerald & Co. is entitled to receive a commission of 3.0% of gross sales in connection with the sale of our class A common stock sold on our behalf. During the year ended December 31, 2014, we sold an aggregate of 538,521 shares of our class A common stock pursuant to the Cantor Sales Agreement, and received gross proceeds of approximately \$5.5 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 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, or the Exchange Act.

The following graph compares the cumulative total return, assuming the investment of \$100 on December 31, 2009, in each of (1) our class A common stock, (2) The NASDAQ Composite Index (U.S. 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, 2014 and 2013 and for the years ended December 31, 2014, 2013 and 2012 are from our audited Consolidated Financial Statements appearing elsewhere in this Annual Report. The following consolidated financial data as of December 31, 2012, 2011 and 2010 and for the years ended December 31, 2011 and 2010 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.

				Yes	ar En	nded December 3	31,			
(In thousands, except per share data)		2014		2013		2012		2011		2010
Statement of operations data										
Revenues:	\$	115,450	\$	89,594	\$	81,487	\$	54,761	\$	61,870
Costs and expenses:										
Costs of goods sold		16,269		12,402		3,030		-		-
Intangible assets impairment		5,631		=		-		-		=
Settlement of legal dispute		-		-		-		(11,100)		
Research and development		20,566		21,524		21,292		33,497		23,955
General and administrative		31,230		25,413		30,157		41,270		27,867
Selling and marketing		14,523		21,059		18,691		8,783		10,201
Total costs and expenses		88,219		80,398		73,170		72,450		62,023
Income (loss) from operations		27,231		9,196		8,317		(17,689)		(153)
Total non-operating income (expense), net		(98)		1,747		(340)		(4,225)		(3,167)
Income (loss) before income taxes		27,133		10,943		7,977		(21,914)		(3,320)
Income tax benefit (provision)		(14,005)		(3,928)		(2,916)		4,608		565
Net income (loss)	\$	13,128	\$	7,015	\$	5,061	\$	(17,306)	\$	(2,755)
Basic net income (loss) per share	\$	0.30	\$	0.17	\$	0.12	\$	(0.41)	\$	(0.07)
Diluted net income (loss) per share	\$	0.30	\$	0.17	\$	0.12	\$	(0.41)		(0.07)
Weighted average common shares outstanding - basic	Φ	43,691	φ	41,716	φ	41,660	Φ	41,839	φ	41,848
Weighted average common shares outstanding - diluted		44,506		42,544		41,785		41,839		41,848
weighted average common shares outstanding - unuted		77,500		42,344		41,703		41,037		71,040
					D	ecember 31,				
(In thousands)		2014		2013		2012		2011		2010
Balance sheet data:										
Cash and cash equivalents	\$	71,622	\$	44,102	\$	52,022	\$	50,662	\$	49,243
Investments, current		22,393		16,003		6,035		24,452		54,524
Working capital		88,514		70,741		52,843		67,835		94,541
Total assets		141,574		136,877		127,796		157,569		149,273
Notes payable, current		8,240		26,892		19,129		20,400		19,522
Notes payable, non-current		17,578		25,828		33,722		39,227		44,439
Total liabilities		59,621		77,908		84,541		118,975		95,443
Retained earnings (accumulated deficit)		(13,732)		(26,860)		(33,875)		(38,936)		(21,630)
Total stockholders' equity		82,312		58,969		43,255		38,594		53,830

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis together with our Consolidated Financial Statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that are based on our current expectations, estimates and projections about our business and operations. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors, including those we discuss under Item 1A - "Risk Factors" and elsewhere in this Annual Report.

Overview

We are a global biopharmaceutical company currently focused on innovative research and development of proprietary drugs to meet major unmet medical needs. In 2014, our new Chief Executive Officer, Peter Greenleaf, outlined a new strategy for us to develop our company into a leading biopharmaceutical company. In 2014, we focused on the execution of this strategy by focusing our efforts and strengthening our overall capabilities in clinical development, securing and growing revenues of our flagship product, AMITIZA® (lubiprostone), and optimizing our investment in our current pipeline while seeking to diversify our science.

First, we have focused our efforts and strengthened our overall capabilities by expanding our management team with industry leaders who bring functional expertise, knowledge and leadership in their fields. The additions of these new executives are in line with our strategic vision. These biopharmaceutical executives equipped us with the depth of scientific leadership necessary to expedite our transformation and to execute on our priorities.

Second, we have secured the growth in revenues of AMITIZA by executing three agreements with our current partners, Takeda and R-Tech. With Takeda, we entered into the Global License Agreement for AMITIZA, expanding Takeda's exclusive rights from North America to all global markets except the U.S., Canada, Japan and China, and we entered into the Takeda Amendment to amend the North America Takeda Agreement, which covers North America for AMITIZA. These new AMITIZA agreements allow us to focus our strengths in our drug development while making AMITIZA available to more patients world-wide. With R-Tech, we entered into a new exclusive global manufacturing and supply agreement, which, among other things, provides us with a lower supply price of lubiprostone and allows us to in certain circumstances qualify a backup supplier for AMITIZA. This new R-Tech agreement will assist our growth of AMITIZA and facilitate our global expansion plans. All three of these new agreements allow us to share in the overall long-term value of AMITIZA. Also, we, along with Takeda, launched a direct-to-consumer campaign in select U.S. markets targeting chronic constipation patients, the largest segment of the market relying on over the counter therapies, who have not yet entered the market for prescription products. In addition, our protection of AMITIZA's intellectual property is vital and in 2014, we resolved our ongoing patent litigation in the U.S. with Par related to AMITIZA's 8 mcg and 24 mcg soft gelatin capsules and we filed a patent infringement action against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. related to the ANDA previously filed by Dr. Reddy's for AMITIZA.

Third, we optimized our investment in our current pipeline against our highest-value targets by focusing on clinical programs that we believe hold the most promise for patients, the highest likelihood for regulatory approval, and the strongest potential for commercial return. We are working with Takeda to accelerate our new formulation work and our pediatric functional constipation program for AMITIZA to uncover all opportunities to shorten our time to market. Ensuring AMITIZA's lifecycle management will enable us to serve a patient community that has few viable options for chronic care and to maintain stable growth in the constipation market. We have also prioritized programs in our current pipeline to maximize our return on investment. In 2014, we have furthered our clinical development of two drug candidates: oral mucositis and non-erosive reflux disease. For our compound unoprostone, we are determining a plan for retinitis pigmentosa and geographic atrophy. We made the decision to discontinue the selling and marketing of RESCULA® (unoprostone isopropyl), as it provided a low return for our shareholders and our company value, and discontinue the clinical development of the intravenous and oral ion channel activator for lumbar spinal stenosis, based on our belief about its lack of commercial viability.

We currently generate revenue mainly from product royalties, development milestone payments, clinical development activities and product sales generated through our partners. 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 our approved products and other compounds, and seek strategic opportunities to in-license non-prostone clinical candidates.

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

Our 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 September 2014, we and Takeda launched a pilot direct-to-consumer advertising campaign for AMITIZA in select U.S. markets for adults with chronic idiopathic constipation. In October 2014, we signed the Takeda Amendment which, among other things, extended the term beyond December 2020 and during the extended term, we will split the annual net sales revenue with Takeda on branded AMITIZA sales. As of April 1, 2015, Takeda will no longer reimburse us for the product detailings of healthcare professionals or for promotional materials used by us. In addition, beginning in 2021, we will provide Par a license to distribute either a generic or authorized generic version of AMITIZA in which we will split the gross profits for the sales of Par's products and if Par decides to distribute an authorized generic we will supply the product at a negotiated supply price.

Japan

In Japan, AMITIZA is currently marketed under the Japan Abbott Agreement for the gastrointestinal indication of 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 NIH reimbursement price approval, was removed. On February 27, 2015, Abbott Laboratories, Inc. and Mylan, Inc. (Mylan), closed Mylan's purchase of Abbott's non-U.S. developed markets specialty and branded generics business. We do not expect any significant changes in the commercialization of AMITIZA in Japan as a result of such transfer. Under the terms of the Japan Abbott Agreement, we received a commercial milestone payment of \$2.5 million during the third quarter of 2014 for the first occurrence of annual net sales of lubiprostone in Japan exceeded ¥5.0 billion.

Global Markets

In October 2014, we and Takeda entered into the Global License Agreement to develop and commercialize AMITIZA. The territories excluded from the Global License Agreement are Canada, the U.S., Japan and the People's Republic of China. Upon the signing of the Global License Agreement, we received an upfront payment of \$14.0 million, recognizing \$8.0 million in the fourth quarter of 2014. Under the terms of the Global License Agreement, we will supply Takeda the clinical and commercial product at a negotiated price. In addition, under the Global License Agreement, Takeda will become the marketing authorization holder in the U.K. and Switzerland in the first half of 2015 and in other countries upon regulatory approval.

Before the execution of the Global License Agreement, we had retained full rights to develop and commercialize AMITIZA ourselves for the rest of the world's markets outside of the U.S., Canada and Japan. In the U.K., AMITIZA was approved for CIC in July 2012. We made AMITIZA available in the U.K. in the fourth quarter of 2013. On March 7, 2014, MHRA notified us that the application for approval of the OIC indication in the U.K. was not approved. Thereafter, we met with the MHRA and since requested review of the application for OIC to address the concerns of the MHRA. We currently await MHRA's decision on the OIC indication. In July 2014, NICE published the technology appraisal guidance recommending the use of AMITIZA in the treatment of CIC and associated symptoms in adults who have failed laxatives. In January 2015, we successfully completed the European MRP for AMITIZA for the treatment of CIC in Austria, Belgium, Germany, Italy, Ireland, Luxembourg, Netherlands and Spain, resulting in a recommendation for marketing authorization. Ireland has approved the marketing authorization.

In Switzerland, AMITIZA was approved to treat CIC in adults in 2009 and OIC in chronic, non-cancer adult patients in July of 2014. In February 2012, we actively marketed 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 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.

In August 2014, we signed an exclusive global manufacturing and supply agreement with R-Tech for clinical and commercial supplies of AMITIZA in most global markets.

In October 2014, we filed AMITIZA for the CIC and the OIC indications with Health Canada. We anticipate a decision in the second half of 2015.

RESCULA (unoprostone isopropyl)

We hold license agreements for RESCULA in the U.S. and Canada and the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China. We have ceased marketing and manufacturing RESCULA in the fourth quarter of 2014 and incurred a \$5.6 million intangible asset impairment related to RESCULA. During February 2015, we alerted physicians that after the March 2015 expiration date, there will be no product available.

Our Other Clinical Development Programs

Lubiprostone

New Formulation

We are developing a new formulation of lubiprostone both for adult and pediatric patients who are unable to tolerate capsules, or for naso-gastric tube fed patients. Takeda has agreed to fund 100% of the cost of this new formulation work and we expect to initiate a phase 3 trial in the second half of 2015.

Pediatric Functional Constipation

There are four planned phase 3 studies for our pediatric functional constipation development program, two of which are currently ongoing and are both testing the soft gelatin capsule formulation of lubiprostone in patients 6 to 17 years of age. The third planned phase 3 study, a 12-week, randomized, placebo-controlled trial, that was initiated in December 2013. The remaining planned phase 3 study, a follow-on, long-term safety extension study, was initiated in March 2014. We are also evaluating the timing of the initiation of the second pivotal trial in our phase 3 program for pediatric functional constipation in children aged 6 months to less than 6 years, which will require the new formulation.

Cobiprostone

Oral Mucositis

In the first quarter of 2014, we completed our phase 1b trial that evaluated the safety and pharmacokinetics of an oral spray formulation of cobiprostone. The results of this phase 1b trial showed that cobiprostone was well-tolerated overall and revealed low systematic exposure. The next phase of clinical development, a phase 2a trial, is expected to begin at the end of the first half of 2015 in the U.S.

Non-Erosive Reflux Disease (NERD)

We began a development program for cobiprostone to treat NERD for patients who have a non-satisfactory response to PPIs. We initiated a phase 2 program in NERD at the end of 2014 in Japan.

Unoprostone Isopropyl

Retinitis Pigmentosa (RP)

In the first half of 2015, we will obtain interim, one-year data from the two-year phase 3 study for RP in Japan, which is being funded by R-Tech. We continue to work with clinical experts and regulators in the U.S. and Europe to determine a go-forward plan for the development of RP in these markets should results from Japan support that course of action. Taken together, these efforts will provide us with the information needed to decide on next steps in RP by mid-2015, with the aim to expand to a global program.

Geographic Atrophy (GA)

A small trial to establish proof of activity has been carried out by clinical investigators in Japan who showed that treatment with unoprostone for over one year delayed the loss of functional retinal area in patients with GA in comparison with the placebo control.

AMITIZA Agreements

North America Takeda Agreement

- Takeda is obligated to pay us a sliding royalty rate based on a percentage of the net sales revenue from the sale of AMITIZA in the U.S. and Canada. The actual percentage depends on the level of net sales revenue attained each calendar year. The gross to net is capped at 20% which protects us from deep discounting. AMITIZA is currently marketed only in the U.S. and during the years ended December 31, 2014, 2013 and 2012 we recognized a total of \$62.8 million, \$52.1 million and \$50.7 million respectively, as product royalty revenue.
- We received a non-refundable payment from Takeda of \$10.0 million upon the commercial sale of AMITIZA for OIC in the second quarter of 2013.
- 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 alternate formulation of AMITIZA, and 70% of the development costs for the treatment of pediatric functional constipation.
- Takeda agreed to reimburse a portion of our expenses related to our specialty sales force. We recognized \$3.4 million, \$61,000 and \$3.6 million of copromotion revenue reflecting these reimbursements for the years ended December 31, 2014, 2013 and 2012, 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 again began co-promoting AMITIZA for OIC in adults with chronic, non-cancer pain in the first quarter of 2014. In December 2014, as a result of the amendment to the North America Takeda Agreement, we ceased co-promoting AMITIZA.

• Our agreements also require Takeda to pay us up to an additional aggregate of \$50.0 million upon the achievement of specified targets for annual net sales revenue from AMITIZA in the U.S. and Canada. Sales of AMITIZA have not met these targets as of December 31, 2014 and 2013.

Global License Agreement

- · Upon signing the Global License Agreement in October 2014, we received a non-refundable upfront payment of \$14.0 million, of which \$8.0 million was allocated to collaboration revenue and \$6.0 million was considered a collaboration obligation to reimburse Takeda for the first \$6.0 million in developmental expenses incurred by Takeda.
- Takeda will be responsible for any additional development activities and costs incurred (including the supply price for any licensed product that is supplied by us to Takeda for development purposes).
- · Under the terms of the Global License Agreement, we will supply Takeda with AMITIZA (purchased from a related party, R-Tech) at a negotiated supply price. There have been no product sales under the agreement as of December 31, 2014.
- Our agreements also require Takeda to pay us up to an additional aggregate of \$35.0 million upon the achievement of specified targets for annual net sales revenue from AMITIZA in global territories covered under the Global License Agreement. Sales of AMITIZA have not met these targets as of December 31, 2014

Japan Abbott Agreement

- · We have recorded product sales revenue of approximately \$29.6 million and \$15.8 million for the years ended December 31, 2014 and 2013, respectively
- · We could receive additional milestone payments based on achieving other specified development and commercialization goals although there can be no assurance that we will receive any such payments.

R-Tech Supply Agreement

Under the exclusive global manufacturing and supply agreement with R-Tech, R-Tech has the exclusive right to manufacture and supply lubiprostone in most global markets. During the years ended December 31, 2014, 2013 and 2012, we recorded the following expenses under all of our agreements with R-Tech:

	Year Ended December 31,						
(In thousands)		2014		2013		2012	
Clinical supplies	\$	396	\$	827	\$	1,450	
Other research and development services		171		194		466	
Commercial supplies		15,776		14,902		3,288	
	\$	16,343	\$	15,923	\$	5,204	

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 (GAAP) 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

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

In October 2009, the Financial Accounting Standards Board (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.

Since 2011, we have entered into the following multiple-element arrangements: (1) research and development studies which are being reimbursed by Takeda and are treated as separate elements within the North America Takeda Agreement, and (2) the Global License Agreement. We evaluated the multiple deliverables under these arrangements 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.

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 North America 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 under the North America Takeda Agreement at contractually predetermined percentages, we recognize revenue when the underlying research and development expenses are incurred, assuming all other revenue recognition criteria are met.

Under the North America 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 North America 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 this 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, by us in Europe (prior to the Global License Agreement), to Takeda under the Global License Agreement and RESCULA sales by us in the U.S. 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 and Takeda due to the absence of discounts and rebates and no right of return under the contracts with Abbott and Takeda. 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 12 months 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 ceased marketing RESCULA during the third quarter of 2014, and all remaining inventory is set to expire during March 2015.

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 North America Takeda Agreement and Japan Abbott Agreement 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.

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 CROs. 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 accrual during the years ended December 31, 2014 and 2013.

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;
 - an estimate of expected volatility based on the historical volatility of our share price; and
- · an estimate for expected forfeitures.

The three factors which most affect stock-based compensation are the fair value of the common stock underlying the stock options, the vesting term of the options, and the volatility of such fair value of the underlying common stock. If our estimates are too high or too low, we may overstate or understate our stock-based compensation expense.

Income Taxes

As part of the process of preparing our Consolidated Financial Statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. We follow the FASB's guidance for accounting for income taxes which requires us to estimate our actual current tax exposure while assessing our temporary differences resulting from the differing treatment of items, such as deferred revenue, 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 U.S. markets or regulatory approvals for products in international markets, could affect our future earnings potential and consequently the amount of deferred tax assets that will be utilized

During 2011, we transferred certain intellectual property and licenses to SAG. Since the transfer of these assets was to a subsidiary, the recognition of a deferred tax asset by SAG is prohibited and the net tax effect of the transaction is deferred in consolidation. The deferred tax liability generated from this transaction is offset by a deferred charge that is being amortized over ten years. As of December 31, 2014, the total deferred charge is \$2.0 million after a net current year amortization and impairment expense of \$3.2 million.

As of December 31, 2014 and 2013, we had foreign net operating loss (NOLs) carry forwards of \$5.9 million and \$11.9 million, respectively. Approximately \$1.4 million of the foreign NOL begins to expire in December 2019, and approximately \$4.5 million of the foreign NOL 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, 2014 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 tax periods no longer being subject to examination has been recorded as a current liability. Other than this expected reversal, 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. 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, 2014 and December 31, 2013

Revenues

The following table summarizes our revenues for the years ended December 31, 2014 and 2013:

	Year Ended				
(In thousands)		2014		2013	
Research and development revenue	\$	7,246	\$	20,354	
Product royalty revenue		62,775		52,100	
Product sales revenue		33,252		16,425	
Co-promotion revenue		3,360		61	
Contract and collaboration revenue		8,817		654	
Total	\$	115,450	\$	89,594	

Total revenues were \$115.5 million in 2014 compared to \$89.6 million in 2013, an increase of \$25.9 million or 28.9%.

Research and development revenue

Research and development revenue was \$7.2 million in 2014 compared to \$20.4 million in 2013, a decrease of \$13.1 million or 64.4%. The decrease was primarily due to the 2013 receipt of the \$10.0 million milestone payment from Takeda upon the first commercial sale of AMITIZA for OIC.

Product royalty revenue

Product royalty revenue represents royalty revenue earned on net sales of AMITIZA in North America and was \$62.8 million in 2014 compared to \$52.1 million in 2013, an increase of \$10.7 million or 20.5%. The increase was primarily due to higher net sales of AMITIZA as reported by Takeda for royalty calculation purposes resulting from higher sales volume.

Product sales revenue

Product sales revenue represents drug product net sales of AMITIZA in Japan and Europe and drug product net sales of RESCULA in the U.S. Product sales revenue was \$33.3 million in 2014 compared to \$16.4 million in 2013, an increase of \$16.9 million or 102.4%. The increase was primarily due to a \$13.8 million increase in AMITIZA sales in Japan and a \$2.5 million milestone payment earned in Japan as a result of the first occurrence of annual net sales of lubiprostone in Japan exceeding ¥5.0 billion.

Co-promotion revenue

Co-promotion revenue represents reimbursements by Takeda of a portion of our co-promotion costs for our specialty sales force. Co-promotion revenue was \$3.4 million in 2014 compared to \$61,000 in 2013, an increase of \$3.3 million or 5408.2%. The increase resulted from our specialty sales force shifting back to co-promoting AMITIZA in 2014 after having shifted away from selling AMITIZA in 2013.

Contract and collaboration revenue

Contract and collaboration revenue was \$8.8 million in 2014 compared to \$654,000 in 2013, an increase of \$8.2 million or 1248.2%. The increase was due to the recognition of \$8.0 million of the upfront payment from Takeda under the Global License Agreement.

Costs of Goods Sold

The following table summarizes our costs of goods sold for the years ended December 31, 2014 and 2013:

	Year I Decem			
(In thousands)	2014		2013	
Product purchases	\$ 16,036	\$	9,241	
Inventory write-off	\$ -	\$	3,003	
Distribution	233		158	
Total	\$ 16,269	\$	12,402	

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Costs of goods sold were \$16.3 million in 2014 compared to \$12.4 million in 2013, an increase of \$3.9 million or 31.2%. The increase in cost of goods sold was primarily due to the increased volume of AMITIZA sales in Japan, partially offset by a \$3.0 million non-cash write-off of RESCULA inventory in 2013 which did not reoccur in 2014.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2014 and 2013:

		Year Ended December 31,					
(In thousands)	2014	1		2013			
Direct costs:							
Lubiprostone	\$	11,002	\$	10,644			
Cobiprostone		1,887		1,269			
Ion Channel Activator		1,664		2,738			
Unoprostone isopropyl		846		1,060			
Other		1,554		2,912			
Total		16,953		18,623			
Indirect costs		3,613		2,901			
Total	\$	20,566	\$	21,524			

Total research and development expenses were \$20.6 million in 2014 compared to \$21.5 million in 2013, a decrease of \$958,000 or 4.5%. The decrease in research and development expenses was primarily due to the discontinuation of our clinical studies for LSS, which were ongoing in 2013, but finished in the first half of 2014. This was partially offset by increased costs for lubiprostone and cobiprostone development and additional personnel.

General and Administrative Expenses

The following summarizes our general and administrative expenses for years ended December 31, 2014 and 2013:

	December 31,						
(In thousands)		2014		2013			
Salaries, benefits and related costs	\$	9,322	\$	8,307			
Legal, consulting and other professional expenses		12,951		7,377			
Stock option expense		1,802		1,260			
Pharmacovigilance		1,289		2,474			
Other expenses		5,866		5,995			
Total	\$	31,230	\$	25,413			

General and administrative expenses were \$31.2 million in 2014 compared to \$25.4 million in 2013, an increase of \$5.8 million, or 22.9%. The increase was primarily due to a significant increase in legal fees incurred in prosecuting a patent infringement lawsuit filed by us in February 2013, partially offset by a reduction in pharmacovigilance costs that were associated with launching AMITIZA in Japan in 2013.

Selling and Marketing Expenses

The following summarizes our selling and marketing expenses for years ended December 31, 2014 and 2013:

	Year Ended December 31,						
(In thousands)		2014		2013			
Salaries, benefits and related costs	\$	2,724	\$	6,735			
Consulting and other professional expenses		5,732		4,599			
Samples expense		276		2,563			
Contract fees		1,816		213			
Data purchases		913		829			
Promotional materials & programs		982		2,208			
Other expenses		2,080		3,912			
Total	\$	14,523	\$	21,059			

Selling and marketing expenses were \$14.5 million in 2014 compared to \$21.1 million in 2013, a decrease of \$6.5 million or 31.0%. The decrease was primarily due to the replacement of our in-house sales force with a lower-cost contract sales force in 2014, and a \$1.5 million non-cash write-off of RESCULA samples in 2013 that did not reoccur in 2014, partially offset by increased commercialization costs in 2014 for AMITIZA in Europe.

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the years ended December 31, 2014 and 2013:

 December 31,			
 2014		2013	
\$ 172	\$	124	
(1,520)		(1,894)	
1,250		3,517	
\$ (98)	\$	1,747	
\$	*** December 2014 \$ 172 (1,520)	\$ 172 \$ (1,520) 1,250	

Interest income was \$172,000 in 2014 compared to \$124,000 in 2013, an increase of \$48,000 or 38.7%. The increase was primarily due to higher cash balances earning interest in 2014.

Interest expense was \$1.5 million in 2014 compared to \$1.9 million in 2013, a decrease of \$374,000 or 19.7%. The decrease was primarily the result of lower debt balances.

Other income was \$1.3 million in 2014 compared to \$3.5 million in 2013, a decrease of \$2.3 million or 64.5%. The decrease was primarily due to a \$1.7 million or 58.7%, decrease in unrealized and non-cash foreign exchange gains.

Income Taxes

For the years ended December 31, 2014 and 2013, our consolidated effective income tax rate was 51.6% and 35.9%, respectively. For the years ended December 31, 2014 and 2013, we recorded a tax expense of \$14.0 and \$3.9 million, respectively. The tax expense for the year ended December 31, 2014 includes the impact of intangible impairments, resulting in approximately \$818,000 of additional expense. Without the intangible impairment, the effective income tax rate would be approximately 48.6%. The change in our effective tax rate in 2014 compared to 2013 was attributable primarily to the changes in the effective foreign and state tax rates, impact of the intellectual property transfer, Subpart F income in the US (partially offset by the lower tax rate in the local jurisdiction), 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, 2014, the remaining valuation allowance against our deferred tax assets was \$2.1 million and related to foreign jurisdictions where it is not more likely than not that these deferred tax assets would be realized.

Comparison of years ended December 31, 2013 and December 31, 2012

Revenues

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

_	2013	ber 31,
	2013	
(In thousands)	2013	2012
Research and development revenue	3 20,354	\$ 21,545
Product royalty revenue	52,100	50,696
Product sales revenue	16,425	5,037
Co-promotion revenue	61	3,576
Contract and collaboration revenue	654	633
Total	89,594	\$ 81,487

Vear Ended

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 U.S., 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 Europe and RESCULA in the U.S. 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 U.S. 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 Europe, and RESCULA in the U.S. 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 Ended December 31,					
(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 trials and alternate 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 unoprostone 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				
		Decemb				
ousands)	2013			2012		
es, benefits and related costs	\$	8,307	\$	8,381		
, consulting and other professional expenses		7,377		12,621		
option expense		1,260		1,349		
nacovigilance		2,474		1,991		
expenses		5,995		5,815		
Total	\$	25,413	\$	30,157		
es, benefits and related costs , consulting and other professional expenses option expense nacovigilance expenses	\$	7,377 1,260 2,474 5,995	\$	12, 1, 1, 5,		

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:

		ded er 31,			
(In thousands)	20	013	20)12	
Salaries, benefits and related costs	\$	6,735	\$	7,232	
Consulting and other professional expenses		4,599		4,220	
Samples expense		2,563		-	
Contract fees		213		-	
Data purchases		829		1,462	
Promotional materials & programs		2,208		576	
Other expenses		3,912		5,201	
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 Ended			
		Decemb	oer 31	,
(In thousands)	<u></u>	2013		2012
Interest income	\$	124	\$	179
Interest expense		(1,894)		(2,346)
Other income (expense), net		3,517		1,827
Total	\$	1,747	\$	(340)

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 \$3.5 million in 2013 compared to \$1.8 million in 2012, an increase of \$1.7 million, or 92.5%. 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 35.9% and 36.6%, 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 changes in the effective foreign and state tax rates, 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.

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 such as the progress of research and development activities, collaboration and licensing efforts and commercialization activities. The financial results of our segments reflect their varying stages of development.

The following table summarizes the financial results and the identifiable assets of our reportable geographic segments:

(In thousands)	Americas	Europe	Asia	Consolidated
Year Ended December 31, 2014				
Total revenues	\$ 74,688	\$ 8,634	\$ 32,128	\$ 115,450
Income (loss) before taxes	27,047	(11,994)	12,080	27,133
Identifiable assets	111,846	24,984	4,744	141,574
Year Ended December 31, 2013				
Total revenues	\$ 73,637	\$ 108	\$ 15,849	\$ 89,594
Income (loss) before taxes	20,983	(12,425)	2,385	10,943
Identifiable assets	95,350	23,843	17,684	136,877
Year Ended December 31, 2012				
Total revenues	\$ 61,026	\$ 30	\$ 20,431	\$ 81,487
Income (loss) before taxes	11,463	(15,861)	12,375	7,977
Identifiable assets	87,731	25,465	14,600	127,796

Our Americas segment activities include AMITIZA revenue and expenses associated with the North America Takeda Agreement and RESCULA revenues and expenses. The segment recorded an income before taxes of \$27.0 million in 2014 compared to \$21.0 million in 2013, an increase of \$6.1 million or 28.9%. This increase was primarily due to non-recurring RESCULA expenses in 2013 consisting of a \$3.0 million write-off of RESCULA inventory and a \$1.5 million write-off of RESCULA samples, as well as decreased Selling and Marketing expenses due to the replacement of our in-house sales force with a lower cost contract sales force in 2014. The 2013 income before taxes of \$21.0 million represents an increase of \$9.5 million or 83.0% from the 2012 income before taxes of \$11.5 million. This increase was 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 prior to the Global License Agreement; costs associated with pipeline development, intellectual property management and licensing activities. The segment recorded a loss before taxes of \$12.0 million in 2014, compared to a loss before taxes of \$12.4 million in 2013, a decrease of \$431,000 or 3.5%. An \$8.0 million upfront payment received in 2014 under the Global License Agreement was offset by a \$4.1 million intangible asset impairment and a \$5.4 million increase in other operating expenses. The 2013 loss before taxes of \$12.4 million represents a decrease of \$3.4 million or 21.7% from the 2012 loss before taxes of \$15.9 million.

Our Asia segment activities include the commercialization of AMITIZA in Japan associated with the Japan Abbott Agreement. The segment recorded an income before taxes of \$12.1 million in 2014 compared to \$2.4 million in 2013, an increase of \$9.7 million or 406.5%. This increase was primarily due to an increase in product sales net of costs of goods sold of \$9.9 million. The 2013 income before taxes of \$2.4 million represents a decrease of \$10.0 million or 80.7%, from the 2012 income before taxes of \$12.4 million. This decrease was primarily attributable to the milestone payment received from Abbott in 2012.

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:

	Year Ended December 31,			
(In thousands)		2014		2013
Cash and cash equivalents	\$	71,622	\$	44,102
Restricted cash, current		213		26,115
Restricted cash, non-current		2,224		2,471
Investments, current		22,393		16,003
Investments, non-current		13,540		7,219
Total	\$	109,992	\$	95,910

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, 2014, our restricted cash consisted primarily of collateral pledged to support Numab's loan with Zurcher Kantonalbank and operating leases with certain financial institutions. As of December 31, 2013, our restricted cash consisted primarily of the collateral pledged to support a loan agreement with The Bank of Tokyo-Mitsubishi UFJ, Ltd. (Tokyo-Mitsubishi Bank), a loan agreement with The Mizuho Bank, Ltd. (Mizuho Bank), Numab's loan with Zurcher Kantonalbank and operating leases with certain financial institutions. During 2014, the loan agreements at the Tokyo-Mitsubishi Bank and the Mizuho Bank were paid in full and the collateral pledged to support those loan agreements was returned to us (see Note 13 in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K).

As of December 31, 2014 and 2013, our short-term investments consisted of U.S. 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 U.S. government securities, certificates of deposit and corporate bonds.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2014, 2013 and 2012:

	Y	ear E	nded December 31	,	
(In thousands)	2014		2013		2012
Cash provided by (used in):					
Operating activities	\$ 30,878	\$	(4,209)	\$	12,000
Investing activities	12,959		(12,616)		(589)
Financing activities	(15,413)		10,581		(8,446)
Effect of exchange rates	(904)		(1,676)		(1,605)
Net increase (decrease) in cash and cash equivalents	\$ 27,520	\$	(7,920)	\$	1,360

Year ended December 31, 2014

Net cash provided by operating activities of \$30.9 million for the year ended December 31, 2014 was primarily due to a net income of \$13.1 million, non-cash expenses totaling \$11.7 million (which includes an intangible assets impairment of \$5.6 million, an increase in deferred charges of \$3.2 million, stock-based compensation expense of \$2.3 million, and depreciation and amortization of \$1.1 million), cash provided by an increase in collaboration obligation of \$6.0 million, and net changes in other assets and liabilities of \$3.7 million, offset by cash used in net changes in receivables and payables of \$3.7 million.

Net cash provided by investing activities of \$13.0 million for the year ended December 31, 2014 was primarily the result of a decrease in restricted cash of \$25.8 million, cash from matured investments of \$14.7 million, and proceeds from investment sales of \$1.7 million, offset by investment purchases of \$29.2 million.

Net cash used in financing activities of \$15.4 million for the year ended December 31, 2014 was primarily due to the payment of notes payable of \$24.9 million, offset by proceeds of \$5.3 million from our "at-the-market" stock offering and proceeds of \$3.8 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, 2014 was a decrease of \$904,000.

Year ended December 31, 2013

Net cash used in operating activities was \$4.2 million for the year ended December 31, 2013. This reflected cash provided by net income of \$7.0 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 \$2.0 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 \$12.6 million for the year ended December 31, 2013 primarily reflected a \$9.6 million increase in restricted cash and a \$2.9 million increase in purchases of investments net of maturities and proceeds.

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 a decrease of \$1.7 million.

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 \$5.1 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.

Commitments and Contractual Obligations

As of December 31, 2014, our principal outstanding contractual obligations related to our loans and our contract research commitments. The following table summarizes these significant contractual obligations:

(In thousands of U.S. dollars)	Total	1	Less than 1 year	1 - 3 years	3 - 5 years	ľ	More than 5 years
Loans	\$ 25,818	\$	8,240	\$ 17,578	\$ -	\$	=
Interest on loans	1,896		998	898	-		-
Operating lease commitments	2,735		1,198	1,537	-		=
Contract research commitments	8,535		7,823	712	-		-
Uncertain tax positions (1)	263		263	-	-		-
	\$ 39,247	\$	18,522	\$ 20,725	\$ =	\$	-

(1) As of December 31, 2014, we have recorded a total income tax liability for uncertain tax positions of approximately \$842,000, of which we expect to settle \$263,000 within the next twelve months and the remaining \$579,000 in an unknown future period (see Note 16 in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

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 \$2.2 million. As of December 31, 2014, the potential amount of payments in the event of Numab's default was \$2.0 million (see Note 12 in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K).

Off-Balance Sheet Arrangements

As of December 31, 2014, 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 1934, as amended.

Funding Requirements

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

- our share of the on-going development program of AMITIZA in the U.S.;
- development, regulatory and marketing efforts in Europe, Asia and other markets for lubiprostone;
- · development and regulatory activities for unoprostone isopropyl in the U.S. and Canada and other countries except Japan, Korea, Taiwan and the People's Republic of China;
- development, marketing and manufacturing activities at SAG;
- · activities to resolve our on-going legal matters;
- the costs involved in obtaining and maintaining proprietary protection for our products, technology and know-how, including litigation costs and the results of such litigation;
- research and development activities for other prostone compounds, including cobiprostone, and 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;
- additional purchases of shares of our class A common stock up to \$2.7 million, for a total of \$5.0 million pursuant to the repurchase program, which total 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 at-the-market sales, public or private equity offerings, debt financings or corporate collaboration and licensing arrangements.

In January 2013 we entered into the 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.

At December 31, 2014, 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

Refer to Note 2 in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

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, 2014.

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, 2014 and December 31, 2013, approximately 33.6% and 17.1%, 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 Exchange Act) as of December 31, 2014. 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, 2014, 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 Exchange Act 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, 2014 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 Exchange Act) for our company. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. 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 (2013)*. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2014.

The effectiveness of our internal control over financial reporting as of December 31, 2014 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) Andrew P. Smith Chief Financial Officer (Principal Financial Officer)

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS. EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following information will be included in our proxy statement, or Proxy Statement, for our 2015 Annual Meeting to be filed within 120 days after the fiscal year end of December 31, 2014, 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 for our 2015 Annual Meeting of Shareholders.

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 for our 2015 Annual Meeting of Shareholders. 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 for our 2015 Annual Meeting of Shareholders.

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 for our 2015 Annual Meeting of Shareholders. 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" In our proxy statement for our 2015 Annual Meeting of Shareholders

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 for our 2015 Annual Meeting of Shareholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

- (a) The following financial statements, financial statement schedule and exhibits are filed as part of this report or incorporated herein by reference:
 - (1) Consolidated Financial Statements. See Index to Consolidated Financial Statements on page F-1.
 - (2) Financial Statement Schedule: Schedule II Valuation and Qualifying Accounts on page F-36. All other schedules are omitted because they are not applicable, not required or the information required is shown in the financial statements or notes thereto.
 - (3) Exhibits. See subsection (b) below.
- (b) Exhibits. The following exhibits are filed or incorporated by reference as part of this report.

Exhibit Number	Description	Reference
2.1	Agreement and Plan of Reorganization, dated as of December 29, 2008, by and among the Company, Sucamp Pharma Holdings, Inc. and Sucampo MS, Inc.	Exhibit 2.1 to the Company's Current Report on Form 8-K (filed December 29, 2008)
2.2	Stock Purchase Agreement, dated December 23, 2010, by and among Dr. Ryuji Ueno, as trustee of the Ryuji Ueno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Sachiko Kuno as trustee of the Sachiko Kuno Revocable Trust under Trust Agreement dated December 20, 2002, Dr. Ryuji Ueno, Dr. Sachiko Kuno, Ambrent Investments S.à.r.l., and Sucampo Pharmaceuticals, Inc	Exhibit 2.1 to the Company's Current Report on Form 8-K (filed December 29, 2010)
3.1	Certificate of Incorporation	Exhibit 3.1 to the Company's Current Report on Form 8-K (filed December 29, 2008)
3.2	Certificate of Amendment	Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2008)
3.3	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)

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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)
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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 an indemnitee	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	Exhibit 10.70 to the Company's Annual Report on Form 10-K (filed March 12, 2014)
10.71^	Consulting Agreement, dated February 10, 2014, between the Company and Dr. Ryuji Ueno	Exhibit 10.71 to the Company's Annual Report on Form 10-K (filed March 12, 2014)
10.72*	Lubiprostone Exclusive Manufacturing and Supply Agreement, dated as of January 1, 2014, by and between Sucampo AG and R-Tech Ueno, Ltd.	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.73*	Settlement and License Agreement, dated September 30, 2014, by and among the Company, Sucampo AG, R-Tech Ueno, Ltd., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.74*	Manufacturing and Supply Agreement, dated as of September 30, 2014, by and between Sucampo AG and Par Pharmaceutical, Inc.	Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.75*	Amendment No. 1, dated September 30, 2014, to Collaboration and License Agreement dated October 29, 2004 and Supplemental Agreement, dated February 1, 2006, by and between Sucampo Pharma Americas, LLC and Takeda Pharmaceutical Company Limited	Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.76	Amendment No. 1, dated September 30, 2014, to the Agreement dated October 29, 2004, by and between Sucampo Pharma Americas, LLC, Takeda Pharmaceutical Company Limited and Sucampo AG	Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.77*	Amendment No. 1, dated September 30, 2014, to Supply Agreement dated October 29, 2004, Supply and Purchase Agreement dated January 25, 2006 and the Addendum to the Supply and Purchase Agreement dated November 6, 2013 by and among Sucampo Pharma Americas, LLC, Takeda Pharmaceutical Company Limited and R-Tech Ueno, Ltd.	Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)

10.78^	Separation Agreement and General Release, dated November 7, 2014, between the Company and Cary Claiborne	Included herewith
10.79*	Global License Agreement, dated October 27, 2014, between Sucampo AG and Takeda Pharmaceuticals International GmbH Limited	Included herewith
10.80^	Employment Agreement, dated as of October 27, 2014, between the Company and Dr. Peter Kiener	Included herewith
10.81^	Employment Agreement, dated as of October 27, 2014, between the Company and Matthais Alder	Included herewith
10.82^	Employment Agreement, dated as of October 27, 2014, between the Company and Dr. Steven Caffé	Included herewith
10.83^	Amendment, dated as of October 27, 2014, to Employment Agreement, effective as of December 31, 2012, between the Company and Thomas J. Knapp	Included herewith
10.84^	Amendment, dated as of October 27, 2014, to Consulting Agreement, dated September 14, 2013, between the Company and Peter Lichtlen	Included herewith
10.85^	Amendment, dated as of October 27, 2014, to Employment Agreement, effective as of December 31, 2012, between the Company and Stanley G. Miele	Included herewith
10.86^	Intentionally left blank	
10.87	Registration Rights Agreement, dated January 15, 2015, by and among the Company, S&R Technology Holdings, LLC, S&R Foundation, Dr. Ryuji Ueno and Dr. Sachiko Kuno.	Exhibit 10.1 to the Company's Form S-3 filed January 16, 2015
10.88*	Stipulation and License Agreement, dated February 5, 2015, by and among the Company, Sucampo AG, R-Tech Ueno, Ltd. and Par Pharmaceutical, Inc.	Included herewith
10.89*	Manufacturing and Supply Agreement, dated as of February 5, 2015, by and between Sucampo AG and Par Pharmaceutical, Inc.	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. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith

[^] Compensatory plan, contract or arrangement.

^{*} Confidential treatment has been granted for portions of this exhibit.

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

Signatures

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

Sucampo Pharmaceuticals, Inc.

March 9, 2015 By: /s/ PETER GREENLEAF

Peter Greenleaf Chief Executive Officer (Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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				
/s/ PETER GREENLEAF Peter Greenleaf	Chief Executive Officer (Principal Executive Officer) Director				
/s/ ANDREW P. SMITH Andrew P. Smith	Chief Financial Officer (Principal Financial Officer)	March 9, 2015			
/s/ WILLIAM L. ASHTON William L. Ashton	Director	March 9, 2015			
/s/ ANTHONY C. CELESTE Anthony C. Celeste	Director	March 9, 2015			
/s/ JOHN JOHNSON John Johnson	Director	March 9, 2015			
/s/ DANIEL P. GETMAN Daniel P. Getman	Chairman of the Board	March 9, 2015			
/s/ BARBARA A. MUNDER Barbara A. Munder	Director	March 9, 2015			
/s/ MAUREEN E. O'CONNELL Maureen E. O'Connell	Director	March 9, 2015			
/s/ ROBERT SPIEGEL Robert Spiegel	Director	March 9, 2015			
/s/ KEI S. TOLLIVER Kei S. Tolliver	Director	March 9, 2015			
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SUCAMPO PHARMACEUTICALS, INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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, 2014 and December 31, 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 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, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland March 9, 2015

SUCAMPO PHARMACEUTICALS, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)

ASSETS:		December 31, 2014		December 31, 2013		
ASSETS:						
Current assets:						
Cash and cash equivalents	\$	71,622	\$	44,102		
Investments, current		22,393		16,003		
Product royalties receivable		18,576		14,829		
Accounts receivable, net		5,338		5,407		
Deferred tax assets, current		476		2,028		
Deferred charge, current		295		673		
Restricted cash, current		213		26,115		
Inventory		-		209		
Prepaid expenses and other current assets		3,411		3,987		
Total current assets		122,324		113,353		
Investments, non-current		13,540		7,219		
Property and equipment, net		763		1,156		
Intangible assets, net		151		6,438		
Deferred tax assets, non-current		571		1,212		
Deferred that assets, non-current Deferred charge, non-current		1,695		4,540		
Restricted cash, non-current		2,224		2,471		
Other assets						
	Φ.	306	Φ.	488		
Total assets	\$	141,574	\$	136,877		
LIABILITIES AND STOCKHOLDERS' EQUITY:						
Current liabilities:						
Accounts payable	\$	4,143	\$	7,614		
Accrued expenses		8,467		5,682		
Deferred revenue, current		2,051		1,365		
Collaboration obligation		6,000		-		
Income tax payable		1,291		701		
Notes payable, current		8,240		26,892		
Other current liabilities		3,618		358		
Total current liabilities		33,810	· 	42,612		
Total Current Habilities		33,810		42,012		
Notes payable, non-current		17,578		25,828		
Deferred revenue, non-current		5,118		6,169		
Deferred tax liability, non-current		820		2,066		
Other liabilities		1,936		1,233		
Total liabilities		59,262		77,908		
Commitments and contingencies (Notes 8 and 11)						
Stockholders' equity:						
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2014 and 2013; no shares issued and						
outstanding at December 31, 2014 and 2013						
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2014 and 2013; 44,602,98	8	-		-		
and 43,315,749 shares issued and outstanding at December 31, 2014 and 2013, respectively		446		432		
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at December 31, 2014 and 2013; no shares						
issued and outstanding at December 31, 2014 and 2013		_		_		
Additional paid-in capital		83,646		72,109		
Accumulated other comprehensive income		14,265		15,601		
Treasury stock, at cost; 524,792 shares at December 31, 2014 and 2013		(2,313)		(2,313)		
Accumulated deficit		(13,732)		(26,860)		
		82,312				
Total stockholders' equity	ø		Φ.	58,969		
Total liabilities and stockholders' equity	\$	141,574	\$	136,877		

SUCAMPO PHARMACEUTICALS, INC.

Consolidated Statements of Operations and Comprehensive Income

(In thousands, except per share data)

Year Ended December 31, 2014 2013 2012 Revenues: \$ \$ Research and development revenue 7,246 20,354 \$ 21,545 62,775 Product royalty revenue 52,100 50,696 Product sales revenue 33,252 16,425 5,037 Co-promotion revenue 3,360 61 3,576 Contract and collaboration revenue 8,817 654 633 Total revenues 115,450 89,594 81,487 Costs and expenses: Costs of goods sold 16,269 12,402 3,030 Intangible assets impairment 5,631 Research and development 20,566 21,524 21,292 General and administrative 31,230 25,413 30,157 Selling and marketing 14,523 21,059 18,691 Total costs and expenses 88,219 80,398 73,170 Income from operations 27,231 9,196 8,317 Non-operating income (expense): 172 179 124 Interest income Interest expense (1,520)(1,894)(2,346)Other income, net 1,250 3,517 1,827 Total non-operating income (expense), net (98) 1,747 (340)10,943 Income before income taxes 27,133 7,977 Income tax provision (14,005)(3,928)(2,916)13,128 7,015 5,061 Net income Net income per share: \$ 0.12 Basic 0.30 0.17 Diluted \$ 0.29 0.16 \$ 0.12Weighted average common shares outstanding: Basic 41,716 41,660 43,691 Diluted 44,506 42,544 41,785 Comprehensive income: Net income \$ 13,128 7,015 5,061 Other comprehensive income (loss): Unrealized loss on pension benefit obligation (978)2 36 Unrealized gain (loss) on investments, net of tax effect (7) (351)(567)(1,724)Foreign currency translation 11,792 6,450 3,373 Total comprehensive income

SUCAMPO PHARMACEUTICALS, INC.

Consolidated Statements of Changes in Stockholders' Equity (In thousands, except share data)

	Class A Common Stock			Class B Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Treasury Stock		A	_ Accumulated Deficit		Total Stockholders' Equity	
	Shares	Amount	Shares Amount		Capital	Income (Loss)	Shares							
Balance at December 31, 2011	15,690,780	\$ 157	26,191,050		262	\$ 59,957	\$ 17,854	186,987	\$ (700) \$		\$	38,594	
Conversion of shares	26,191,050	262	(, , ,		(262)	2.233	-	-	-		-		2 222	
Employee stock option expense Stock issued upon exercise of stock	-	-	-		-	,	-	-	-		-		2,233	
options Stock issued under employee stock	79,525	1	-		-	311	-	-	-		-		312	
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	_	_	_		_	_	_		(-,-,,	,	5,061		5,061	
Balance at December 31, 2012	41,964,905	420				62,521	16,166	457,030	(1,977)	(33,875)	_	43,255	
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"	3,623	-	-		-	25	-	-	-		-		25	
offering	749,383	7	-		-	5,274	-	-	_		-		5,281	
Foreign currency translation	-	-	=		-	<u>-</u>	(567)	-	-		-		(567)	
Unrealized loss on investments, net														
of tax effect	-	-	-		-	-	2	-	-		-		2	
Windfall tax benefit from stock-						212							212	
based compensation	-	-	-		-	213	-	-	(22.6	,	-		213	
Treasury stock, at cost	-	-	-		-	-	-	67,762	(336)			(336)	
Net income					-				- (2.212		7,015		7,015	
Balance at December 31, 2013	43,315,749	432	-		-	72,109	15,601	524,792	(2,313)	(26,860)		58,969	
Employee stock option expense Stock issued upon exercise of stock	-	-	-		-	2,287	-	-	-		-		2,287	
options	742,865	9	-		-	3,780	_	-	-		-		3,789	
Stock issued under employee stock														
purchase plan	5,853	-	-		-	36	-	-	-		-		36	
Stock issued under "at-the-market"	520 521	-				5 221							5.226	
offering Windfall tax benefit from stock-	538,521	5	-		-	5,321	-	_			-		5,326	
based compensation	_	_	-		_	113	-	_	_		-		113	
Unrealized loss on pension benefit obligation	_		_		_	_	(978)	_			_		(978)	
Unrealized loss on investments, net							` /						,	
of tax effect	-	-	-		-	-	(7)	-	-		-		(7)	
Foreign currency translation Net income			-		-		(351)	-			13,128		(351) 13,128	
Balance at December 31, 2014	44.602.988	\$ 446				\$ 83,646	\$ 14.265	524.792	\$ (2.313) \$	(13.732)	s	82.312	

SUCAMPO PHARMACEUTICALS, INC. Consolidated Statements of Cash Flows

(In thousands)

Year Ended December 31, 2014 2013 2012 Cash flows from operating activities: 13,128 \$ 7,015 \$ Net income (loss) \$ 5,061 Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: Depreciation and amortization 1,090 1,488 1,488 Intangible assets impairment 5,631 Deferred tax provision (benefit) 770 (1,678)(23,026)Deferred charge 23,922 3,223 673 Stock-based compensation 2,287 1,744 2,233 Amortization of premiums on investments 110 82 67 Notes payable paid-in-kind interest 2.024 Unrealized currency translation gains (1,146)(2,023)(1,300)Shortfall from stock-based compensation (227)Changes in operating assets and liabilities: 3,256 Accounts receivable 67 (4,047)Unbilled accounts receivable 732 1,303 Product royalties receivable (3,747)(654)(3,380)Inventory (163)206 87 Prepaid and income taxes receivable and payable, net 592 560 2,998 2,242 Accounts payable (3,437)(1,453)Accrued expenses 2,868 (4,685)15 Deferred revenue (191)(3,126)(95)Collaboration obligation 6,000 Accrued interest payable (32)(32)Other assets and liabilities, net 3,714 (2,365)(1,200)Net cash provided by (used in) operating activities 30,878 (4,209)12,000 Cash flows from investing activities: Purchases of investments (29,153)(10,127)(23,609)Proceeds from the sales of investments 1,700 755 750 6,485 27,790 Maturities of investments 14,650 Purchases of property and equipment (66)(168)(439)Purchases of intangible assets (3,000)Purchase of other investing activities (432)Changes in restricted cash 25,828 (9,561)(1,649)12,959 (12,616)Net cash provided by (used in) investing activities (589)Cash flows from financing activities: 10,600 Proceeds from notes payable Repayment of notes payable (24,904)(7,539)(7,500)Proceeds from exercise of stock options 3,789 2,337 311 36 25 20 Proceeds from employee stock purchase plan Proceeds from "at-the market" stock issuance 5,326 5,281 Purchase of treasury stock (336)(1,277)Windfall benefit from stock-based compensation 340 213 (15,413)10,581 (8,446) Net cash provided by (used in) financing activities Effect of exchange rates on cash and cash equivalents (904)(1,676)(1,605)27.520 Net increase (decrease) in cash and cash equivalents (7,920)1,360 Cash and cash equivalents at beginning of period 44,102 52,022 50,662 71.622 44,102 52,022 Cash and cash equivalents at end of period Supplemental cash flow disclosures: 129 Cash paid for interest \$ \$ 156 \$ 157 \$ Tax refunds received 76 \$ 103 \$ 3,658 \$ 9,166 4,939 \$ Tax payments made \$ 3,665

1. Business Organization and Basis of Presentation

Description of the Business

Sucampo Pharmaceuticals, Inc., (Company) is a global biopharmaceutical company focused on innovative research and development of proprietary drugs to meet major unmet medical needs.

The Company is currently focused on developing compounds known as prostones, which are ion channel activators, to treat gastrointestinal, ophthalmic, 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, product sales and clinical development activities. The Company expects to continue to incur significant expenses for the next several years as the Company continues its research and development activities, seeks regulatory approvals and additional indications for approved products and other compounds, seeks global partnering opportunities for its approved products and compounds, and seeks strategic opportunities for in-licensing non-prostone clinical candidates.

AMITIZA is being marketed in the U.S. for three gastrointestinal indications under the October 2014 collaboration and license agreement (North America Takeda Agreement) with Takeda Pharmaceutical Company Limited (Takeda). These indications are chronic idiopathic constipation (CIC) in adults, irritable bowel syndrome with constipation (IBS-C) in adult women and opioid-induced constipation (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 North America Takeda Agreement while Takeda is primarily responsible for commercialization of AMITIZA in the U.S. and Canada. The Company and Takeda initiated commercial sales of AMITIZA in the U.S. for the treatment of CIC in April 2006, for the treatment of IBS-C in May 2008 and for the treat of OIC in May 2013. In October 2014, the Company and Takeda executed amendments to the North America Takeda Agreement as well as to the ancillary agreements which, among other things, extended the term of the North America Takeda Agreement beyond December 2020. During the extended term, the Company will split the annual net sales revenue of the branded AMITIZA products. In addition, beginning in April 2015, Takeda will no longer reimburse the Company for the product details performed by the Company's sales force or for promotional materials used by the sales force. As a result, the Company will not use a sales force to promote AMITIZA after the end of 2014.

In October 2014, the Company and its affiliate, Sucampo AG, (SAG) (the Company and SAG together, Company Entities), along with R-Tech Ueno, Ltd. (R-Tech), Takeda and certain affiliates of Takeda (collectively, Takeda Pharmaceutical) executed a settlement and license agreement (Settlement and License Agreement) with Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (the foregoing three entities collectively, Par) that resolves the patent litigation in the U.S. related to the Company's AMITIZA (lubiprostone) 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule product. Under the terms of the Settlement and License Agreement, the Company Entities and R-Tech will grant Par a non-exclusive license to market Par's generic version of lubiprostone 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule (collectively, Licensed Products) in the U.S. for the indications approved for AMITZA beginning on January 1, 2021, or earlier under certain circumstances. Also beginning on January 1, 2021, the Company Entities will split the gross profits of the Licensed Products sold during the term of the Settlement and License Agreement, which continues until each of the Company's patents has expired. In the event Par elects to launch an authorized generic product, the Company will supply Par with the product under the terms of a manufacturing and supply agreement at a negotiated price. Additionally, the Company Entities, R-Tech, Takeda Pharmaceutical, and Par have agreed to dismiss with prejudice the patent litigation filed against Par in the U.S. District Court for the District of Delaware.

In Japan, lubiprostone is being developed and marketed under a license, commercialization and supply agreement (Japan Abbott Agreement) with Abbott Japan Co. Ltd., (Abbott) for the treatment of CIC in Japan. The Company received approval of its new drug application, (NDA) for AMITIZA for the treatment of chronic constipation, (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 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. On February 27, 2015, Abbott Laboratories, Inc. and Mylan, Inc. (Mylan) closed Mylan's purchase of Abbott's non-U.S. developed markets specialty and branded generics business. The Company does not expect any significant changes in the commercialization of AMITIZA in Japan as a result of such transfer. Under the terms of the Japan Abbott Agreement, the Company received a commercial milestone payment of \$2.5 million during the third quarter of 2014 for the first occurrence of annual net sales of lubiprostone in Japan exceeded ¥5.0 billion.

In the U.K., the Company received approval in September 2012 from the Medicines and Healthcare Products Regulatory Agency (MHRA) for the use of AMITIZA to treat CIC. The Company filed for the OIC indication, but in March 2014 the Company received notification from MHRA that the application for the OIC indication was not approved and we have since resubmitted the application for OIC for re-review to MHRA. The Company currently awaits MHRA's decision on the OIC indication. The Company made AMITIZA available in the U.K. in the fourth quarter of 2013. In July 2014, National Institute of Health and Care Excellence (NICE) published the technology appraisal guidance recommending the use of AMITIZA in the treatment of CIC and associated symptoms in adults who have failed laxatives. In January 2015, the Company successfully completed the European mutual recognition procedure (MRP) for AMITIZA for the treatment of CIC in select European countries, resulting in a recommendation for marketing authorization.

In Switzerland, AMITIZA was approved to treat CIC in 2009. In 2012, the Company reached an agreement with the Bundesamt fur Gesundheit, (BAG), the Federal Office of Public Health in Switzerland, 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 Spezialitätenliste 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. In July 2014, AMITIZA was approved for the treatment of OIC in chronic, non-cancer adult patients by the Swissmedic, the Swiss Agency for Therapeutic Products.

In October 2014, SAG and Takeda's affiliate, Takeda Pharmaceuticals International GmbH Limited, entered into an exclusive global license agreement (Global License Agreement) to develop and commercialize AMITIZA. The territories excluded from the Global License Agreement are Canada, the U.S., Japan and the People's Republic of China. Canada and the U.S. are covered by the North America Takeda Agreement, and Japan is covered by the Japan Abbott Agreement. The Global License Agreement is effective until it expires on a country-by-country basis on the fourteenth (14th) anniversary of the date of first commercial sale in that country. Under the terms of the Global License Agreement, SAG will receive a nonrefundable upfront payment of \$14 million from Takeda for exclusive rights to develop and commercialize AMITIZA in the global markets covered by the Global License Agreement. In addition, SAG will also be eligible for up to \$35 million in additional commercial milestone payments contingent on the achievement of certain net sales revenue targets. Takeda will be responsible for all development activities and costs, except that SAG will assume responsibility for the first \$6 million in development expenses incurred by Takeda. SAG will supply Takeda with AMITIZA at a negotiated supply price. In addition, Takeda will become the marketing authorization holder and will be responsible for all commercialization and regulatory activities for AMITIZA in the territories covered by the Global License Agreement.

The Company holds license agreements for RESCULA in the U.S. and Canada and the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China (R-Tech Territory). A supplemental new drug application (sNDA) for RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension was approved by the U.S. Food and Drug Administration (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 big potassium channel activator, which is different from other IOP lowering agents. The Company has ceased marketing RESCULA in the fourth quarter of 2014, and in the third quarter of 2014 the Company incurred a \$5.6 million intangible assets impairment related to RESCULA. In February 2015, the Company alerted physicians that it has ceased to manufacture the product.

The Company's other clinical development programs include the following:

New Formulation of Lubiprostone

The Company has been developing a new formulation of lubiprostone, both for adult and pediatric patients who are unable to take capsules and for naso-gastric tube fed patients. Takeda is funding 100% of the costs of this new formulation work and the Company expects to initiate a phase 3 trial in the second half of 2015.

Pediatric Functional Constipation

Two of the four planned phase 3 studies for the Company's pediatric functional constipation development program are ongoing, both of which are testing the soft gelatin capsule formulation of lubiprostone in patients 6 to 17 years of age. The third planned phase 3 study, a 12-week, randomized, placebo-controlled trial was initiated in December 2013. The remaining planned phase 3 study, a follow-on, long-term safety extension study, was initiated in March 2014. The Company is also evaluating the timing of the initiation of the second pivotal trial in our phase 3 program for pediatric functional constipation in children aged 6 months to less than 6 years, which will require the new formulation.

Cobiprostone for Oral Mucositis

In the first quarter of 2014, the Company completed its phase 1b trial that evaluated the safety and pharmacokinetics of an oral spray formulation of cobiprostone. The results of this phase 1b trial showed that cobiprostone was well-tolerated overall and revealed low systematic exposure. The next phase of clinical development, a phase 2a trial, is expected to begin at the end of the first half of 2015.

Cobiprostone for Non-Erosive Reflux Disease (NERD)

The Company announced it will begin a development program for cobiprostone to treat NERD for patients who have a non-satisfactory response to proton pump inhibitors. The Company initiated a phase 2 program in NERD at the end of 2014.

Unoprostone Isopropyl for Retinitis Pigmentosa (RP)

In the first half of 2015, the Company will obtain interim, one-year data from the two-year phase 3 study for RP in Japan, which is being funded by R-Tech. The Company continues to work with clinical experts and regulators in the U.S. and Europe to determine a go-forward plan for development of RP in these markets should results from the Japanese study prove supportive. Taken together, these efforts will provide the Company with the information needed to decide on the next steps in RP by mid-2015.

Unoprostone Isopropyl Geographic Atrophy (GA)

A small trial to establish proof of activity has been carried out by a clinical investigator in Japan, who showed that treatment with unoprostone for over one year delayed the loss of functional retinal area in patients with GA in comparison with the placebo control.

Basis of Presentation

The accompanying Consolidated Financial Statements of the Company have been prepared in accordance with generally accepted accounting principles in the U.S. of America, (GAAP) and the rules and regulations of the Securities and Exchange Commission, (SEC). The Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiaries: SAG, based in Zug, Switzerland, through which the Company conducts certain worldwide and European operations; Sucampo Pharma, LLC, based in Tokyo and Osaka, Japan, through which the Company conducts its Asian operations; Sucampo Pharma Americas LLC, based in Bethesda, Maryland, through which the Company conducts operations in North and South America and Sucampo Pharma Europe, Ltd., based in Oxford, U.K. 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.

Revisions to Previously Issued Financial Statements

While preparing historical financial statements for the year ended December 31, 2013 and quarters ended March 31, 2014 and June 30, 2014, the Company identified certain immaterial errors in the presentation of certain line items in the previously reported financial statements. In accordance with ASC Topic 250, Accounting Changes and Error Corrections, ASC Topic 250-10-S99-1, Assessing Materiality, and ASC Topic 250-10-S99-2, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, the Company evaluated these errors and, based on an analysis of quantitative and qualitative factors, determined that they were not material, individually or in aggregate, to any previously issued financial statements and, therefore, amendment of previously filed reports with the SEC was not required. The Company is including herein the correction of all such immaterial errors that have not been revised in its previous periodic filings.

The Company has revised the Consolidated Statements of Operations and Comprehensive Income for the years ended December 31, 2013 and 2012, the three months March 31, 2014, and the Consolidated Balance Sheets as of December 31, 2013 and 2012 to correct errors in the recognition of indirect taxes at its Swiss subsidiary. The errors affect the years ended December 31, 2012 and 2013 and the periods ended March 31, 2013, June 30, 2013, September 30, 2013 and March 31, 2014. During those periods, the Company overstated its indirect tax liability and understated net income.

The Company has also revised the Consolidated Statements of Cash Flows for the year ended December 31, 2013 to correct errors in the classification of foreign exchange gains and losses in net cash used in operating activities, investing activities and the effect of exchange rates on cash and cash equivalents and the change in net income. The errors in classification affect the year ended December 31, 2013 and the periods ended September 30, 2013, June 30, 2013 and March 31, 2013. These errors have no effect on the balances of cash and cash equivalents.

Selected Items - Annual		As Previously Reported	Revision Adjustment	As Revised
Consolidated Balance Sheet		D		2012
(In thousands)	Φ.		ion as of December 31	,
Other assets	\$	584 \$	()	
Total assets		136,973	(96)	136,877
Other liabilities		2,150	(917)	1,233
Total liabilities		78,825	(917)	77,908
Accumulated deficit Total stockholders' equity		(27,681) 58,148	821 821	(26,860) 58,969
Consolidated Statements of Operations and Comprehensive Income				
(In thousands)			f the year ended Decei	
Other income (expense), net	\$	1,602 \$	225	\$ 1,827
Total non-operating income (expense), net		(565)	225	(340)
Income (loss) before income taxes		7,752	225	7,977
Net income		4,836	225	5,061
Comprehensive income		3,148	225	3,373
Consolidated Statements of Operations and Comprehensive Income (In thousands, except per share data)		Presentation as of	f the year ended Decei	nher 31, 2013
Other income (expense), net	\$	2,921 \$		\$ 3,517
Total non-operating income (expense), net	Ψ	1,151	596	1,747
Income (loss) before income taxes		10,347	596	10,943
Net income		6,419	596	7,015
Net income per share: Basic		0.15	0.02	0.17
Net income per share: Diluted		0.15	0.01	0.16
Comprehensive income		5,854	596	6,450
Consolidated Statements of Cash Flows				
(In thousands)	_	Presentation as of	f the year ended Decei	mber 31, 2013
Net cash provided by (used in) operating activities	\$	(5,418) \$	1,209	\$ (4,209)
		(13,881)	1,265	(12,616)
Net cash provided by (used in) investing activities		(13,001)	1,200	(12,010

ected Items - Quarterly		Reported		Adjustment		Revised			
Consolidated Balance Sheet									
(In thousands)		Presentation as of March 31, 2014							
Other Assets	\$	455	\$	28	\$	483			
Other liabilities		1,596		(917)		679			
Total liabilities		78,839		(917)		77,922			
Accumulated deficit		(27,006)		945		(26,061)			
Total stockholders' equity		65,406		945		66,351			
Consolidated Statements of Operations and Comprehensive Income									

Previously

Revision

As

Componented Statements	~-	o per acrons and	comprenensive income
(In thougands)			

(In thousands)	Presentation as of the three months ended March 31, 2014						
Other income (expense), net	\$ (323) \$	124 \$	(199)				
Total non-operating income (expense), net	(666)	124	(542)				
Income (loss) before income taxes	1,939	124	2,063				
Income tax benefit (provision)	(1,264)	(44)	(1,308)				
Net income	675	80	755				
Comprehensive income	564	80	644				

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 at December 31, 2014 primarily represented collateral pledged to support a loan guarantee and development agreement (Numab 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 \$2.4 million at December 31, 2014.

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

Current and Non-Current Investments

Current and non-current investments consist primarily of U.S. 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, 2014 and 2013, approximately \$37.0 million, or 33.6%, and \$16.4 million, or 17.1%, respectively, of the Company's cash, cash equivalents, restricted cash and investments were issued or insured by the U.S. government or U.S. government agencies. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

Revenues from Takeda, an unrelated party, accounted for 71.3%, 81.3% and 74.4% of the Company's total revenues for the years ended December 31, 2014, 2013 and 2012, respectively. Accounts receivable and product royalties receivable from Takeda accounted for 88.5% and 88.2% of the Company's total accounts receivable and product royalties receivable at December 31, 2014 and 2013. Revenues from another unrelated party, Abbott, accounted for 27.8%, 17.6% and 19.3% of the Company's total revenues for the years ended December 31, 2014, 2013 and 2012. The Company depends significantly upon collaborations with Takeda and Abbott, and its activities may be impacted if these relationships are disrupted (see Note 14).

The Company has an exclusive supply arrangement with 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 12).

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 (as defined below) payable at December 31, 2014 and 2013 were less than the estimated fair values (see Note 13.) 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

Accounts receivable primarily represents amounts due under the North America Takeda Agreement and Japan Abbott Agreement. The Company recorded an allowance for doubtful accounts of approximately \$25,000 and \$440,000 at December 31, 2014 and 2013, respectively, related to certain disputed Takeda invoices. Accounts receivable of approximately \$779,000 was charged off against the allowance for doubtful accounts during the year ended December 31, 2014.

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

The Company reviews definite lived intangible assets for impairment when events or changes in circumstances indicate that the carrying value of its intangible assets may not be recoverable. The carrying value of an intangible asset is assessed for impairment whenever anticipated future undiscounted cash flows from an intangible asset are estimated to be less than its carrying value. The amount of impairment loss recognized is the amount the carrying value exceeds its fair value (see Note 6).

Revenue Recognition

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

Multiple-Element Arrangements

The Company evaluated the multiple deliverables within the AMITIZA agreements in accordance with the guidance of multiple deliverables under ASC 605-25 to determine whether the deliverables can be separated for revenue recognition purposes. The separation criteria include whether the deliverables have standalone value and whether objective reliable evidence of fair value 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 AMITIZA agreements are more fully described in Note 14 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.

Research and Development Revenue

The Company applied 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 North America 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.

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.

Product Royalty Revenue

Product royalty revenue represents royalty revenue earned on net sales of AMITIZA under the North America Takeda Agreement, and is recorded on an accrual basis when earned in accordance with contractual terms, collectability is reasonably assured and all other revenue recognition criteria are met.

Product Sales Revenue

Product sales revenue consists of AMITIZA sales under the Japan Abbott Agreement, the Global License Agreement, and prior to the Global License Agreement, by the Company in Europe, and RESCULA sales by the Company in the U.S. 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. There have been no product sales as of December 31, 2014 under the Global License Agreement.

RESCULA product sales consist of RESCULA sales in the U.S. 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 prior to and up to 12 months 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 has ceased marketing RESCULA during the third quarter of 2014 and all remaining inventory is set to expire during March 2015.

The Company's three largest wholesale customers accounted for 89.0% and 96.2% of its RESCULA product sales for the years ended December 31, 2014 and 2013, respectively.

Co-promotion Revenue

Takeda reimbursements of co-promotion costs under the North America Takeda Agreement, including costs associated with the Company's 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 this agreement, and as such, we record reimbursements of these amounts on a gross basis as co-promotion revenue. In December 2014, as a result of the amendment to the North America Takeda Agreement, we ceased co-promoting AMITIZA.

Contract and Collaboration Revenue

Contract and Collaboration revenue relates to development and consulting activities and includes \$8.0 million of the upfront payment received from Takeda in 2014 under the Global License Agreement.

The Company considers its participation in joint committees under the Japan Abbott Agreement and North America Takeda Agreement 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.

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 also includes product sales of RESCULA that are deferred until the product is sold to end-user customers or until wholesale customers return the product to the Company. 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, 2014 and 2013, total deferred revenue was approximately \$7.2 million and \$7.5 million, respectively.

	December 31,							
(In thousands)	 2014		2013					
Deferred revenue, current	\$ 2,051	\$	1,365					
Deferred revenue, non-current	5,118		6,169					
	\$ 7,169	\$	7,534					
Deferred revenue to related parties, included in total deferred revenue:								
Deferred revenue to related parties, current	\$ 453	\$	477					
Deferred revenue to related parties, non-current	4,141		4,925					
Total	\$ 4,594	\$	5,402					

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 (CROs) are accrued when it is considered probable that the milestone event will be achieved.

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. 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, 2014 and 2013.

Employee Stock-Based Compensation

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 several subjective variables. The assumptions used to estimate the fair value of stock options granted for the years ended December 31, 2014, 2013 and 2012 were as follows:

	Ye	Year Ended December 31,					
	2014	2013	2012				
Expected volatility	70% - 72%	65% - 75%	62% - 64%				
Risk-free interest rate	1.63% - 2.01%	1.23% - 1.40%	0.76% - 1.60%				
Expected term (in years)	5.28 - 6.25	5.50 - 6.25	5.50 - 6.25				
Expected dividend yield	0%	0%	0%				

Expected Volatility: expected volatility is calculated using the Company's historical stock prices.

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

Expected Term: the Company elected to use the "simplified" method to calculate the expected term of share-based awards. The Company has used a lattice based model to determine the expected term for 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 years ended December 31, 2014, 2013 and 2012 has been reduced for estimated forfeitures as such expense is based upon awards expected to ultimately vest. Accounting guidance on share-based payments requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. During the years ended December 31, 2014, 2013 and 2012, the estimated forfeiture rate ranged from 10.0% to 30.94%.

Employee stock-based compensation expense recorded in the Company's Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2014, 2013 and 2012 was as follows:

	Year Ended December 31,						
(In thousands)		2014		2013		2012	
Research and development expense	\$	349	\$	293	\$	535	
General and administrative expense		1,816		1,260		1,349	
Selling and marketing expense		122		191		349	
Total		2,287		1,744		2,233	
Employee stock-based compensation expense per basic and diluted share of common stock	\$	0.05	\$	0.04	\$	0.05	

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

In September 2011, the Company internally transferred certain intellectual property and licenses from the Company's subsidiaries, including the U.S. based subsidiary, to SAG. Since the transfer of these assets was to a related party, the recognition of a deferred tax asset by SAG is prohibited and the net tax effect of the transaction is deferred in consolidation. The tax liability generated from this transaction is offset by a deferred charge that is being amortized over ten years. Following the decision of the International Court of Arbitration of the International Chamber of Commerce on the North America Takeda Agreement in July 2012, the Company determined that the internal transfer of the intellectual property was only partially complete and is continuing to evaluate whether the U.S. rights related to AMITIZA will transfer to SAG in the future. This resulted in a reassessment of the deferred charge, deferred tax liability and the mix of profits and losses earned in each jurisdiction. For the year ended December 31, 2012, the Company recorded a benefit of approximately \$1.9 million related to the partial reversal of the internal transfer and reduced the deferred charge and deferred tax liability by approximately \$23.8 million and \$24.1 million, respectively. As of December 31, 2014 and 2013, the total deferred charge is \$2.0 million and \$5.2 million, respectively, after a net current year amortization and impairment expense of \$3.2 million and \$673,000, 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 derecognition of uncertain tax positions. If the recognition threshold is met, the Company recognizes a tax benefit measured at the largest amount of the tax benefit that, in its judgment, is more than 50% likely to be realized upon settlement.

The Company has recorded an income tax liability of approximately \$842,000 and \$679,000, including interest, for uncertain tax positions as of December 31, 2014 and 2013, respectively. As of December 31, 2014, \$263,000 and \$579,000 are reflected as other current liabilities and other liabilities, respectively, in the accompanying Consolidated Balance Sheets. 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. 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, 2014 and 2013 mainly pertained to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes, as well as uncertain tax positions related to related party interest in foreign jurisdictions. During the twelve months ended December 31, 2014, the liability for income taxes has increased by approximately \$163,000. This increase in the liability is related primarily to current year activity in the U.S. 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 reverse certain prior period liabilities as a result of tax periods no longer being subject to examination; therefore, the amount of \$263,000 expected to reverse within the next twelve months has been recorded as a current liability. Other than this expected reversal, 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 2011, 2012, 2013 and 2014 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 Financial Accounting Standards Board (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.

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. In addition, the actuarial gains and losses of the Swiss Pension plan are recorded in comprehensive income.

Recent Accounting Pronouncements

In April 2014, the FASB issued Accounting Standards Update 2014-08, "Presentation of Financial Statements and Property, Plant and Equipment". Under the new standard, only disposals representing a strategic shift in operations that have a major effect on the organization's operations and financial results, or a business activity classified as held for sale, should be presented as discontinued operations. Additionally, it expands the disclosure requirements for discontinued operations to provide more information regarding the assets, liabilities, income and expenses of discontinued operations. This update is effective for interim and annual periods beginning after December 15, 2014, and early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers". While the standard supersedes existing revenue recognition guidance, it closely aligns with current GAAP. Under the new standard, revenue is recognized at the time a good or service is transferred to a customer for the amount of consideration received for that specific good or service. It is effective for annual reporting periods beginning after December 15, 2016, including interim reporting periods, and early adoption is not permitted. Entities may use a full retrospective approach or report the cumulative effect as of the date of adoption. The Company is currently evaluating the impact the adoption of this standard will have on the Company's consolidated financial statements.

In August 2014, the FASB issued Accounting Standards Update 2014-15, "Presentation of Financial Statements-Going Concern". The new standard provides guidance regarding management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The new standard is effective for annual reporting periods beginning after December 15, 2016, including interim reporting periods, and early adoption is permitted. The Company is currently evaluating the impact of adopting this standard, but does not expect it will have a material impact on the Company's consolidated financial statements.

3. Net Income per Share

Basic net income per share is computed by dividing net income by the sum of the weighted average class A and class 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 per share for the years ended December 31, 2014, 2013 and 2012 is shown below:

	YTD December 31,						
(in thousands, except per share data)		2014	2013			2012	
Basic net income per share:							
Net income	\$	13,128	\$	7,015	\$	5,061	
Weighted average class A and B common shares outstanding		43,691		41,716		41,660	
Basic net income per share	\$	0.30	\$	0.17	\$	0.12	
Diluted net income per share:							
Net income	\$	13,128	\$	7,015	\$	5,061	
Weighted average class A and B common shares outstanding for diluted net income							
per share		43,691		41,716		41,660	
		015		020		105	
Assumed exercise of stock options under the treasury stock method		815		828		125	
		44,506	_	42,544		41,785	
Diluted net income per share	\$	0.29	\$	0.16	\$	0.12	

The potentially dilutive securities used in the calculations of diluted net income per share at December 31, 2014, 2013 and 2012 are as follows:

		December 31,	
(In thousands)	2014	2013	2012
Employee stock options	1,124	2,129	2,811
Non-employee stock options	255	410	450

The following securities were excluded from the computation of diluted net income per share as their effect would be anti-dilutive as of December 31, 2014, 2013 and 2012:

		December 31,	
(In thousands)	2014	2013	2012
Employee stock options	3,012	530	596

4. Current and Non-Current Investments

At December 31, 2014 and 2013, current and non-current investments consisted of the following securities:

December 31, 2014								
<i>a</i>		G		Unrealized		Unrealized		F . W .
(In thousands)		Cost		Gains		Losses		Fair Value
Current:								
U.S. government agencies	\$	4,203	\$	1	\$	-	\$	4,204
Certificates of deposits		2,500		=		=		2,500
Corporate bonds		4,575		-		(3)		4,572
U.S. commercial paper		11,109		8		-		11,117
Total	\$	22,387	\$	9	\$	(3)	\$	22,393
Non-current:								
U.S. government agencies	\$	8,047	\$	=	\$	(15)	\$	8,032
Certificates of deposits		5,000						5,000
Corporate bonds		509		-		(1)		508
Total	\$	13,556	\$	=	\$	(16)	\$	13,540

	December 31, 2013										
(In thousands)		Cost	Uı	nrealized Gains	_	nrealized Losses	Fa	ir Value			
Current:											
U.S. government securities	\$	1,000	\$	-	\$	-	\$	1,000			
U.S. government agencies		9,048		3		-		9,051			
Certificates of deposit		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 deposit	\$	2,500					\$	2,500			
Corporate bonds		511		-		(1)		510			
Total	\$	7,223	\$	-	\$	(4)	\$	7,219			

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 Measurements at Reporting Date Using							
	Quoted Price	es in			Significant			
	Active Market	ts for	Signific	ant Other	Unobservable			
December 31, 2014	Identical Ass	sets	Observa	ble Inputs	Inputs			
(In thousands)	(Level 1)		(Le	evel 2)	(Level 3)			Total
U.S. government securities	\$	-	\$	14,850	\$	-	\$	14,850
U.S. government agencies		-		12,686		-		12,686
U.S. commercial paper		-		15,092		-		15,092
Certificates of deposits		-		8,000		-		8,000
Corporate bonds		-		10,181		-		10,181
Money market funds		3,111						3,111
Total assets measured at fair value (a)	\$	3,111	\$	60,809	\$	-	\$	63,920

(a) included in total assets are approximately \$28.0 million of cash equivalents

	Fair Value Measurements at Reporting Date Using					
December 31, 2013 (In thousands)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total		
U.S. government securities	\$ -	\$ 1,000	\$ -	\$ 1,000		
U.S. commercial paper	-	13,260	-	13,260		
Municipal securities	-	6,449	-	6,449		
Certificates of deposits	-	1,700	-	1,700		
Corporate bonds	-	6,000	-	6,000		
Money market funds	-	5,533	-	5,533		
Variable rate demand notes	5,955	-	-	5,955		
Total assets measured at fair value	\$ 5,955	\$ 33,942	\$ -	\$ 39,897		

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.

There were no transfers between levels during the years ended December 31, 2014 and 2013.

5. Property and Equipment

Property and equipment consists of the following at December 31, 2014 and 2013:

	Decem	ber 31,	
(In thousands)	 2014		2013
Computer and office machines	\$ 2,622	\$	2,607
Furniture and fixtures	473		480
Leasehold improvements	 1,415		1,444
Total cost	 4,510		4,531
Less: accumulated depreciation	(3,747)		(3,375)
Total	\$ 763	\$	1,156

Depreciation expense for the years ended December 31, 2014, 2013 and 2012 was approximately \$422,000, \$512,000 and \$542,000, respectively.

The leasehold improvements as of December 31, 2014 and 2013 are tenant improvements to the Company's headquarters in Bethesda, Maryland.

6. Intangible Assets

The Company reviews definite lived intangible assets for impairment when events or changes in circumstances indicate that the carrying value of its intangible assets may not be recoverable. The carrying value of an intangible asset is assessed for impairment whenever anticipated future undiscounted cash flows from an intangible asset are estimated to be less than its carrying value. The amount of impairment loss recognized is the amount the carrying value exceeds its fair value.

During the three months ended September 30, 2014 the Company ceased RESCULA direct commercialization activities and ceased marketing RESCULA for its approved FDA indication. Accordingly, the Company recorded an impairment charge of \$5.6 million during the three months ended September 30, 2014 which represented the full amount of the remaining balances of the unamortized intangibles related to its two RESCULA license agreements described below. Both license agreements were for the development and commercialization of RESCULA for its approved indication and for any new indications for unoprostone isopropyl. Of the total impairment charge, \$1.5 million is included in the Company's Americas segment, and \$4.1 million is included in the Company's Europe segment for the twelve months ended December 31, 2014. There were no impairment charges recorded during the twelve months ended December 31, 2013 and 2012.

In April 2009, the Company entered into an agreement with R-Tech (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 U.S. 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. Under the terms of the 2009 R-Tech Agreement, the Company made upfront and milestone payments totaling \$3.5 million, of which \$3.4 million was allocated to an intangible asset and is included in "intangible assets, net" in the accompanying Consolidated Balance Sheet as of December 31, 2013. During the three months ended September 30, 2014, the Company ceased direct commercialization activities for RESCULA and has fully impaired the unamortized value of this intangible asset, resulting in a charge of \$1.5 million. The Company had been amortizing the \$3.4 million intangible over the 10-year life of the 2009 R-Tech Agreement, which the Company believed approximated the useful life of the underlying rights and data for the approved FDA indication. Amortization expense was approximately \$227,000 and \$341,000 for the twelve months ended December 31, 2014 and 2013, respectively. The unamortized amount included in intangible assets was nil at December 31, 2014 and \$1.8 million at December 31, 2013.

In March 2011, the Company entered into a license agreement with R-Tech for unoprostone isopropyl, (2011 R-Tech Agreement) expanding the Company's development and commercialization rights as well as its territories beyond their previously agreed territory of the U.S. and Canada to the rest of the world, with the exception of the R-Tech Territory. Pursuant to the 2011 R-Tech Agreement, the Company made payments to R-Tech of \$6.0 million, which is reflected in "intangible assets, net" in the accompanying Consolidated Balance Sheet as of December 31, 2013. During the three months ended September 30, 2014, the Company ceased direct commercialization activities for RESCULA and has fully impaired the unamortized value of this intangible asset, resulting in a charge of \$4.1 million. The Company had been amortizing the \$6.0 million intangible over the 10-year life of the 2011 R-Tech Agreement, which the Company believed approximated the useful life of the underlying rights and data for the indication previously approved in Europe. Amortization expense was approximately \$409,000 and \$613,000 for the twelve months ended December 31, 2014 and 2013, respectively. The unamortized amount included in intangible assets was nil at December 31, 2014 and \$4.4 million at December 31, 2013.

7. Accrued Expenses

Accrued expenses consist of the following at December 31, 2014 and 2013:

	I	December 31,				
(In thousands)	2014			2013		
Research and development costs	\$ 3	,537	\$	1,775		
Employee compensation	3	,459		2,531		
Selling and marketing costs		163		584		
Legal service fees		612		14		
Other accrued expenses		696		778		
Total	\$ 8	,467	\$	5,682		

8. Collaboration Obligation

Under the Global License Agreement (see Note 14), the Company received an upfront payment from Takeda of \$14.0 million in 2014, of which the Company is obligated to reimburse Takeda for the first \$6.0 million in developmental expenses incurred by Takeda.

9. Other Current Liabilities

Other current liabilities consist of the following at December 31, 2014 and 2013:

	Decem	ber 31,
(In thousands)	2014	2013
Indirect taxes payable	3,075	-
Other liabilities	543	358
Total	\$ 3,618	\$ 358

10. Other Liabilities

Other liabilities consist of the following at December 31, 2014 and 2013:

	December 31,		
(In thousands)	 2014	2	013
Deferred leasehold incentive	 137		255
Deferred rent expense	243		341
Defined benefit obligation	977		-
Other liabilities	 579		637
Total	\$ 1,936	\$	1,233

Defined benefit obligation relates to defined benefit pension plans for employees in the Company's subsidiary in Switzerland (Swiss Plan). The Swiss Plan is a government-mandated retirement fund that provides employees with a minimum investment return. The minimum investment return is determined annually by the Swiss government and was 1.75% in 2014 and 1.50% in 2013. Under the Swiss Plan, the Company and certain of its employees with annual earnings in excess of government determined amounts are required to make contributions into a fund managed by an independent investment fiduciary. Employer contributions must be in an amount at least equal to the employee's contribution. Minimum employee contributions are based on the respective employee's age, salary, and gender. As of December 31, 2014, the Swiss Plan had an unfunded net pension obligation of approximately \$977,000, plan assets of approximately \$1.8 million and projected benefit obligation of approximately \$2.8 million. The entire liability is listed as non current because plan assets are more than enough to pay expected benefit payments over the next year. The Company recognized pension expense of \$221,000 for the year ended December 31, 2014 related to the Swiss Plan.

While the Swiss Plan originated in 2011, the Company only accounted for the Swiss Plan in accordance with ASC 715-30 *Defined Benefit Plans - Pensions* starting in 2014. The Company evaluated the impact of not recording the net pension obligation in the Consolidated Balance Sheet and corresponding charges in Net income and Total comprehensive income in the Statement of Operations and Comprehensive Income, and the omission of the required pension disclosures in prior years, and concluded that the effect was immaterial. The Company corrected the error in 2014 by recording an out of period adjustment to the net pension obligation liability of \$366,000, with an offsetting amount in Net Income of \$11,000 and Total comprehensive income of \$355,000. The impact of the correction of the error in 2014 was also considered immaterial.

The following tables provide reconciliations of the changes in the Swiss Plan's projected benefit obligations and assets, and the assumptions used at December 31, 2014.

Reconciliation of Projected Benefit Obligation	Decemb	per 31, 2014
(in thousands)		
Projected benefit obligation at beginning of year	\$	1,708
Service cost		191
Interest cost		43
Plan participants' contributions		165
Actuarial loss (gain)		653
Benefits paid		83
Expenses Paid		(8)
Premiums Paid		(66)
Projected benefit obligation at end of year	\$	2,769

Reconciliation of Fair Value of Plan Assets	December 31, 2014
(in thousands)	ф 1.242
Fair value of plan assets at beginning of year Actual return on plan assets	\$ 1,342 42
Employer contribution	234
Plan participants' contributions	165
Benefits paid	83
Expenses Paid	(8)
Premiums Paid	(66)
Fair value of plan assets at end of year	\$ 1,792
	·
Funded status at end of year	\$ (977)
	
	Year ended
Reconciliation of amounts recognized in Consolidated Statements of Operations and Comprehensive Income	December 31, 2014
(in thousands)	
Net loss	\$ (978)
Total amount recognized in accumulated other comprehensive income	\$ (978)
Accumulated contributions in excess of net periodic benefit cost	1
Funded status at end of year	\$ (977)
	Year ended
Net periodic pension cost included the following components	December 31, 2014
(in thousands)	
Service cost	\$ 191
Interest cost	43
Expected return on assets	(30)
Amortization of unrecognized net loss	17
Net periodic pension cost	\$ 221
	Year ended
Changes in plan assets and benefit obligations recognized in other comprehensive income	December 31, 2014
(in thousands)	
Net loss arising during year	\$ 641
Amortization or settlement of net loss	(17)
Total recognized in other comprehensive income	\$ 624
	<u> </u>
Total loss recognized in net periodic cost and other comprehensive income	\$ 845
r r r r r r r r r r r r r r r r r r r	
Estimated amounts to be amortized from accumulated other comprehensive income over the next year	December 31, 2014
(in thousands)	December 01, 2011
Net loss	\$ 73
Net loss	\$ 73
Additional year-end information for plans with projected benefit obligations in excess of plan assets	\$ 73 December 31, 2014
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands)	
Additional year-end information for plans with projected benefit obligations in excess of plan assets	December 31, 2014
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation	December 31, 2014 \$ 2,769
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation	December 31, 2014 \$ 2,769 2,469
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation	December 31, 2014 \$ 2,769 2,469
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets	December 31, 2014 \$ 2,769 2,469 1,792
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014 1.0%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014 1.0%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014 1.0%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows (in thousands)	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014 1.0%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows (in thousands) Employee Contributions	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014 1.0% 1.5%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows (in thousands) Employee Contributions 2015	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014 1.0%
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows (in thousands) Employee Contributions 2015 Benefit Payments	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014 1.5% \$ 151
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows (in thousands) Employee Contributions 2015 Benefit Payments 2015	December 31, 2014 \$ 2,769 2,469 1,792 December 31, 2014 79% 12% 6% 3% 100% Year ended December 31, 2014 2.5% 2.1% 1.5% December 31, 2014 1.0% 1.5% \$ 151
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows (in thousands) Employee Contributions 2015 Benefit Payments 2015 Benefit Payments 2016	December 31, 2014
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows (in thousands) Employee Contributions 2015 Benefit Payments 2015 Benefit Payments 2015 Benefit Payments 2016 2017	December 31, 2014
Additional year-end information for plans with projected benefit obligations in excess of plan assets (in thousands) Projected benefit obligation Accumulated benefit obligation Fair value of plan assets Weighted average allocation of plan assets Debt Securities Real Estate Other Investments Cash Total Weighted average assumptions used to determine net periodic pension cost Discount or settlement rates Expected long-term rates of return on assets Rates of increase in compensation levels Weighted average assumptions used to determine future benefit obligations Discount rate Rates of increase in compensation levels Expected future cash flows (in thousands) Employee Contributions 2015 Benefit Payments 2015 Benefit Payments 2016	December 31, 2014

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11. Commitments and Contingencies

Operating Leases

The Company leases office space in the U.S., Switzerland, and Japan, under operating leases through 2017. At December 31, 2014, total future minimum, non-cancelable lease payments under operating leases are as follows:

(In thousands of U.S. dollars)	ember 31, 2014
2015	\$ 1,198
2016	1,189
2017	244
2018	104
2019	=
Total minimum lease payments	\$ 2,735

Rent expense for all operating leases was \$1.4 million, \$1.5 million and \$1.6 million for the years ended December 31, 2014, 2013 and 2012, 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 2017 under these agreements as of December 31, 2014 were approximately \$8.5 million.

The maximum contingent liability under the Numab Agreement (see Note 12) in the event that Numab defaults under its loan with Zurcher Kantonalbank is \$2.2 million. As of December 31, 2014, the potential amount of payments in the event of Numab's default is \$2.0 million.

12. Related Party Transactions

R-Tech Ueno, Ltd.

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 S&R Technology Holding, LLC (S&R), which in turn is the Company's controlling stockholder. Dr. Ueno was the Company's Chief Executive Officer and Chairman of the Company's Board of Directors (Board or Board of Directors) through March 3, 2014 and was our Chief Scientific Officer through March 18, 2014.

The Company does not own manufacturing facilities for the production of commercial quantities of AMITIZA or preclinical or clinical supplies of the other prostone compounds that the Company is testing in its development programs. Instead, the Company contracts with R-Tech as the sole manufacturer of the Company's products to produce AMITIZA, RESCULA, cobiprostone and ion channel activators and any of the Company's future prostone compounds. The Company has entered into multiple exclusive supply arrangements with R-Tech and has granted to R-Tech the exclusive right to manufacture and supply AMITIZA and other products and compounds to the Company to meet its commercial and clinical requirements. Since 2003, the Company has received upfront, development and milestone payments under these agreements totaling \$9.0 million through December 31, 2014. With the exception of the exclusive supply agreements with Takeda, R-Tech is prohibited from supplying AMITIZA to anyone other than the Company during this period. The Company's supply arrangement with R-Tech also provides that R-Tech will assist the Company in connection with applications for marketing approval for AMITIZA, including assistance with regulatory compliance for chemistry, manufacturing and controls. Either the Company or R-Tech may terminate the supply arrangement in the event of the other party's uncured breach or insolvency.

The Company recorded the following expenses under all of its agreements with R-Tech for the years ended December 31, 2014, 2013 and 2012:

	Y	ear En	ded December 31	,		
(In thousands)	 2014	2013			2012	
Clinical supplies	\$ 396	\$	827	\$	1,450	
Other research and development services	171		194		466	
Commercial supplies	15,776		14,902		3,288	
	\$ 16,343	\$	15,923	\$	5,204	

Deferred revenues under the Company's agreements with R-Tech consist of the following at December 31, 2014 and 2013.

	Year Ended	December 31,
(In thousands)	2014	2013
Deferred revenue, current	\$ 453	477
Deferred revenue, non-current	4,141	4,925
	\$ 4,594	5,402

R-Tech has a 30-year lease with Ueno Fine Chemicals Industry, LTD. (Ueno Fine Chemical) for the land on which R-Tech's manufacturing facility that produces lubiprostone is located. There are approximately 18 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 had been in litigation in Japan over the terms of the lease, including whether or not the lease should be terminated. In December 2014 the parties resolved the dispute and R-Tech's lease remains in effect with no expected adverse effects on the Company's supply of lubiprostone.

Numab AG

In September 2011, the Company entered into the Numab Agreement with Numab. Under the terms of the Numab Agreement, which extends through September, 2016, 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 \$2.2 million as of December 31, 2014.

As of December 31, 2014, collateral of CHF 2.2 million had been deposited by the Company and Numab has utilized CHF 2.0 million of its loan facility, or approximately \$2.0 million. At December 31, 2014 and 2013, the Company has a recorded guarantee liability of \$1.0 million and \$663,000, respectively, in collateral callable to meet a potential loan default by Numab.

13. Notes Payable

In November 2010, the Company entered into a \$1,000,000,000, approximating \$11.6 million as of the closing date, secured term loan agreement with the Tokyo-Mitsubishi Bank. The loan agreement provided for the extension of credit for the period of one year that could be renewed annually upon the agreement of the Company and the Tokyo-Mitsubishi Bank. The loan agreement was not renewed in November 2014 and the outstanding loan balance was paid in full at that time. The outstanding loan balances included in the accompanying Consolidated Balance Sheets were nil and \$9.5 million as of December 31, 2014 and 2013, respectively. 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 had deposited \$14.9 million with the Tokyo-Mitsubishi Bank and is recorded as "restricted cash, current" in the accompanying Consolidated Balance Sheets as of December 31, 2013. The collateral was returned to the Company upon the retirement of the loan.

In March 2013, the Company entered into a \$1,000,000,000,000, approximating \$10.6 million as of the closing date, secured term loan agreement with the Mizuho Bank. The loan agreement provided 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. The outstanding loan balance was paid in full during the fourth quarter of 2014. The outstanding loan balances included in the accompanying Consolidated Balance Sheets were nil and \$9.5 million as of December 31, 2014 and 2013, respectively. 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 had deposited \$11.0 million with the Mizuho Bank and is recorded as "restricted cash, current" in the accompanying Consolidated Balance Sheet as of December 31, 2013. The collateral was returned to the Company upon the retirement of the loan.

Subordinated Unsecured Promissory Notes

In connection with the SAG acquisition in 2010, the Company issued a subordinated unsecured promissory note (Notes) to the Ueno Trust and Kuno Trust, former shareholders of SAG. 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, 2014 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, nil, and \$2.2 million for the three years ended December 31, 2014, 2013 and 2012, 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 as shown in the table below.

The carrying value at December 31, 2014 and 2013 and the fair value at December 31, 2014 of the Notes were as follows:

	F		Carrying Value				
	Dec	December 31,			December 31,		
(In thousands)		2014		2014		2013	
Loan agreements	\$	-	\$	=	\$	19,008	
Promissory notes, Sellers of SAG		26,317		25,818		33,712	
	\$	26,317	\$	25,818	\$	52,720	
Notes payable, current			\$	8,240	\$	26,892	
Notes payable, non-current				17,578		25,828	
			\$	25,818	\$	52,720	

The Company's debt obligations are subject to the fair value disclosure requirements as discussed in Note 4 above and are classified as Level 2 securities.

14. Collaboration and License Agreements

North America Takeda Agreement

In October 2004, we entered into an agreement with Takeda to develop and commercialize AMITIZA for gastrointestinal indications in the U.S. and Canada. The original agreement was amended on February 1, 2006 through a supplemental agreement, and in October 2014 we and Takeda and certain Takeda affiliates executed amendments to the agreement. Collectively, these are referred to as the North America Takeda Agreement. Payments to the Company under these agreements include a non-refundable upfront payment, non-refundable development and commercial milestone payments, reimbursement of certain development and co-promotion costs and product royalties.

The Company has received a total of \$160.0 million in upfront and development milestone payments through December 31, 2014 under the North America 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 North America 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 North America Takeda Agreement for the year ended December 31, 2014:

	Cash ived Through cember 31,	R	Revenue Reco	0	zed for the Sember 31,	Year	Ended	R fo	Accounts Receivable or the Year Ended December 31,	Def	mount ferred at cember 31,
(In thousands)	 2014	Through 2012 2013 2014						2014 (1)		2014	
Collaboration revenue:											
Up-front payment associated with the Company's obligation to participate in joint committees	\$ 2,375	\$	1,199	\$	147	\$	147	\$		\$	882
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	123,087		106,451		10,354		7,221		939		-
Total	\$ 280,711	\$	254,075	\$	20,354	\$	7,221	\$	939	\$	-
Product royalty revenue	\$ 335,626	\$	239,327	\$	52,100	\$	62,775	\$	18,576	\$	
	24.455		••••	Φ.		Φ.	2.260		1 220	Φ.	
Co-promotion revenue	\$ 31,475	\$	29,392	\$	61	\$	3,360	\$	1,338	\$	

(1) Includes billed and unbilled accounts receivable.

Upon execution of the North America 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 North America Takeda Agreement. During each of the years ended December 31, 2014, 2013 and 2012, the Company recognized approximately \$147,000 of this deferred amount as collaboration revenue on the Consolidated Statements of Operations and Comprehensive Income.
- 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. The Company has recorded product royalty revenue of approximately \$62.8 million, \$52.1 million and \$50.7 million for the years ended December 31, 2014, 2013 and 2012, respectively. This revenue is recorded as product royalty revenue in the Consolidated Statements of Operations and Comprehensive Income.
- 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 North America 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. 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 North America 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 North America Takeda Agreement. The Company decided to conduct one additional phase 3 efficacy studies 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 North America 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.

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.

The reimbursement of co-promotion costs under the Supplemental Takeda Agreement expired on May 31, 2011. Co-promotion costs after May 31, 2011 were reimbursed under the Takeda Agreement. The previous reimbursement terms of the Supplemental Takeda Agreement were based on a per diem amount by the number of our sales representatives in the field promoting AMITIZA. After May 2011, the Company was reimbursed on actual details presented to health care prescribers. The Company has recognized approximately \$3.4 million, \$61,000 and \$3.6 million of revenues for the years ended December 31, 2014, 2013 and 2012, 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 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.

Global License Agreement

On October 17, 2014, the Company and Takeda entered into the Global License Agreement to develop and commercialize AMITIZA. The territories excluded from the Global License Agreement are Canada, the U.S., Japan and the People's Republic of China. Canada and the U.S. are covered by the North America Takeda Agreement, and Japan is covered by the Japan Abbott Agreement. Switzerland and the U.K. have already received regulatory approval for AMITZA to be marketed and sold. All other territories covered under the Global License Agreement will need to have regulatory approval before AMITZA can be sold.

Under the terms of the Global License Agreement, the Company will supply Takeda with AMITIZA (purchased from a related party, R-Tech) at a negotiated supply price. The Company also received a nonrefundable upfront payment of \$14.0 million from Takeda for exclusive rights to develop and commercialize AMITIZA in the global markets covered by the Global License Agreement. In addition, the Company is also eligible for up to \$35.0 million in additional commercial milestone payments contingent on the achievement of certain net sales revenue targets. Takeda will be responsible for all development activities and costs, except that the Company will assume responsibility for the first \$6.0 million of those development expenses incurred by Takeda.

The Global License Agreement is considered a multiple-element arrangement for accounting purposes. The Company identified the rights to use the Company's license to develop and commercialize AMITIZA and the sale of AMITIZA product at a negotiated price as the deliverables. During the fourth quarter of 2014, the Company received a \$14.0 million milestone payment and allocated \$8.0 million to the right to use the license and \$6.0 million to a collaboration obligation to reimburse Takeda for the first \$6.0 million in developmental expenses incurred. There were no product sales to Takeda under the Global License Agreement during 2014

Japan Abbott Agreement

In February 2009, the Company entered into the Japan Abbott Agreement to develop and commercialize lubiprostone for the treatment of CIC in Japan. The agreement grants Abbott the right of exclusive negotiation to any additional indications for which lubiprostone is developed in Japan under all relevant patents, knowhow and trademarks. Under the terms of the Japan Abbott Agreement, payments to the Company include sales of product at a negotiated sales price, 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.

The Company has recorded product sales revenue under the Japan Abbott Agreement of approximately \$32.1 million, which includes a \$2.5 million net sales milestone, and \$15.8 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, the Company has received a total of \$37.5 million in up-front and development milestone payments under the Japan Abbott Agreement, including most recently a \$15.0 million development milestone payment received in December 2012 for the first commercial sale of AMITIZA in Japan. Under the Japan 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 Japan Abbott Agreement for the year ended December 31, 2014:

(In thousands)	TI Dece	Received brough mber 31, 2014		Revenue Reco	0	ized for the cember 31, 2013	Year	Ended		Accounts Receivable the Year Ended December 31, 2014	(Foreign Currency Effects	De	Amount eferred at cember 31, 2014
Collaboration revenue:														
Up-front payment associated with the Company's obligation to participate in	Ф	0.46	Ф	100	ф	52	ф	20	ф		Ф	112	ф	452
joint committees	\$	846	\$	189	\$	52	\$	39	\$	=	\$	113	\$	453
Research and development revenue														
Up-front payment - remainder	\$	9,154	\$	9,302	\$	-	\$	-	\$	-	\$	(148)	\$	-
Development milestone payment		27,500		27,755		-		-		-		(255)		-
Total	\$	36,654	\$	37,057	\$	-	\$	-	\$	-	\$	(403)	\$	-
Product sales revenue	\$	50,902	\$	5,023	\$	15,807	\$	32,088	\$	1,980	\$	(36)	\$	-

15. Stockholders' Equity

Capital Structure

The Company has two classes of common stock authorized; class A common stock and class B common stock. In 2012, the company's majority stockholder and only holder of the Company's class B common stock converted all of its outstanding shares of class B common stock into shares of the Company's class A common stock. The Company is not authorized to issue additional shares of class B common stock except in limited circumstances. 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.

Cantor Sales Agreement

In January 2013 the Company entered into a sales agreement with Cantor Fitzgerald & Co., (Cantor Sales Agreement), which enables the Company to offer and sell up to an aggregate of \$20.0 million of shares of its class A common stock through Cantor Fitzgerald & Co. as the Company's sales agent. Sales of the Company's class A common stock under the Cantor Sales Agreement are sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (Securities Act). Cantor Fitzgerald & Co. is entitled to receive a commission of 3.0% of gross sales in connection with the sale of the Company's class A common stock. During the year ended December 31, 2014, the Company sold an aggregate of 538,521 shares of its class A common stock, and received gross proceeds of approximately \$5.5 million, before deducting issuance expenses, pursuant to the Cantor sales Agreement. During the year ended December 31, 2013, the Company sold an aggregate of 749,383 shares of its class A common stock, and received gross proceeds of approximately \$5.3 million, before deducting issuance expenses, pursuant to the Cantor sales Agreement.

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 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 2014, no shares of the Company's class A common stock were repurchased. In 2013, the Company repurchased 67,762 shares of its class A common stock under this program at a cost of \$336,000. All shares of class A common stock purchased in 2013 were purchased in January, February and March of 2013.

Stock Option Plans

Amended and Restated 2001 Stock Incentive Plan

In 2001, the Company adopted the 2001 Stock Incentive Plan (2001 Plan) to provide common stock incentives to certain eligible employees, officers, directors, consultants and advisors of the Company. In 2003, the Board amended the 2001 Plan (Amended 2001 Plan) to allow for a maximum of 8,500,000 shares of class A common stock to be issued under all awards. In August 2005, the Board granted 510,000 stock options to non-employees under the Amended 2001 Plan. These non-employee stock options vested immediately and have a weighted average exercise price per share of \$5.85. In 2006, the Board determined no further options would be granted under the Amended 2001 Plan. Non-employee options outstanding and exercisable under the Amended 2001 Plan at December 31, 2014 and 2013 totaled 255,000 and 410,000, respectively, with a remaining contractual life of .25 and 1.33 years, respectively. Employee options outstanding and exercisable under the Amended 2001 Plan at December 31, 2014 and 2013 totaled 113,900 and 255,000, respectively, with a remaining contractual life of .93 and 2.34 years, respectively.

A summary of the non-employee stock option activity for the year ended December 31, 2014 under the Amended 2001 Plan is presented below:

	Shares	Weighted Average Exercise Price Per Share		ce Per Contractual Term		regate Intrinsic Value
Options outstanding, December 31, 2013	410,000	\$	5.85			
Options exercised	(155,000)		5.85			
Options outstanding, December 31, 2014	255,000		5.85	0.25	\$	2,149,650
Options exercisable, December 31, 2014	255,000		5.85	0.25	\$	2,149,650

A summary of the employee stock option activity for the year ended December 31, 2014 under the Amended 2001 Plan is presented below:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2013	146,200	\$ 10.00		
Options exercised	(6,800)	10.00		
Options expired	(25,500)	10.00		
Options outstanding, December 31, 2014	113,900	10.00	0.93	\$ 487,492
Options exercisable, December 31, 2014	113,900	10.00	0.93	\$ 487

2006 Stock Incentive Plan

In 2006, the Board approved the 2006 Stock Incentive Plan, which has been amended and restated (as amended and restate, 2006 Plan), and reserved 8,500,000 shares of class A common stock for issuance under the 2006 Plan. Option awards under the 2006 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. At December 31, 2014, a total of 3,195,271 shares were available for future grants under this plan.

The 2006 Plan includes an "evergreen" provision by which the number of shares of the Company's class A common stock available for issuance increases automatically on the first day of each calendar year by 5.0% of the aggregate number of shares of the Company's class A and B common stock outstanding on such date, or such lesser number as the Board may determine. The 2006 Plan also provides 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 Plan as of January 1, 2013 and 2014 pursuant to the "evergreen" provision was zero.

A summary of the employee stock option activity for the year ended December 31, 2014 under the 2006 Plan is presented below:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2013	2,513,063	\$ 5.03		
Options granted	2,703,995	7.68		
Options exercised	(618,377)	4.54		
Options forfeited	(383,915)	4.72		
Options expired	(193,275)	4.81		
Options outstanding, December 31, 2014	4,021,491	6.93	8.57	\$ 29,560,979
Options exercisable, December 31, 2014	937,765	6.02	6.08	\$ 7,746,764

During 2014, performance-based stock options granted to the Company's Chief Executive Officer totaled 200,000 and vest when the Company's stock price meets or exceeds \$16.00 over a continuous 30 day trading period. These options expire on the four year anniversary of the grant if not vested at that time, and if vested, expire on July 30, 2028. The Company used a Monte Carlo approach and a Geometric Brownian Motion stock-pricing model to estimate the fair value of these options. During 2014, the Company also granted time-based stock options to all eligible employees. For certain eligible employees, the granted stock options had accelerated vesting conditions. Those accelerated-vesting conditions applied to 450,000 stock options and cliff vest after four years, but one third of the total award may vest each time certain pre-determined strategic objectives of the Company have been met. The granted stock options expire ten years from date of grant, and the Company used a Black-Scholes option-pricing model to estimate the fair value of these options. Time-based stock options granted totaled 2,053,245 and vest in equal annual installments over four years from date of grant and expire ten years from date of grant and expire ten years from date of grant.

The weighted average grant date fair value of options granted during the years ended December 31, 2014, 2013 and 2012 were \$7.68, \$7.36, and \$6.30, respectively. As of December 31, 2014, approximately \$7.6 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards are expected to be recognized over a weighted average period of 3.4 years. When an option is exercised, the Company issues a new share of class A common stock. In one instance an exercise was net share settled whereby 69,499 options were exercised but only 32,870 shares were issued by the Company.

Employee Stock Purchase Plan

In 2006, the Board approved a 2006 Employee Stock Purchase Plan (ESPP) and reserved 4,250,000 shares of class A common stock for issuance under the ESPP. As of December 31, 2014, 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, as amended. Under the ESPP, eligible employees may purchase common stock through payroll deductions of up to 10.0% of compensation during the plan period. On January 19, 2015, the Compensation Committee of the Board approved the change in the purchase price to 85.0% of market price at the end of each plan period, which is generally three months. A total of 5,853, 3,625 and 3,550 shares of common stock were purchased under the ESPP during the years ended December 31, 2014, 2013 and 2012, respectively. The Company received approximately \$35,000, \$24,000, and \$20,000 upon purchase of shares under the ESPP for the years ended December 31, 2014, 2013 and 2012, respectively.

Tax Benefits

As of December 31, 2014, the balance of the Company's additional paid-in capital pool related to tax windfall benefits from the stock option exercises was \$325,000.

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.

16. Income Taxes

Income (loss) before income taxes for the years ended December 31, 2014, 2013 and 2012 is as follows:

	Year Ending December 31,							
	 2014		2013		2012			
U.S.	\$ 18,005	\$	9,175	\$	8,580			
Foreign	9,128		1,768		(603)			
	\$ 27,133	\$	10,943	\$	7,977			

The provision (benefit) for income taxes consists of the following for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,								
(In thousands)	2	2014	2013	2012					
Current tax provision (benefit):									
U.S. Federal	\$	11,319	\$ 5,198	\$	1,431				
U.S. State		1,351	1,008		658				
Foreign		793	(582)		51				
Total current tax provision (benefit)		13,463	5,624		2,140				
Deferred provision (benefit):									
U.S. Federal		(172)	(1,783)		1,248				
U.S. State		(16)	(279)		(193)				
Foreign		730	366		(279)				
Total deferred provision (benefit)		542	(1,696)		776				
		_							
Total income tax provision (benefit)	\$	14,005	\$ 3,928	\$	2,916				

Deferred tax assets (liabilities), net, consist of the following as of December 31, 2014 and 2013:

	Decem	ber 31,	
	2014		2013
(In thousands)	 		
Deferred tax assets:			
Foreign net operating loss carry-forwards	\$ 1,409	\$	2,538
State net operating loss carry-forwards	3		38
Deferred revenue	1,803		2,143
Accrued expenses	734		1,637
Tax benefits on stock options	2,063		2,378
Inventory	615		1,243
Property and equipment	15		-
Other	 207		220
Gross deferred tax assets	6,849		10,197
Deferred tax liabilities:			
Property and equipment	(122)		(202)
Intangibles	(4,368)		(7,070)
Gross deferred tax liabilities	(4,490)		(7,272)
			, ,
Less: valuation allowance	(2,132)		(1,751)
Net deferred tax assets (liabilities)	\$ 227	\$	1,174

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, 2014, 2013 and 2012:

	Year Ended December 31,								
(In thousands)	2014	2013	2012						
Federal tax provision (benefit)	35.0%	35.0%	34.0%						
State taxes, net of federal tax benefit	2.1%	4.9%	7.3%						
General business credits	0.0%	0.0%	-0.5%						
Changes in valuation allowance	1.4%	-21.6%	-3.9%						
Nondeductible expenses	1.7%	1.3%	1.6%						
Stock based compensation	-0.1%	-2.8%	12.3%						
Impact of intangible transfer	5.8%	7.3%	-18.0%						
Impact of uncertain tax positions	-0.2%	-0.1%	-4.1%						
Adjustment to deferred tax asset	0.5%	11.1%	-10.1%						
Impact of foreign operations	-3.7%	0.3%	5.7%						
Subpart F income	9.1%	0.0%	0.0%						
Change in tax rates	0.0%	0.6%	12.0%						
Changes in other tax matters	0.0%	-0.1%	0.3%						
	51.6%	35.9%	36.6%						

At December 31, 2014 and 2013, the Company had foreign net operating loss carry-forwards of \$5.9 million and \$11.9 million, respectively. Approximately \$1.4 million of the foreign NOLs begin to expire in December 2019, and \$4.5 million of the foreign NOLs do not expire. As of December 31, 2014 and 2013, the Company had no NOLs in the U.S.

As of December 31, 2014 and 2013, the Company had a valuation allowance on its deferred tax assets of \$2.1 million and \$1.8 million, respectively. The net increase in the valuation allowance of \$381,000 was due to additional NOLs in foreign jurisdictions where management believes that it is more likely than not that a portion of the NOL balance will expire prior to utilization and due to other deferred tax assets generated in the period for which a valuation allowance was provided.

In September 2011, the Company internally transferred certain intellectual property and licenses from the Company's subsidiaries, including the U.S. based subsidiary, to SAG. Since the transfer of these assets was to a related party, the recognition of a deferred tax asset by SAG is prohibited and the net tax effect of the transaction is deferred in consolidation. The tax liability generated from this transaction is offset by a deferred charge that is being amortized over ten years. Following the decision of the International Court of Arbitration of the International Chamber of Commerce on the North America Takeda Agreement in July 2012, the Company determined that the internal transfer of the intellectual property was only partially complete and is continuing to evaluate whether the U.S. rights related to AMITIZA will transfer to SAG in the future. This resulted in a reassessment of the deferred charge, deferred tax liability and the mix of profits and losses earned in each jurisdiction. For the year ended December 31, 2012, the Company recorded a benefit of approximately \$1.9 million related to the partial reversal of the internal transfer and reduced the deferred charge and deferred tax liability by approximately, \$23.8 million and \$24.1 million respectively. As of December 31, 2014 and 2013, the total deferred charge is \$2.0 million and \$5.2 million, respectively, after a net current year amortization and impairment expense of \$3.2 million and \$673,000, respectively.

The valuation allowance at December 31, 2014 and 2013 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 and may partially remove the valuation allowance of its foreign subsidiaries in 2015. To the extent the Company determines that all or a portion of its valuation allowance is no longer necessary, the Company will recognize an income tax benefit in the period such determination is made for the reversal of the valuation allowance. Once the valuation allowance is eliminated in whole or in part, it will not be available to offset the Company's future tax provision.

The Company has recorded a total income tax liability of approximately \$842,000 and \$679,000, including interest for uncertain tax positions as of December 31, 2014 and 2013, respectively. The Company expects to reverse \$263,000 of the liability within the next twelve months and has reflected this amount as other current liabilities. The remaining \$579,000 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, 2014 and 2013 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, for the years ended December 31, 2014, 2013 and 2012 is as follows:

	Year Ended December 31,						
		2014		2013		2012	
Balance at January 1	\$	550	\$	979	\$	1,226	
Increases for tax positions taken during prior periods		(91)		4		207	
Decreases in unrecognized tax benefits related to settlements with taxing authorities		-		(467)		(536)	
Increases for tax positions taken during current period		253		34		82	
Balance at December 31	\$	712	\$	550	\$	979	

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision. During 2014, 2013 and 2012, the Company recorded approximately \$1,000, \$22,000 and \$42,000, respectively, of interest related to uncertain tax positions. Other than the decrease related to tax years no longer subject to examination, 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 2011, 2012, 2013 and 2014 remain open and subject to examination in the major tax jurisdictions in which tax returns are filed. The tax years 2009-2011 were examined by the U.S. tax authorities and resulted in no tax adjustments.

17. Segment Reporting

The Company has determined that it has three reportable segments based on the Company's method of internal reporting, which disaggregates business by geographic location. These segments are the Americas, Europe and Asia. The Company evaluates the performance of these segments based on income (loss) from operations, as well as other factors, that depend on the development status of these geographies. Such measures include the progress of its research and development activities, collaboration and licensing efforts, commercialization activities, product sales and other factors. The reportable segments have historically derived their revenue from joint collaboration and strategic alliance agreements. Transactions between the segments consist primarily of loans and the provision of research and development services. Following is a summary of financial information by reportable geographic segment:

(In thousands)		Americas		Europe		Asia	C	Consolidated
Year Ended December 31, 2014								
Research and development revenue	\$	7,246					\$	7,246
Product royalty revenue		62,775						62,775
Product sales revenue		741		422		32,089		33,252
Co-promotion revenue		3,360						3,360
Contract and collaboration revenue		566		8,212		39		8,817
Total revenues		74,688		8,634		32,128		115,450
Costs of goods sold		444		407		15,181		16,032
Intangible assets impairment		1,502		4,129		-		5,631
Research and development expenses		11,566		5,023		3,455		20,044
Depreciation and amortization		601		460		29		1,090
Other operating expenses		32,340		11,259		1,823		45,422
Income (loss) from operations		28,235		(12,644)		11,640		27,231
Interest income		132		6		34		172
Interest expense		(1,364)		(9)		(147)		(1,520)
Other non-operating expense, net		44		653		553		1,250
Income (loss) before income taxes	\$	27,047	\$	(11,994)	\$	12,080	\$	27,133
Capital expenditures	\$	61	\$	2	\$	3	\$	66
As of December 31, 2014								
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Property and equipment, net	\$	566	\$	83	\$	114	\$	763
Identifiable assets, net of intercompany loans and investments	\$	111,846	\$	24,984	\$	4,744	\$	141,574
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)		3,697		3,517
Income (loss) before income taxes	\$	20,983	\$	(12,425)	\$	2,385	\$	10,943
Capital expenditures	\$	40	\$	105	\$	23	\$	168
A. (D								
As of December 31, 2013	ø	960	¢.	110	Ф	175	Ф	1 157
Property and equipment, net	\$	869	\$	112	\$	175	\$	1,156
Identifiable assets, net of intercompany loans and investments	\$	95,350	\$	23,843	\$	17,684	\$	136,877

(In thousands)	A	mericas	Europe	Asia		Consolidated
Year Ended December 31, 2012						
Research and development revenue	\$	6,189	\$ -	\$	15,356	\$ 21,545
Product royalty revenue		50,696	=		-	50,696
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)		1,937	1,827
Income (loss) before income taxes	\$	11,463	\$ (15,861)	\$	12,375	\$ 7,977
Capital expenditures	\$	401	\$ 3,470	\$	-	\$ 3,871

18. Quarterly Financial Data (unaudited)

			2014 Quar	ters	Ended	
(In thousands, except per share data)	Dece	ember 31	September 30		June 30	March 31
Total revenues	\$	37,757	\$ 31,463	\$	24,069	\$ 22,161
Income from operations	\$	17,048	\$ 3,643	\$	3,811	\$ 2,729
Net income	\$	9,283	\$ 1,480	\$	1,610	\$ 755
Net income per share:						
Basic	\$	0.21	\$ 0.03	\$	0.04	\$ 0.02
Diluted	\$	0.21	\$ 0.03	\$	0.04	\$ 0.02

	2013 Quarters Ended							
(In thousands, except per share data)		December 31		September 30		June 30		March 31
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)	\$	2,323	\$	1,523	\$	6,245	\$	(3,076)
Net income (loss) per share:								
Basic	\$	0.06	\$	0.04	\$	0.15	\$	(0.07)
Diluted	\$	0.05	\$	0.04	\$	0.15	\$	(0.07)

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. See "Revisions to Previously Issued Financial Statements" in Note 1.

19. Subsequent Events

On January 16, 2015, the Board voted to increase the authorized size of the Board from eight to nine members and appointed Robert J. Spiegel, M.D., FACP to the Board as a Class II member to fill such new vacancy.

On January 30, 2015, Andrew P. Smith was appointed as the Chief Financial Officer of the Company.

In January 2015, the Company successfully completed the European MRP for AMITIZA for the treatment of CIC in Austria, Belgium, Germany, Italy, Ireland, Luxembourg, Netherlands and Spain, resulting in a recommendation for marketing authorization in these markets. Ireland has notified the Company that it has approved AMITIZA for CIC.

On February 27, 2015, Abbott and Mylan closed Mylan's purchase of Abbott's non-U.S. developed markets specialty and branded generics business, which included the Japan Abbott Agreement.

On March 4, 2015, Messrs. Anthony Celeste and William Ashton advised the Board that they will not stand for election at the 2015 annual shareholder meeting and will resign effective May 28, 2015 from the Board of Directors. The Board has decided to reduce the size of the Board from nine to seven members and will determine if there is a need to increase the size of the Board in the future. In addition, to address proportionality in the classes of directors based on the classification of the Board, on March 5, 2015, Robert J. Spiegel resigned as a Class II director of the Board and was immediately re-elected to the Board by unanimous vote of the Board as a Class III director. Dr. Spiegel was not a member of any committee of the Board and will not receive any new or additional compensation as a result of his reappointment but will continue to be entitled to receive the same compensation he had received prior to his resignation.

On March 9, 2014, the Company announced that it had received a press release from R-Tech concerning the preliminary data from the Phase III RP trial. In light of the information in that release, the Company determined not to engage in any further development of unoprostone. Under those circumstances, the Company notified R-Tech that it would rescind and return all of its rights and interests in and to the licenses for unoprostone to R-Tech. By doing such, R-Tech could find other partners for the development and commercialization of unoprostone outside of Japan.

Schedule II - Valuation and Qualifying Accounts

(In thousands)	 Balance at Beginning of Year	 Additions Charged to Costs and Expenses	=	 Deductions	Balance at End of Year
Allowance for doubtful accounts:					
2012	\$ -	\$ 280	(a)	\$ =	\$ 280
2013	\$ 280	\$ 160	(a)	\$ -	\$ 440
2014	\$ 440	\$ 364	(a)	\$ (779) (b)	\$ 25
Valuation allowance for deferred tax assets:					
2012	\$ 4,467	\$ 1,073	(c)	\$ (1,398) (c)	\$ 4,142
2013	\$ 4,142	\$ -		\$ (2,391) (d)	\$ 1,751
2014	\$ 1,751	\$ 381	(e)	\$ -	\$ 2,132

- (a) In 2012, 2013 and 2014, the increase in allowance for doubtful accounts is associated with certain disputed Takeda invoices.
- (b) The 2014 deduction from allowance for doubtful accounts resulted from a charge-off of certain disputed Takeda invoices.
- (c) In 2012, the net decrease in valuation allowance for deferred tax assets 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 for deferred tax assets 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.
- (e) In 2014, the net increase of \$381,000 in valuation allowance for deferred tax assets was primarily due to the additional NOL's in foreign jurisdictions where management believes it is more likely than not a portion of the NOL balance will expire prior to utilization.

Sucampo Pharmaceuticals, Inc. Exhibit Index

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. (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)
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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)
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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 an indemnitee	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	Exhibit 10.70 to the Company's Annual Report on Form 10-K (filed March 12, 2014)
10.71^	Consulting Agreement, dated February 10, 2014, between the Company and Dr. Ryuji Ueno	Exhibit 10.71 to the Company's Annual Report on Form 10-K (filed March 12, 2014)
10.72*	Lubiprostone Exclusive Manufacturing and Supply Agreement, dated as of January 1, 2014, by and between Sucampo AG and R-Tech Ueno, Ltd.	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.73*	Settlement and License Agreement, dated September 30, 2014, by and among the Company, Sucampo AG, R-Tech Ueno, Ltd., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.74*	Manufacturing and Supply Agreement, dated as of September 30, 2014, by and between Sucampo AG and Par Pharmaceutical, Inc.	Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.75*	Amendment No. 1, dated September 30, 2014, to Collaboration and License Agreement dated October 29, 2004 and Supplemental Agreement, dated February 1, 2006, by and between Sucampo Pharma Americas, LLC and Takeda Pharmaceutical Company Limited	Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.76	Amendment No. 1, dated September 30, 2014, to the Agreement dated October 29, 2004, by and between Sucampo Pharma Americas, LLC, Takeda Pharmaceutical Company Limited and Sucampo AG	Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)
10.77*	Amendment No. 1, dated September 30, 2014, to Supply Agreement dated October 29, 2004, Supply and Purchase Agreement dated January 25, 2006 and the Addendum to the Supply and Purchase Agreement dated November 6, 2013 by and among Sucampo Pharma Americas, LLC, Takeda Pharmaceutical Company Limited and R-Tech Ueno, Ltd.	Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q (filed November 7, 2014)

10.78^	Separation Agreement and General Release, dated November 7, 2014, between the Company and Cary Claiborne	Included herewith
10.79*	Global License Agreement, dated October 27, 2014, between Sucampo AG and Takeda Pharmaceuticals International GmbH Limited	Included herewith
10.80^	Employment Agreement, dated as of October 27, 2014, between the Company and Dr. Peter Kiener	Included herewith
10.81^	Employment Agreement, dated as of October 27, 2014, between the Company and Matthais Alder	Included herewith
10.82^	Employment Agreement, dated as of October 27, 2014, between the Company and Dr. Steven Caffé	Included herewith
10.83^	Amendment, dated as of October 27, 2014, to Employment Agreement, effective as of December 31, 2012, between the Company and Thomas J. Knapp	Included herewith
10.84^	Amendment, dated as of October 27, 2014, to Consulting Agreement, dated September 14, 2013, between the Company and Peter Lichtlen	Included herewith
10.85^	Amendment, dated as of October 27, 2014, to Employment Agreement, effective as of December 31, 2012, between the Company and Stanley G. Miele	Included herewith
10.86^	Intentionally left blank	
10.87	Registration Rights Agreement, dated January 15, 2015, by and among the Company, S&R Technology Holdings, LLC, S&R Foundation, Dr. Ryuji Ueno and Dr. Sachiko Kuno.	Exhibit 10.1 to the Company's Form S-3 filed January 16, 2015
10.88*	Stipulation and License Agreement, dated February 5, 2015, by and among the Company, Sucampo AG, R-Tech Ueno, Ltd. and Par Pharmaceutical, Inc.	Included herewith
10.89*	Manufacturing and Supply Agreement, dated as of February 5, 2015, by and between Sucampo AG and Par Pharmaceutical, Inc.	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. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith

[^] Compensatory plan, contract or arrangement.

^{*} Confidential treatment has been granted for portions of this exhibit.

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

SEPARATION AGREEMENT AND RELEASES

This Separation Agreement and Releases ("Separation Agreement") is made and entered into as of the 11/7/14, by and between Cary Claiborne (hereinafter "Executive") and Sucampo Pharmaceuticals, Inc. ("SPI"), a corporation organized under the laws of the State of Delaware, and its affiliates (hereinafter collectively referred to as the "Company").

WHEREAS, Executive and SPI are parties to an Employment Agreement dated as of December 31, 2012 (hereinafter, the "Employment Agreement");

WHEREAS, Executive and Company intend to settle any and all claims that Executive may have against Company as a result of any act, occurrence, decision, event or omission occurring at any time prior to the signing of this Separation Agreement, including, but not limited to, any matter or fact arising out of Executive's employment with SPI, compensation during the employment, the termination of Executive's employment, or the events giving rise to the Employment Agreement or this Separation Agreement;

WHEREAS, the parties have had extensive negotiations concerning the terms and conditions of the Executive's separation arrangement from the Company, and they have agreed upon such terms and conditions as set forth in this Separation Agreement;

NOW, THEREFORE, in consideration of the severance payments and benefits, obligations and covenants all contained herein, the parties agree as follows:

 Termination of Employment. Executive's last day of active employment with the Company is November 7, 2014.

- 2. Separation Agreement. Executive understands that any payments or benefits paid or granted to him pursuant to this Separation Agreement represent consideration for signing this Separation Agreement and are not salary, wages or benefits to which Executive was already entitled. Executive understands that, in light of the circumstances surrounding his employment with the Company, the Company chose to terminate the Employment Agreement, but in consideration for Executive's execution of this Separation Agreement, the Company has agreed to provide the Executive with payment and benefits in excess of the payments and benefits described in the Employment Agreement for such termination. Executive understands that he will not receive any payments or benefits from the Company unless (a) he executes this Separation Agreement and does not revoke it within the time period permitted herein, and (b) he complies with all obligations in this Separation Agreement and does not breach it. Pursuant to the terms of this Separation Agreement, Executive will receive the following benefits:
 - a. payment of Executive's base salary through November 7, 2014;
 - b. a lump sum severance payment of \$171,752.31, less all taxes and withholdings, to be made by no later than ten (10) business days following the execution of Exhibits A and B in accordance with Section 9 of this Separation Agreement without any revocation having occurred;
 - c. in the event you elect COBRA, the COBRA continuation premium payments will be made by the Company during the six (6) month period following the termination date;
 - the accelerated vesting of 111,151 unvested options upon Executive's termination of employment; and

- e. payment for any accrued and unused PTO through November 7, 2014.
- Release of Claims by Executive. Executive and the Company intend to settle any and all claims that Executive may have against the Company as a result of the hiring of Executive, Executive's employment, Executive's compensation while employed, and the termination of Executive's employment. Executive agrees that in exchange for SPI's promises in the Agreement and in exchange for the separation pay and benefits to be paid to Executive as described in the Agreement, Executive, on behalf of Executive and Executive's heirs, successors and assigns, hereby releases and forever discharges the Company, its predecessors, successors, and assigns, and their respective boards of directors, board committees, officers, directors, shareholders, agents, employees, and insurers (the "Released Parties"), from all liability for damages and from all claims that Executive may have against the Released Parties arising from or relating to the hiring of Executive, Executive's compensation while employed, Executive's employment, the termination of Executive's employment, and any other actions, decisions, alleged omissions, or events occurring on or prior to the signing of this Separation Agreement.
- A. Executive understands and agrees that Executive's release of claims in this Separation Agreement includes, but is not limited to, any claims Executive may have under Title VII of the Federal Civil Rights Act of 1964, as amended; the Americans with Disabilities Act, the Equal Pay Act, the Fair Labor Standards Act, the Employee Retirement and Income Security Act, the Age Discrimination in Employment Act, the Family and Medical Leave Act, the Maryland Fair Employment Practices Act, or any other federal, state, or local statute, ordinance, or law.

- B. Executive also understands that Executive is giving up all other claims, whether grounded in contract or tort theories, including, but not limited to, wrongful discharge, breach of contract, tortious interference with contractual relations, promissory estoppel, detrimental reliance, breach of the implied covenant of good faith and fair dealing, breach of express or implied promise, breach of manuals or other policies, breach of fiduciary duty, assault, battery, fraud, invasion of privacy, intentional or negligent misrepresentation, defamation, including libel, slander, discharge defamation and self-publication defamation, discharge in violation of public policy, whistleblower, intentional or negligent infliction of emotional distress, or any other theory, whether legal or equitable.
- C. Executive will not institute any lawsuit against the Released Parties arising from or relating to the hiring of Executive, Executive's employment, Executive's compensation while employed, the termination of Executive's employment, or any other actions, decisions, alleged omissions, or events occurring prior to the signing of this Separation Agreement.
- D. To the extent required by law, nothing contained in this Separation Agreement will be interpreted to prevent Executive from filing a charge with a governmental agency or participating in or cooperating with an investigation conducted by a governmental agency. However, Executive agrees that Executive is waiving the right to any monetary damages or other individual legal or equitable relief awarded as a result of any such proceeding related to any claim against the Released Parties arising from or relating to the hiring of Executive, Executive's employment, Executive's compensation while employed, the termination of Executive's employment, or any other actions, decisions, alleged omissions, or events occurring on or prior to the signing of this Separation Agreement.

- E. Notwithstanding any of the foregoing, this Separation Agreement shall not apply with respect to any rights or claims which Executive may have under this Separation Agreement itself or to any rights or benefits Executive may have related to vested accrued benefits under the terms of the Company's benefit plans or to the Executive's right to be indemnified by the Company pursuant to the terms of its bylaws and the law of the State of Delaware.
- F. Executive expressly acknowledges that he has been given the opportunity to take twenty-one (21) days to review this Separation Agreement before signing it, and that he has been advised to consult with an attorney before signing it. Executive acknowledges that he understands that he may revoke this Separation Agreement, insofar as it extends to potential claims under the Age Discrimination in Employment Act, by informing the Company of Executive's intent to revoke this release within seven (7) days following the execution of this Separation Agreement, and that this Separation Agreement is not effective or enforceable until that seven-day revocation period has expired. Executive understands that any such revocation must be stated in writing and delivered by hand or by certified mail-return receipt requested to Max Donley, Executive Vice President of Human Resources, Sucampo Pharmaceuticals, Inc., 4520 East West Highway, Third Floor, Bethesda, Maryland 20814. If Executive exercises this right to revoke or rescind, the Company shall have no obligation to provide severance pay or benefits to Executive as provided by the Agreement.
- G. Executive acknowledges that the Company's obligation to provide any severance pay or benefits pursuant to the Agreement shall not become effective or enforceable until this Separation Agreement has been executed and the revocation period identified above has expired without notice of revocation having been made.

- H. Executive agrees that he will forfeit all amounts payable by the Company under this Separation Agreement if he challenges the validity of this Separation Agreement. Executive also agrees that if he violates this Separation Agreement by suing the Company or the other Released Parties, in the event that the Company is the prevailing party, Executive will pay all costs and expenses of defending against the suit incurred by the Released Parties, including reasonable attorneys' fees, and return all payments received by Executive on or after the termination of his employment.
- I. Executive hereby acknowledges and states that Executive has read this Separation Agreement; this Separation Agreement is written in language which is understandable to Executive, that Executive fully appreciates the meaning of the terms of this Separation Agreement, and that Executive enters into this Separation Agreement freely and voluntarily.
- 4. Release of Claims by Company. The Company, its boards of directors, board committees, officers, directors, shareholders, agents, and employees agree and forever discharge and release Executive, his heirs, assign, executors and administrators from any and all claims, actions, causes of action, grievances, arbitrations, suits, proceedings, debts, controversies, agreements, attorney fees, judgments, demands, and damages whatsoever, in law or equity, arising from or relating to any actions, decisions, alleged omissions, or events occurring on or prior to the signing of this Separation Agreement, except any action or proceeding which the Company may be required or requested to take against Executive as a result of any regulatory agency action. This includes, but is not limited to, any claims arising from or relating to Executive's employment with, and recruitment to, the Company, and Executive's termination of employment. Nothing in this Separation Agreement releases or waives Company's right to enforce any breach or violation of this Separation Agreement.

- 5. Confidentiality. Executive agrees that this Separation Agreement and the Employment Agreement are confidential and agrees not to disclose any information regarding the terms of this Separation Agreement or the Employment Agreement, except to his immediate family and any tax, legal or other counsel he has consulted regarding the meaning or effect hereof or as required by law, and he will instruct each of the foregoing not to disclose the same to anyone. The Company agrees to disclose any such information only to any tax, legal or other counsel of the Company as required by law. Further, Executive shall not affirmatively make any public or private statements about his employment or separation from the Company except to his immediate family and any tax, legal or other counsel he has retained, unless authorized in writing by the Company; except however, that in response to any inquires from any media or third party, Executive only can state that "Executive and the Company have agreed to part ways on an amicable basis upon the conclusion of the Employment Agreement." Company shall provide dates of employment and positions held by Executive in response to any inquiry made by a third party for any purpose regarding Executive's employment by the Company, and shall not be required to provide any other reference for Executive, whether oral or written.
- 6. Executive Cooperation. As long as there is no conflict between Executive's legal interests and those of the Company, Executive agrees that he shall, to the extent reasonably requested in writing, cooperate with and serve in any capacity requested by the Company in any investigation and/or threatened or pending litigation (now or in the future) in which the Company is a party, and regarding which Executive, by virtue of his employment with the Company, has knowledge or information relevant to said investigation or litigation including, but not limited to (i) meeting with representatives of the Company to prepare for testimony and to provide truthful information regarding his knowledge, (ii) acting as the Company's representative, and (iii)

providing, in any jurisdiction in which the Company requests, truthful information or testimony relevant to the investigation or litigation. Company agrees to reimburse Executive's reasonable expenses incurred for his cooperation under this Paragraph 6 and to compensation Executive for his time on a mutually agreeable basis.

Executive also agrees to cooperate with the Company and its counsel in connection with any matters relating to the Company in which Executive has been compelled, by subpoena or other compulsory, to testify or produce documents. Executive shall provide notice to the Company within 48 hours of receiving such notice and agrees to (i) meet with the Company's representatives and attorneys (ii) provide the attorneys with any documents requested, and (iii) prepare for any appearance with the Company's attorneys.

Executive, at his own expense, may retain his own counsel, in lieu of or in addition to, the Company's counsel. Executive's appointment of his own counsel shall in no way interfere with his obligation to cooperate with the Company as described herein.

7. Mutual Non-Disparagement. Executive and the Company agree that, at all times following the signing of this Separation Agreement, they shall not engage in any disparagement or vilification of the other, and shall refrain from making any false, negative, critical or otherwise disparaging statements, implied or expressed, concerning the other, including, but not limited to, the management style, methods of doing business, the quality of products and services, role in the community, treatment of employees or the circumstances and events regarding Executive's employment separation. Executive acknowledges that the only persons whose statements may be attributed to the Company for purposes of this Separation Agreement not to make disparaging statements shall be each member of the Board of Directors of the SPI and each of SPI's senior executive officers. The parties further agree to do nothing

that would damage the other's business reputation or good will. Nothing in this Separation Agreement prevents the Company responding to subpoenas, government inquiries or other obligations they may have under the law or from reporting criminal activities to appropriate authorities.

- Agreement. Executive and the Company will be bound by and comply with all provisions of Article 5 of the Employment Agreement, for the durations expressly stated in Article 5, all of which are incorporated by reference into this Separation Agreement. Aside from Article 5 of the Employment Agreement, which is incorporated herein, this Separation Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, the Employment Agreement. In addition, no provision of this Separation Agreement may be amended, modified, changed, altered, or supplemented except by a writing that is signed by Executive and by the Company.
- 9. Post-Employment General Release and Termination Certificate. As consideration for the payments and benefits Executive receives under this Separation Agreement, Executive agrees to execute the Termination Certificate attached as Exhibit A by November 14, 2014. If Executive fails to execute and return such documents to the Company by November 28, 2014, Executive forfeits his right to all payments and benefits in the Separation Agreement.
- 10. <u>Indemnification Rights</u>. In the event Executive is named as a defendant in a lawsuit because of his role as an officer, manager, or employee of the Company, Executive shall be entitled to the same indemnification rights and directors and officers liability coverage he had while employed by the Company. In any such lawsuit, the Company shall have the option of

designating counsel for Executive and Executive agrees that his counsel shall enter into a joint defense agreement with the attorneys for the Company and any of its officers, directors, shareholders, employees, or other agents or representatives with respect to their common defense.

- 11. <u>Severability</u>. Any provisions of this Separation 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 Separation Agreement be deemed to be a valid and binding agreement enforceable in accordance with its terms.
- 12. <u>Controlling Law</u>. This Separation 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.
- Arbitration. Any controversy, claim, or breach arising out of or relating to this Separation 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 the Employment Agreement as incorporated into this Separation Agreement.

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 Separation 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 Separation 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.

EXECUTIVE ACKNOWLEDGES THAT HE HAS READ THIS ENTIRE SEPARATION AGREEMENT CAREFULLY, AS THIS SEPARATION AGREEMENT INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS (AS ALLOWED BY LAW) WHICH HE MAY HAVE AGAINST THE COMPANY INCLUDING CLAIMS PURSUANT TO THE AGE DISCRIMINATION IN EMPLOYMENT ACT.

IN WITNESS WHEREOF, Executive after due consideration and consultation, has authorized, executed, and delivered this Separation Agreement all as of the date first above written.

Cary Claiborne

Sucampo Pharmaceuticals, Inc.

by Peter Greenleaf

Chief Executive Officer

TERMINATION CERTIFICATE

I hereby certify that I do not have in my possession or under my control, nor have I failed to return, any "Company Materials" as defined in that certain Employment Agreement entered into before Sucampo Pharmaceuticals, Inc., a Delaware corporation, and me, dated as of December 31, 2012.

I further certify that I have complied with and will continue to comply with all the terms of the Separation Agreement.

Cary Claiborne
11/7/14

Date

Exhibit 10.79

*** Text Omitted and Filed Separately Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2

LICENSE, DEVELOPMENT, COMMERCIALIZATION AND SUPPLY AGREEMENT FOR LUBIPROSTONE

by and between

Takeda Pharmaceuticals International GmbH

and

SUCAMPO AG

Dated as of October 17, 2014

LICENSE, DEVELOPMENT, COMMERCIALIZATION AND SUPPLY AGREEMENT FOR LUBIPROSTONE

This LICENSE, DEVELOPMENT, COMMERCIALIZATION, AND SUPPLY AGREEMENT FOR LUBIPROSTONE ("<u>Agreement</u>") is entered into as of October 17, 2014, by and between **Sucampo AG**, a corporation organized under the laws of Switzerland with principal offices at Baarerstrasse 22, CH-6300, Zug, Switzerland ("<u>Sucampo</u>") and **Takeda Pharmaceuticals International GmbH**, a corporation organized under the laws of Switzerland with principal offices at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland ("<u>Takeda</u>"). Each of Takeda and Sucampo is sometimes referred to individually herein as a "<u>Party</u>" and collectively as the "<u>Parties</u>".

BACKGROUND

WHEREAS, Sucampo has rights in the Sucampo Patent Rights and the Sucampo Background Technology related to the Product in the Field in and outside the Territory (as such terms are hereinafter defined);

WHEREAS, Takeda and its Affiliates form a pharmaceutical group of companies with research, development and manufacturing activities worldwide; and

WHEREAS, Takeda desires to obtain, and Sucampo is willing to grant to Takeda, an exclusive license (except as to Sucampo and its Affiliates) to Develop the Licensed Product in the Field in the Territory and outside of the Territory for the Territory, an exclusive license (including as to Sucampo and its Affiliates) to Commercialize the Licensed Product in the Field in the Territory under an exclusive license (including as to Sucampo and its Affiliates as further described hereinafter) to the Product Trademark and a non-exclusive license to undertake Secondary Packaging of the Product in and outside the Territory for the Territory (as such terms are hereinafter defined).

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

ARTICLE 1 DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this ARTICLE 1 shall have the meanings specified below:

"Adverse Event/Reaction" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. In addition to the foregoing, in the context of Clinical Studies in the Field in the applicable country in the Territory, an Adverse Event/Reaction will also mean events associated with and/or possibly attributable to the Clinical Studies or Clinical Study procedures. For the avoidance of doubt, an "Adverse Event/Reaction" includes all occurrences which would be regarded as "adverse drug reactions" under Applicable Law in the applicable country in the Territory.

"Affiliate" means, with respect to a Party, any Person that, directly or indirectly, controls, or is controlled by, or is under common control with, such Party. For purposes of this definition, "control" means (a) ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the voting equity interests in the case of any other type of legal entity, (b) status as a general partner in any partnership, or (c) any other arrangement whereby a Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity.

"Agreed Quality" has the meaning set forth in Section 9.1.3.

"Agreement" means this License, Development, Commercialization and Supply Agreement for Lubiprostone, as identified in the preamble, including all Exhibits hereto, as this Agreement (including such Exhibits) may be amended from time to time in accordance with its terms.

"Alliance Manager" means the person appointed by each Party from within their respective organization to coordinate and facilitate the communication, interaction and cooperation of the Parties pursuant to this Agreement. The Alliance Managers shall be the primary contact between the Parties with respect to the activities conducted pursuant to this Agreement.

"Ancillary Agreements" means the Quality Agreement, Pharmacovigilance Agreement or any other agreements the Parties will confirm as Ancillary Agreements.

"Annual Net Sales" means the cumulative Net Sales during any given Calendar Year.

"Applicable Law" means all federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations or orders of Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or exercise of rights hereunder.

"Audited Party" has the meaning set forth in Section 8.6.

"Auditing Party" has the meaning set forth in Section 8.6.

"Background Technology" means any Technology except for Developed Technology that a Party (a) has developed or acquired prior to the Effective Date and/or (b) can show it developed entirely independently of and without any reference to any information, data or materials of the other Party or its Affiliates. For the avoidance of doubt, Background Technology of Sucampo shall be deemed to, and shall, include the Sucampo Background Technology.

"Back-Up Supplier" means a Person selected by Sucampo to provide the Licensed Product in the event the supplier initially selected by Sucampo fails to deliver or is at risk to not be able to deliver the Compound or Licensed Product according to terms hereunder.

"Business Day" means a day, other than a Saturday or Sunday, on which banking institutions in the applicable country in the Territory are supposed to be open for business.

"Calendar Year" means each successive period of twelve (12) consecutive calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31, 2014, and the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which the Term ends and end on the last day of the Term.

"cGCP" means the then-current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials for pharmaceuticals as set forth in the International Conference on Harmonization (ICH) guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," and equivalent regulations or standards in the applicable country in the Territory and any update thereto and any other policies or guidelines applicable to the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials for pharmaceuticals in such country in the Territory, and/or any applicable foreign equivalents thereof, and any updates to any of the foregoing.

"cGMP" means the quality systems and then-current good manufacturing practices applicable to the manufacture, labeling, packaging, handling, storage, and transport of the Compound and the Product, as set forth by the EMA, the FDA, and equivalent foreign regulations or standards and any update thereto and any other policies or guidelines applicable to the manufacture, labeling, packaging, handling, storage, and transport of pharmaceutical products in the applicable country in the Territory, and/or any applicable foreign equivalents thereof, and any updates to any of the foregoing.

"CC Indication" means the prophylactic or therapeutic use in the prevention and/or treatment of chronic constipation.

"Clinical Data" means all data with respect to any product containing the Compound for use in the Field that is made, collected or otherwise generated anywhere in the world under or in connection with the Clinical Studies for a product containing the Compound for use in the Field (as opposed to Pre-Clinical Data or non-clinical data derived from laboratory studies, disease models and animal studies) in the applicable country in the Territory. Clinical Data includes, but is not limited to, validated clinical databases.

"Clinical Study(ies)" means Phase I Study, Phase II Study, Phase IV Study conducted anywhere in the world, or such other tests or studies in humans conducted anywhere in the world.

"CMC Data" means the data contained in the chemistry, manufacturing and controls section of an IND or MAA (or similar sections of their counterparts in the applicable countries in the Territory) for Regulatory Approval of the Licensed Product in the Field in the applicable country in the Territory.

"Commercialization" or "Commercialize" means any and all activities (whether before or after Regulatory Approval) directed to the commercialization of the Licensed Product in the Field in the applicable country in the Territory, including pre-launch and post-launch marketing, Promoting, distributing (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering the Licensed Product to customers), offering to sell and selling, sales force efforts, detailing, advertising, marketing, sales and distribution, pricing, contracting managed markets and medical affairs, including publications, medical education, medical information, clinical science liaison activities, investigator initiated sponsored research programs health economics and outcomes research, the preparation, filing, and maintenance of Regulatory Approvals, including the filing of annual updates, Phase IV Studies, Post Approval Marketing Studies and other activities similar to any of the activities listed above that directly relate to the Licensed Product in the Field in such country in the Territory. For purposes of this Agreement, "Commercialization" shall not include activities constituting Manufacturing under this Agreement. When used as a verb, "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

"Commercialization Plan" means a written one (1) year plan for the Commercialization of the Licensed Product in the Field in Key Markets in the Territory as further described in Section 7.1.

"Commercially Reasonable Efforts" means, with respect to the efforts to be expended, or considerations to be undertaken, by a Party or its Affiliate with respect to any objective, activity or decision to be undertaken hereunder, reasonable, good faith efforts to accomplish such objective, activity or decision as such Party would normally use to accomplish a similar objective, activity or decision under similar circumstances, it being understood and agreed that with respect to the Development or Commercialization of the Licensed Product, such efforts and resources shall be consistent with those efforts and resources commonly used by a Party under similar circumstances for similar products owned by it or to which it has similar rights, which product, as applicable, is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products sold by third parties in the marketplace, the patent and other proprietary position of the compound or product, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the product taking into considerations, among other factors, third party costs and expenses including among other things any royalties, milestone and other payments required under this Agreement, and the pricing and reimbursement relating to the product. Commercially Reasonable Efforts shall be determined on a market-by-market and indication-by-indication basis for the Licensed Product, as applicable, and it is anticipated that the level of effort will change over time, reflecting changes in the status of the Licensed Product, as applicable, and it is anticipated that the level of effort will change over time, reflecting changes in the status of the Licensed Product, as applicable, and it is anticipated that the level of effort will change over time, reflecting changes in the status of the Licensed Product; as applicable, and it is reasonable opinion afte

"Committee(s)" has the meaning set forth in Section 3.1.1. Each of the JWG and JSC is sometimes referred to individually herein as a "Committee" and collectively as the "Committees."

"Competing Product" has the meaning set forth in Section 7.5.

"Compound" means lubiprostone as further described in EXHIBIT A, and its salts, metabolites, as well as any active pro-drugs, isomers, tautomers, hydrates and polymorphs.

"Confidential Information" means any and all information or material, whether oral, visual, in writing or in any other form, that has been disclosed to the Receiving Party or any of its Affiliates by or on behalf of the Disclosing Party or any of its Affiliates pursuant to this Agreement or in connection with the transactions contemplated hereby or any discussions or negotiations with respect thereto, including pursuant to the Confidentiality Agreement and that may be reasonably understood from notices or legends, the nature of such information itself or the circumstances of such information or materials' disclosure to be confidential or proprietary to the Disclosing Party. For the avoidance of doubt, "Confidential Information" of Sucampo ("Sucampo Confidential Information") shall include the Sucampo Background Technology, Sucampo Developed Technology, Sucampo Developed Patent Rights, Pre-Clinical Data, Clinical Data, CMC Data, Manufacturing Data and other Data, content, Sucampo Know-how, unpublished patent applications (including any patent applications included as part of the Sucampo Patent Rights) and Technology and all other information and materials, disclosed or made available by or for Sucampo or its Affiliates to Takeda and/or its Affiliates that relate to Sucampo's research, clinical development, non-clinical development, marketing, sales and promotion (including, financial information, procurement requirements, purchasing and manufacturing information, customer lists and other customer-related information, business forecasts and sales, pricing information, detailing-related information, and marketing and merchandising plans and information), or other aspects of Sucampo's business. For the avoidance of doubt, "Confidential Information" of Takeda ("Takeda Confidential Information") shall include the Takeda Developed Technology and Takeda Developed Patent Rights and other Data, content, know-how, unpublished patent applications (including any patent applications included as part of the Takeda Developed Patent Rights) and Technology and all other information and materials, disclosed or made available by or for Takeda or its Affiliates to Sucampo and its Affiliates that relate to Takeda's research, clinical development, non-clinical development, marketing, sales and promotion (including, without limitation, financial information, procurement requirements, purchasing and manufacturing information, customer lists and other customer-related information, business forecasts and sales, pricing information, detailing-related information, and marketing and merchandising plans and information), or other aspects of Takeda's business.

"Confidentiality Agreement" means the Confidentiality Agreement by and between Takeda Pharmaceuticals International GmbH and Sucampo Pharmaceuticals, Inc., effective as of April 1, 2013, as amended.

"Control" or "Controlled" means, with respect to any Confidential Information, Technology, Patent Right, Other Intellectual Property Right, Data, Data Exclusivity or Regulatory Filing, either (a) ownership of such item or (b) possession of the right to grant a license or sublicense (but only to the extent of such right).

"Core Data Sheet" means a document prepared by the Regulatory Approval holder containing, in addition to the Company Core Safety Information (CCSI), material relating to the CC Indication, IBS-C Indication OIC Indication, dosing, pharmacokinetics, and other information on the Licensed Product for use in the Field in the applicable country in the Territory based on scientific data that are positioned on appropriate prescribing information for safe and effective use of the Licensed Product in the Field in such country in the Territory.

"Corporate Names" means (a) in the case of Takeda, the Trademark Takeda and the Takeda corporate logo or such other names and Trademarks used generally by Takeda and its Affiliates in their business (and not relating to a specific product or Technology) as Takeda may designate in writing from time to time, and (b) in the case of Sucampo, the Trademark Sucampo and the Sucampo corporate logo or such other names and Trademarks used generally by Sucampo and its Affiliates in its business (and not relating to a specific product or Technology), together with any variations and derivatives thereof.

"Data" means the Pre-Clinical Data, Clinical Data, CMC Data and Manufacturing Data and any other data and information generated by or on behalf of one or both of the Parties during the Term in connection with the Compound and Licensed Product.

"<u>Data Exclusivity</u>" means any data or market exclusivity granted with respect to the Licensed Product in the Field in the applicable country in the Territory by any Regulatory Authority as of the Effective Date or at any time during the Term.

"Development" or "Develop" means all development and research and all pre-clinical and clinical activities conducted relating to the Licensed Product, including test method development and stability testing, toxicology, animal studies, formulation, process development, manufacturing scale-up, quality assurance/quality control development for Clinical Studies in the Field, statistical analysis and report writing, and Clinical Studies in the Field, including clinical trial design, operations, data collection and analysis and report writing, publication planning and support, risk assessment mitigation strategies, health economics outcomes research planning and support, clinical laboratory work, disposal of drugs and regulatory activities in connection therewith, the transfer of information, materials, Licensed Product regulatory documentation and other Technology with respect to the foregoing, in the Field. When used as a verb, "Developing" means to engage in Development and "Developed" has a corresponding meaning.

"Development Plan" means a written rolling three (3) year plan for the Development of the Licensed Product in the Field in the applicable country in the Territory, as such plan may be amended or updated from time to time in accordance with Section 4.1.1.

"Developed Patent Rights" has the meaning set forth in Section 2.1.4.

"Developed Technology" has the meaning set forth in Section 2.1.4.

"Developing Parties" has the meaning set forth in Section 2.1.4.

"Disclosing Party" means the Party disclosing Confidential Information; provided that, with respect to each Party's confidentiality obligations, a Party owning certain property as provided hereunder shall be considered the Disclosing Party and the other Party shall be considered the Receiving Party regardless of which Party discloses such information.

- "Discretionary Changes" has the meaning set forth in Section 9.1.10.
- "Dispute" has the meaning set forth in EXHIBIT G.
- "Disputed Matter" has the meaning set forth in Section 3.1.5.
- "<u>Distributor</u>" means any Third Party (other than any of Takeda's Affiliates) appointed by Takeda to Commercialize in the applicable country in the Territory the Licensed Product purchased from Takeda, its Affiliates or other Sublicensees (regardless of whether such Third Party has the right or obligation to provide Secondary Packaging services with respect to such Licensed Product).
 - "DMF" means drug master file or other comparable application or filing with the applicable Regulatory Authority in the applicable country in the Territory.
 - "Effective Date" means the date first set forth in the preamble to this Agreement.
- "EMA" means the European Medicines Agency or any successor agency with a similar scope of responsibility regarding the regulation of human pharmaceutical products in the European Union.
 - "Emergency Arbitrator" has the meaning set forth in Section 6 in EXHIBIT G.
 - "European Paediatric Investigation Plan" shall have the meaning set forth in Section 4.3.4/EXHIBIT M.
 - "Existing Regulatory Approvals" means those Regulatory Approvals listed in EXHIBIT B hereof.
- "FDA" means US Food and Drug Administration or any successor agency with responsibility regarding the regulation of human pharmaceutical products in the United States.
 - "Field" means all prophylactic and therapeutic uses in animals and humans for all gastrointestinal indications related to the Compound.
- "First Commercial Sale" means the first bona fide commercial sale of a Licensed Product for use or consumption in the Field in any country in the Territory by Takeda, its Affiliates or Sublicensees to a Third Party (other than any of Takeda's Affiliates) in such country in the Territory after all required applicable Regulatory Approvals for such country have been granted.

"Force Majeure" has the meaning set forth in Section 17.10.

"GAAP" means generally accepted accounting principles recognized in any applicable country in the Territory, and being subject to International Financial Reporting Standard (IFRS) as applicable.

"GSDB" has the meaning set forth in Section 6.3.

"IBS-C Indication" means the prophylactic or therapeutic use in the prevention and/or treatment of constipation-predominant irritable bowel syndrome.

"IND" means an Investigational New Drug Application or other comparable application or filing with the applicable Regulatory Authority in the applicable country in the Territory, including but not limited to clinical trial application, necessary to commence Clinical Studies in such country in the Territory.

"Indemnification Claim Notice" has the meaning set forth in Section 16.3.1.

"Indemnitee" means any Sucampo Indemnitees or Takeda Indemnitees claiming indemnification under Sections 16.1 or 16.2, as applicable.

"Infringement" has the meaning set forth in Section 11.5.1.

"Infringement Notice" has the meaning set forth in Section 11.5.1.

"Inventory Sale Period" shall mean the period set forth in Section 12.3 (c).

"JWG" has the meaning set forth in Section 3.1.1(b).

"JSC" has the meaning set forth in Section 3.1.1(a).

"Key Markets" shall mean Brazil, Italy, Mexico, Russia, Saudi Arabia, South Korea, Switzerland, UK.

"<u>Latent Defect</u>" means with respect to Licensed Product delivered to Takeda according to Section 9.2, a Licensed Product non-conforming to Sucampo's warranty for the Licensed Product set forth in Section 9.1.2, such that (i) the related non-conformance of such Licensed Product is not readily discoverable or not reasonably expected to be readily discoverable based on Takeda's, its Affiliates' or other Sublicensees' normal, industry-standard and Commercially Reasonable Efforts for incoming-goods inspections, as the case may be and (ii) the non-conformance was not caused directly or indirectly by the Secondary Packaging or any acts or omissions of Takeda, its Affiliates, Sublicensees, Subcontractors or any other parties for whom Takeda is responsible hereunder.

"<u>Licensed Product</u>" means any product comprising the Compound (whether as sole active ingredient or in combination with one or more other active ingredients), including all dosage forms, dosage strengths and delivery modes. Examples of package presentations of the Licensed Product are specified in EXHIBIT H. The term "Licensed Product" as used herein may be used to reference one or more than one Licensed Product.

"Losses" has the meaning set forth in Section 16.1.

"Manufacture" or "Manufacturing" means all activities related to the manufacturing of a Compound or Licensed Product, including manufacturing of Licensed Product for Development and Commercialization, primary packaging in bottle and blister pack (consisting of labeling the bottle of the Licensed Product with appropriate batch number and the blister foil of the Licensed Product with the Product Trademark and lot number), in-process and Licensed Product testing, validation, process improvement, and process development, release of Licensed Product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of Licensed Product, ongoing stability tests and regulatory activities related to any of the foregoing. The Parties agree and acknowledge that Secondary Packaging shall be excluded from the definition of "Manufacturing".

"Manufacturing Data" means all information and data relating to or used in connection with the manufacturing of the Compound and/or Licensed Product by Sucampo or its Affiliates or other Third Parties working under authority of such entities, including without limitation, such information and data as generated or used during process development, stability studies, formulation development, scale-up of manufacturing, production of preclinical and clinical product batches, validation studies, development of quality assurance/quality control testing, and related regulatory affairs; and all information and data contained in the DMF or in the CMC section of an IND or MAA (or their counterparts in other countries) with respect to the Compound and/or Licensed Product. Notwithstanding the foregoing, to the extent Sucampo and/or its Affiliates do not have rights to such know-how, the term "Manufacturing Data" shall exclude any proprietary manufacturing know-how described in a DMF that was disclosed by a contract manufacturer of Sucampo or its Affiliates directly to the Regulatory Authority (and not to Sucampo or its Affiliates), which know-how had been entirely independently and separately developed by such contract manufacturer prior to the first agreement between Sucampo and/or its Affiliates and such contract manufacturer or which Sucampo and/or its Affiliates otherwise do not Control or have the right to disclose.

"Market Withdrawal" means the removal or correction of a Licensed Product in the Field in the applicable country in the Territory which involves a minor violation that would not be subject to legal action by the applicable Regulatory Authority or which involves no violation, including without limitation, normal stock rotation practices, routine equipment adjustments and repairs.

"Marketing Authorization Application" or "MAA" means, with respect to any Licensed Product, an application or other comparable application or filing and all amendments and supplements thereto filed with the applicable Regulatory Authority requiring such filing, including all documents, Data, and other information concerning such Licensed Product which are necessary for obtaining Regulatory Approval to Manufacture and Commercialize such Licensed Product in the applicable country in the Territory.

"Net Sales" means, for any period, the total amount billed or invoiced on sales of Licensed Product in the Field in the applicable country in the Territory by Takeda or its Affiliates less the following deductions (specifically excluding any payments made by Takeda or its Affiliates to Sucampo pursuant to this Agreement), in each case related specifically to the Licensed Product in such country in the Territory and actually allowed and taken by such Third Parties and, in the case of items (i), (ii) and (v) only, not otherwise recovered by or reimbursed to Takeda or its Affiliates:

- (i) trade, cash and quantity discounts (other than price discounts granted at the time of invoicing and already included in the gross amount invoiced);
 - (ii) price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to Regulatory Authorities;
- (iii) taxes on sales (such as business tax, value added taxes, sales or use taxes), but not including taxes assessed against the income derived from such sales, and import and customs duties;
- (iv) freight, insurance and other transportation and handling charges to the extent added to the sale price and set forth separately as such in the total amount invoiced, as well as any out-of-pocket and arms-length fees for services provided by wholesalers and warehousing chains related to the distribution of the Licensed Product in the Field in such country in the Territory that are treated as sales allowances under GAAP, provided that such out-of-pocket fees are consistent with those charged across Takeda's product line; and
- (v) amounts repaid or credited by reason of rejections, defects, [...***...] percent ([...***...]%) return credits, recalls or returns or because of retroactive price reductions (including rebates or wholesaler charge backs.

Where any reduction in the amount of Net Sales is based on sales of a bundle of products in which the Licensed Product for use in the Field in such country in the Territory is included, the reduction in price or deduction therefrom would be allocated as actually credited unless such Licensed Product receives a higher than pro rata share of any reduction or deduction that the bundled set of products receives. In such case, the reduction or deduction therefrom shall be allocated to such Licensed Product on a no greater than a pro rata basis based on the sales value (i.e., the unit average selling price multiplied by the number of units) of such Licensed Product relative to the sales value contributed by the other products in the bundle with respect to such sale.

Subject to the above, Net Sales shall be calculated in accordance with Takeda's standard internal policies and procedures, which must be in accordance with GAAP. Net Sales shall not include (i) sales, transfers or dispositions between or among Takeda or its Affiliates, unless such Affiliates are end-users, but shall include the subsequent final sales to non-Affiliate Third Parties by any such Affiliates, or (ii) sampling for preclinical, clinical, promotional or educational purposes conducted by or on behalf of Takeda for the Licensed Product in the Field in such country in the Territory in accordance with Takeda's usual and customary business practices.

All Net Sales will be calculated in United States Dollars.

If Takeda or its Affiliates appoint Distributors for the Licensed Product in the Field in such country in the Territory, Net Sales will include the Net Sales invoiced by Takeda or its Affiliates to such Distributors, but it will not include any sales of the Licensed Product in the Field in such country in the Territory made by any such Distributors.

"OIC Indication" means the prophylactic or therapeutic use in the prevention and/or treatment of opioid induced constipation.

"Other Indication(s)" means any indication for use of the Compound other than the Field.

"Other Intellectual Property Rights" means (a) any domains, designs, copyrights, copyright registrations, copyright rights, moral rights and similar rights throughout the world (including, without limitation, the foregoing with respect to computer software, firmware, programming tools, drawings, specifications, databases and documentation) and (b) any rights, title and interests in all trade secrets and trade secret rights arising under common law, state law, federal law or laws of foreign countries.

"Party" means each of Takeda or Sucampo individually; Takeda and Sucampo are collectively referred to herein as "Parties", as identified in the preamble to this Agreement.

"Patent Defect" means with respect to Licensed Product delivered to Takeda according to Section 9.2, a Licensed Product non-conforming to Sucampo's warranty for the Licensed Product, as set forth in Section 9.1.3, such that (i) the related non-conformance of such Licensed Product may be readily discovered or should be reasonably expected to be readily discoverable based on Takeda's, its Affiliates' or other Sublicensees' normal, industry-standard and Commercially Reasonable Efforts for incoming-goods inspections procedures, as the case may be and (ii) was not caused directly or indirectly by the Secondary Packaging or any acts or omissions of Takeda, its Affiliates, Sublicensees, Subcontractors or any other parties for whom Takeda is responsible hereunder.

"Patent Rights" means the rights and interests in and to all patents and patent applications throughout the world, including provisional applications, divisional applications, continuation applications, continuation applications, continuation applications, continuations, restorations, including adjustments, revalidations, reissues, re-examinations, patent term extensions, supplementary protection certificates and any similar rights, including so-called pipeline protection rights, introduction patents, registration patents and patents of addition of any foregoing patents and patent applications throughout the world.

"Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture, or other entity or organization, in any case whether for-profit or not-for profit, and including, without limiting the generality of any of the foregoing, a government or political subdivision, department or agency of a government.

"Pharmacovigilance Agreement" has the meaning set forth in Section 6.3.

"Phase I Study" means a human clinical trial of a product containing the Compound, the principal purpose of which is a preliminary determination of safety or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise.

"Phase II Study" means, collectively, a Phase IIa Study and a Phase IIb Study.

"Phase IIa Study." means a human clinical trial of a product containing the Compound, the principal purpose of which is a demonstration of proof of concept in the target patient population or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise.

"Phase IIb Study" means a human clinical trial of a product containing the Compound, the principal purpose of which is to find the dose range in the target patient population or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise.

"Phase III Study" means a human clinical trial of a product containing the Compound on a sufficient number of subjects that is designated to establish that such product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support marketing of such product, including all tests, studies, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise.

"Phase IV Study" means a human clinical trial of a product containing the Compound that is not included in the original MAA submission for the Product for an indication, including studies conducted to fulfill commitments made as a condition of the Regulatory Approval of the MAA or any subsequent human clinical trials requested, required or recommended by the Regulatory Authority(ies) in the Territory as a condition of maintaining such Regulatory Approval.

"<u>Post-Approval Marketing Studies</u>" means a human clinical trial or other test or study with respect to the Product for use in the Field in the Territory, which test or study is conducted on a voluntary basis by a Party (rather than under a mandate from a Regulatory Authority in the applicable country in the Territory in order to obtain or maintain Regulatory Approval for the Licensed Product in the Field in such country in the Territory) after the MAA for the Licensed Product in the Field in such country in the Territory. Any human clinical study that is intended to expand the label for the Licensed Product for use in the Field in such country in the Territory shall be a Clinical Study. Subject to the foregoing, Post-Approval Marketing Studies may include clinical studies conducted in support of pricing or reimbursement for the Licensed Product in the Field in such country in the Territory, epidemiological studies, modeling and pharmacoeconomic studies, post-marketing studies, investigator sponsored studies, and health economic studies.

"Pre-Clinical Data" means data derived from a study to test the Compound for use in the Field, including, but not limited to, laboratory studies, toxicology, safety pharmacology, disease models and animal models.

"Pricing Approval" means any and all pricing or reimbursement approvals, licenses, registrations, or authorizations of any applicable Regulatory Authority necessary to Commercialize the Licensed Product in the Field in a particular country in the Territory.

"Product Labels and Inserts" means (a) any display of written, printed or graphic matter upon the immediate container, outside container, wrapper or other packaging of the Licensed Product or (b) any written, printed or graphic material on or within the package from which the Licensed Product is to be dispensed.

"Product Trademark" means (i) the Trademark AMITIZA, (ii) the Trademarks as and in the exact form listed on EXHIBIT C, (iii) in the event the Trademark AMITIZA or any other Trademarks listed in EXHIBIT C have not been registered to Sucampo at least one (1) year prior to the date of the estimated launch of the Licensed Product in the Field in the applicable country in the Territory or should any registration of the Product Trademark in any country of the Territory be withdrawn or be refused or should the Product Trademark be not acceptable to Takeda due to linguistic reasons or the applicable Regulatory Authorities in such country in the Territory do not approve that the Licensed Product uses the Trademark AMITIZA or any other Trademarks listed in EXHIBIT C in such country, then any other Trademarks for Commercializing the Licensed Product in the Field in such country in the Territory as designated and agreed upon by both Parties in advance and (iv) any current or future modifications or variances of the foregoing Trademarks, but excluding the Corporate Names, that are designated by Sucampo in advance and in writing to be used for Commercializing the Licensed Product in the Field in a particular country in the Territory.

"Promote" or "Promotion" means those activities to implement marketing plans and strategies aimed at encouraging the appropriate use of a particular prescription or other pharmaceutical product, including detailing. When used as a verb, "Promote" means to engage in such activities.

"Promotional Materials" means all written, printed, digital or graphic material, other than Product Labels and Inserts, intended for use by representatives in Promoting the Licensed Product for use in the Field in the applicable country in the Territory, including visual aids, file cards, premium items, clinical study reports, reprints, drug information updates, and any other promotional support items.

"Proposed Disclosure" has the meaning set forth in Section 10.4.1.

"Provisional Relief" has the meaning set forth in Section 5 in EXHIBIT G.

"Publication Policies" has the meaning set forth in Section 10.4.2.

"Quality Agreement" means the agreement to be entered into between Takeda and Sucampo, under which the Parties shall address Product quality issues to assure the Licensed Product is Manufactured and packaged according to Applicable Law in the applicable country in the Territory.

"Recall" means the removal or correction of a Licensed Product in the Field in a particular country in the Territory. Recall does not include a Market Withdrawal.

"Receiving Party." means the Party receiving Confidential Information; provided that, with respect to each Party's confidentiality obligations, a Party owning certain property as provided hereunder shall be considered the Disclosing Party and the other Party shall be considered the Receiving Party regardless of which Party discloses such information.

"Regulatory Approval(s)" means any and all approvals, licenses (including product and establishment licenses), permits, certifications, registrations, or authorizations of any Regulatory Authority necessary to Develop, Manufacture, Promote, distribute, transport, store, use, sell, import, export or otherwise distribute, dispose of and Commercialize the Licensed Product for use in the Field in the applicable country in the Territory, including all INDs, MAAs and the manufacturing license and marketing registration required under the Applicable Law of such applicable country in the Territory, or any update thereto, and Pricing Approvals, or pre-and Post-Approval Marketing Studies, labeling approvals, technical, medical and scientific licenses.

"Regulatory Authority(ies)" means any national, supra-national, regional, federal, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity (including, without limitation, the EMA and any governmental unit having jurisdiction over the Development, Manufacture, Secondary Packaging and Commercialization of the Licensed Product in the Field in the applicable country in the Territory).

"Regulatory Filings" means, with respect to the Licensed Product in the Field in the applicable country in the Territory, all applications, registrations, submissions, dossiers, notifications, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from the Regulatory Authorities (including minutes and official contract reports relating to any communications with any Regulatory Authority) and all supporting documents and all Pre-Clinical Data, Clinical Data and CMC Data (including all Clinical Studies and Post-Approval Marketing Studies), and all data contained in any of the foregoing, including all INDs, MAAs, Adverse Event/Reaction files and complaint files.

"Required Change" has the meaning set forth in Section 9.1.10.

"Rolling Forecast" has the meaning set forth in Section 9.1.5(a).

"Secondary Packaging" means all the activities related to labeling of primary packaged bulk bottles or bulk blister packs of Licensed Product including packaging of labelled bottles or blister packs of the Licensed Product into a carton with a leaflet, including sourcing of all packaging materials such as labels, cartons and leaflets.

"Serious Adverse Event/Reaction" means an Adverse Event/Reaction that (i) results in death; (ii) is life-threatening; that is, an event where the patient and/or clinical investigation subject was at risk of death at the time of the event and not an event that, hypothetically, might have caused death if it had been more severe; (iii) requires hospitalization or prolongation of existing hospitalization; (iv) results in persistent or significant disability or incapacity; (v) is a congenital anomaly or birth defect in the fetus/child, fetal death, spontaneous abortion and serious adverse reactions in the neonate; (vi) involves suspected infection via a Licensed Product of an infectious agent or (vii) may not be immediately life-threatening or result in death or hospitalization and may jeopardize the subject or require medical or surgical intervention to prevent one of the outcomes listed in (i) - (vi). For the avoidance of doubt, a "Serious Adverse Event/Reaction" includes all occurrences which would be regarded as "serious adverse drug reactions" under Applicable Law of the applicable country in the Territory.

"Service Process Agent" has the meaning set forth in Section 8 in EXHIBIT G.

"SKU(s)" means Stock Keeping Unit(s) and different pack formats used to identify Manufacturing and distribution of the Licensed Product in the Field in the applicable country in the Territory.

"Specifications" means the processes, methods, formulae, analyses, instructions, standards, know-how, testing and control procedures, information and specifications relating to the Manufacture and packaging (including Secondary Packaging) of the Licensed Product for the Field in the applicable country in the Territory as reflected in the Quality Agreement and Regulatory Approvals.

"Specified Court" has the meaning set forth in Section 7 in EXHIBIT G.

"Sublicensee" means any Person (including a Takeda Affiliate) to whom Takeda sublicenses any rights as permitted under Section 2.1.2.

"Subcontractor" means any Person to whom Takeda or Sucampo has subcontracted the performance of its obligations or activities as provided hereunder.

"Sucampo" means Sucampo AG, as identified in the preamble to this Agreement.

"Sucampo Background Technology" means all Background Technology Controlled by Sucampo or any of its Affiliates, as of the Effective Date or at any time during the Term, that is reasonably necessary or beneficial for Developing or Commercializing the Licensed Product in the Field in the applicable country in the Territory.

"Sucampo Data Exclusivity" means all Data Exclusivity Controlled by Sucampo or any of its Affiliates, as of the Effective Date or at any time during the Term, in relation to Developing or Commercializing the Licensed Product in the Field in the applicable country in the Territory.

"Sucampo Developed Patent Rights" has the meaning set forth in Section 2.1.4.

"Sucampo Developed Technology" has the meaning set forth in Section 2.1.4.

"Sucampo Developing Parties" has the meaning set forth in Section 2.1.4.

"Sucampo Indemnitee(s)" has the meaning set forth in Section 16.1.

"Sucampo Know-how" means all information owned or Controlled by Sucampo or any of its Affiliates, as of the Effective Date or during the Term, that is related to the Licensed Product in the Field that is necessary or useful for the Development or Commercialization of such Licensed Product. Know-How excludes any Information contained within Sucampo's published Patents Rights.

"Sucampo Other Intellectual Property Rights" means all Other Intellectual Property Rights Controlled by Sucampo or any of its Affiliates, as of the Effective Date or at any time during the Term, that is reasonably necessary or beneficial for Developing or Commercializing the Licensed Product in the Field in the applicable country in the Territory.

"Sucampo Patent Rights" means all Patent Rights in the applicable country during the Term, including patents applied for and issued in such country after the Effective Date, and that would otherwise be infringed, absent a license, by any of Takeda's or its Sublicensees' or Subcontractors' activities authorized under this Agreement, including but not limited to the Development or Commercialization of the Licensed Product in the Field in such country. Sucampo Patent Rights include, but are not limited to, the patents and patent applications set forth in EXHIBIT D, which may be amended from time-to-time by Sucampo, at its option and in its sole discretion, solely to add additional patents and patent applications.

"Supply Price" means the applicable supply price as set forth in EXHIBIT H.

"Takeda" means Takeda Pharmaceuticals International GmbH, as identified in the preamble to this Agreement.

"Takeda Developed Patent Rights" has the meaning set forth in Section 2.1.4.

"Takeda Developed Technology" has the meaning set forth in Section 2.1.4.

"Takeda Developing Parties" has the meaning set forth in Section 2.1.4.

"Takeda Indemnitee(s)" has the meaning set forth in Section 16.2.

"<u>Technology</u>" means, collectively, proprietary information, ideas, concepts, know-how, data, trade secrets, materials (including tangible chemical, biological or other physical materials), inventions, discoveries, improvements, derivatives, modifications, processes, methods of use, methods of manufacturing, analysis, and compositions of matter, of technical nature whether or not patentable.

"Term" has the meaning set forth in Section 12.1.

"Terminated Country" has the meaning set forth in Section 12.2.5.

- "Terminated Licensed Product" has the meaning set forth in Section 12.2.5.
- "Territory" means worldwide excluding the United States, Canada, Japan, and People's Republic of China.
- "Third Party" means any Person that is not a Party.
- "Third Party Claim(s)" has the meaning set forth in Section 16.1.
- "Third Party Royalties" means all fees, milestones, royalties and other payments payable to a Third Party (other than to any of Takeda's Affiliates or other Sublicensees) in consideration for intellectual property rights reasonably necessary for Takeda to carry out the activities under this Agreement, including the Development or Commercialization of a Licensed Product in the Field in the applicable country in the Territory.
- "Trademark" means (a) any trademark, trade dress, brand mark, service mark, brand name, logo or business symbol, Internet domain name and e-mail address, whether or not registered, or any application, renewal, extension or modification thereto, and (b) all goodwill associated therewith.
 - "Transition Activities" has the meaning as set forth in Section 13.1.
 - "Transition Period" has the meaning as set forth in ARTICLE 13.

ARTICLE 2 LICENSE GRANTS; EXCLUSIVITY

2.1 License Grants

- 2.1.1 <u>Sucampo Grants.</u> Subject to the terms and conditions of this Agreement, during the Term, Sucampo hereby grants to Takeda, solely under the Sucampo Patent Rights, Sucampo Know-how, Sucampo Confidential Information and Sucampo Other Intellectual Property Rights, in and to the Sucampo Background Technology and Sucampo Data Exclusivity Rights:
- (a) (i) an exclusive (except as to Sucampo and its Affiliates) and non-transferable (except to the extent set forth in Section 17.8) right and license, with the right to grant sublicenses solely in accordance with Section 2.1.2, to Develop the Licensed Product in the Field in the applicable country in the Territory (ii) a non-exclusive and non-transferable (except to the extent set forth in Section 17.8) right and license, with the right to grant sublicenses solely in accordance with Section 2.1.2 to perform Development outside the Territory of the Licensed Product in the Field for any country in the Territory;

(b)	an exclusive (including as to Sucampo and its Affiliates) and non-transferable (except to the extent set forth in Section 17.8) right
and license, with the right to grant	sublicenses solely in accordance with Section 2.1.2, to Commercialize the Licensed Product in the Field in the applicable country in
the Territory;	

- (c) an exclusive (except as to Sucampo and its Affiliates) and non-transferable (except to the extent set forth in Section 17.8) right and license, with the right to grant sublicenses solely in accordance with Section 2.1.2, to use and reference in Regulatory Filings for a particular country in the Territory (other than any Regulatory Filings in connection with Manufacturing the Licensed Product) any Data (other than Manufacturing Data) Controlled by Sucampo or its Affiliates necessary to support such Regulatory Filings in such country in the Territory; and
- (d) a non-exclusive and non-transferable (except to the extent set forth in Section 17.8) right and license, with the right to grant sublicenses solely in accordance with Section 2.1.2, to undertake Secondary Packaging of the Licensed Product in the Territory and outside the Territory solely for the purpose of use and importation into the Territory and to import and export the Licensed Product outside of the Territory solely for the purpose of Commercialization of the Licensed Product in the Territory.
- 2.1.2 <u>Right to Sublicense and Subcontract</u>. Subject to the following, Takeda may perform any activities in support of its Commercialization of the Licensed Product in the Field in the applicable country in the Territory or of any Development and Secondary Packaging of the Licensed Product in or outside of the Territory for the Territory, through its Affiliates or contracting with a Third Party. Such Subcontractors may include Distributors, wholesalers and any services providers. Subject to and in accordance with the terms and conditions of this Agreement, Takeda shall have the right to grant sublicenses under Section 2.1.1 ((a) (b) (c) and (d)) and Section 2.1.3 to any of its Affiliates and any Subcontractors, for such Subcontractors in the event the type of activities to be performed or Applicable laws require a subcontractor to possess a sublicense.

Takeda shall provide a list of the names of its Affiliates Developing and Commercializing the Product on EXHIBIT J and update such list annually, and in any event not more than once a year.

Takeda shall not be obliged to notify Sucampo of the appointment of any Subcontractors in the Territory for Commercialization activities and in or outside of the Territory for Development activities and Secondary Packaging for the Territory.

Under its agreements with its Sublicensees and Subcontractors, Takeda shall protect Sucampo's interests and rights in its Confidential Information and intellectual property rights to at least the same extent of this Agreement.

Any rights sublicensed by Takeda to any Affiliate or Subcontractor as hereunder provided shall be of no greater scope than the license granted to Takeda under Section 2.1.1 and Section 2.1.3 and such sublicense shall terminate upon the expiration or termination of this Agreement.

Takeda shall not be relieved of its obligations pursuant to this Agreement as a result of such sublicense or appointment of any Subcontractors and shall remain fully responsible and liable for any action or omission of such Subcontractors and Sublicensees which would constitute a breach of this Agreement if committed by Takeda as if Takeda had committed such action or inaction itself.

Takeda shall, at its own expense, investigate each report and indication of breach of any sublicense or appointment of any Subcontractor, and Takeda shall promptly report to Sucampo any breach learned of or discovered by Takeda. Takeda shall diligently enforce the terms and conditions of each sublicense, including without limitation, by pursuing all appropriate judicial and administrative action and relief in the event of any material breach of the Sublicense.

In no event shall Sucampo or any of its Affiliates have any obligation to assume any obligations or liabilities, or be under any obligation or requirement of performance, under any such sublicense or appointment to Subcontractors either extending beyond Sucampo's obligations and liabilities under this Agreement or otherwise.

2.1.3 <u>License to Sucampo Corporate Names and Product Trademarks</u>. Subject to the terms and conditions of this Agreement, during the Term, Sucampo hereby grants to Takeda a non-exclusive right and license, with a right to sublicense to Sublicensees, to use Sucampo Corporate Names in the Territory only to the extent necessary to Commercialize the Licensed Product in the Field in the applicable country in the Territory and an exclusive right and license, with a right to sublicensees, to use the Product Trademarks solely to perform the Secondary Packaging in or outside the Territory for the Territory and Commercialize the Licensed Product in the Field in the applicable country in the Territory. Takeda shall not use the Product Trademarks other than for the purpose expressly and specifically set forth in this Section 2.1.3 and shall use Commercially Reasonable Efforts to comply with its then current trademark usage guidelines and specifications, notice requirements, stylistic, quality and other guidelines and specifications in connection with the use of the Product Trademarks in the Field in the applicable country in the Territory. All use of the Product Trademarks by Takeda, and all goodwill associated with such use, shall inure to the benefit of Sucampo. Notwithstanding the exclusive right and license granted to Takeda under this Section 2.1.3 and for the sake of good order, nothing in this Section shall prevent Sucampo from using the Product Trademarks in any of its global promotion or information activities relating to Sucampo its Affiliates and its product portfolio, including but not limited to listing the Product Trademarks in its annual reports.

- Development of Developed Technology and Developed Patent Rights. In the event that Sucampo or any of its Affiliates (or any of 2.1.4 their respective employees, contractors, agents or subcontractors) (collectively, the "Sucampo Developing Parties") or Takeda or any of its Affiliates (or any of their respective employees, contractors, agents or Subcontractors) (collectively, the "Takeda Developing Parties") (the Sucampo Developing Parties and Takeda Developing Parties, together, the "Developing Parties" and individually, the "Developing Party") conceives, creates, develops or otherwise reduces to practice in connection with their activities under this Agreement, regardless of whether such conception, creation, development or reduction to practice is done independently by or on behalf of one Developing Party or jointly by any Developing Party with any other Developing Parties and/or any other Person: (a) any Technology (which may or may not be patentable) (but expressly excluding Background Technology of either Party or its Affiliates ("Developed Technology") and/or (b) any Patent Rights (but expressly excluding any Sucampo or Takeda Patent Rights as of the Effective Date of this Agreement or any Product Trademarks or Other Intellectual Property Rights as of the Effective Date of this Agreement, Sucampo's and Takeda's Other Intellectual Property Rights and other intellectual property rights in and to the Sucampo and Takeda Background Technology and Sucampo's intellectual property rights in and to the Data Exclusivity, Product Trademarks and Sucampo and Takeda's Corporate Names and any other underlying intellectual property rights that are Controlled by Sucampo or Takeda prior to the Effective Date or obtained or acquired independently of this Agreement after the Effective Date) ("Developed Patent Rights") then, each of the Developing Parties agrees (for itself and its Affiliates), that it shall promptly notify and disclose to the other Party such Developed Technology and Developed Patent Rights after the conception, creation or discovery thereof and the Parties hereby agree, to the fullest extent permitted by Applicable Law, as and between the Parties and their respective Affiliates and other Developing Parties the following ownership provisions:
- Takeda shall be the sole and exclusive owner of all right, title and interest in and to the Developed Technology conceived, created, developed or reduced to practice solely by the Takeda Developing Parties ("Takeda Developed Technology") and all Developed Patent Rights conceived, created, developed or reduced to practice solely by the Takeda Developing Parties ("Takeda Developed Patent Rights") in each case, throughout the world but only with respect to Takeda Developed Technology not related to the Compound or Licensed Product. Takeda Developed Technology related to the Compound or Licensed Product shall be assigned to Sucampo on request and shall on assignment be treated as "Sucampo Developed Technology". Any exercise by Takeda, the Takeda Developing Parties and any of their Sublicensees or Subcontractors in and to their rights to the Takeda Developed Technology (and any intellectual property rights therein or thereto) and Takeda Developed Patent Rights shall be subject to the terms and conditions of this Agreement, including, without limitation, Section 2.1.2 and ARTICLE 10 and ARTICLE 11. Takeda hereby agrees to grant to Sucampo on written request an unrestricted, perpetual, irrevocable, fully paid-up, royalty-free, transferable, sublicenseable (through multiple levels of sublicensees) worldwide exclusive (except as to Takeda, the Takeda Developing Parties and any of their Sublicensees) right and license, free from any liens or encumbrances, to use make, have made, sell, offer to sell, and otherwise dispose of, commercialize and exploit (and have others exercise such rights on behalf of Sucampo) all or any portion of the Takeda Developed Technology (and any Patent rights therein or thereto) and Takeda Developed Patent Rights, in any form or media (now known or later developed).

To the fullest extent permitted by Applicable Law, as and between the Parties, Sucampo shall be the sole and exclusive owner of all (b) right, title and interest in and to the Developed Technology other than the Takeda Developed Technology not related to the Compound or the Licensed Product ("Sucampo Developed Technology") and all Developed Patent Rights relating to the Sucampo Developed Technology ("Sucampo Developed Patent Rights") in each case, throughout the world. For clarification, any Developed Technology that relates to the Compound or the Licensed Product will be owned by Sucampo, and if a patent application is filed for the said Developed Technology relating to the Compound or the Licensed Product, said patent will be a "Sucampo Patent Right". Sucampo Developed Technology shall, in each of the foregoing cases, be licensed to Takeda under Section 2.1.1 for the purpose of and in accordance with all of the terms and conditions of this Agreement. In exchange for the foregoing licenses granted by Sucampo to Takeda pursuant to Section 2.1.1 and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, to the maximum extent permitted by Applicable Law, Takeda shall cause the Takeda Developing Parties to, irrevocably grant, convey, transfer, assign and deliver to Sucampo all ownership, right, title and interest in and to such Sucampo Developed Technology (and all intellectual property rights therein or thereto) and Sucampo Developed Patent Property Rights, in perpetuity and throughout the world, effective immediately upon the inception, conception, creation or development thereof. Sucampo shall pay for or reimburse Takeda for all inventor's remuneration required to be paid under Applicable Law. To the extent that any Sucampo Developed Technology (or any intellectual property rights therein or thereto) or Sucampo Developed Patent Rights are not assignable as provided in this Section 2.1.4 or that Takeda or any of the Takeda Developing Parties retain any ownership, rights, title or interest in or to any Sucampo Developed Technology (or any intellectual property rights therein or thereto) or Sucampo Developed Patent Rights in any jurisdictions in the world then, in exchange for the licenses granted by Sucampo to Takeda pursuant to Section 2.1.1 and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, to the maximum extent permitted by Applicable Law, Takeda hereby agrees, at Sucampo's request and expense, to consent to and join in any action to enforce such rights, and hereby agrees to grant to Sucampo an unrestricted, perpetual, irrevocable, fully paid-up, royalty-free, fully transferable, sublicensable (through multiple levels of sublicensees), exclusive (except as to Takeda and other Takeda Developing Parties) right and license, throughout the world, free from any liens or encumbrances, to use, make, have made, sell, offer to sell, and otherwise dispose of, commercialize and exploit (and have others exercise such rights on behalf of Sucampo) all or any portion of the Sucampo Developed Technology (or any intellectual property rights therein or thereto) and Sucampo Developed Patent Rights, in any form or media (now known or later developed).

- (c) Each Party agrees to (and will cause its Developing Parties to), at the Patent owner's expense, take all reasonable additional actions and execute such agreements, instruments and documents as may be required, both during and after the Term, and agrees otherwise to give to the other Party any assistance required in order to perfect the rights set forth in this Section 2.1.4, including without limitation, obtaining patents registrations, and to apply for, obtain, perfect, evidence, sustain and enforce Takeda's and Sucampo's Patent Rights in connection with their respective Developed Technology and Developed Patent Rights for Takeda and in any jurisdictions throughout the world for Sucampo.
- 2.1.5 <u>Publication</u>. Publication or presentation of a manuscript related to any Developed Technology or Developed Patent Rights under this ARTICLE 2 shall be governed by Section 3.1.3(b)(viii) and Section 10.4.2.
- 2.1.6 <u>Product Diversion</u>. To the extent permitted by Applicable Law, Sucampo shall not, and shall cause its Affiliates and sublicensees not to, knowingly or intentionally Commercialize the Licensed Product in the Field in any country in the Territory. Should Sucampo become aware of any unauthorized Commercialization of Licensed Product in the Field in any country in the Territory, it shall use Commercially Reasonable Efforts to stop such unauthorized Commercialization.
- 2.2 <u>No Implied Licenses</u>. No license or other right is or shall be created or granted hereunder by implication, estoppel or otherwise for any purpose. All such licenses and rights are or shall be granted only as expressly and specifically provided in this Agreement.
- 2.3 <u>Retained Rights.</u> All rights not expressly and specifically granted under this ARTICLE 2 are reserved by Sucampo and may be exercised or practiced by Sucampo for any purpose. In addition to and without limiting the generality of the foregoing, for purposes of this Agreement (and without affecting any other agreements between the parties which may exist), Sucampo retains any and all other rights under the Sucampo Patent Rights and Sucampo Background Technology to develop, make, have made, modify, use, market, promote, sell, have sold, export, import, distribute, commercialize or otherwise exploit the Compound and the Licensed Product in the Field outside of the Territory and, (b) subject to Section 5.2 below, for Other Indications anywhere in the world.

ARTICLE 3 ADMINISTRATION OF THE COLLABORATION

3.1 <u>Committees</u>

- 3.1.1 <u>Committees' Establishment.</u> Within thirty (30) days of the Effective Date, Sucampo and Takeda shall establish the following committees (the "Committees"):
- (a) a Joint Steering Committee ("JSC") with responsibility for managing the collaboration and resolving any conflicts, overseeing Commercialization-related activities with respect to the Licensed Product in the Field in the Territory and overseeing the JWG (as defined hereinafter); and
- (b) a Joint Working Group ("<u>JWG</u>") with responsibility for overseeing Development-related activities with respect to the Licensed Product in the Field in the applicable country in the Territory, including the regulatory approach and filing strategy designed to generate the successful submission and approval of the Licensed Product in the Field in such applicable country in the Territory.

Within thirty (30) days of the establishment of the foregoing Committees, the Committees shall meet to prepare such procedures and mechanisms as may be reasonably necessary for their operation to assure the most efficient conduct of each Party's obligations under this Agreement.

3.1.2 JSC

(a) Membership. Sucampo and Takeda shall each designate two (2) of its employees or its Affiliates' employees to serve as members of the JSC (or such other equal number of representatives as the Parties may agree). The initial members of the JSC will be determined by each Party within thirty (30) days from the Effective Date of this Agreement. Each representative of the JSC shall have the requisite experience and seniority to make decisions on behalf of the Parties with respect to issues falling within the jurisdiction of the JSC. The chairperson shall serve for a term of one (1) year, beginning on the Effective Date or an anniversary thereof, as the case may be. The right to name the chairperson of the JSC shall alternate between the Parties. The initial chairperson shall be selected by Sucampo. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JSC by giving written notice to the other Party; provided such substitute meets the criteria defined herein. Neither Party shall have the right to remove a sitting member of the other Party.

(b)	Responsibilities. The JSC shall have the responsibilities set forth in Section 3.1.1(b), including to:		
	(i) on the Co	Oversee and discuss strategies for Commercialization of the Licensed Product in the Field in the applicable country in immercialization Plan and any material updates, amendments, modifications to the Commercialization Plan;	
	(ii)	Oversee and coordinate the overall development strategy including Phase IV Studies;	
	(iii)	Review and coordinate the activities and monitor the progress of the JWG;	
	(iv)	Review and approve material updates, amendments, modifications of the Development Plan;	
	(v)	Review any budget related to activities under the Development Plan versus actual expenses;	
qualify a Back-up Supplier for the Territ	(vi) tory;	Review and approve any material changes in Manufacturing of the Licensed Product for the Territory and strategy to	
	(vii)	Review progress under the Commercialization Plan;	
	(viii)	Review the initial Promotional Materials for Key Markets;	
formulations or delivery systems;	(ix)	Review the product lifecycle plans for the Product including indication and label extension, new dosage forms and new	
	(x)	Resolve any Disputed Matters referred to the JSC by the JWG; and	

3.1.3 <u>JWG</u>

of this Agreement.

(xi)

Perform such other functions as the Parties may mutually agree in writing, except where in conflict with any provision

(a) Membership. Sucampo and Takeda shall each designate an appropriate equal number of its employees or its Affiliates' employees to
serve as members of the JWG, such appropriate equal number to be mutually agreed upon by the Parties. Each Party shall designate to be a member of the JWG at least
one (1) representative from its regulatory department, one (1) representative from its clinical development department, one (1) representative from their CMC
department and one (1) representative from their supply chain department. Each representative of the JWG shall have the requisite experience and seniority to make
decisions on behalf of the Parties with respect to issues falling within the jurisdiction of the JWG. The chairperson shall serve for a term of one (1) year beginning on
the Effective Date or an anniversary thereof, as the case may be. The right to name the chairperson of the JWG shall alternate between the Parties. The initial
chairperson shall be selected by Takeda. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its
previously designated representatives to the JWG by giving written notice to the other Party; provided such substitute meets the criteria defined herein. Neither Party shall have the right to remove a sitting member of the other Party.
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- (b) <u>Responsibilities</u>. The JWG shall coordinate operational activities of the Parties in the performance of the Development Plan and conduct those activities as directed by the JSC and shall have the responsibilities set forth in Section 3.1.3(b), including to:
- (i) Review and discuss the Development Plan and any material updates, amendments, and modifications to the Development Plan;
 - (ii) Review and compile the applicable budgets with a presentation of the budget by items versus actual expenses for the
- (iii) Review and evaluate progress under the Development Plan, including without limitation all health, safety and quality concerns;

JSC;

- (iv) Discuss plans and protocols for all pre-clinical, CMC and Clinical Studies in the Field in the Territory prepared in support of obtaining or maintaining Regulatory Approvals for the Licensed Product in the Field in the applicable country in the Territory;
- (v) Unless otherwise agreed by the Parties, review a high level regulatory plan for all proposed initial submissions for the Licensed Product in the Field to Regulatory Authorities in the applicable country in the Territory;
- (vi) Discuss the plans and protocols for and monitor the progress of all Clinical Studies and other development activities for the Licensed Product in the Field anywhere in the world;
- (vii) Assess the potential impact of Clinical Studies conducted anywhere in the world on Product Labels and Inserts for the Licensed Product in the Field in the applicable country in the Territory;

- (viii) Discuss publication or presentations strategies for the applicable country in the Territory related to the Licensed Product in the Field pursuant to Clinical Studies in the Field in the applicable country in the Territory that is based on Data developed by or for either Party and its Affiliates; and
- (ix) Review Manufacturing related matters including the forecasts for the supply of the Licensed Product, production planning for the Licensed Product, Back-up Supplier qualification, Secondary Packaging; and
- (x) Perform such other Development functions as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.
- 3.1.4 <u>Committee Meetings.</u> Each Committee shall establish a schedule of times for regular meetings. The JSC shall meet semi-annually and the JWG shall meet at least quarterly until Regulatory Approval has been obtained from the Regulatory Authority in the Key Markets and thereafter on an as needed basis to carry out the responsibilities of the JWG unless the applicable Committee otherwise agrees, or unless otherwise required by this Agreement. Meetings may be held in person, by telephone or videoconference, provided that at least one meeting per Calendar Year shall be held in person. Such in-person meeting shall alternate between the respective offices of Takeda and Sucampo or such other locations mutually agreed upon by the applicable Committee. The chairperson of each Committee (or its designee) shall prepare and circulate to each Committee member an agenda for each Committee meeting reasonably in advance of each meeting. At each Committee meeting, the presence of at least one (1) member designated by each Party shall constitute a quorum. Each Party may invite non-voting employees to attend any meeting of the JSC and shall notify the other Party reasonably in advance, but no later than ten (10) Business Days prior to the meeting date. The Committees shall keep minutes of their meetings that record all decisions and all actions recommended or taken in reasonable detail. The chairperson (or its designee) of each Committee shall circulate a draft of the minutes no later than ten (10) Business Days after each meeting and each member of the Committee shall have the opportunity to comment on the draft minutes. The minutes shall be approved, disapproved or revised as necessary within thirty (30) days of each meeting; provided, however, that if the Parties cannot agree as to the content of the minutes, such minutes will be finalized to reflect such disagreement. The chairperson of each Committee or its designee shall circulate final minutes of each meeting to each Committee member.
- 3.1.5 <u>Decision-Making</u>. Except as otherwise provided herein, decisions of each Committee shall be made by consensus with each Party having one (1) single vote. Each Committee shall use Commercially Reasonable Efforts to reach agreement on any and all matters for which it is responsible. In the event that, despite such Commercially Reasonable Efforts, agreement on a particular matter cannot be reached by a Committee within fifteen (15) Business Days after the Committee first meets to consider such matter (each such matter, a "<u>Disputed Matter</u>"), then the following procedure shall apply:

(a) <u>.</u>	JWG Disputed Matters.	Disputed Matters arising from the JWC	3 shall be referred for resolution to the	JSC. The JSC shall initiate
discussions in good faith to resolve	each Disputed Matter wi	thin ten (10) Business Days of receipt of	of the notice of such Disputed Matter.	In the event that the JSC does
not reach agreement on such Disput	ed Matter within fifteen	(15) Business Days from the date of init	iation of such discussions, such Disput	ted Matter shall be referred to
senior management for resolution in	accordance with Section	3.1.5(c).		

- (b) <u>JSC Disputed Matters</u>. Disputed Matters first arising in the JSC or not resolved by the JSC which had first arisen in the JWG shall be referred to senior management for resolution in accordance with Section 3.1.5(c).
- (c) <u>Management Negotiations</u>. In the event that the JSC cannot resolve a Disputed Matter, either Party may, by written notice to the other, refer such Disputed Matter to the Parties' respective senior management for good faith negotiations. In the event that, despite good faith efforts, resolution of such Disputed Matter cannot be reached by senior management of the Parties within thirty (30) Business Days of its referral then:
- (i) with respect to any Disputed Matter that relates to the Commercialization of the Licensed Product in the Territory under this Agreement, Takeda shall have final decision-making authority; and
- (ii) with respect to any Disputed Matter that relates to Development of the Licensed Product in order to Commercialize the Licensed Product in the Field in the Territory, the final decision-making authority shall rest with Takeda;
- (iii) with respect to any Disputed Matter that relates to Manufacturing of the Licensed Product, the final decision-making authority shall rest with Sucampo; provided, however, that in the event the Disputed Matter relating to Manufacturing of the Licensed Product will have a direct impact or effect on the Commercialization of the Licensed Product, the final decision-making authority shall rest with Takeda.
- 3.2 <u>Limitations on Authority.</u> Each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly and specifically provided for in this Agreement, or the Parties expressly so agree in writing. In addition to and without limiting the generality of the foregoing, (a) no Committee shall substitute for either Party's ability to exercise any rights set forth under this Agreement nor excuse the performance of any obligation set forth under this Agreement, (b) no Committee shall have the authority to make any determination that a Party is in breach of this Agreement, or that a Party has engaged or not engaged in acts related to breach and (c) no Committee shall have the power to amend, modify or waive compliance with this Agreement, which may only be amended or modified, or compliance with which may only be waived, solely as and to the extent provided in Section 17.5.

- 3.3 Interactions Between a Committee and Internal Teams. The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. Nothing contained in this Article shall prevent a Party from making routine day-to-day decisions relating to the conduct of those activities for which it has a performance or other obligation hereunder, provided that such decisions are consistent with the then-current Commercialization Plan or Development Plan, as applicable, and the terms and conditions of this Agreement and all Applicable Law. Each of the Parties shall appoint one representative who possesses a general understanding of development, regulatory and commercialization issues to act as its Alliance Manager. The role of the Alliance Manager is to act as a first point of contact between the Parties. The Alliance Managers shall have the right to attend all meetings of any committees that the Parties may decide to form hereunder and may act as designees of the co-chair of the JSC to organize and facilitate JSC meetings. The Alliance Managers shall also work together to facilitate the communication and coordination between the Parties solely related to matters that the JSC has the authority to oversee under Section 3.1.2(b), and in the event the Alliance Managers fail to resolve any deadlock in good faith between the Parties within fifteen (15) days, the Alliance Managers shall immediately refer such deadlock to the JSC for resolution. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager upon written notice to the other Party's Alliance Manager.
- 3.4 <u>Expenses</u>. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, a Committee.
- 3.5 <u>Purpose of the Committees</u>. The Parties acknowledge and agree that the Committees are strictly for the purposes of decision-making and governance of the Agreement.
- 3.6 <u>Communication</u>. With regard to the Parties' entire relationship, the Parties shall cooperate and provide support in connection with each other's reasonable requests and shall promptly respond to each other's communications.

ARTICLE 4 DEVELOPMENT

4.1 <u>Development Plan</u>

- 4.1.1 Initial Plan. The Development of the Licensed Product for use in the Field in the applicable country in the Territory shall be governed by the Development Plan attached to this Agreement as EXHIBIT L, which includes (a) the Development program to be conducted by Takeda on an activity-by-activity, Licensed Product-by-Licensed Product and country-by-country basis in the Territory and the study design and (b) the budget for the Development program on an activity-by-activity, Licensed Product-by-Licensed Product and country-by-country basis, which Development program is designed to generate all the Clinical Data and regulatory information required to obtain or maintain the Regulatory Approval required for Takeda to be able to Commercialize the Licensed Product in the Field in such applicable country in the Territory. For the avoidance of doubt, any Clinical Studies other than Post-Approval Marketing Studies and Phase IV Studies performed by Takeda shall be included in the Development Plan. For the avoidance of doubt, the Development Plan, including any updates and amendments to the Development Plan in accordance with Section 4.1.2, must be reviewed and approved by the JSC before it becomes effective.
- 4.1.2 <u>Amendments.</u> Commencing in the first full Calendar Year after the Effective Date and continuing during the Term, Takeda shall prepare and submit no later than January 31 of each Calendar Year for review and approval by the JSC appropriate amendments and updates to the Development Plan to the extent necessary, as determined by Takeda in its reasonable discretion. Takeda shall use Commercially Reasonable Efforts to take into consideration Sucampo's comments on the amendments and updates to the Development Plan, including but not limited to any comments relating to a potential impact on activities relating to the Licensed Product in a country or jurisdiction outside of the Territory.
- 4.2 <u>Responsibilities</u>. Takeda shall be solely responsible for conducting all Development activities set forth in the Development Plan provided, however, that Sucampo shall conduct any stability activities, including stability testing, required to obtain and maintain the Regulatory Approvals in the applicable country in the Territory, unless otherwise agreed by the JSC; provided, however, that any protocol for stability testing shall be approved by JSC.
 - 4.3 <u>Development Activities</u>

- 4.3.1 T akeda shall use Commercially Reasonable Efforts to Develop the Licensed Product in the Field in the applicable country in the Territory in accordance with the Development Plan, the terms and conditions of this Agreement, all Applicable Law and cGCP. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, Takeda shall use Commercially Reasonable Efforts to conduct any and all Clinical Studies set forth in the Development Plan. If in addition to the Clinical Studies described in the Development Plan, as amended or updated, the EMA or any other Regulatory Authority in the applicable country in the Territory requires or recommends any Phase IV Studies or any other Clinical Studies in the Field in the applicable country in the Territory as a condition to obtaining Regulatory Approval for the Licensed Product in the Field in such applicable country in the Territory or maintaining such Regulatory Approval, Takeda shall use Commercially Reasonable Efforts to decide whether or not to conduct such studies.
- 4.3.2 <u>O ther Post-Approval Marketing Studies</u>. Takeda shall use Commercially Reasonable Efforts to conduct and direct any Post-Approval Marketing Studies that Takeda, in its sole discretion, decides to conduct. Takeda shall use Commercially Reasonable Efforts to take into consideration Sucampo's comments on the protocol of any Post-Approval Marketing Studies, including but not limited to any comments relating to a potential impact on activities relating to the Product in a country or jurisdiction outside of the Territory. For the avoidance of doubt, any Post-Approval Marketing Studies and Phase IV Studies shall be included in the Commercialization Plan.
- 4.3.3 <u>E uropean Paediatric Investigation Plan.</u> Sucampo shall use Commercially Reasonable Efforts to conduct and direct the European Paediatric Investigation Plan at its own costs and shall bear all responsibilities related to the performance of the European Paediatric Investigation Plan. Sucampo shall use its Commercially Reasonable Efforts to keep the JWG informed of the progress of the European Paediatric Investigation Plan. For the avoidance of doubt, Sucampo will not be required to perform any additional studies other than those studies set for the European Paediatric Investigation Plan attached as EXHIBIT M.
- 4.3.4 <u>P ost Allocation</u>. Sucampo shall be exclusively responsible for any Development costs (including for clarification, the Supply Price for any Licensed Product that are supplied by Sucampo to Takeda for Development purposes) set forth in the budgetary portion of the Development Plan attached to this Agreement and as may be amended for up to an aggregate total of [...***...] United States Dollars (USD [...***...]) for Developing the Licensed Product in the Field in all countries in the Territory. Takeda shall be responsible for all Development costs (including for clarification, the Supply Price for any Licensed Product that are supplied by Sucampo to Takeda for Development purposes) above [...***...] United States Dollars (USD [...***...]). For the avoidance of doubt, any and all costs or fees related to the European Paediatric Investigation Plan are not included in the [...***...] United States Dollars (USD [...***...]) of Development costs which are stated in this Section 4.3.4 and will be the sole responsibility of Sucampo as provided in Section 4.3.3.

4.3.5 Other Development Activities. In the event the JWG or the JSC identifies an opportunity to expand and optimize the Licensed Product in the applicable country in the Territory such as expanding the label for the Licensed Product for use in the

Field in such applicable country in the Territory, the Parties shall discuss the possibility of Takeda amending the Development Plan (including any Clinical Studies in the Field in the applicable country in the Territory required to expand the label of the Licensed Product for use in the Field in the applicable country in the Territory) to pursue any such opportunities at Takeda's sole cost and expense, subject to the review of the JSC.

4.4 <u>C onduct of Development</u>

- 4.4.1 <u>Compliance</u>. The Parties shall use Commercially Reasonable Efforts to perform their obligations under the Development Plan in a good scientific manner and in compliance with the Development Plan, the terms and conditions of this Agreement, cGCP and all Applicable Law.
 - 4.4.2 <u>Cooperation</u>. The Parties shall reasonably cooperate through the JWG in the performance of the Development Plan.
- 4.4.3 <u>Segregation</u>. Takeda shall, and shall cause each of its Sublicensees to, establish, internal procedures consistent with industry best practices (including, without limitation, the procedures set forth below) to keep and maintain all Sucampo Background Technology, Sucampo's Confidential Information, Pre-Clinical Data, Clinical Data, CMC Data and any other Data provided by or for Sucampo in a secure environment and prevent the contamination of any of the foregoing that is received or made accessible in accordance with the terms and conditions under this Agreement.
- 4.5 Records. The Parties shall maintain records of their Development activities under the Development Plan in sufficient detail in good scientific manner appropriate for Patent application and regulatory purposes and in accordance with all Applicable Law and otherwise in a manner that reflects all work done and results achieved in the performance of the Development Plan. In addition to and not in lieu or limitation of the foregoing, each Party shall calculate and maintain detailed records of its Development costs. To the extent that, consistent with a Development Plan, a Party incurs Development costs, such Party shall provide the other Party with a reasonably detailed written invoice for such Development costs, and such Development costs shall be accounted for in the calendar quarter in which such invoice is received by the other Party. A Party shall provide to the other Party, within thirty (30) days after the end of each calendar quarter, a reasonably detailed written invoice showing an itemized statement of the Development costs together with adequate documentation for all expenses submitted hereunder. Such invoices shall set forth, among other things, a comparison of actual Development costs to expense budgets included in the applicable Development Plan and the cash settlement required between the Parties. Each Party agrees to make any required cash settlements of any undisputed amounts with the other Party within thirty (30) days following receipt of the applicable quarterly invoice issued by the other Party and provide a written notice of the basis of any disputed amounts to the other Party within fifteen (15) business days after receipt of the applicable quarterly invoice. Each Party shall notify the other Party in writing as soon as possible upon becoming aware that it may or will exceed the annual budget for the Development of any Licensed Product approved in the applicable Development Plan. The Parties will promptly meet to discuss the nature and extent by which the Party may exceed the annual budget and various ways to prevent, avoid or mitigate future expenses. Neither Party shall exceed the annual budget for the Development of a Licensed Product without the prior written consent of the other Party. The Parties shall retain such records for at least ten (10) years after the expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law or agreed to in writing by the Parties. Subject to ARTICLE 10, a Party shall provide the other Party, upon reasonable request, a copy of such records to the extent reasonably required for the performance of the requesting Party's obligations and exercise of its rights under this Agreement. Although the Parties agree that there is no intent to develop any Technology under the Development Plan or otherwise, each Party agrees to maintain a policy that requires its employees and consultants to record and maintain any Technology developed during the Development Plan in accordance with generally accepted practice in the industry.

- 4.6 <u>Right to audit.</u> Upon reasonable advance notice to the other Party and subject to the other Party's customary rules and restrictions with respect to site visits by non-Party personnel, a Party shall have the right, but not the obligation, to not more than once per year, except where there exists a reasonable cause to perform one (1) or more audits, (a) have access to the other Party's or any of its Sublicensee's and Subcontractors' facilities in which Development activities are performed, the investigators, project managers, other employees, contractors and other personnel performing the Development activities; (b) have access to and the right to examine reasonable information, books and records; (c) visit, examine and audit the other Party's and any Sublicensee's and Subcontractors' facilities in which the Development activities are performed and any containers or other equipment used in the work conducted for the Development activities, including any areas where the Compound is stored or handled; (d) inspect the work conducted and Development activities; and (e) audit and obtain copies of licenses, authorizations, approvals or written communications from any Regulatory Authority in connection with such Development activities, in each of the foregoing cases, during normal business hours in order that the Auditing Party may be assured as to whether the Development activities are being performed in conformance with the Development Plan and Applicable Law and otherwise in accordance with this Agreement.
- 4.7 <u>Technology Transfer.</u> As soon as reasonably practicable after the Effective Date and from time to time during the Term, Sucampo shall disclose to Takeda such of the Sucampo Patent Rights and Sucampo Background Technology that are necessary for Takeda to exercise its rights and perform its obligations to Develop and Commercialize the Licensed Product in the Field in any country in the Territory. During the Term, Sucampo will provide Takeda with reasonable technical assistance relating to the use of the Sucampo Patent Rights and Sucampo Background Technology, solely to the extent expressly permitted under this Agreement and the license granted to Takeda herein.

4.8 <u>Supply of Licensed Product.</u> Sucampo shall use Commercially Reasonable Efforts to supply the Licensed Product to Takeda as reasonably required for the completion of the Development of the Licensed Product in the Field in the applicable country in the Territory. Takeda shall be responsible for its and its employees', agents', Sublicensees', Affiliates', and Subcontractors' use, storage, handling and disposition of such Licensed Product. Unless otherwise directed by Sucampo, upon suspension, discontinuation or completion of the Development of the Licensed Product in the Field in any country in the Territory, Takeda shall: (a) promptly provide to Sucampo an accounting of the receipt and disposition of such Licensed Product, (b) at Sucampo's sole option and cost and expense, and to the extent reasonably possible, return to Sucampo or its designee properly all unused supplies of such Licensed Product in accordance with all Applicable Law and any requirements of or instructions by Sucampo, and (c) promptly provide to Sucampo a written notice by a duly authorized representative of Takeda of such return of such Licensed Product. Takeda shall not, and shall ensure that its employees, agents and contractors, including the investigators, its Affiliates and other Sublicensees shall not: (a) use such Licensed Product except as expressly and specifically described in this Agreement and the Development Plan; (b) distribute, transfer or release such Licensed Product to any other Person for any purpose or use, except as expressly and specifically required by the Development Plan. In addition to and not in lieu or limitation of the foregoing, Takeda shall (i) limit access to such Licensed Product to only the participants of any Clinical Studies in the Field in the applicable country in the Territory who have provided their informed consent and who are under the principal investigator's supervision, as expressly and specifically described in the Development Plan; and (ii) hold, store and transport such Licensed Product in co

ARTICLE 5 DEVELOPMENT AND COMMERCIALIZATION OF OTHER INDICATIONS

5.1 Reporting. From time to time during the Term, Sucampo and its Affiliates may seek to develop or commercialize Other Indication(s) in the Territory. Sucampo shall provide Takeda with written notice of such Other Indication(s) within thirty (30) Business Days after the Phase IIa Study reports or other similarly advanced Clinical Study reports are available for such Other Indication(s). The notice shall include such information with regard to such Other Indication(s) as Sucampo and its Affiliates reasonably determines is necessary to permit Takeda and its Affiliates to evaluate such Other Indication(s) and its/their potential marketability in the Territory for purposes of determining whether to exercise the option described in Section 5.2.

Takeda Right of First Option to Negotiate for Other Indications. Takeda shall have [...***...] ([...***...]) days from the date of the notice referred to in Section 5.1 to provide a written response as to whether it wishes to participate in negotiations with Sucampo with respect to such Other Indication(s) opportunity in the Territory, provided that Takeda agrees that, if it determines not to participate in such negotiations prior to the end of such period, it shall in good faith provide written notice to Sucampo promptly upon such determination. If Takeda's response indicating whether or not it wishes to participate in negotiations with respect to such Other Indication(s) opportunity in the Territory is not delivered to Sucampo within the [...***...] ([...***...]) day response period, Takeda shall no longer have the right to exercise such Other Indication(s) opportunity, as applicable, and Sucampo shall be free to discuss such Other Indication(s) opportunity, as applicable, with any Third Party without further obligation to Takeda. If Takeda indicates in its response delivered within such [...***...] ([...***...]) day period that it wishes to participate in negotiations with Sucampo with respect to such Other Indication(s) opportunity in the Territory, the Parties shall then negotiate in good faith for a period of [...***...] ([...***...]) days after Takeda's notice to Sucampo to include such Other Indication(s), as applicable, under a license agreement with the same legal terms and conditions as this Agreement. During the first period of [...***...] ([...***...]) days and the second period of [...***...] ([...***...]) days, Sucampo shall discuss exclusively with Takeda such Other Indication(s) opportunity in the Territory. If terms and conditions other than the legal terms and conditions of such license agreement have not been agreed upon by the Parties within the foregoing period, Sucampo shall be entitled to negotiate with Third Parties for the development and commercialization of such Other Indication(s) w

ARTICLE 6 REGULATORY

6.1 <u>Regulatory Filings; Regulatory Approvals</u>

6.1.1 Ownership. To the maximum extent permitted by Applicable Law, Takeda or its Affiliates shall own all Regulatory Filings in the Territory, including all Regulatory Approvals (excluding all Regulatory Filings and Regulatory Approvals in connection with the Manufacturing of the Licensed Product) and Takeda, its Affiliates or Distributors shall file the Marketing Authorization Applications (where no Existing Regulatory Approvals exist), register (where no Existing Regulatory Approvals exist) and maintain (including submitting variations of) all such Regulatory Approvals, including obtaining any variations or renewals thereof at Takeda's sole cost and expense for the Licensed Product in the Field in the applicable country in the Territory. To the maximum extent permitted by Applicable Law, Sucampo shall own all Regulatory Approvals in the Territory, including obtaining any variations or renewals thereof at Sucampo's sole cost and expense. Each Party agrees that neither it nor its Affiliates will do anything to adversely affect any of the Regulatory Approvals or other Regulatory Filings. Notwithstanding the foregoing and for the avoidance of doubt, to the maximum extent permitted by Applicable Law, Sucampo shall own all Data in accordance with Section 11.1 below.

6.1.2 Regulatory Strategy; Preparation and Maintenance of Regulatory Filings; Communications.

(a) <u>Development of Regulatory Strategy</u>. Takeda shall be responsible for the regulatory strategy (other than for Manufacturing) and will be part of the Development and Commercialization Plans as applicable. The Parties shall use Commercially Reasonable Efforts to cooperate and consult with each other, through the JWG, in good faith, to support the strategies for all Regulatory Filings in the Field in the applicable country in the Territory for the Licensed Product including the impact on the Regulatory Approvals outside the Territory, and Takeda shall update the Development and Commercialization Plans in accordance with Section 4.1.2.

(b) <u>Preparation of Regulatory Filings; Review of Regulatory Filings; Maintenance of Regulatory Approvals.</u>

Sucampo shall provide all Data, documents and support reasonably required for the successful transfer to Takeda of all Existing Regulatory Approvals for the Licensed Product (other than Existing Regulatory Approvals for Manufacturing) in all countries of the Territory as well as all Data, documents and support for applying, and obtaining Regulatory Approval where no Existing Regulatory Approvals exist in any applicable country in the Territory and for maintaining such Regulatory Approvals. Sucampo shall bear all costs for such Data, documents and support to the extent under Sucampo's Control and Takeda shall bear the cost for the Data, documents and support which is not under the Control of Sucampo. Subject to the terms of this Agreement, Takeda shall: (i) use Commercially Reasonable Efforts to implement the regulatory strategy for Clinical Studies in the Development Plan (other than Post-Approval Marketing Studies) including interactions with Regulatory Authorities; (ii) use Commercially Reasonable Efforts to prepare and submit Regulatory Filings in the applicable country in the Territory, where no Existing Regulatory Approvals exists for the Licensed Product other than Regulatory Filings for Manufacturing the Licensed Product (provided that the Parties shall reasonably cooperate with each other regarding such preparation and submission); and (iii) other public disclosure and confidentiality provisions in this Agreement notwithstanding, use Commercially Reasonable Efforts in obtaining, referencing and using all Regulatory Filings, Pre-clinical Data, Clinical Data and CMC Data for the Licensed Product (including but not limited to countries outside of the Territory) solely for use in the applicable country in the Territory in connection with the Regulatory Filings, without any additional compensation from Sucampo. At Sucampo's reasonable request, and subject to Applicable Law, Takeda shall use Commercially Reasonable Efforts to provide Sucampo with (a) copies of such Regulatory Filings in the applicable country in the Territory in the Field, material Preclinical Data, material Clinical Data, material CMC Data and other material Data generated by or for Takeda in connection with the Licensed Product and this Agreement within ninety (90) days of the Regulatory Filings, and (b) other material information as soon as practicable and otherwise keep Sucampo informed of any material developments from time to time.

(ii) Sucampo shall also provide Takeda in a timely manner with samples, standards and disposable items as the transfer of analytical methods, necessary for local laboratory control, required by Regulatory Authorities for obtaining, maintaining (including amending) Regulatory Approvals and/or for product certification and customs clearance for the Licensed Product in the Field in the applicable country in the Territory. As necessary, the Parties shall sign specific agreements to govern the matters relating to the supply of such samples, standards and disposable items and the transfer of analytical methods to Takeda at the latest before the first items are sent to Takeda. Each Party shall furthermore give prompt notice to the other Party in the event it becomes aware of any upcoming changes in Applicable Law to maintain the Existing Regulatory Approvals in the Territory. It is agreed by the Parties that the Data shall remain the property of Sucampo.

Promptly after the Effective Date, Sucampo shall use Commercially Reasonable Efforts to assign and transfer and/or (iii) cause its Affiliates to assign and transfer the Existing Regulatory Approvals for the Licensed Product in the Field in all countries in the Territory to Takeda or an Affiliate of Takeda in the Territory (excluding all Regulatory Approvals in connection with the Manufacturing of the Licensed Product). Takeda or an Affiliate of Takeda shall use Commercially Reasonable Efforts to become the holder of the Existing Regulatory Approvals for the Licensed Product in the Field in each country in the Territory (excluding all Regulatory Approvals in connection with the Manufacturing of the Licensed Product) and take appropriate steps for the transfers to occur as soon as possible. If required by Applicable Law or if requested by Takeda, Sucampo shall execute power of attorney in favor of Takeda and/or its Affiliates, and shall execute all documents as may reasonably be required by the Regulatory Authorities in the applicable country in the Territory to enable Takeda and/or its Affiliates to apply for, obtain and maintain the Regulatory Approvals for the Licensed Product in the Field in such country and become the holder thereof (other than any Regulatory Approval in connection with the Manufacturing of the Licensed Product). Sucampo shall furthermore provide all reasonable support necessary (at Takeda's own cost) to enable the successful transfer and assignment of the Existing Regulatory Approvals to Takeda (excluding all Regulatory Approvals in connection with the Manufacturing of the Licensed Product), including providing (i) necessary documents or other materials required by Applicable Law in such country in the Territory, (ii) access and reference to any relevant Regulatory Filings outside the Territory, and (iii) Regulatory Filings with the FDA, in a format and standard reasonably requested by Takeda, in each case at Takeda's sole cost and expense. Until such Regulatory Approvals are fully transferred to Takeda or its Affiliate, Sucampo or its Affiliate shall perform, at Sucampo's expense, reasonable activities with respect to such Existing Registration Approval and shall continue to maintain the Existing Regulatory Approvals, in each of the foregoing cases, at Takeda's sole cost and expense.

- (c) <u>Communications; Regulatory Meetings</u>. After the Regulatory Authorities in the applicable country in the Territory have approved the MAA, Sucampo shall, at Takeda's sole cost and expense, cooperate with Takeda's reasonable requests relating to, and provide support in responding to, communications from Regulatory Authorities in such applicable country in the Territory related to the Licensed Product in the Field, including using Commercially Reasonable Efforts to provide comments on Takeda's submissions and responses within ten (10) Business Days from the time of receipt by Sucampo or sooner if required by such Regulatory Authorities.
- (d) Occurrences or Information Arising out of Sucampo Manufacturing Activities. During the Term, Sucampo will discuss in good faith at the JWG any planned Manufacturing activity in the Territory and, only to the extent that any Licensed Product that is supplied by Sucampo to Takeda under this Agreement is Manufactured outside of the Territory and any planned Manufacturing activity outside of the Territory, that Sucampo is aware could potentially affect a Regulatory Filing or Regulatory Approval that is owned by Takeda or its Affiliates for the Licensed Product in the Field in the applicable country in the Territory under Section 6.1.1, and such activities shall always follow the change request procedure in this Agreement and the Quality Agreement. Sucampo shall also inform Takeda, without undue delay following, and in any event within a period not to exceed seven (7) Business Days, of any occurrences or information arising out of Sucampo's Manufacturing activities that Sucampo is aware have or could reasonably be expected to have adverse regulatory compliance and/or reporting consequences concerning the Licensed Product in the Field in the applicable country in the Territory, including actual or threatened Regulatory Filing withdrawals or labeling changes to the Licensed Product in the Field in such applicable country in the Territory.
- (e) <u>Regulatory Authority Inspections</u>. During the Term, each Party will be responsible for handling and responding to any Regulatory Authority inspections with respect to such Party's role in the Development, Manufacture and Commercialization of the Licensed Product. Each Party will provide to the other Party any information reasonably requested by the other Party and all significant information requested by any Regulatory Authority in the applicable country in the Territory concerning any governmental inspection related to the Licensed Product, and will allow Regulatory Authorities in such applicable country in the Territory to conduct inspections upon the request of such Regulatory Authority. In the event such Regulatory Authorities conduct an inspection, the Party under inspection will inform the other Party of the occurrence of such inspection, and invite the other Party to participate in the inspection process.
- (f) <u>Violations or Deficiencies Relating to the Licensed Product</u>. In the event a Party is inspected by any Regulatory Authority in the applicable country in the Territory relating to the Licensed Product, the inspected Party will notify the other Party without undue delay, and in any event within a period not to exceed seven (7) Business Days, of any written alleged violations or deficiencies relating to the Licensed Product, and any proposed corrective actions to be taken. The inspected Party shall as expeditiously as practicable take any such corrective action required to comply with the provisions of this Agreement and Applicable Law of such country. Prior to submission of any written response submitted to any applicable Regulatory Authority in the applicable country in the Territory, to the extent reasonably practicable, the other Party may review and comment on any portion of the response regarding written alleged violations or deficiencies relating to the Product; provided that the inspected Party shall have final say regarding the content of any submission to such Regulatory Authority.

- 6.2 <u>Product Labels and Inserts.</u> Takeda shall own and be responsible for the manufacturing of all Product Labels (for Secondary Packaging) and Inserts for the Licensed Product in the Field in the applicable country in the Territory. Takeda shall provide to Sucampo the initial artwork and the amended versions for such Product Labels and Inserts, for Sucampo's consent within five (5) Business Days, which shall not be unreasonably withheld or conditioned, provided that the absence of answer from Sucampo during this five (5) Business Days period shall be considered as consent to the artwork provided by Takeda. The Product Labels and Inserts for each country in the Territory shall comply with Applicable Law and Regulatory Approval in such country in the Territory.
- Pharmacovigilance Administration. The Parties shall enter into a Pharmacovigilance Agreement detailing the procedures of the pharmacovigilance system administration including but not limited to the exchange of safety related information and safety reporting procedures, which shall be separately agreed within ninety (90) days of the Effective Date of this Agreement (the "Pharmacovigilance Agreement"). Such procedures shall at all times include any measures necessary for each Party to fully comply with Applicable Law and such procedures may be amended with the Parties' mutual agreement from time to time. Sucampo has the responsibility of maintaining the Global Safety Database ("GSDB") for the Licensed Product and generating and compiling periodic safety update reports ("PSUR"/"PBERER") and development safety update reports ("DSUR"). Takeda, including any Affiliate and Distributor, has the responsibility for the pharmacovigilance system administration of the Compound and Licensed Product in the Field in the applicable country in the Territory including but not limited to operating any call centers, conducting any reporting obligations of Adverse Events/Reactions, literature monitoring, submitting safety related information to Sucampo required to be included in the GSDB, submitting any PSUR/PBERER and DSUR, any other applicable pharmacovigilance report (including but not limited to risk management plan ("RMP") or any periodic safety report). Takeda shall pay for all costs of the local pharmacovigilance system administration. Takeda shall pay Sucampo for all costs for the maintenance of the GSDB and the generation and compiling PSUR/PBERER and DSUR on a prorata basis of the number of cases reported by Takeda for the Territory over the total number of cases reported worldwide but in no event shall Takeda, including its Affiliates, [...***...] and under the Collaboration and Licence Agreement between Takeda Pharmaceutical Company Limited and Sucampo Pharmaceuticals, Inc. made on October 29, 2004. For instance, if Takeda reports ten (10) cases a year for the Territory and the total amount of cases reported worldwide is one hundred (100), then Takeda shall pay only ten percent (10%) of the costs for the maintenance of the GSDB. The current estimated cost for processing a case is [...***...] United States Dollars (USD [...***...]). Takeda shall be responsible and bear all costs associated with the management and the reporting of the local safety databases. Sucampo and Takeda shall ensure that they and their Affiliates provide each other with all information and data reasonably required to allow Sucampo and Takeda to each comply with its regulatory obligations in or outside of the Territory. For clarification, the Pharmacovigilance Agreement shall govern with respect to matters in connection with the pharmacovigilance administration for the Compound and Licensed Product; provided that the cost allocation of such pharmacovigilance system administration and GSDB shall be governed by this Section

6.4 Recalls and Market Withdrawals

- 6.4.1 <u>Notification</u>. Each Party shall make every reasonable effort to notify the other Party promptly upon its determination that any event, incident or circumstance has occurred that may result in the need for a Recall or Market Withdrawal of the Licensed Product in the applicable country in the Territory, and include in such notice the reasoning behind such determination and any supporting facts. The timelines for such notification will be mutually agreed by the Parties in the Quality Agreement.
- 6.4.2 <u>Initiation</u>. Both Parties shall jointly discuss whether to voluntarily implement any Recall and upon what terms and conditions the Licensed Product shall be subject to a Recall in the applicable country in the Territory. If time allows, both Parties shall jointly discuss and the JSC shall determine whether to voluntarily implement a Market Withdrawal in the applicable country in the Territory and upon what terms and conditions the Licensed Product shall be subject to a Market Withdrawal or otherwise temporarily or on a limited basis withdrawn from sale in such applicable country in the Territory; provided that notwithstanding the foregoing or anything to the contrary in this Agreement, Takeda may, in accordance with its Commercially Reasonable Efforts and generally applied internal regulations with respect to compliance and Adverse Events/Reactions and Serious Adverse Events/Reactions and the terms and conditions of the Pharmacovigilance Agreement or the Quality Agreement as applicable, cause Takeda and its Sublicensees and Subcontractors to, cease or suspend (on a country-by-country and Licensed Product-by-Licensed Product basis) the Development and Commercialization of the Licensed Product in the Field in the applicable country in the Territory, as applicable, upon reasonable written notice to, and good faith consultations with, Sucampo prior to any such cessation or suspension in the event that (a) such cessation or suspension is required by the applicable Regulatory Authority in the applicable country in the Territory or (b) Takeda reasonably and in good faith believes that such cessation or suspension is needed in order to limit any potential material liability of the Parties due to any health and safety issues reported in connection with such Development and

Commercialization, including any reported Adverse Events/Reactions or Serious Adverse Events/Reactions. In addition to and not in lieu or limitation of the foregoing, in the event that Sucampo and Takeda are unable to agree within appropriate timelines whether or not to voluntary implement a Recall or Market Withdrawal of the Licensed Product in the applicable country in the Territory, notwithstanding anything herein to the contrary, Takeda shall make the final determination. If a Recall is mandated by a Regulatory Authority in a particular country in the Territory, Takeda shall initiate such a Recall to be in compliance with Applicable Law in such country. In the event of any Recall, Market Withdrawal or other withdrawal of the Licensed Product in the applicable country in the Territory, each Party shall provide, and cause its Affiliates and other Sublicensees to provide, any and all assistance and support required by Applicable Law in such country, or reasonably requested by the other Party; provided that for clarification, Takeda shall be responsible for initiating such Recall, Market Withdrawal or other withdrawal of such Licensed Product. For the avoidance of doubt, (a) the Recall or Market Withdrawal of a Licensed Product under this Section 6.4.2 shall be determined on a Licensed Product-by-Licensed Product basis and on a country-by-country basis in the Territory, and (b) the Recall or Market Withdrawal of a Licensed Product in a particular country in the Territory may, but shall not automatically, affect the Development or Commercialization of any other Licensed Product or any other country in the Territory.

Responsibility. In the event of a Recall or Market Withdrawal of the Licensed Product or any lot(s) thereof in any country in the Territory, Takeda shall bear all costs and expenses of such Recall or Market Withdrawal including expenses and other costs or obligations of Third Parties, the cost and expense of notifying customers and the costs and expenses associated with the Market Withdrawal or Recall of the Licensed Product in such country and the cost and expenses of destroying the Licensed Product recalled from such country, if necessary, unless such Recall or Market Withdrawal was solely caused by: (a) the Manufacturing (other than Secondary Packaging) and supply of the Licensed Product solely as and in the form supplied by Sucampo to Takeda for commercial distribution and use in the Field in the applicable country in the Territory; provided that the defect of the Licensed Product that resulted in the Market Withdrawal or Recall is a Patent Defect or Latent Defect, or (b) Sucampo's final determination to implement a voluntary Recall or Market Withdrawal of the Licensed Product in such country in the Territory after the Parties are unable to agree with respect to the same and it is later determined that such Recall or Market Withdrawal was not necessary, in which case Sucampo shall pay for all reasonable costs and expenses of such Recall or Market Withdrawal to the extent such Recall or Market Withdrawal was caused by Sucampo.

6.5 Complaints. Each Party shall maintain a record of all complaints it receives from a Third Party with respect to any Licensed Product in the Field in any country in the Territory and shall refer to the other Party complaints that it receives concerning the Licensed Product in the Field in any country in the Territory within forty-eight (48) hours of its receipt of the same as provided for in the Quality Agreement; provided that all complaints concerning suspected or actual Licensed Product occurrence of any of the following: mixed strengths in same bottle, foreign product in container/package, foreign matter in vial, general package contamination, label mix, missing label, missing or incorrect lot/expiration on primary or secondary (if secondary packaging has tamper-evident tape) package, missing package insert (if design includes a PI), and missing tamper evident tape shall be delivered within twenty-four (24) hours of receipt of the same as provided for in the Quality Agreement. Each Party shall be responsible for investigating complaints and taking corrective action as necessary at its own cost and expense and, shall use Commercially Reasonable Efforts in providing all reasonable efforts and collaboration with the other Party in the resolution of complaints, and shall train its employees on the proper handling and resolution of complaints concerning the Licensed Product as provided for in the Quality Agreement; provided that the costs and expenses therefor shall be borne by the Party solely liable for the complaints, or by both Parties based on the allocation of liability, if they are jointly and severally liable for the complaints; provided that for clarification, the foregoing shall not waive, modify, limit, restrict, condition or otherwise affect the cost allocation between the Parties in the event of a Recall or Market Withdrawal pursuant to Section 6.4 above.

ARTICLE 7 COMMERCIALIZATION OF LICENSED PRODUCT

7.1 Commercialization Plan

- 7.1.1 Initial Commercialization Plan. Approximately six (6) months prior to the estimated date for the filing of the first MAA Takeda shall prepare and submit to the JSC for review and comments the initial Commercialization Plan by Key Markets. For countries of the Territory where there is an Existing Regulatory Approval upon the Effective Date of this Agreement, the initial Commercialization Plan shall be prepared by Takeda within sixty (60) days of the Effective Date. The initial Commercialization Plan for the Key Markets in the Territory shall include:
 - (a) the pre-launch plan with key regulatory milestones to be achieved in the launch period and through years three (3) and five (5);
 - (b) the number of full-time representative equivalents to be deployed during the launch and during the first five (5) years of the Term;
 - (c) volume and sales forecasts for the five (5) next years;
 - (d) marketing plans to achieve revenue and sales forecasts; and
 - (e) budget allocation in percentages of the total budget with regard to activities specified in the Commercialization Plan.

- 7.1.2 <u>Update of the Commercialization Plan</u>. The Commercialization Plan shall be revised annually by Takeda and submitted to the JSC for review and comments on or before November 30 of each year.
- 7.2 <u>Responsibility.</u> Subject to the terms and conditions of this Agreement, Takeda shall be responsible for all aspects of Commercializing the Licensed Product in the Field in the applicable country in the Territory in accordance with the Commercialization Plan and all Applicable Law.
- 7.3 Costs. Takeda will be responsible for the costs of Commercialization in the Territory, including the costs of developing Promotional Materials, scientific meetings, CME-related educational symposia, promotional marketing programs, sales training, distribution, salaries and similar expenses, as appropriate.
- Promotional Materials. During the Term, Takeda shall be solely responsible for creating and developing Promotional Materials to be used in 7.4 connection with the Promotion of the Licensed Product in the Field in the applicable country in the Territory. First version of Promotional Material for the Key Markets are subject to the prior review and comment by the JSC on a Licensed Product-by-Licensed Product basis and on a country-by-country basis in the Territory. Takeda shall ensure that all Promotional Materials comply with all Applicable Law in the applicable country in the Territory and do not infringe or otherwise violate the intellectual property or other rights of any Third Party. To the extent that any Promotional Materials are required by Applicable Law to be submitted to the Regulatory Authority in the applicable country in the Territory, Takeda shall make such submissions, and Takeda shall be the Regulatory Authority liaison on all marketing, advertising and Promotional matters. Sucampo shall use Commercially Reasonable Efforts to provide Takeda with copies of Promotional Materials used by Sucampo, its Affiliates, its licensees and distributors. During the Term, Takeda shall only use such Promotional Materials for the Promotion of the Licensed Product in the Field in such applicable country in the Territory in compliance in all respects with this Agreement and all Applicable Law and after the Term, Sucampo shall own all rights in the Promotional Materials provided by Sucampo to Takeda during the Term anywhere in the world. For the avoidance of doubt, any Promotional Material created and developed by or on behalf of Takeda or its Affiliates will be owned by Takeda after the Term. As part of the foregoing, to the maximum extent permitted by Applicable Law, Takeda agrees that it shall and hereby does, and shall cause its Affiliates to, irrevocably grant, convey, transfer, assign and deliver to Sucampo all right, title and interest in and to such Promotional Materials provided by Sucampo to Takeda during the Term (and all intellectual property rights therein or thereto), throughout the world. Notwithstanding the foregoing, Sucampo agrees not to exercise its ownership or license rights with respect to the Promotional Materials with respect to a Licensed Product in any particular country in the Territory until the earlier of (a) the termination of Takeda's right to Promote or Commercialize such Licensed Product in such country pursuant to Section 12.2.2 below, and (b) the expiration or termination of this Agreement.

- 7.4.1 <u>Presentation and Promotion of the Licensed Product.</u> The Commercialization Plan shall describe, with respect to Key Markets, the manner in which the Licensed Product in the Field in the applicable country in the Territory will be presented and described to the medical community in any Promotional Materials or other materials and any placement of the Corporate Names of the Parties, in each case as and to the extent expressly and specifically permitted according to Section 11.4 and by Applicable Law in the applicable country in the Territory and with the Product Labels and Inserts for the Licensed Product approved by the applicable Regulatory Authority in such applicable country in the Territory.
- Non-Compete. For a period of [...***...] ([...***...]) years from the First Commercial Sale, on a country by country basis, to the extent permitted by Applicable Law, Takeda and Sucampo shall refrain, and shall cause their respective Affiliates to refrain from, promoting, marketing, selling, offering for sale, distributing, commercializing or otherwise exploiting in any country of the Territory in the Field any small molecule oral pharmaceutical product that have the same mode of action as the Licensed Product (i.e. chloride channel activator), for Takeda other than the Licensed Product and other than Takeda's pharmaceutical products in the Field as of the Effective Date (a "Competing Product"), without the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed. The Parties acknowledge and agree that the following specific pharmaceutical products shall be considered as Competing Products: Linaclotide, Prucalopride Methylnaltrexone and Naloxegol.

ARTICLE 8 CONSIDERATION

- 8.1 <u>Upfront Payment</u>. In consideration of the rights and licenses granted under this Agreement, Takeda shall make a nonrefundable payment to Sucampo in the amount of [...***...] United States Dollars (USD [...***...]), against proper invoice within thirty (30) days of the Effective Date.
- 8.2 <u>Payments on Annual Net Sales.</u> Takeda shall make each of the following non-refundable and non-creditable payments to Sucampo against proper invoice, in the amounts set forth below, each on a one (1) time basis as specified below:

Annual Net Sales Milestones and Due Date	Payment	
, , , , , , , , , , , , , , , , , , , ,	[***] United States Dollars (USD [***]) within thirty (30) Business Days after the occurrence of the submission of the report demonstrating the event	
Aggregate Annual Net Sales for the Licensed Product in all countries in the Territory first exceed [***] Million United States Dollars (USD [***]) in a calendar year	[***] United States Dollars (USD [***]) within thirty (30) Business Days after the occurrence of the submission of the report demonstrating the event	
Aggregate Annual Net Sales for the Licensed Product in all countries in the Territory first exceed [***] United States Dollars (USD [***]) in a calendar year	[***] United States Dollars (USD [***]) within thirty (30) Business Days after the occurrence of the submission of the report demonstrating the event	

8.3 Supply Price. Promptly after shipment of Licensed Product to Takeda, Sucampo shall, subject to Section 4.4.3, invoice Takeda the Supply Price for such Licensed Product shipped to Takeda. Takeda shall pay the Supply Price for such Licensed Product within sixty (60) days after such invoice is received by Takeda, provided that if Takeda rejects such Licensed Product pursuant to Section 9.7 due to a Patent Defect, a Latent Defect or because the delivery of such Licensed Product is not in compliance with the quantities set forth on the relevant purchase order, then, in the case the Licensed Product is not in compliance with the quantities set forth in the purchase order, payment shall still be due for the quantities actually shipped to and received and accepted by Takeda pursuant to Section 9.7 below within sixty (60) days after such invoice is received by Takeda or, in the case of an allegation of a Patent Defect or Latent Defect, payment shall then be due within sixty (60) days after receipt by Takeda of notice from the independent laboratory pursuant to Section 9.7 below that such allegation is not the case. In the event that during the term of this Agreement the Supply Price does not allow for commercially viable margins for Takeda, as decided by Takeda using Commercially Reasonable Efforts, or otherwise has an impact on the Commercialisation of the Product in the Territory, then the Parties will enter good faith negotiations to discuss and agree to a potential reduction of the Supply Price. Specifically in the event Takeda attains the Annual Net Sales Milestones described in Section 8.2, the Parties shall discuss and shall agree in good faith to an adjustment in the Supply Price for the Licensed Product within three (3) months following the attained Annual Net Sales Milestones, which such reduction being [... ***...] percent ([...***...]%).

- Third Party Royalties. If any of Takeda's activities under this Agreement, including the Development or Commercialization of the Licensed Product by Takeda in a particular country in the Territory or outside the Territory infringes or misappropriates or otherwise makes unauthorized use of any intellectual property rights of a Third Party (other than Takeda's Affiliates or other Sublicensees) in such country such that Takeda cannot carry out the activities under this Agreement (such as but not limited to use, Develop or Commercialize the Licensed Product) in such country as provided for herein without infringing, misappropriating or making unauthorized use of the intellectual property rights of such Third Party (other than Takeda's Affiliates or other Sublicensees), then each Party shall promptly notify the other Party upon becoming aware of the same and, Sucampo shall, use Commercially Reasonable Efforts to, within three (3) months: (a) obtain such licenses and rights as are necessary for Takeda to Develop or Commercialize the Licensed Product in the Field in such country as expressly provided for herein and Sucampo shall be solely responsible for the payment of all such Third Party Royalties or (b) replace or modify any affected Sucampo Background Technology so that it does not infringe or misappropriate at Sucampo's sole cost and expense. Notwithstanding the above, after expiration of the before mentioned three (3) month period, Takeda may at its sole discretion decide to negotiate with such Third Party to obtain such licenses and rights as are necessary for Takeda to Develop or Commercialize the Licensed Product in the Field in such country. The payments due to Sucampo according to this Agreement shall be reduced to the extent Takeda pays Patents or Trademarks royalties to any Third Parties in connection with Takeda's activities under this Agreement, such as Development, Secondary Packaging, or Commercialization of the Licensed Product in the Field in the applicable country of the Territory.
- 8.5 <u>Payment Dates and Reports.</u> Starting with the month following the calendar quarter in which the First Commercial Sale occurs in any country in the Territory and continuing thereafter during each calendar quarter of the Term within fifteen (15) days following the end of each calendar quarter, Takeda shall provide one consolidated report based on GAAP showing on a Licensed Product-by-Licensed Product basis and on a country-by-country basis a statement identifying the amount of Net Sales during the relevant calendar quarter.
- Financial Audit Rights. Each Party shall keep and maintain for at least ten (10) years complete and accurate records in sufficient detail to allow confirmation of any payment and Development cost calculations made hereunder, unless under local Applicable Law a longer timeframe is required. Upon the written request of a Party ("Auditing Party") and not more than once in each Calendar Year, the other Party ("Audited Party") shall permit an independent certified public accounting firm of internationally-recognized standing, selected by the Auditing Party (provided that the Auditing Party shall not without the Audited Party's prior written consent select the same public accounting firm that conducts the Auditing Party's annual financial statement audit) and reasonably acceptable to the Audited Party, at the Auditing Party's expense, to have access, with not less than thirty (30) days' notice, during normal business hours, to the records of the Audited Party and its Affiliates as may be reasonably necessary to verify the accuracy of the payments hereunder for any Calendar Year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm will be instructed to provide its audit report first to the Audited Party, and will be further instructed to redact

any Confidential Information of the Audited Party not relevant to verifying the accuracy of payments or Development costs prior to providing that audit report to the Auditing Party. The accounting firm's audit report shall state whether the applicable report(s) is/are correct or not, and, if applicable, the specific details concerning any discrepancies. No other information shall be shared. If such accounting firm concludes that additional monies were owed by the Audited Party to the other, the Audited Party shall pay the additional monies against invoice within thirty (30) days of the date the Audited Party receives such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by the Auditing Party; provided if an error in favor of the Auditing Party of more than ten percent (10%) is discovered, then the Audited Party shall pay the reasonable fees and expenses charged by such accounting firm. Any audit reports provided hereunder shall be the Confidential Information of the Audited Party. Takeda shall either: (a) require each of its Affiliates to maintain similar books and records and to open such records for inspection to the accounting firm in the manner paralleling that set forth in this Section 8.5, or (b) obtain such audit rights from its Affiliates for itself and exercise such audit rights on behalf of Sucampo upon Sucampo's request and disclose the results thereof to Sucampo. In either case Sucampo shall be deemed the Auditing Party, and such Affiliates and other Sublicensees of Takeda the Audited Party for purposes of this Section 8.6.

- 8.7 Withholding Taxes. All payments made under this Agreement shall be free and clear (exclusive of) of any withholding taxes required by Applicable Law. Where any sum due to be paid to a Party hereunder is subject to any withholding tax under Applicable Law of a particular country in the Territory, the Parties shall use Commercially Reasonable Efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax under Applicable Law in such country, or not all documents required to claim benefits of any applicable double taxation agreement or treaty are made available to the paying Party at least five (5) Business Days prior to the payment, the paying Party shall deduct any withholding taxes from payment and pay such withholding or similar tax to the appropriate Regulatory Authority in such country, deduct the amount paid from the amount due to the receiving Party and secure and send to the receiving Party to its reasonable satisfaction an available evidence of such obligation together with proof of payment.
- 8.8 Payments. All payments due under this Agreement shall be payable in United States Dollars (USD) other than the Supply Price, which shall be payable in JPY unless Sucampo has notified Takeda in writing that Sucampo will change the Manufacturing site and will Manufacture the Licensed Product through its Back-Up Supplier; in which case, Sucampo will advise Takeda of the applicable currency to be applied to the Supply Price at the agreed exchange rate. Unless expressly specified otherwise herein, all payments under this Agreement shall be by appropriate electronic funds transfer in immediately available funds to the following bank account of the applicable Party:

Bank information

For Sucampo:

For USD
Bank: [...***...]
Address: [...***...]
Swift Code: [...***...]
Account: [...***...]
IBAN Number: [...***...]
Contact Person: [...***...]
For JPY
Bank: [...***...]
Address: [...***...]
Swift Code: [...***...]
Account: [...***...]
IBAN Number: [...***...]
Contact Person: [...***...]
Swift Code: [...***...]
Account: [...***...]
IBAN Number: [...***...]
Address: [...***...]
Address: [...***...]
Address: [...***...]
Address: [...***...]
Account: [...***...]
Account: [...***...]

Each payment shall reference this Agreement and identify the obligation under this Agreement that the payment satisfies.

8.9 <u>Supply Price Adjustment.</u> On a yearly basis the Parties will adjust for any changes in the exchange rate between: (a) the currency in which Sucampo pays for its labor and, overhead and JPY solely to the extent any changes in the exchange rate exceeds [...***...] % from the Contract Rates (defined below) and (b) the currency in which revenues from Net Sales are received and USD based on the weighted average exchange rate over the prior consecutive twelve (12) month period from the date that the consolidated report is being prepared by Takeda pursuant to Section 8.5. On the first business day of the third month of any calendar quarter prior to the quarter of application, the Parties shall establish the exchange rates ("Contract Rates") to be applied to the following quarter's costs (for those costs denominated in currencies different from the currency in which the costs of labor and overhead are denominated) by calculating the average exchange rate over the prior consecutive twelve (12) month period. The source of the Contract Rates and the exchange rates will be the European Central Bank.

8.10 No Other Compensation. Unless otherwise agreed to by the Parties and set forth in writing, Sucampo and Takeda hereby agree that the terms of this Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by each Party to the other in connection with the transactions contemplated herein. Neither Party has previously paid or entered into any other commitment to pay, whether orally or in writing, any employee, agent or contractor of the other Party, directly or indirectly, or any consideration, compensation or benefits, monetary or otherwise, in connection with the transactions contemplated herein other than as expressly and specifically set forth in this Agreement.

ARTICLE 9 SUPPLY

9.1 General

- 9.1.1 Strategy. The Parties, through the JWG, shall provide regular updates on the supply of Licensed Product in the applicable country in the Territory, and issues related thereto. The Parties will review the supply strategy on an ongoing basis to ensure adequate risk mitigation for supply by Sucampo of the Licensed Product. Sucampo shall keep Takeda reasonably informed of inventory or production issues that it is aware may affect the availability of Licensed Product. Takeda hereby acknowledges and agrees that it shall, and shall cause each of its Affiliates and other Sublicensees to, exclusively purchase the Licensed Product from Sucampo during the Term, subject to Applicable Law. Sucampo agrees and acknowledges that it shall supply to Takeda the quantities specified in the forecast attached in EXHIBIT O and that Takeda has no commitment to order further quantities of Licensed Product. Under no circumstances shall Sucampo withhold supply from Takeda, including, but not limited to, during a dispute between the Parties. The Parties acknowledge and agree that Sucampo is not obligated to provide copies of or access to the Manufacturing Data to Takeda except to the extent required for Takeda to comply with its obligations under this Agreement, including without limitation its Adverse Event/Reaction reporting obligations and the filing and maintenance of Regulatory Filings.
- 9.1.2 <u>Manufacturing by Sucampo</u>. In accordance with the applicable terms and conditions of this Agreement, Sucampo shall use Commercially Reasonable Efforts to Manufacture (excluding Secondary Packaging) or have Manufactured by an Affiliate or a Subcontractor on the conditions as stated on Section 9.1.3 in compliance with the Specifications and test and deliver to Takeda and/or its Affiliates or Sublicensees its entire requirement of Licensed Product, for the Commercialization.

- 9.1.3 Sucampo represents and warrants that all such Licensed Product Manufactured (other than Secondary Packaging) and supplied by or on behalf of Sucampo has been and shall:
- (a) be Manufactured in accordance and in compliance with Applicable Law in the countries in the Territory where such Licensed Product is to be distributed for sale in the Field, including cGMP;
- (b) be Manufactured in accordance with the applicable Regulatory Filings and Regulatory Approvals in the countries in the Territory where such Licensed Product is to be distributed for sale in the Field;
- (c) upon delivery, not be adulterated or misbranded as defined by Applicable Law in the countries in the Territory where such Licensed Product is to be distributed for sale in the Field;
- (d) upon delivery, not have reached the term of [...***...] ([...***...]) months on a total shelf life which shall not be in any event less than of [...***...] ([...***...]) months;
 - (e) be free from material defects in materials and workmanship; and
 - (f) be in compliance with all Specifications for such Licensed Product

(hereinafter collectively "Agreed Quality").

9.1.4 <u>Sufficient Inventories</u>. For the Term, and subject to the timely supply of the Rolling Forecast pursuant to Section 9.1.5, Sucampo shall use Commercially Reasonable Efforts to cause its supplier to maintain sufficient inventories of Compound required to Manufacture the Licensed Product (other than Secondary Packaging) in order to ensure timely delivery of the Licensed Product. Sucampo shall cause its supplier to maintain a safety stock of Compound equal to [... ***...] ([...***...]) months of forecast demand based on Takeda's most recent Rolling Forecast.

9.1.5 Forecasts and Orders

(a) No later than [...***...] during the Term, Takeda will provide Sucampo with an updated [...***...] ([...***...]) month rolling forecast of the Licensed Product to be Manufactured and supplied by or on behalf of Sucampo (each a "Rolling Forecast") for the [...***...] ([...***...]) month period commencing at the beginning of the following month with the first [...***...] ([...***...]) months considered a purchase order period. Each Rolling Forecast will be broken down for each month of such period by: (i) the Licensed Product, (ii) the quantity (by SKU of Licensed Product). The first [...***...] ([...***...]) months of each new Rolling Forecast will constitute the new purchase order for which Takeda will be obligated to purchase and take delivery of the Licensed Product.

- (b) Except as set forth herein, all months of the Rolling Forecast other than the first [...***...] ([...***...]) months will set forth Takeda's estimate of its requirements for the supply of Licensed Product on a Licensed Product-by-Licensed Product basis and on a country-by-country basis in the Territory, and the Rolling Forecast for the months [...***...] ([...***...]) through [...***...] ([...***...]) of each Rolling Forecast will not be binding.
- (c) In the event that the Rolling Forecast sets forth more than [...***...] ([...***...]) capsules as samples of Licensed Product, the Parties will in good faith renegotiate the Supply Price for samples.
- 9.1.6 <u>Purchase Order.</u> All purchases of Licensed Product shall be pursuant to written purchase orders consistent with Section 9.1.5(a), which shall be placed by Takeda at least sixty (60) days prior to the date of which such Licensed Product shall be delivered to Takeda or the applicable Affiliate or Sublicensee. Each such purchase order will be consistent with the purchase order period of the most recent Rolling Forecast. If a purchase order for any month which is binding pursuant to Section 9.1.5(a) and 9.1.5(b) above is not submitted by the above deadline, then the quantity of the Licensed Product that Takeda is committed to purchase for such binding month shall carry forward and be added to the next calendar month until fulfilled; provided that notwithstanding the foregoing, Takeda must issue a purchase order therefor prior to the end of the then-current calendar year. Each purchase order hereunder shall specify the desired quantities of each Licensed Product and the delivery dates therefor.
- 9.1.7 <u>Acceptance of Orders.</u> Orders and delivery dates will be deemed accepted unless Takeda and/or its Affiliate or Sublicensee receives written notice of rejection within ten (10) Business Days. Sucampo may only reject an order (a) that lists products that are not covered by this Agreement, (b) that is inconsistent with the amounts permitted by Section 9.1.5 and Section 9.1.6 or (c) during a supply constraint situation in accordance with Section 9.3 below.
- 9.1.8 Secondary Packaging by Takeda. Subject to the terms and conditions of this Agreement, Takeda has the responsibility to perform the Secondary Packaging of the Licensed Product supplied by Sucampo for the Development and Commercialization of the Licensed Product in accordance and in compliance with any applicable Specifications for the Secondary Packaging and Applicable Law in the countries in the Territory where such Licensed Product is to be Commercialized, including cGMP. All costs in connection with the Secondary Packaging of the Licensed Product, including any and all additional incremental costs resulting from changes to the Specifications for Secondary Packaging that are required to export the Licensed Product to countries in the Territory on a country-by-country basis under Applicable Law shall be borne by Takeda.

- 9.1.9 <u>Subcontracting.</u> Takeda hereby authorizes that Sucampo may subcontract the Manufacturing of the Compound and the Licensed Product. The Parties acknowledge and agree that Takeda may subcontract the Secondary Packaging of the Licensed Product in accordance with Section 2.1.2 above. Sucampo shall not be relieved of its obligations pursuant to this Agreement as a result of such appointment of any Subcontractors and shall remain fully responsible and liable for any action or omission of such Subcontractors which would constitute a breach of this Agreement if committed by Sucampo as if Sucampo had committed such action or inaction itself.
- 9.1.10 <u>Changes Control</u>. Sucampo shall, and shall cause its appointed Third Parties to, promptly implement any changes to the Licensed and/or its Specifications that are required by Applicable Law or by Regulatory Authorities (collectively, "Required Changes") in accordance with the change control procedure set forth in the Quality Agreement. For changes to the Licensed Product and/or its Specifications that are not Required Changes, including but not limited to subcontracting of Manufacturing or Secondary Packaging (collectively, "Discretionary Changes"), the requesting Party shall notify the other Party in advance of such Discretionary Changes in order to obtain such Party's prior written approval, such approval not to be unreasonably withheld or delayed, in accordance with the change control process to be established under the Quality Agreement. Sucampo shall implement any such changes only upon prior approval of Takeda. The Parties shall, to the extent commercially reasonable under the circumstances, cooperate in making such changes.
- 9.1.11 Costs of Changes. All costs and expenses associated with Required Changes shall be shared equally between the Parties. All costs and expenses associated with Discretionary Changes shall be borne by the Party requesting such change, provided, however, that if a Discretionary Change is supported by both Parties and is foreseen to improve the commercial viability or the health and safety of a Licensed Product in the Territory, the costs of such Discretionary Change shall be shared equally between the Parties. Costs associated with changes requested by Sucampo solely in order to optimize the Manufacturing process (other than Secondary Packaging) of the Licensed Product (but which do not otherwise improve the commercial viability or health and safety of a Licensed Product), shall be borne by Sucampo. All changes required for Secondary Packaging shall be covered by Takeda.

- Back-Up Supplier. Sucampo shall use Commercially Reasonable Efforts to provide Takeda, within ninety (90) days after the Effective Date, with 9.1.12 a written list of Third Party contract manufacturer(s) (other than for Secondary Packaging) identified by Sucampo to act as potential Back-Up Suppliers. The Parties will discuss the strategy to qualify the Back-Up Supplier in the meetings of the JSC and JWG. Not later than [...***...], Sucampo shall identify one or more Third Party contract manufacturers reasonably acceptable to Takeda to act as a secondary source for the Manufacture and supply of the Licensed Product. Not later than twelve (12) months after [...***...], Sucampo shall use Commercially Reasonable Efforts to obtain all Regulatory Approvals required for the Back-Up Supplier to Manufacture and supply the License Product for use in Development and Commercialization of such Licensed Product as provided under this Agreement. Sucampo will be responsible for all costs associated with qualifying the Back-Up Suppliers, including costs for materials, start up, validation and test batches, stability testing and equipment. Upon written request by Takeda from time to time, Sucampo shall provide a reasonably detailed written report of Sucampo's efforts and progress to qualify the Back-Up Suppliers as required hereunder. Sucampo shall ensure that the Back-Up Supplier has the capacity to Manufacture and supply the Licensed Product in sufficient quantities to meet Takeda's binding forecast in any given quarter in the event of an interruption to the primary source of supply. Sucampo, at their cost, shall prepare and submit to the applicable Regulatory Authorities all information and filings, and take such other actions reasonably required, to obtain and maintain the Regulatory Approvals required for the Back-Up Supplier to Manufacture and supply the Licensed Product for Development and Commercialization activities under and during the Term of this Agreement. For the avoidance of doubt, Takeda shall continue to purchase the Licensed Product directly from Sucampo in the event that it is necessary for Sucampo to use the Back-Up Supplier to Manufacture, and supply to Takeda, the Licensed Product. Under no circumstances shall Sucampo willfully withhold supply of the Compound or the Licensed Product from Takeda during the Term of this Agreement, including, but not limited to, during a dispute with Takeda.
- 9.2 <u>Delivery.</u> Sucampo shall deliver the Licensed Product CIP at the packaging site of Sucampo (Incoterms 2010) for Licensed Product primary packaged in blisters PCI located in Philadelphia, USA and for the Licensed Product primary packaged in bottles Aphena Pharma Solutions, located in Whippany, NJ USA, subject to the release of the relevant Licensed Product as per Section 9.4. Takeda shall designate to Sucampo the carrier which will take delivery of the Licensed Product. Sucampo shall contact such carrier when the Licensed Product is ready for shipping and shall arrange for collection, and transportation of the Licensed Product. Sucampo shall inform Takeda two (2) Business Days prior to pick-up by the carrier. Takeda shall bear the costs for transport of the Licensed Product and will be invoiced directly by the carrier. Delivery documents shall include purchase order number, quantity, copy of the certificate of analysis, items codes and description, lot number, manufacturing date of the Licensed Product, number of shippers, weight, number of pallets, and any other documents in accordance with the terms of the Quality Agreement.

- Limited Supply. In the event that the Licensed Product in the Field in the Territory is not meeting Takeda's requirements for the Licensed Product in excess of [...***...] ([...***...]%) of the Binding Forecast in a given quarter, Sucampo shall notify Takeda of such shortage as soon as possible upon becoming aware of the same. In the event there is a short supply of the Licensed Product in the Territory and Sucampo cannot supply the Licensed Product to Takeda in an amount equal to Takeda's firm order, then Sucampo shall use Commercially Reasonable Efforts to allocate available Licensed Product and cause its Third Party manufacturer to allocate Manufacturing capacity to provide to Takeda in each month that such a shortfall exists (and in each month thereafter until the shortfall to Takeda is remedied) the Licensed Product in an amount equal to (a) the amount of available Compound or Licensed Product and/or related manufacturing capacity, multiplied by (b) a fraction the numerator of which is (i) the aggregate of firm orders made by Takeda over the subsequent twelve (12) month period including the shortfall month and the denominator of which is (ii) the sum of (x) the aggregate quantity of firm orders made by Takeda over the subsequent twelve (12) month period including the shortfall months and (y) the aggregate quantity of Compound or Licensed Product over the same twelve (12) month period required by other licensees in a country outside of the Territory by reference to firm orders placed with Sucampo for such licensees' requirements outside of the Territory. In the event Takeda terminates this Agreement according to Section 12.2.2(a), Sucampo shall assist Takeda with initiating, implementing and finishing the qualification of an alternative supplier of Licensed Product capable of supplying Takeda and its Affiliates and Sublicenses with its requirements of Licensed Product. Any Third Party direct and documented out-of-pocket costs actually incurred by Takeda that are reasonably required and necessary and directly attributable to the qualification of an alternative supplier and for which Takeda is able to provide supporting documentation therefor shall be borne by Sucampo; provided that: (a) Takeda will promptly provide Sucampo with an itemized list of all such documented actual third party direct out-of-pocket costs and the Parties shall negotiate in good faith to mutually agreed upon any such third party direct and documented out-of-pocket costs prior to Takeda incurring such costs, and (b) the Parties will use Commercially Reasonable Efforts and cooperate to minimize any such costs.
- 9.4 <u>Testing and Release</u>. Testing and release of the Licensed Product for the applicable country in the Territory shall be made at the cost and expense of Sucampo, in accordance with Quality Agreement and Applicable law. During the Term, Sucampo will conduct the commercial stability program with respect to the Licensed Product pursuant to Applicable Law, at its own expense.
- 9.5 Records. At its own cost, Sucampo shall keep and maintain documentation and records with respect to Manufacturing (other than Secondary Packaging), testing and delivery of Licensed Product in accordance with Applicable Law. At its own cost, Takeda shall keep and maintain documentation and records with respect to Secondary Packaging, testing and delivery of Licensed Product to end users in accordance with Applicable Law.
- 9.6 <u>Quality Agreement</u>. A Quality Agreement shall be executed between Sucampo and Takeda within ninety (90) days of the Effective Date and in any event no later than the first order of Licensed Product.

Non-Conforming Shipment. Takeda will have a period of ninety (90) Business Days from the date of its or its Affiliates, Subcontractor or Sublicensees (as applicable) receipt of a shipment of the Licensed Product to: (a) inspect and reject such shipment for Patent Defects and (b) report any discrepancy in the quantity of the SKUs of the Licensed Product for such shipment. If Takeda provides Sucampo with a notice of non-conformity in respect of any discrepancy in the quantity of the SKUs of the Licensed Product for any shipment within such ninety (90) Business Day period then, as Takeda's sole and exclusive remedy under this Agreement, Takeda shall have the option of: (i) in the event of a shortfall in the quantity of the delivered Licensed Product, (x) requiring Sucampo to, and Sucampo shall, promptly supply Takeda with such additional Licensed Product as is necessary to meet the amount ordered or (y) paying for the quantity actually received in accordance with the provisions of ARTICLE 8 without requiring Sucampo to supply any additional Licensed Product as is necessary to meet the amount ordered or (ii) in the event of an excess in the quantity of the delivered Licensed Product, (x) returning the excess units to Sucampo, at Sucampo's sole cost and expense, through the carrier used to deliver the Licensed Product to Takeda (or such other carrier as Sucampo may direct in writing), or (y) accepting any such excess Licensed Product as against future orders of such Licensed Product. In each case, Takeda shall pay for the quantity actually received and accepted unless otherwise agreed in writing by the Parties. In the event that Takeda has the right to and elects to reject any such shipment for a Patent Defect, Takeda shall provide Sucampo with written notice of such rejection for any Patent Defect within such period of ninety (90) Business Days together with samples of the non-conforming Licensed Product in the relevant shipment for testing. In the case of Licensed Product with Latent Defects, Takeda will promptly, and in no event more than ninety (90) Business Days of Takeda knowing of any such Latent Defect, notify Sucampo in writing of such Latent Defect and provide Sucampo with samples of the non-conforming Licensed Product in the relevant shipment for testing. If Sucampo disagrees with Takeda regarding Takeda's rejection of a shipment or portion thereof based on a Patent Defect or a Latent Defect, the Parties will submit samples of such shipment to a mutually acceptable independent laboratory for testing. If such independent laboratory determines that the shipment did not contain a Patent Defect or a Latent Defect, Takeda will bear all expenses of shipping the Licensed Product to and from and the testing by such independent laboratory for such shipment. If Sucampo or such independent laboratory confirms that such shipment did contain a Patent Defect or a Latent Defect, Sucampo will (i) as soon as practicable, give Takeda a credit for any amount paid with respect to that portion of the Licensed Product which had a Patent Defect or Latent Defect, (ii) bear all of Takeda's reasonable direct and documented out-of-pocket expenses of returning such Licensed Product to Sucampo or its designee, and (iii) all reasonable direct and documented out-of-pocket expenses of shipping Licensed Product to and from and the testing by such independent laboratory. Sucampo or Takeda, as directed by Sucampo, will dispose of any non-conforming portion of any shipment in accordance with all Applicable Law, at Sucampo's expense for any reasonable direct and documented out-of-pocket costs actually incurred by Takeda for such disposal.

9.8 Quality Audits

- 9.8.1 Sucampo shall use Commercially Reasonable Efforts to make available facilities being used to Manufacture the Licensed Product (other than Secondary Packaging) and relevant manufacturing records for audit by Takeda or its designee for regulatory or quality assurance purposes upon reasonable notice and at reasonable times during normal business hours and subject to Sucampo's customary rules and restrictions with respect to site visits by non-Sucampo personnel; provided, however, that the audit by Takeda hereunder shall be no more than once per year, except where there exists a reasonable cause to perform one (1) or more audits. This shall include reasonable access for Takeda and its representatives to the facility and all records and personnel required for the sole purpose of conducting such quality assurance audits of Sucampo. In the event of: (a) any investigations or requests from the applicable Regulatory Authorities regarding the Manufacturing process, Product quality control and cGMP compliance and stability of the Licensed Product (other than Secondary Packaging), or (b) any occurrence of Market Withdrawals Recalls, Adverse Events/Reactions or Serious Adverse Events/Reactions caused by or alleged to be caused by defects in the Manufacturing process of the Licensed Product (other than Secondary Packaging), in each of the foregoing cases, such access shall be provided as promptly as possible to Takeda or its designee, subject to Sucampo's customary rules and restrictions with respect to site visits by non-Sucampo personnel. Sucampo will co-operate with Takeda representatives for all of these purposes, and shall use Commercially Reasonable Efforts to promptly correct any reasonable deficiencies noted during the audits. All information from the audit will be considered the Confidential Information of Sucampo.
- 9.8.2 Takeda shall use Commercially Reasonable Efforts to make available facilities being used for Secondary Packaging of the Licensed Product and relevant packaging records for audit by Sucampo for regulatory or quality assurance purposes upon reasonable notice and at reasonable times during normal business hours and subject to Takeda's customary rules and restrictions with respect to site visits by non-Takeda personnel; provided, however, that the audit by Sucampo hereunder shall be no more than once per year, except where there exists a reasonable cause to perform one (1) or more audits. This shall include reasonable access for Sucampo and its representatives to the facility and all records and personnel required for the sole purpose of conducting such quality assurance audits of Takeda. In the event of: (a) any investigations or requests from the applicable Regulatory Authorities regarding the Development, Commercialization or Secondary Packaging of the Licensed Product, or (b) any occurrence of Market Withdrawals, Recalls, Adverse Events/Reactions or Serious Adverse Events/Reactions (except if the foregoing is caused or alleged to be caused by defects in the Manufacturing process of the Licensed Product (other than Secondary Packaging)) then, in each of the foregoing cases, such access shall be provided as promptly as possible, subject to Takeda's customary rules and restrictions with respect to site visits by non-Takeda personnel. Takeda will co-operate with Sucampo's representatives for all of these purposes, and shall use Commercially Reasonable Efforts to promptly correct any reasonable deficiencies noted during the audits. All information from the audit will be considered the Confidential Information of Takeda.

ARTICLE 10 CONFIDENTIALITY AND NON-DISCLOSURE

10.1 <u>Confidentiality</u>

- 10.1.1 Nondisclosure Obligations. The Receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose, other than the purpose of the Parties to perform their respective obligations or to exercise their respective rights under this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party shall treat Confidential Information as it would its own proprietary information which in no event shall be with less than a reasonable standard of care, and take reasonable precautions to prevent the disclosure of Confidential Information to a Third Party, except as explicitly set forth herein, without written consent of the Disclosing Party.
- 10.1.2 <u>Exceptions to Confidentiality.</u> The Receiving Party's obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party to the extent that such Confidential Information:
- (a) is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like or is made generally available by a Third Party, in each case, other than through a wrongful act, fault or negligence on the part of the Receiving Party or a breach of this Agreement;
 - (b) is received from a Third Party without restriction and with the right to disclose such Confidential Information;
- (c) the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party;
- (d) the Receiving Party can demonstrate by competent evidence was independently developed by or for the Receiving Party without reference to, use of or disclosure of the Disclosing Party's Confidential Information; or
 - (e) is released from the restrictions set forth in this Agreement by the express prior written consent of the Disclosing Party.

Notwithstanding the foregoing, specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

- 10.1.3 Authorized Disclosures. The Receiving Party may disclose Confidential Information to the extent that such disclosure is:
- (a) made in response to an order of a court of competent jurisdiction or other Regulatory Authority or any political subdivision or regulatory body thereof of competent jurisdiction; provided that the Receiving Party shall first have, if reasonably possible, given notice to the Disclosing Party and given the Disclosing Party, at such Disclosing Party's own expense, a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order be held in confidence by such court or Regulatory Authority or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such order shall be limited to that information which is legally required, in the reasonable opinion of legal counsel to the Receiving Party, to be disclosed in such response to such court or governmental order;
- (b) otherwise required by Applicable Law or the requirements of a major national securities exchange (e.g., Japan or U.S. Securities and Exchange Commission), in the reasonable opinion of legal counsel to the Receiving Party, provided that the Party disclosing such Confidential Information shall exercise its Commercially Reasonable Efforts to obtain a protective order or other reliable assurance that confidential treatment will be accorded and if possible give the other Party a reasonable opportunity to review and comment on any such disclosure in advance thereof (but not less than five (5) Business Days, if possible, prior to the date of such disclosure);
- (c) made to an applicable Regulatory Authority in any country in the Territory as useful or required in connection with any filing, application or request for Regulatory Approval; provided that reasonable measures shall be taken to assure confidential treatment of such information;
- (d) reasonably necessary in filing or prosecuting of Sucampo Patent Rights directed to the Compound or the Licensed Product in the applicable country in the Territory or (ii) reasonably necessary in defending litigation related to Sucampo Patent Rights in the applicable country or jurisdiction in the Territory if such litigation relates to this Agreement, provided that the other Party is informed and consulted at least thirty (30) days prior to the disclosure where possible; and
- (e) to the extent necessary, and subject to sublicensing and subcontracting provisions set forth in this Agreement, to its Affiliates and Sublicensees, and its and their directors, officers, employees, consultants, contractors or subcontractors, under written agreements of confidentiality substantially similar to and at least as restrictive as those set forth in this Agreement, who have a need to know such information in connection with a Party performing its obligations or exercising its rights under this Agreement.

- 10.2 <u>Patient Information</u>. The Parties shall abide (and cause their respective Affiliates and Sublicensees to abide), and take (and cause their respective Affiliates and Sublicensees to take) reasonable and appropriate actions to ensure that all Third Parties conducting or assisting with any clinical development activities hereunder in accordance with, and subject to the terms of, this Agreement, shall abide, to the extent applicable, by all Applicable Law in the applicable country in the Territory concerning the confidentiality or protection of patient identifiable information and other patient protected health information.
- 10.3 Ownership of Confidential Information. The Receiving Party agrees that it shall not receive any right, title or interest in, or any license or right to use, the Disclosing Party's Confidential Information (including all copies, extracts and portions thereof) or any intellectual property rights therein, by implication or otherwise, except as expressly and specifically permitted herein. All rights relating to the Disclosing Party's Confidential Information that are not expressly granted hereunder to the Receiving Party are reserved and retained by the Disclosing Party.

10.4 <u>Press Releases; Publications; Use of Name and Disclosure of Terms</u>

10.4.1 Press Release. The Parties have agreed upon the content of a press release which shall be issued substantially in the form attached hereto as EXHIBIT I as soon as practicable after the execution and delivery of this Agreement. Except for the press release set forth on EXHIBIT I, each Party shall maintain the confidentiality of all provisions of this Agreement and this Agreement itself, subject to the terms of this Agreement. For subsequent press releases relating to this Agreement or the Parties' relationship hereunder, each Party (or its Affiliate) shall use Commercially Reasonable Efforts to submit to the other Party a draft of such press release for review and comment by the other Party at least five (5) Business Days prior to the date on which such Party plans to issue such press release ("Proposed Disclosure"), and shall review and consider in good faith any comments provided by the other Party. Except for the press release set forth on EXHIBIT I, each Party shall maintain the confidentiality of all provisions of this Agreement and this Agreement itself, subject to the terms of this Agreement. Without the prior written consent of both Parties, no Party shall make any press release or other public announcement of or otherwise disclose to any Third Party this Agreement or any of its provisions, except for: (a) disclosure to those of its and its Affiliates' and Sublicensees' directors, officers, employees, accountants, attorneys, advisers and agents whose duties reasonably require them to have access to the Agreement, provided that such directors, officers, employees, accountants, attorneys, advisers, and agents are required to maintain the confidentiality of the Agreement to the same extent as if they were Parties hereto under written agreements of confidentiality substantially similar and at least as restrictive as those set forth in this Agreement, (b) such disclosures as may be required by Applicable Law pursuant to Section 10.1.3, and (c) disclosure of the terms of this Agreement by either Party to its existing or potential investors, lenders, collaborative partners or, in the case of a change of control, acquirers as part of their due diligence investigations, provided, however, that such existing investors, lenders, collaborative partners or acquirers have agreed to maintain the confidentiality of the terms of this Agreement and to use such information solely for the purpose of such due diligence investigation under written agreements of confidentiality substantially similar to and at least as restrictive as those set forth in this Agreement.

<u>Publications</u>. All publications, abstracts, manuscripts and presentations (including information to be presented verbally) that disclose results of 10.4.2 Clinical Studies or Post-Approval Marketing Studies for a Licensed Product in the Field in the applicable country in the Territory shall be reviewed and approved by each Party. Each Party shall provide to the other Party the opportunity to review each of the submitting Party's proposed abstracts, manuscripts or presentations (including information to be presented verbally) in the applicable country in the Territory that relate to any Development activities or otherwise with respect to the Licensed Product for use in the Field in such applicable country in the Territory, at least thirty (30) days prior to its intended presentation or submission for publication and each Party agrees, upon written request from the other Party given within such thirty (30)-day period, not to submit such abstract or manuscript for publication or to make such presentation until Sucampo is given up to thirty (30) days from the date of such written request to seek appropriate Patent protection for any material in such publication or presentation that it reasonably believes may be patentable. Once an abstract, manuscript or presentation has been reviewed and approved by each Party, the exact same abstract, manuscript or presentation does not have to be provided again to the other Party for review for a later submission for publication; provided that once the abstract or manuscript is accepted for publication or the presentation is finalized, the submitting Party shall provide the other Party with a copy of the final version of such abstract, manuscript or presentation. Each Party also shall have the right to require that any of its Confidential Information (but not the results of the Clinical Studies or Post-Approval Marketing Studies for a Licensed Product in the Field in the applicable country in the Territory that have been approved for disclosure pursuant to the Publication Policies) that is disclosed in any such proposed publication or presentation be deleted prior to such publication or presentation. In any permitted publication or presentation by a Party, the other Party's contribution shall be duly recognized, and co-authorship shall be determined in accordance with customary standards. For the avoidance of doubt and notwithstanding the foregoing, this Section 10.4.2 shall not limit or restrict Sucampo's ability to publish or present publicly available information for Other Indications within the applicable country in the Territory (except to the extent that Takeda has exercised its right of refusal for a particular Other Indication in such country in the Territory and the Parties have reached written agreement with respect to the same under Section 5.2) or otherwise, provided that in each case such publication or presentation does not contain Takeda's Confidential Information.

ARTICLE 11 INTELLECTUAL PROPERTY RIGHTS

- 11.1 <u>Sucampo Intellectual Property Rights.</u> As between the Parties, Sucampo shall have sole and exclusive ownership of the Compound and Licensed Product (and any improvements, modifications or derivative works to such Compound and Licensed Product) and all right, title and interest (subject to the licenses granted in this Agreement) in and to any and all Sucampo Patent Rights, Sucampo Background Technology and Product Trademarks and all Technology in connection with the Compound and Licensed Product (and any improvements modifications or derivative works to such Compound and Licensed Product) anywhere in the world, including all Pre-Clinical Data, Clinical Data, CMC Data and other Data in connection with the Licensed Product, and any improvements, modifications or derivative works to any of the foregoing
- Patent Filing, Prosecution and Maintenance. Sucampo and its Affiliates, acting through patent counsel of its choice, and in reasonable consultation with Takeda solely during the Term, shall be responsible for the preparation, filing, prosecution and maintenance of the Sucampo Patent Rights in the applicable country in the Territory. During the Term, Sucampo shall diligently prosecute all filed patent applications included in the Sucampo Patent Rights and maintain all issued patents included in the Sucampo Patent Rights, except as otherwise set forth below. During the Term, Sucampo shall use Commercially Reasonable Efforts to notify Takeda within thirty (30) days in the event (however not later than ninety (90) days before any relevant patent deadline date for filing documents, paying fees or any required action) that Sucampo or its Affiliates decide not to prepare, file, prosecute and/or maintain any of the Sucampo Patent Rights in the Field in any country in the Territory and, upon the receipt of such notice, Takeda shall then have the right and option to do so in such country at its own expense, except for the Sucampo Patent Rights mentioned in EXHIBIT N, for which Sucampo shall solely bear all fees and costs Takeda has paid to prosecute and maintain such Sucampo Patent Rights. Any Sucampo Patent Right for which Takeda assumes the responsibility to prepare, file, prosecute and/or maintain pursuant to this Section 11.2 shall remain part of the Sucampo Patent Rights and shall be solely and exclusively owned by Sucampo and Sucampo shall grant to Takeda a non-exclusive, royalty free, perpetual license for any such Sucampo Patent Right outside the Field. In the event Takeda has made the final decision to not Commercialize in a country of the Territory, the Parties shall discuss in good faith whether Sucampo shall be further obliged to prosecute and maintain the Sucampo Patent Rights in such country of the Territory.
- 11.3 <u>Information and Cooperation.</u> During the Term, Sucampo shall (a) provide Takeda with copies of all patent applications filed with respect to the Sucampo Patent Rights and other material submissions and correspondence with any patent office in the applicable country in the Territory relating thereto, in sufficient time to allow for reasonable review and comment by Takeda, (b) provide Takeda and its patent counsel with an opportunity to consult with Sucampo and its patent counsel regarding the filing and

contents of any such application, amendment, submission or response with respect to the Sucampo Patent Rights in such country and (c) provide notice of filing of new Sucampo Patent Rights to Takeda in any country in the Territory within ten (10) Business Days of such filing. Sucampo hereby agrees that the advice and suggestions of Takeda and its patent counsel shall be taken into reasonable consideration by Sucampo and its patent counsel in connection with each filing; provided that Sucampo and its patent counsel shall make the final determination in connection with each filing. For [...***...], Takeda shall be invited to briefing teleconferences with Sucampo's counsel to discuss case strategy at least [...***...] ([...***...]) month before [...***...] in case [...***...] or thereof is refused by the relevant [...***...], Sucampo shall use Commercially Reasonable Efforts to (a) appeal the decision through [...***...] and (b) [...***...].

- 11.4 <u>Product Trademarks</u>. As between the Parties, Sucampo and its Affiliates shall own all Product Trademarks and all goodwill associated therewith. Sucampo shall be responsible at its own cost and expense for the filing, prosecution, defense, maintenance and renewal before all Trademark offices in the relevant country in the Territory of all Product Trademarks and shall use Commercially Reasonable Efforts to ensure Product Trademarks exist in such country in the Territory, and that any registered Product Trademarks are maintained during the Term.
- Sucampo shall keep Takeda promptly informed of all filings made for Product Trademarks including sending Takeda a copy of any such filing and otherwise shall keep Takeda informed of all material developments in relation to the Product Trademarks.
- 11.4.2 Neither Sucampo nor any Affiliate of Sucampo shall use the Product Trademark in the Territory or grant a license to a third party under the Product Trademark in the Territory during the Term.
- 11.4.3 Takeda shall not reproduce or use (or authorize the reproduction or use of) the Product Trademarks or Sucampo's Corporate Name in any manner whatsoever other than as expressly authorized by this Agreement.
- During the Term and after any expiration or termination of this Agreement, Takeda shall not use as its own any service mark, service name, trade name, trademark, design or logo(s) confusingly similar to (i) any Product Trademarks or Sucampo's Corporate Name, including without limitation any mark, word or design that incorporates the word "AMITIZA", "Sucampo", "Sucampo AG", or "Sucampo Pharmaceuticals, Inc." or any Product Trademarks on Exhibit C of the License Agreement, or any mark, word or design confusingly similar thereto.

- 11.4.5 Takeda shall not challenge the validity of the Product Trademarks or Sucampo's Corporate Name, nor shall Takeda challenge Sucampo's or Sucampo's Affiliates' ownership of the Product Trademarks or Sucampo's Corporate Name or the enforceability of Sucampo's Or Sucampo's Affiliates' rights therein, anywhere in the world.
- In the event of a determination by final court decision or under a definitive settlement by Sucampo that the Commercialization of Product in the Territory, on account of the use of a Product Trademark, infringes the trademark rights of a third party in the Territory, then, Sucampo shall: (a) indemnify and hold Takeda harmless against any such third party claim or proceeding above brought against Takeda, including damages and reasonable attorney's fees; provided, however, that any obligation to indemnify shall be excluded if Takeda fails to promptly notify Sucampo of the assertion of any such claims; (b) At Sucampo's option, finance the re-packaging operation or, if necessary, replace, free of charge, all Licensed Products in stock at Takeda that are no longer saleable on account of the infringement of a third party trademark.

11.5 <u>Intellectual Property Legal Actions</u>

- Notice of Third Party Infringement and Third Party Litigation. In the event (a) either Party becomes aware of any possible infringement of any Sucampo Patent Rights or Sucampo Background Technology relating to the Licensed Product or any Product Trademark in the Field in the applicable country in the Territory, (b) either Party becomes aware of the submission by any Third Party of regulatory filing in the applicable country in the Territory for a product that seeks approval to sell the Compound in the Field, or the regulatory approval is granted upon such regulatory filing, (c) either Party becomes aware of any interference, opposition, or a nullity action being filed in the applicable country in the Territory against any Sucampo Patent Right that relates to the Development, Manufacture, or Commercialization by a Third Party of a Licensed Product in the Field in the applicable country in the Territory, or (d) either Party becomes aware of the institution or threatened institution of any suit by a Third Party against such Party for patent infringement involving the Development, Manufacture, or Commercialization of any Licensed Product in the Field in the applicable country in the Territory (each, an "Infringement"), that Party shall promptly notify the other Party and provide it with all details of such Infringement of which it is aware (each, an "Infringement Notice").
- Sucampo's Right to Enforce and Defend. In the event of an Infringement, Sucampo and its Affiliates shall have the right and option to initiate legal proceedings, through counsel of its choosing, or take other reasonable steps in good faith regarding such Infringement in reasonable consultation with Takeda. Sucampo shall use Commercially Reasonable Efforts to inform and consult with Takeda at least sixty (60) days in advance of any due dates, such that Takeda is able to reasonably comment on the enforcement or defense strategy, and Sucampo shall reasonably consider Takeda's comments and suggestions to the strategy; provided, however, Sucampo and its Affiliates shall make the final decision as to the enforcement or defense strategy. If Sucampo and its Affiliates do not take or initiate reasonable steps in good faith to initiate legal proceedings or take other actions regarding the Infringement within thirty (30) days from any Infringement Notice, then Takeda and its Affiliates shall have the right and option to do so at their own expense.

- No Settlement and Allocation of Damages. Neither Party shall settle any Infringement claim nor proceeding under this Section 11.5 without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. If either Takeda and/or Sucampo collects any settlement or judgment from any Third Party infringers, the Parties shall first allocate any such amounts to each Party equal to their respective attorneys' fees, litigation costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of the attorneys' fees, litigation costs and expenses of both Parties). To the extent that any such award of damages represents lost gross margin, any additional amounts collected shall be payable to each Party equal to their respective share of lost gross margin, as demonstrated by written records. To the extent that any such award of damages does not represent lost gross margin or there are damages remaining after the allocation based on lost gross margin, any additional amounts collected shall be allocated based the Party's respective effort to collect any settlement or judgment.
- 11.5.4 <u>Right to Representation</u>. In addition to Takeda's right and option to initiate legal proceedings or take other actions regarding the Infringement pursuant to Section 11.5.2 above, Takeda and its Affiliates shall have the right, at their own expense, to participate and be represented by counsel that it selects, in any legal proceedings or other action instituted under this Section 11.5 by Sucampo.
- 11.5.5 <u>Cooperation</u>. In any action, suit or proceeding instituted under this Section 11.5, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such action, suit or proceeding, the other Party shall join therein and shall be represented using counsel of its own choice, at the requesting Party's expense.

ARTICLE 12 TERM AND TERMINATION

- 12.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Agreement, shall expire on a country-by country basis (within the Territory) on the fourteenth (14th) anniversary of the date of First Commercial Sale in a country in the Territory (the "Term"). The Term shall be renewable upon the mutual agreement of both Parties.
 - 12.2 <u>Termination</u>
 - 12.2.1 <u>Termination for Material Breach</u>.

- (a) If either Party materially breaches this Agreement, the non-breaching Party shall have the right to terminate this Agreement by written notice unless the breaching Party remedies the default within ninety (90) calendar days after receipt of written notice of such default.
- (b) In the event of a material breach by any of the Parties of anti-bribery and anti-corruption obligations defined in Sections 15.2.2 and 15.2.3, the non-breaching Party shall have the right to terminate this Agreement in its entirety with immediate effect.
- 12.2.2 <u>Partial Termination by Takeda</u>. Notwithstanding the provisions of Section 12.2.1(a) above, Takeda shall have the right to terminate this Agreement by giving thirty (30) days prior written notice on a Licensed Product-by-Licensed Product basis and country-by-country basis in the Territory for the following circumstance:
- (a) In the event Sucampo fails to cure a supply shortage of the Licensed Product in the Field in the applicable country in the Territory within [...***...] days ([...***...]) days of Sucampo's prior written notice of such shortage to Takeda pursuant to Section 9.3 (other than a supply shortage due to Force Majeure as set forth in Section 9.3), then Takeda shall have the right to terminate this Agreement with respect to such Licensed Product for which there is a supply shortage and in such country where the supply shortage occurs, or
- (b) Upon written notice to Sucampo, Takeda using Commercially Reasonable Efforts advised that Takeda will not Develop and Commercialize the Licensed Product in the Field in the country in the Territory. The non-Development or non-Commercialization of the Licensed Product shall not be considered as constituting a material breach of this Agreement
- 12.2.3 <u>Termination for Insolvency.</u> Notwithstanding the provisions of Section 12.2.1(a) above, in the event a Party files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.
- 12.2.4 <u>Termination for Material Adverse Event</u>. In the event that either of the Parties has a reasonable health and safety concern, including due to any Adverse Event or Serious Adverse Event, with respect to the Compound or Licensed Product, then either Party may terminate this Agreement on a product-by-product basis effective immediately upon written notice to the other Party.

- 12.2.5 For the avoidance of doubt, the termination of this Agreement with respect to a Licensed Product in any applicable country in the Territory in accordance with Sections 12.2.1(a) or 12.2.2 ("Terminated Licensed Product") shall not affect the rights and obligations of the Parties with respect to any remaining Licensed Product in such country and this Agreement shall remain in full force and effect with respect to such remaining Licensed Product. In addition, the termination of this Agreement with respect to a country in the Territory in accordance with Sections 12.2.1(a) or 12.2.2 ("Terminated Country") shall not affect the rights and obligations of the Parties with respect to the remaining countries in the Territory and this Agreement shall remain in full force and effect with respect to such remaining countries.
- 12.3 <u>Consequences of Partial Termination</u>. Upon the partial termination of this Agreement with respect to any Terminated Licensed Product in any country in the Territory or Terminated Country, in each of the foregoing cases, pursuant to Sections 12.2.1(a) or 12.2.2 or above, the following shall apply with respect to such Terminated Licensed Product or Terminated Country, as applicable:
- (a) all rights and licenses granted by Sucampo to Takeda with respect to the Terminated Licensed Product and Terminated Country under this Agreement and the Ancillary Agreements, including under Sections 2.1.1, 2.1.2, 2.1.3 and 2.1.4 of this Agreement, shall automatically terminate;
- (b) all Sublicense Agreements and all written agreements with Subcontractors for any Terminated Licensed Product and in any Terminated Country shall automatically terminate;
- any Licensed Product in the Terminated Country under this Agreement shall, in each of the foregoing cases, promptly cease to the extent permitted by Applicable Law but in no case shall Sucampo be required to purchase the inventory of the Licensed Product, provided however that Takeda may elect to continue selling the inventory Licensed Product until depletion (the "Inventory Sale Period"). It is agreed by the Parties that the licenses granted to Takeda under Sections 2.1.1 and 2.1.3 shall continue during the Inventory Sale Period;
- Takeda shall cease all use of, and shall cause its Affiliate and other Sublicensees and subcontractors to cease all use of, the Sucampo Background Technology, Sucampo Patent Rights (except for the term of the Inventory Sale Period), Promotional Materials provided by Sucampo to Takeda according to Section 7.4, Product Trademarks (except for the term of the Inventory Sale Period), Sucampo's Confidential Information, Pre-Clinical Data, Clinical Data and CMC Data and any other data, information, materials and Technology provided by or for Sucampo for the Terminated Licensed Product and Terminated Country and, at the request of Sucampo, shall return or destroy, and thereafter upon request provide to Sucampo written confirmation of such destruction, all data, files, records and other materials in its possession or control relating to any of the foregoing or embodiments of any of the foregoing, or containing or comprising Sucampo Confidential Information, provided that Takeda may keep one (1) copy of each relevant document until ten (10) years following expiry of the batch with the latest expiry or, if longer, for the term required by Applicable Law for the purpose of complying with record keeping obligations under Applicable Law;

- (e) Takeda, its Subcontractors or Distributors as applicable, shall provide to Sucampo: (i) one (1) copy of all Regulatory Filings for the Terminated Licensed Product and/or in the Terminated Country (including, without limitation, all Regulatory Approvals and other documents necessary to Develop, Promote and Commercialize the Terminated Licensed Product and/or all Regulatory Approvals in the Terminated Country, as applicable, as they exist as of the date of such termination with respect to such Terminated Licensed Product and/or Terminated Country) and (ii) all Data, documents and support for such Regulatory Filings, including all documents and filings contained in or referenced in any of the foregoing, and all raw and summarized Data for any Clinical Studies and Post-Approval Marketing Studies in the Field in the applicable country in the Territory (and where reasonably available, electronic copies thereof). To the maximum extent permitted by Applicable Law, Takeda, its Subcontractors or Distibutors as applicable, shall also assign all of its right, title and interest to any of the foregoing to Sucampo. Sucampo shall have the right to obtain specific performance of Takeda's obligations referenced in this Section 12.2.5 and/or, in the event of failure to obtain an assignment, Takeda hereby consents and grants to Sucampo the right to access and reference (without any further action required on the part of Takeda, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such Regulatory Filings for any regulatory or other use or purpose, provided that, if Sucampo reasonably deems it necessary, Takeda will provide written confirmation to the Regulatory Authority for such grant or assignment. In each case such assignment (or access) shall be made within thirty (30) days after such expiration or termination; and
- (f) Unless otherwise expressly and specifically agreed in an Ancillary Agreement, all Ancillary Agreements with respect to such Terminated Licensed Product and Terminated Country shall automatically and simultaneously terminate.
- 12.4 <u>Consequences of Expiration or Termination of Agreement.</u> Upon the expiration or termination of this Agreement in its entirety, the following shall apply to all countries in the Territory:
 - (a) all rights and licenses granted by Sucampo to Takeda under this Agreement and the Ancillary Agreements shall automatically terminate;
- (b) all Development and Commercialization activities under this Agreement shall promptly cease to the extent permitted by Applicable Law, but in no case shall Sucampo be required to purchase the inventory of the Licensed Product, provided however that Takeda may elect to continue selling the inventory Licensed Product until depletion. It is agreed by the Parties that the licenses granted to Takeda under Sections 2.1.1 and 2.1.3 shall continue during the Inventory Sale Period;

- Technology, Sucampo Patent Rights (except for the Inventory Sale period), Promotional Materials provided by Sucampo to Takeda according to Section 7.4, Product Trademarks except for the Inventory Sale period), Sucampo Confidential Information, Pre-Clinical Data, Clinical Data and CMC Data and any other data, information, materials and Technology provided by or for Sucampo; each Party, at the request of the other Party, shall return or destroy, and thereafter upon request provide to the other Party written confirmation of such destruction, all data, files, records and other materials in its possession or control relating to the other Party's Technology, or containing or comprising the other Party's Confidential Information; provided that notwithstanding the foregoing, and subject to ARTICLE 10 of this Agreement, Sucampo shall have the right to continue to use any of Takeda Confidential Information incorporated into, necessary or useful for the exercise of its rights under this Agreement in respect of, or otherwise in connection with the use, disposition or commercialization and exploitation of any of the Data, Developed Technology, Developed Patent Rights, the Compound, the Licensed Product or the Promotional Materials or to the extent Sucampo may retain rights to such Confidential Information under this Agreement or any of the Ancillary Agreements and provided that Takeda may keep one (1) copy of each relevant document until ten (10) years following expiry of the batch with the latest expiry or, if longer, for the term required by Applicable Law for the purpose of complying with record keeping obligations under Applicable Law;
- (d) Takeda shall provide to Sucampo: (i) one (1) copy of all Regulatory Filings (including, without limitation, all Regulatory Approvals and other documents necessary to Develop and Commercialize the Licensed Product, as they exist as of the date of such expiration or termination) and (ii) all Data, documents and support for such Regulatory Filings, including all documents and filings contained in or referenced in any of the foregoing, and all raw and summarized Data for any Clinical Studies and Post-Approval Marketing Studies in the Field in the applicable country in the Territory (and where reasonably available, electronic copies thereof). To the maximum extent permitted by Applicable Law, Takeda shall also assign all of its right, title and interest to any of the foregoing to Sucampo. Sucampo shall have the right to obtain specific performance of Takeda's obligations referenced in this Section 12.4 and/or, in the event of failure to obtain an assignment, Takeda hereby consents and grants to Sucampo the right to access and reference (without any further action required on the part of Takeda, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such Regulatory Filings for any regulatory or other use or purpose, provided that, if Sucampo reasonably deems it necessary, Takeda will provide written confirmation to the Regulatory Authority for such grant or assignment. In each case such assignment (or access) shall be made within thirty (30) days after such expiration or termination.

- 12.5 <u>Surviving Provisions.</u> The rights and obligations set forth in this Agreement shall extend beyond the Term or termination of this Agreement only to the extent expressly and specifically provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of Sections 2.1.3, 2.1.4, 2.2, 4.4.3, 4.5, 4.6, 7.4 (but only with respect to the last 6 sentences only), 8.6, 8.7, 8.10, 9.5, 11.1, 11.4 (to the extent set forth therein), 11.5, 12.2.5, 12.4, 12.5, 12.6, , 15.7 and 15.10 and those of ARTICLE 10 and ARTICLE 17 and, to the extent applicable, all other Sections or Articles referenced in any such Section or Article and including ARTICLE 1, shall survive such expiration or termination.
- 12.6 <u>Continued Obligations.</u> Upon expiration or termination of this Agreement, in whole or in part, for any reason, nothing herein shall be construed to release either Party from any accrued rights or obligations that matured prior to the effective date of such expiration or termination, nor preclude either Party from pursuing any right or remedy it may have hereunder or at law or in equity with respect to any breach of this Agreement.

ARTICLE 13 TRANSITION PERIOD

- 13.1 The Parties acknowledge and agree that certain transition activities and obligations ("<u>Transition Activities</u>") are required in connection with the transition of the Licensed Products in Switzerland and United Kingdom to ensure that Takeda and/or its Affiliates can effectively Commercialize the Licensed Product in Switzerland and United Kingdom after the Effective Date until the Existing Regulatory Approvals have been successfully transferred to Takeda or a Third Party designated by Takeda (hereinafter referred to as the "<u>Transition Period</u>"). Each of Takeda and Sucampo shall perform or otherwise comply with the terms and conditions of the Transition Activities. Each Party shall carry its internal costs. The Parties shall prepare a Transition Plan within thirty (30) days after the Effective Date to set forth the responsibilities of each Party during the Transition Period.
- 13.2 <u>Use of Sucampo Corporate Name.</u> During the Transition Period, and subject to the terms and conditions of this Agreement, Sucampo hereby grants to Takeda a non-exclusive right and license, with a right to sublicense to Sublicensees, to use Sucampo Corporate Names in the Territory to solely perform its Transition Activities during the Transition Period. Takeda shall not use the Sucampo Corporate Names other than for the purpose expressly and specifically set forth in this Section 13.2 and in Section 2.1.3.

13.3 <u>Transition Activities.</u>

13.3.1 Without limitation to the generality of the foregoing, Takeda is authorized to Commercialize the Licensed Product under the Existing Regulatory Approvals in Switzerland and United Kingdom. Sucampo acknowledges that as part of Takeda's Commercialization activities in Switzerland and United Kingdom during the Transition Period, Takeda or its Subcontractors will perform the following Transition Activities: marketing activities, collection of orders, invoicing, distribution of the Licensed Product, and booking of sales.

13.3.2 During the Transition Period, Sucampo shall provide Takeda with all information and support for the Commercialization of the Licensed Product in Switzerland and in United Kingdom. Sucampo shall provide Takeda with any and all relevant information, including but not limited to pharmacovigilance relevant data, promotional materials, and prices of the Licensed Product. Sucampo shall continue to maintain the Existing Regulatory Approvals in Switzerland and United Kingdom until completion of the transfer of the Existing Regulatory Approvals to Takeda, at Takeda's sole cost and expense. Sucampo shall invoice Takeda these regulatory fees within thirty (30) days of incurring such fees and Takeda shall pay such invoice within sixty (60) days of the receipt of such invoice. During the Transition Period, Sucampo shall be responsible for the Transition Activities which are all activities and obligations as the Marketing Authorization holder for the Licensed Product, including but not limited to customer support, medical support, pharmacovigilance activities, complaint handling, local batch release and approval of promotional materials. Sucampo shall invoice Takeda the external costs associated with its Transaction Activities within thirty (30) days of incurring such fees and Takeda shall pay such invoice within sixty (60) days of the receipt of such invoice.

13.4 <u>Inventory Purchase.</u> During the Transition Period, the inventory to be made available to Takeda for sale is the inventory set forth on Exhibit P ("<u>Inventory</u>"). The supply of the Inventory to Takeda shall be subject to the relevant Sections under ARTICLE 9: 9.1 (except for 9.1.3(d)), 9.4, 9.5, 9.7, 9.8). Such Inventory shall be housed and maintained by Sucampo, at Sucampo's expense, at a facility(ies) owned or Controlled by Sucampo and has been or, promptly after the date hereof, will be segregated and marked as Takeda inventory. After review of the Inventory as soon as practicable after the Effective Date, Takeda will place an order for the amount of Inventory it has determined in its sole discretion to purchase, at the Supply Price specified in EXHIBIT H. Takeda may, at its sole discretion, purchase inventory that does not meet the Agreed Quality under Section 9.1.3. Upon receipt of the such order, Sucampo shall invoice Takeda and Takeda shall pay such invoice within sixty (60) days of receipt of such invoice. Title shall pass to Takeda upon delivery of the Inventory.

Once Takeda has determined that it can accept orders from the customers for the Licensed Product, Takeda shall notify Sucampo in writing of the carrier which will take delivery of the Inventory. Sucampo shall deliver the Inventory FCA at the Alloga (Dubendorf, Switzerland) or Alliance Healthcare (Normanton, UK) (Incoterms 2010) in accordance with Takeda's order, subject to the release of the Inventory in accordance with Section 9.4. Takeda shall designate to Sucampo the carrier which will take delivery of the Inventory. Sucampo shall contact such carrier when the Inventory is ready for shipping and shall arrange for collection, and transportation of the Inventory. Sucampo shall inform Takeda two (2) Business Days prior to pick-up by the carrier. Takeda shall bear the costs for transport of the Inventory and will be invoiced directly by the carrier. Delivery documents shall include purchase order number, quantity, copy of the certificate of analysis, items codes and description, lot number, manufacturing date of the Inventory, number of shippers, weight, number of pallets, and any other documents in accordance with the terms of the Quality Agreement under Section 13.6. Sucampo shall deliver all Inventory in conformity with the Agreed Quality (except for Section 9.1.3 (d)). In the event that the Inventory is not sold by December 31, 2014, Sucampo shall at its sole discretion either buy back the remaining Inventory at the Supply Price in EXHIBIT H or have it destroyed at Sucampo's costs, being agreed that in the event of destruction Sucampo shall reimburse the amount paid by Takeda to purchase the Inventory.

- 13.5 Additional Product Supplied During the Transition Period. During the Transition Period, the Licensed Product supplied by Sucampo to Takeda shall include Secondary Packaging with Sucampo's dress. Such Licensed Product shall be subject to ARTICLE 9, including conforming to the Agreed Quality except for the incoterm specified in Section 9.2 as delivery of the licensed Product ordered during the Transition Period shall occur CIP at Catalent Pharma Solutions Ltd., Frankland Road, Blagrove, Swindon, Wiltshire, SN5 8YG, UK.
- 13.6 Other Ancillary Agreements related to the Transition Period. The Parties shall use their best efforts to agree on the terms of a Quality Agreement and of a Pharmacovigilance Agreement effective during the Transition Period.
- 13.7 <u>Unused Promotional Materials.</u> Promptly after the expiration of the Transition Period, Sucampo shall return to Takeda or destroy or cause to be destroyed, at Takeda's discretion, any and all unused sales materials related to the Licensed Product in Switzerland and the United Kingdom.

ARTICLE 14 EMPLOYEES

The Parties have considered the possibility of whether TUPE is triggered by this Agreement, and have agreed as follows:

- 14.1 <u>For purposes of this Section 14:</u>
- 14.1.1 "Unexpected Employee" has the meaning set forth in Section 14.4.
- 14.1.2 "Unexpected Employee Liability" has the meaning set forth in Section 14.5.

- 14.1.3 "TUPE" means, as appropriate, (a) the European Union's Acquired Rights Directives Nos. 77/187/EEC and/or 01/23/EC; (b) the Transfer of Undertakings (Protection of Employment) Regulations 2006; (c) the legislation enacted in any Member State of the European Union, or in any State within the European Economic Area which is not a Member State of the European Union, giving effect to the said Directives; and (d) any similar legislation in those or any other jurisdiction; as amended, updated, re-enacted or extended from time-to-time.
- 14.1.4 "Successor Provider" means any third party (including without limitation any Affiliate of TAKEDA) who, at any time after the Effective Date, will provide similar services to those provided, or carries out tasks which were undertaken, by Sucampo (itself and/or using a third party) before the Effective Date.
- 14.1.5 "Protected Unexpected Employee" means any Unexpected Employee who cannot be dismissed and remains employed with or is reinstated by Takeda or a Successor Provider, for the reasons set out in Section 14.5.5.
- 14.1.6 "Dismissed Employee" means any employee of Takeda or a Successor Provider who is dismissed because a Protected Unexpected Employee cannot be dismissed, or is reinstated, for the reasons set out in Section 14.5.5.
- 14.2 The Parties believe that there is neither the transfer of an economic entity, nor the transfer of an activity, by which this Agreement triggers the application of TUPE.
- 14.3 Strictly without prejudice to and without limiting Sucampo's obligations under the Agreement, Sucampo shall ensure that neither the employment of any person, nor any liabilities relating thereto, shall transfer by operation of TUPE from Sucampo and/or any subcontractor (of whatever tier) of Sucampo to Takeda or any Successor Provider, as a consequence of the execution of this Agreement.
- 14.4 It is agreed that in the event that any person (an "Unexpected Employee") alleges or establishes that his/her employment with Sucampo or any subcontractor (of whatever tier), or any liabilities or obligations relating to his employment or its termination, transfers to Takeda or any Successor Provider, by virtue of the application of TUPE, upon the Effective Date:
 - 14.4.1 where either Party becomes aware of such allegation or finding, that Party will notify the other Party as soon as reasonably practicable;
- 14.4.2 Takeda will then allow Sucampo or any subcontractor (of whatever tier) 21 calendar days either to offer employment to the Unexpected Employee or take other steps so as to effect a written withdrawal of that such settlement requires Takeda to be a party for it to validly settle claims against Takeda, Takeda will co-operate with this and Sucampo indemnifies Takeda for Takeda's liabilities under such settlement agreement);

- 14.4.3 if at the end of such 21-day period the Unexpected Employee is or still alleges to be an employee of Takeda or any Successor Provider, then within 14 (fourteen) calendar days of the end of such twenty-one (21)-day period Takeda or the Successor Provider (as appropriate) shall elect in writing to Sucampo to follow either (a) or (b) below:
- (a) If Takeda or the Successor Provider (as appropriate) elects option (a), it shall thereafter employ the Unexpected Employee; and notwithstanding the definition of Unexpected Employee Liability set out below, no costs, claims, losses, damages, liabilities, reasonable expenses, payments made under reasonable settlement agreements, statutory redundancy pay, contractual redundancy pay or entitlements (such as pension-related entitlements) triggered by redundancy, which relate to the period after the date of the written election of this option (a), shall constitute Unexpected Employee Liabilities.
- (b) If Takeda or the Successor Provider (as appropriate) elects option (b), then TAKEDA shall, or shall procure that any Successor Provider (as appropriate) shall, dismiss the Unexpected Employee, as follows. During the twenty-first (21) days after such written election, Sucampo may upon notification to Takeda conduct (on Takeda's or the Successor Provider's behalf, and with reasonable co-operation by Takeda or the Successor Provider, including in the provision of appropriate information to Sucampo) any process in relation to such dismissal as it reasonably considers necessary to reduce the chances of legal action by the Unexpected Employee in relation to his/her dismissal. After such 21 day period (or earlier if notified in writing by Sucampo) Takeda (or the Successor Provider, as appropriate) shall dismiss the Unexpected Employee.
- 14.5 For purposes of this Section 14, "Unexpected Employee Liability" means any costs (including without limitation all salary, benefit, pension and other employment costs), claims, losses, damages, liabilities, reasonable expenses (including without limitation all legal and court costs), payments made under reasonable settlement agreements, statutory redundancy pay, contractual redundancy pay, and any entitlements (such as pension-related entitlements) triggered by redundancy, relating to:
 - 14.5.1 any Unexpected Employee (other than any Protected Unexpected Employee) being employed by Takeda or a Successor Provider;
- 14.5.2 any Protected Unexpected Employee being employed by Takeda or a Successor Provider up to the date of the dismissal of his or her corresponding Dismissed Employee;

- 14.5.3 any Unexpected Employee's dismissal by Takeda or a Successor Provider in accordance with Section 14.4.3(b);
- 14.5.4 Sucampo's conduct of any process under Section 14.4.3(b);
- 14.5.5 Takeda's (or a Successor Provider's, as appropriate) dismissal of any other employee in the event that an Unexpected Employee cannot be dismissed, and remains or is reinstated as a Takeda (or a Successor Provider's) employee, because of national laws which set an order of social selection for dismissal or which otherwise prevent (as opposed to merely rendering unlawful) the dismissal of the Unexpected Employee;
 - 14.5.6 any Unexpected Employee's allegations or claims relating to periods prior to the alleged transfer of undertaking; and/or
- 14.5.7 information and consultation obligations generally under TUPE in respect of the TUPE transfer or potential transfer of which the Unexpected Employee claims to be a part.
- 14.6 Sucampo shall fully indemnify, keep indemnified and, within thirty (30) calendar days of invoice, evidence from TAKEDA or the Successor Provider (as applicable) for such Unexpected Employee Liabilities having been incurred.

ARTICLE 15 REPRESENTATIONS AND WARRANTIES

- 15.1 <u>Mutual Representations and Warranties</u>. Sucampo and Takeda represent and warrant to the other, as of the Effective Date, as follows:
- 15.1.1 <u>Corporate Power</u>. Such Party is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has full corporate power and authority to enter into this Agreement and to perform its obligations hereunder, and it has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
- 15.1.2 <u>Due Authorization</u>. Such Party has taken all necessary corporate action required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.
- 15.1.3 <u>Binding Agreement</u>. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with the terms hereof subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

15.1.4 <u>Conflicts.</u> The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) does not conflict with or violate any provision of the articles of incorporation, bylaws or any similar instrument of such Party, as applicable, in any material way and (b) does not conflict with, violate or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

15.2 <u>Compliance with Applicable Law</u>

- 15.2.1 Sucampo and Takeda each represents, warrants and covenants to the other that it shall comply, in all material respects, with Applicable Law relating to such Party's rights, duties, responsibilities and obligations set forth in this Agreement.
- 15.2.2 Takeda hereby makes each of the representations and warranties set forth in Exhibit K as if such representations and warranties were set forth in this Section 15.2, and such representations and warranties are incorporated by reference into this Agreement and made a part hereof. Takeda shall comply with each of the covenants set forth in EXHIBIT K as if each such covenant were set forth in this Section 15.2, and such covenants are incorporated by reference into this Agreement and made a part hereof. Takeda may update any provision of EXHIBIT K at any time, and from time to time, upon written notice to Sucampo to the extent reasonably necessary to implement changes in Applicable Law and Regulations or changes in policies of enforcement.
- 15.2.3 Sucampo and Takeda acknowledge and agree that there are anti-bribery and anti-corruption laws to which Sucampo and Takeda are subject, that prohibit the payment, or offering, or receiving, as the case may be, of anything of value to, or from, a government employee, or official, or private individual, for the purpose of (a) inducing or influencing any governmental act, or decision affecting Sucampo or Takeda, (b) to help Sucampo or Takeda obtain or retain any business, or (c) to otherwise improperly benefit Sucampo's or Takeda's business activities, and such laws prohibit Sucampo and Takeda from being involved with clients, contractors, agents, advisors or other Third Parties involved in such activity. Each Party agrees to refrain from any activity in connection with this Agreement that would constitute a contravention by that Party of such laws. Notwithstanding Section 12.2 above, breach of this Section 15.2 by either Party shall entitle the other Party to terminate this Agreement with immediate effect to the extent legally and clinically possible.
- 15.2.4 The Parties acknowledge and agree that the payments provided under this Agreement constitutes fair market value for the performance of each Party's obligations and exercise of its rights under this Agreement and shall not be used in a manner that violates applicable anti-bribery and anti-corruption laws.

15.3 <u>Intellectual Property</u>

- 15.3.1 Ownership. Sucampo represents and warrants that Sucampo and its Affiliates have the right to grant the licenses granted to Takeda herein (whether through ownership or otherwise) with respect to all Sucampo Background Technology, Sucampo Patent Rights, Sucampo Know-How and Product Trademarks, Corporate Names, Trademarks and Other Intellectual Property Rights that are licensed to Takeda pursuant to the terms and conditions of this Agreement or that are necessary for Sucampo and Takeda to perform their obligations pursuant to the terms of this Agreement and the Ancillary Agreements (all such rights, collectively, the "Sucampo Rights").
- 15.3.2 To the knowledge of Sucampo, Sucampo represents and warrants to Takeda that Sucampo or an affiliate thereof have obtained from the inventors of Sucampo Background Technology and Sucampo Patent Rights valid and enforceable agreements assigning to Sucampo or an affiliate thereof each such inventor's entire right, title and interest in and to all such technology or has claimed such right, title and interest under the applicable employee invention law
- 15.3.3 To the knowledge of Sucampo, Sucampo represents and warrants to Takeda that, as of the Effective Date, neither Sucampo nor any of its Affiliates (including Sucampo Pharmaceuticals, Inc.) has received any letters or oral communication by a Third Party relating to the claimed infringement of such Third Party's intellectual property rights by the import, use, manufacture or sale of the Compound or Licensed Product in the Field in the Territory.
- 15.3.4 To the knowledge of Sucampo, Sucampo represents and warrants to Takeda that neither Sucampo nor any of its Affiliates nor Takeda has infringed, is infringing or will infringe, in connection with the license of Sucampo Rights or the Manufacture (by Sucampo or third party manufacturer contracted by Sucampo anywhere in the world) and sale of the Licensed Product to Takeda for the Commercialization of the Licensed Product by Takeda in the Territory and the import, Manufacture (Secondary Packaging) and export of the Licensed Product in any material respect the rights of any third party with regard to any of such third party's intellectual property.
- 15.3.5 To the knowledge of Sucampo, Sucampo represents and warrants to Takeda that as of the Effective Date, no material claims by any Third Party are pending, or to the knowledge of Sucampo, threatened with regard to the ownership or licensing by Sucampo of the Sucampo Rights.
- 15.3.6 To the knowledge of Sucampo, Sucampo represents and warrants to Takeda that as of the Effective Date, no material claims by any Third Party are pending, or to the knowledge of Sucampo, threatened with regard to the infringement of such Third Party's intellectual property rights by Sucampo or any of its Affiliates.

- 15.3.7 To the knowledge of Sucampo, Sucampo represents and warrants to Takeda that all Sucampo Patent Rights have been duly registered and/or filed with or issued by each appropriate Regulatory Authority in each applicable jurisdiction in the Territory, all necessary affidavits of continuing use have been timely filed and all necessary maintenance fees have been timely paid to continue all such Sucampo Patent Rights in effect. None of the Sucampo Patent Rights have expired or been declared invalid, in whole or in part, by any Regulatory Authority. There are no ongoing material interferences, oppositions, reissues, reexaminations or other proceedings involving any of the Sucampo Rights in any patent office or similar administrative agency, apart from the following:
 - Appeal No. OA/42/2012/PT/CH, Patent No. 224855 (Patent application No. IN/PCT/2002/516/CHE) in India
 - IPAB Case No. SR.NO.278/2011/PT/CH, Patent No. 223147 (Patent application No. 460/CHENO/2003) in India
 - Appeal to Brazilian Patent application No. PI 0014869-5
 - Appeal to Brazilian Patent application No. PI0114042-6)
 - Case No. 89121423N01, Patent No. I 281918 (Patent application No. 89121423) in Taiwan
- 15.3.8 To the knowledge of Sucampo, as of the Effective Date, there are no inquiries, actions, investigations or other proceedings pending before or threatened by any Regulatory Authority in any country in the Territory with respect to the Licensed Product or any facility where the Licensed Product is Manufactured, and Sucampo, to its knowledge, has not received written notice threatening any such inquiry, action, investigations or other proceeding.
- 15.3.9 To the knowledge of Sucampo, as of the Effective Date, the Manufacture (other than Secondary Packaging) of the Licensed Product has been conducted by Sucampo, its Affiliates and subcontractors, to the extent necessary, in compliance in all material respects with Applicable Law.
- 15.3.10 <u>Right to Grant Licenses and Assignments</u>. Sucampo represents and warrants to Takeda that it has the right to grant to Takeda the rights, licenses and assignments granted under this Agreement, free and clear of any and all encumbrances and without the need for any assignments, releases, consents, approvals, immunities or other rights not yet obtained. Sucampo represents, warrants and covenants that it will not enter into an agreement that is inconsistent with the rights, licenses and assignments granted to Takeda in this Agreement.

- 15.3.11 No Existing Claims. Sucampo represents and warrants to Takeda that there is, to Sucampo's knowledge, as of the Effective Date, no claim or demand of any Person in writing pertaining to, or any proceeding which is pending or threatened that challenges Sucampo's interest in the Sucampo Rights in the applicable country in the Territory or makes any adverse claim of ownership thereof. Sucampo represents and warrants to Takeda that, as of the Effective Date, none of the relevant Sucampo Rights are the subject of any pending or threatened, adverse claim, judgment, injunction, order, decree or agreement restricting its use for the Licensed Product in the Field in the applicable country in the Territory.
- 15.3.12 <u>Disclosure and Delivery.</u> Sucampo represents, warrants and covenants that Sucampo shall, to its knowledge, have the full right and legal capacity to disclose and deliver the Sucampo Patent Rights, Sucampo Background Technology and Product Trademark to Takeda to exercise such rights with respect to the Sucampo Patent Rights, Sucampo Background Technology and Product Trademark solely as and to the extent expressly permitted under this Agreement without violating the rights of Third Parties.
- 15.3.13 <u>Maintaining Existing Licenses and Rights.</u> Subject to Section 11.2 above, Sucampo represents, warrants and covenants that Sucampo shall use Commercially Reasonable Efforts to maintain all rights and licenses executed by Sucampo that materially affect Takeda's rights with respect to the Licensed Product in the Field in the applicable country in the Territory as and to the extent set forth in this Agreement. Sucampo represents, warrants and covenants that Sucampo shall use Commercially Reasonable Efforts ensure Product Trademarks are registered and maintained in the applicable country in the Territory for the Licensed Product in the Field during the Term.
- 15.3.14 <u>Future Authorizations</u>. Each Party shall use Commercially Reasonable Efforts to obtain and maintain during the Term all authorizations, consents and approvals, governmental or otherwise, necessary for such Party to grant the rights and licenses granted by such Party under this Agreement and to perform its obligations under this Agreement.
- 15.3.15 Non-Infringement. As of the Effective Date, each Party is not aware of any intellectual property rights owned or controlled by a Third Party that would be infringed or misappropriated by the Development and Commercialization of the Licensed Product in the Field in the applicable country in the Territory, and such Party has received no written claims relating to any such infringement or misappropriation.
- 15.4 <u>Secondary Packaging by Takeda</u>. Takeda represents and warrants that the Secondary Packaging of the Licensed Product performed by Takeda shall: (a) be in accordance and in compliance with Applicable Law in the countries in the Territory where such Licensed Product in the Field is to be Commercialized, including cGMP; (b) be in accordance with the applicable Regulatory Filings and Regulatory Approvals in the countries in the Territory where such Licensed Product in the Field is to be Commercialized; and (c) be in compliance with applicable Specifications for the Secondary Packaging of such Licensed Product.

- No Debarment. Each Party certifies as of the Effective Date that neither Party has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by any Regulatory Authority. Each Party further certifies as of the Effective Date that it has not used prior to the Effective Date and shall not use during the Term, any employee, agent or independent contractor (including, in the case of Takeda, any Subcontractor) who has been debarred by any Regulatory Authority or, to such Party's knowledge, is the subject of debarment proceedings by any Regulatory Authority. Each Party further represents, warrants and covenants that it has not sanctioned, suspended, excluded or otherwise declared ineligible from any Regulatory Authority healthcare program. In the event that during the Term, such Party (i) becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible; (ii) received notice of an action or threat of an action with respect to any such debarment, suspension, exclusion, sanction or ineligibility, such Party shall immediately notify the other Party. Notwithstanding Section 12.2 above, in the event a Party becomes debarred by a Regulatory Authority during the Term, the other Party shall have a right to terminate this Agreement upon thirty (30) days written notice to the debarred Party.
- 15.6 <u>No Litigation</u>. As of the Effective Date, Sucampo represents and warrants that there is no pending, settled or, to its knowledge, threatened litigation with respect to the Compound or the Licensed Product in the applicable country in the Territory or against that Party that may affect such Party's ability to perform its obligations or exercise its rights under this Agreement.
- 15.7 <u>Affiliate and other Sublicensee and Subcontractor Compliance.</u> Either Party represents and warrants that it shall remain responsible for any breach of its obligations hereunder by any of its Affiliates, Sublicensees and Subcontractors as applicable.
- 15.8 When any representation, warranty, covenant or agreement contained in this Agreement is expressly qualified by reference "to the knowledge of Sucampo" or words of similar, then Sucampo shall be deemed to have knowledge if any of its employees or any of its Affiliates employees (including but not limited to Sucampo Pharmaceuticals, Inc.) at the time of the execution of this Agreement has actual knowledge, or ought reasonably to have knowledge, given their particular position and responsibilities.
- 15.9 <u>Warranty Disclaimer</u>. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE COMPOUND, THE LICENSED PRODUCT, ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY EXPRESSLY AND SPECIFICALLY DISCLAIMS ALL WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE.

15.10 <u>Limited Liability.</u> NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, EXCEPT IN CIRCUMSTANCES OF WILFUL MISCONDUCT BY A PARTY OR ITS AFFILIATES, OR WITH RESPECT TO EACH PARTY'S INDEMNIFICATION OBLIGATIONS SET FORTH IN ARTICLE 16 AND ANY OTHER INDEMNIFICATION OBLIGATIONS OF SUCH PARTY UNDER THIS AGREEMENT, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR LOST PROFITS OF ANY KIND OR FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, LOST PROFITS OR LOST REVENUES, OR COST/EXPENSE OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY.

ARTICLE 16 INDEMNIFICATION; INSURANCE

- 16.1 <u>Indemnification by Takeda</u>. Takeda agrees to indemnify, defend and hold harmless Sucampo and its Affiliates and their respective employees, agents, officers, directors and permitted assigns ("<u>Sucampo Indemnitees</u>") from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' fees and other expenses of litigation and/or arbitration) (collectively, "<u>Losses</u>") resulting from a claim, suit or proceeding made or brought by a Third Party against Sucampo or its Affiliates (collectively, a "<u>Third Party Claim</u>") arising out of or resulting from:
- (a) Any breach of representations or warranties made by Takeda (and if applicable Takeda's Affiliate or Sublicensees) in ARTICLE 15;
- (b) Negligence of Takeda (and if applicable Takeda's Affiliate or Sublicensees) in conducting any Development of the Licensed Product, if conducted by Takeda, Takeda's Affiliates or Sublicensees;
- (c) The Commercialization by Takeda (or, if applicable Takeda's Affiliates or its Sublicensee(s)) (including without limitation, product liability claims);

(d)	The failure of Takeda (and, if applicable Takeda's Affiliates or its sub-licensee(s) or subcontractors) to comply with any provision
of this Agreement, or with any Appl	icable Law, regulations and/or administrative decisions relating to any Licensed Product,

except in each case to the extent caused by the negligence or wilful misconduct of Sucampo or its Affiliates.

- 16.2 <u>Indemnification by Sucampo</u>. Sucampo agrees to indemnify, defend and hold harmless Takeda and its Affiliates and their respective employees, agents, officers, directors and permitted assigns ("<u>Takeda Indemnitees</u>") from and against any and all Losses resulting from a Third Party Claim arising out of or resulting from the following:
 - (a) Any breach of representations or warranties made by Sucampo (and if applicable Sucampo's Affiliate) in ARTICLE 15;
- (b) The Manufacturing (excluding Secondary Packaging) and the supply of the Licensed Product by Sucampo's Affiliates or its subcontractors or other parties for whom Sucampo is responsible;
- (c) Any product liability claim in the applicable country in the Territory to the extent resulting from any Latent Defect or Patent Defect of the Licensed Product:
- (d) Infringement, misappropriation or violation of any Patent Rights, any rights, title and interests in Trademarks, Other Intellectual Property Rights, publicity, privacy or other intellectual property or other proprietary rights of any Third Party (other than each Party's Affiliates), in each of the foregoing cases, solely in the Field in the applicable country;

The failure of Sucampo (and, if applicable Sucampo's Affiliates or its subcontractors or other parties for whom Sucampo is responsible) to comply with any provision of this Agreement, Ancillary Agreement or with any Applicable Law, regulations and/or administrative decisions relating to any Licensed Product, except in each case to the extent caused by the negligence or wilful misconduct of Takeda or its Affiliates.

- 16.3 <u>Procedures for Indemnification.</u> The obligations of an indemnifying Party under Section 16.1 and Section 16.2 shall be governed by and contingent upon the following:
 - 16.3.1 Notice of Claim. Each Party shall give the other Party prompt written notice of any Third Party Claim (an "Indemnification Claim Notice"). Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of the Loss claimed (to the extent that the nature and amount of such Loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all material papers and official documents received in respect of any such Third Party Claim. Notwithstanding the foregoing, the Parties hereby acknowledge and agree that the failure to give an Indemnification Claim Notice shall not relieve the indemnifying Party of its indemnification obligations under this Agreement except and only to the extent that the indemnifying Party is actually and materially prejudiced with respect to a Third Party Claim by the failure to give timely notice by the indemnified Party.

- Assumption of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the indemnified Party within fourteen (14) days after the indemnifying Party's receipt of an Indemnification Claim Notice or sooner if necessary. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgement that the indemnifying Party is liable to indemnify any Takeda Indemnitees or Sucampo Indemnitees (as applicable) in respect of such Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any indemnified Party's claim for indemnification.
 - 16.3.3 <u>Control of the Defense.</u> Upon the assumption of the defense of a Third Party Claim by the indemnifying Party:
- (a) the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party, which shall be reasonably acceptable to the indemnified Party;
- (b) the indemnified Party shall promptly deliver to the indemnifying Party all original notices and documents (including court papers) received by the indemnified Party in connection with the Third Party Claim; and
- the indemnifying Party shall not be liable to the indemnified Party for any legal expenses subsequently incurred by such indemnified Party or any Takeda Indemnitee or Sucampo Indemnitee (as applicable) in connection with the analysis, defense or settlement of the Third Party Claim. To the extent that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless an Indemnitee from and against the Third Party Claim, the indemnified Party shall reimburse the indemnifying Party for any reasonable and documented out-of-pocket costs and expenses (including reasonable attorneys' fees and costs of suit) and any Loss actually incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such indemnified Party or Indemnitee.
 - 16.3.4 <u>Right to Participate in the Defense</u>. Without limiting Section 16.3.2 or Section 16.3.3, any Takeda Indemnitee or Sucampo Indemnitee (as applicable) shall be entitled to participate in, but not control, the defense of a Third Party Claim and to retain counsel of its choice for such purpose; provided that such retention shall be at its own expense unless, (a) the indemnifying Party has failed to assume the defense and retain counsel in accordance with Section 16.3.2 (in which case the indemnified Party shall control the defense), or (b) the interests of the Indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under Applicable Law, ethical rules or equitable principles.

- 16.3.5 <u>Settlement.</u> The indemnifying Party shall not have the right to consent to the entry of any judgment or enter into any settlement or otherwise dispose of any Third Party Claim without the prior written consent of the indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Third Party Claim by an indemnified Party that is reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.
- 16.3.6 <u>Cooperation.</u> Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the indemnified Party shall, and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making itself and its employees and agents and other Indemnitees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the indemnified Party for any out-of-pocket expenses in connection therewith.
- Insurance. Each Party shall obtain and carry in full force and effect the minimum insurance requirements set forth herein, which shall protect Indemnites with respect to events covered by Section 16.1 and Section 16.2. Such insurance (a) shall be primary insurance with respect to each Party's own participation under this Agreement, and (b) shall be issued by a recognized insurer rated by A.M. Best "A-VII" (or its equivalent) or better, or an insurer pre-approved in writing by the other Party. The types of insurance, and minimum limits shall be General liability insurance with a minimum limit of [...***...] United States Dollars (USD [...***...]) in aggregate. General liability insurance or other insurances (such as Clinical Trial Insurance) shall include, at a minimum, Clinical Trial Insurance and, beginning at least thirty (30) days prior to First Commercial Sale of any Licensed Product, product liability insurance. Upon request by a Party, the other Party shall provide Certificates of Insurance evidencing compliance with this Section 16.4. The insurance policies shall be under claims made form. Either Party shall use its Commercially Reasonable Efforts to continue to maintain such insurance after the expiration or termination of this Agreement for period of five (5) years from the date of last sale under this Agreement. Notwithstanding the foregoing, either Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies.

ARTICLE 17 MISCELLANEOUS

- Governing Law. This Agreement and all disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the substantive laws of the State of New York lywithout regard to conflict of laws principles, except that (a) questions affecting the construction and effect of any Patent Rights shall be determined by the Applicable Law in the country in which the Patent Rights shall have been granted; (b) matters related to Regulatory Filings and Regulatory Approval shall be governed by the Applicable Law in the applicable country in the Territory; and (c) any matters not subject to being construed, governed, interpreted and applied in accordance with the substantive laws of the State of New York or required by Applicable Law to be exclusively resolved pursuant to the Applicable Law in the applicable country in the Territory, shall be resolved by the Applicable Law in such applicable country. The Parties hereby exclude the United Nations Convention on Contracts for the International Sale of Goods from this Agreement.
- 17.2 <u>Arbitration</u>. In the event of any dispute, difference or question arising out of or relating this Agreement, the construction thereof, or the rights, duties or liabilities of either Party hereunder the Parties shall initiate an arbitration proceeding to be conducted in accordance with the procedures set forth in EXHIBIT G.

17.3 Notices

17.3.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing and in English, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or by internationally recognized overnight delivery service that maintains records of delivery, or transmitted by facsimile (with transmission confirmed), addressed to the Parties at their respective addresses specified in Section 17.3.2, or to such other address as the Party to whom notice is to be given may have been provided in writing to the other Party, in accordance with this Section 17.3. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or upon receipt (at the place of delivery) if sent by an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 17.3 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

17.3.2 Addresses for Notice

For Takeda:

Takeda Pharmaceuticals International GmbH Thurgauerstrasse 130 8152 Glattpark-Opfikon Zurich, Switzerland

Fax:

Attention: Head of Legal

For Sucampo:

Sucampo AG Baarerstrasse 22 CH-3600 Zug Switzerland Fax:

Attention: Secretary & Director

With a copy to:

Sucampo Pharmaceuticals, Inc. 4520 East West Highway
Bethesda, MD 20814
Fax: 301-961-3440

Attention: Commercial Officer

With a copy to: Executive Vice President, Chief Legal Officer & Corporate Secretary

17.4 Equitable Relief. The Parties acknowledge and agree that the restrictions set forth in Sections 2.1.4, 2.1.6 and 7.5, ARTICLE 10 and ARTICLE 11 are reasonable and necessary to protect the legitimate interests of the Parties and that neither Party would have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of Sections 2.1.4, 2.1.6 and 7.5, and ARTICLE 10 and/or ARTICLE 11 may result in irreparable injury to the other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of Sections 2.1.4, 2.1.6 and 7.5, ARTICLE 10 and/or ARTICLE 11 by a Party, the other Party shall be entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. Nothing in this Section 17.4 is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

- Amendment; Waiver. This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a written instrument signed by duly authorized representatives of both Parties or, in the case of waiver, signed by duly authorized representatives of the Party waiving compliance. The delay or failure of a Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by a Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.
- 17.6 <u>No Third Party Beneficiaries</u>. Except as set forth in Section 16.1 and Section 16.2, the provisions of this Agreement are for the sole benefit of the Parties and their permitted successors and permitted assigns and none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, without limitation, any employee or creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.
- 17.7 Relationship of the Parties. Nothing in this Agreement shall be construed (a) to create or imply a partnership, association, joint venture or fiduciary duty between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder or under any of the Ancillary Agreements, or (d) to give either Party the right to bind the other or to create any duties or obligations between the Parties, except as expressly set forth herein. All Persons employed by a Party shall be employees of such Party and not of the other Party and all costs/expenses and obligations incurred by reason of such employment shall be for the account and expense of such Party. The Parties agree that the rights and obligations under this Agreement are not intended to constitute a partnership or similar arrangement that will require separate reporting for tax purposes in the applicable country in the Territory.
- 17.8 Assignment and Successors. This Agreement is personal to both Parties and neither Party shall sell, transfer, assign, delegate, pledge or otherwise dispose other than Takeda's right to sublicense its rights as and to the extent expressly and specifically permitted under Sections 2.1.1, 2.1.2 and 2.1.3 or subcontract the performance of its obligations as and to the extent expressly and specifically permitted under Section 2.1.2 of this Agreement and Sucampo's right to subcontract its Manufacturing obligations under Section 9.1.9 of this Agreement whether by operation of law, change of control or otherwise, in whole or in part without the prior written consent of the other Party, except that either Party may, on providing written notice to the other, assign this Agreement and its rights, obligations and interests hereunder, in whole or in part, without the written consent of the other Party to any of its Affiliates or to any purchaser of all or substantially all of its assets and/or all or substantially all of its assets to which this Agreement relates or to any successor corporation resulting from any merger or consolidation of such assigning Party with or into such corporation. Any permitted assignee of all of a Party's rights under this Agreement shall be deemed to be a party to this Agreement as though named herein. Any attempted assignment or delegation in violation of this Section 17.8 shall be void.

- 17.9 <u>Binding Effect</u>. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party, provided that such Party, if it survives, shall remain jointly and severally liable for the performance of such delegated obligations under this Agreement.
- 17.10 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties under this Agreement which is not within the reasonable control of the Party affected, not due to malfeasance, and which, with the exercise of due diligence could not have been avoided ("Force Majeure"), including, without limitation, fire, explosion, flood, earthquake, war, accident, strike, riot, terrorist attacks, civil commotion, acts of God, or the like, will not excuse such Party from the performance of its obligations or duties under this Agreement (other than payment obligations), but will suspend such performance during the continuation of Force Majeure; provided that (a) the Party prevented from performing its obligations or duties because of Force Majeure shall be required to, as soon as reasonably possible, notify the other Party hereto of the occurrence and particulars of such Force Majeure and shall be required to provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure and with notice of the termination thereof and (b) the Party so affected shall use Commercially Reasonable Efforts to avoid or remove such causes of nonperformance. Upon termination of Force Majeure, the obligation to perform any previously suspended obligation or duty shall promptly recommence. If performance is prevented for more than ninety (90) days then, notwithstanding Section 12.2 above, the unaffected Party may terminate this Agreement upon written notice to the affected Party (such termination may be on a country-by-country or Licensed Product-by-Licensed Product basis).
- 17.11 <u>Headings; References</u>. Article, Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Exhibit shall mean references to such Article, Section or Exhibit of this Agreement, (b) references in any section to any clause are references to such clause of such section, and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or as amended if expressly stated in this Agreement.
- 17.12 <u>Interpretation</u>. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties acknowledge and agree that: (a) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (b) the terms and provisions of this Agreement shall be construed fairly as to all Parties and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

- 17.13 Severability. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions or parts thereof of this Agreement, or the application hereof to any circumstances, to be illegal, invalid or to be unenforceable in a final non-appealable order, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, in each case provided that the basic purpose and structure of this Agreement is not altered.
- 17.14 Entire Agreement. This Agreement and the Ancillary Agreements constitute the entire agreement between the Parties with respect to the subject matter of the Agreement. This Agreement and the Ancillary Agreements supersede all prior agreements and understandings, whether written or oral, with respect to the subject matter of the Agreement, including the Confidentiality Agreement and all other confidentiality agreements entered in to between the Parties with respect to the subject matters hereof. Each Party confirms that it is not relying on, and expressly disclaims reliance on, any representations, warranties or covenants of the other Party except as specifically set out in this Agreement or any of the Ancillary Agreements. All Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Exhibits and this Agreement, the terms of this Agreement shall govern. To the extent of any conflict or inconsistency among this Agreement or any of the Ancillary Agreements, the terms and conditions of this Agreement shall govern, except that in case of discrepancy between any provision of the Agreement and the Quality Agreement or the Pharmacovigilance Agreement, then (i) as to matters related to quality the provisions of the Quality Agreement shall prevail or related to pharmacovigilance the provisions of the Pharmacovigilance Agreement shall prevail and (ii) as to all other matters the Agreement shall control.
- 17.15 <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.

- 17.16 <u>Expenses</u>. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective attorneys and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.
- 17.17 <u>Further Assurance</u>. Each Party shall perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to give effect to this Agreement.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

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TAKEDA PHARMACEUTICALS INTERNATIONAL GMBH

By: (Signature)	By: (Signature)	-
(Printed Name) Peter Greenleaf	(Printed Name)	-
(Title) President & Director.	(Title)	_
	By: (Signature)	-
	(Printed Name)	-
	(Title)	-
	90	

EXHIBIT A COMPOUND, ISOMERS AND TAUTOMERS

Chemical Name: [...***...]

Code Name: SPI-0211, SPL-0211, RU-0211

CAS Number: 333963-40-9

Monocyclic Tautomer CAS Number: 136790-76-6

*Confidential Treatment Requested

EXHIBIT B EXISTING REGULATORY APPROVALS

Japan

MA holder: Sucampo Pharma Ltd., Osaka

MA number: 22400AMX 0073300

MA date: 29 June 2012 Tradename: Amitiza

Strength: soft capsule 24 mcg

Indication: chronic constipation, excluding constipation caused by

organic diseases

Switzerland

MA holder: Sucampo AG, Zug

MA number: 59'275

MA date: 16 November 2009, renewed 22 May 2014

Tradename: Amitiza

Strength: soft capsule 24 mcg

Indication: chronic idiopathic constipation (16 November 2009)

Opioid-induced constipation (30 June 2014)

United Kingdom

MA holder: Sucampo Pharma Europe Ltd., Abingdon

MA number: PL21341-0003 MA date: 10 September 2012

Tradename: Amitiza

Strength: soft capsule 24 mcg

Indication: chronic idiopathic constipation

United States of America

MA holder: Sucampo Pharma Americas LLC, Bethesda MA number: NDA 21908

31 January 2006 MA date:

Tradename: Amitiza

Strength: soft capsule 24 mcg and 8 mcg

Indication: chronic idiopathic constipation (24 mcg; 31 January

2006)

Irritable bowel syndrome with constipation (8 mcg; 29 April 2008)

Opioid-induced constipation (24 mcg; 19 April 2013)

EXHIBIT C PRODUCT TRADEMARKS

TM AMITIZA List

2014/9/26

Trade Mark	Country	Class	Appl. No.	Appl. Date	Pub. No.	Pub. Date	Regist, No.	Regist Date	Status
AMITIZA	China	5	6323075	2007/10/15	6323075	2009/12/27	6323075	2010/3/28	Registered
AMITIZA (KANJI)	China	5	6323131	2007/10/15	6323131	2009/12/27	6323131	2010/3/28	Registered
AMITIZA	Korea	5	2007-0050050	2007/9/27	2008-0047523	2008/8/6	0768676	2008/11/13	Registered
AMITIZA (Hankul)	Korea	5	2007-0050052	2007/9/27	2008-0047524	2008/8/6	0768677	2008/11/13	Registered
AMITIZA	TAIWAN	5	96048172	2007/10/12			01328125	2008/9/16	Registered
AMITIZA (KANJI)	TAIWAN	5	96048175	2007/10/12			01328126	2008/9/16	Registered
AMITIZA	India	5	1605121	2007/9/24	1605121	2008/10/30	1605121	2009/3/31	Registered
AMITIZA	Hong-Kong	5	300956683	2007/9/18	300956683	2008/6/20	300956683	2008/9/30	Registered
AMITIZA	Argentina	5	2.835.256	2008/6/30			2.382.651	2010/7/26	Registered
AMITIZA	Australia	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Austria	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Belize	5	5833.08	2008/11/11			5833.08	2009/3/10	Registered
AMITIZA	Benelux	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Bolivia	5	SM-3091-08	2008/7/1			149492	2014/2/6	Registered
AMITIZA	Brazil	5	829878971	2008/7/3			829878971	2010/11/9	Registered
AMITIZA	Chile	5	834196	2008/8/21			863.467	2009/10/20	Registered
AMITIZA	Colombia	5	8067125	2008/7/1			377947	2009/4/29	Registered
AMITIZA	Costa Rica	5	2008-0006350	2008/7/1		2008/11/14	185262	2009/1/30	Registered
AMITIZA	Cyprus	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Czech Republic	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Denmark	5	A0005625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Ecuador	5	202244	2008/7/17			1310-09	2009/2/18	Registered
AMITIZA	El Salvador	5	100423-2008	2008/7/2			00182	2009/4/20	Registered
AMITIZA	Estonia	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Finland	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	France	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Germany	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Greece	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Guatemala	5	2323-09	2008/9/3			168865	2010/3/25	Registered
AMITIZA	Guyana	5	22849A	2008/9/4			022849	2011/6/6	Registered
AMITIZA	Hungary	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Iceland	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Ireland	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Italy	5	A0006625	2006/12/8			910673	2006/12/8	Registered

TM AMITIZA List 2014/9/26

Trade Mark	Country	Class	Appl. No.	Appl. Date	Pub. No.	Pub. Date	Regist No.	Regist Date	Status
AMITIZA	Jersey	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Latvia	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Lithuania	5	A0006625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Mexico	5	944352	2008/6/30			1095909	2009/4/21	Registered
AMITIZA	New Zealand	5	761908	2007/1/12			761908	2007/7/12	Registered
AMITIZA	Nicaragua	5	2008-003355	2008/9/23		2008/11/5	2010089140 LM	2010/2/11	Registered
AMITIZA	Panama	5	175099	2008/9/18			175099	2008/9/18	Registered
AMITIZA	Paraguay	5	34153/2008	2008/9/11			329706	2010/3/19	Registered
AMITIZA	Peru	5	0360805-2008	2008/7/18			148228	2009/1/30	Registered
AMITIZA	Poland	5	A0006625	2006/12/8			910873	2006/12/8	Registered
AMITIZA	Portugal	5	A0006625	2006/12/8	-		910873	2006/12/8	Registered
AMITIZA	Slovakia	5	A0008625	2006/12/8			910673	2006/12/8	Registered
AMITIZA	Slovenia	5	A0006625	2006/12/8			910873	2006/12/8	Registered
AMITIZA	Spain	5	A0008625	2006/12/8			910873	2006/12/8	Registered
AMITIZA	Suriname	5	21570	2008/9/4			21570	2008/9/4	Registered
AMITIZA	Sweden	5	A0005625	2006/12/8			910873	2006/12/8	Registered
AMITIZA	Switzerland	5	A0005625	2006/12/8			910873	2006/12/8	Registered
AMITIZA	United Kingdom	5	A0005625	2006/12/8	1		910873	2006/12/8	Registered
AMITIZA	Uruguay	5	395873	2008/9/10			395873	2011/1/12	Registered
AMITIZA	Venezuela	5	2008-02988	2008/7/4			P304021	2010/6/3	Registered
AMITIZA	WIPO	5	A0005625	2006/12/8			910673	2006/12/8	Registered
(amitiza & balance device)	СТМ	5	010724656	2012/3/14	010724656	2012/5/18	010724656	2012/8/27	Registered

EXHIBIT D SUCAMPO PATENT RIGHTS

AMITIZA Patent List 2014/10/17

Title	Country	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date	Exclusivity Ends	Status	EP Designated Country
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	U.S.A.	09/688351	2000/10/16			6583174	2003/6/24	2020/10/16	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	U.S.A. DIV	10/383581	2003/3/10	2004-0235885	2004/11/25	7417067	2008/8/26	2020/10/16	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	U.S.A. CA	12/144000	2008/6/23	2008-0255227	2008/10/16	8088934	2012/1/3	2021/5/18	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	U.S.A. CA2	13/289386	2011/11/4			8097649	2012/1/17	2020/10/16	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	U.S.A. CA3	13/337391	2011/12/27						pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Taiwan	89121423	2000/10/13			I 281918	2007/6/1	2020/10/12	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Argentina	P000105407	2000/10/13	026046	2002/12/26	-spr-admonate	Emouro response		pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Argentina DIV	P20130100275	2013/1/30						pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Canada	2385732	2000/10/13			2385732	2009/2/10	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	China	00814313.7	2000/10/13	1379769	2002/11/13	00814313.7	2006/8/9	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Korea	2002-7004709	2000/10/13	2002-0068521	2002/8/27	0830061	2008/5/9	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Australia	76856/00	2000/10/13	780342	2005/3/17	780342	2005/7/7	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Australia DIV	2004242503	2004/12/24	2004242503	2007/6/21	2004242503	2007/10/4	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	New Zealand	518020	2000/10/13	518020	2004/2/27	518020	2004/6/8	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	South Africa	2002/2312	2000/10/13			2002/2312	2002/12/24	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Brazil	PI 0014869	2000/10/13	PI 0014869	2002/6/25				pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Mexico	PA/A/2002/003756	2000/10/13			247886	2007/8/6	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Mexico DIV	MX/A2007/005720	2007/5/11			279953	2010/10/14	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	India	NPCTG002614OHE	2000/10/13			224855	2008/10/23	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Israel	148803	2000/10/13	148803	2006/7/5	148803	2006/10/6	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Turkey	2002/01032	2000/10/13	2002/01032	2002/8/21	2002/01032	2005/10/21	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Russia	2002112984	2000/10/13	2002112984	2004/1/20	2275368	2008/4/27	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Czech	PV2002-1037	2000/10/13			303625	2012/12/5	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hungary	P0203746	2000/10/13	P0203746	2003/3/28	229647	2013/12/19	2020/10/13	Granted	

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Title	Country	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date	Exclusivity Ends	Status	EP Designated Country
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hungary DIV	P1300369	2013/6/11						pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Norway	20021736	2000/10/13			330258	2011/3/14	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	EPC	00966462.4	2000/10/13	1220849	2002/7/10	1220849	2004/5/19	2020/10/13	Granted	OF FREE PLANSE STORE STORE SO
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	EPC DIV	04005836.4	2004/3/11	1426361	2004/6/9	1426361	2008/7/30	2020/10/13	Granted	**************************************
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hong Kong	02107337.5	2002/10/7	1045693	2002/12/6	1045693	2005/1/21	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hong Kong DIV	04109640.1	2004/12/6	1068792	2005/4/1	1068792	2009/4/24	2020/10/13	Granted	
ANTI-CONSTIPATION COMPOSITION	U.S.A.	09/655760	2000/9/5			6414016	2002/7/2	2020/9/5	Granted	
ANTI-CONSTIPATION COMPOSITION	U.S.A. DIV3	11/142251	2005/6/2	2005-0222195	2005/10/6	8071613	2011/12/6	2020/9/5	Granted	
ANTI-CONSTIPATION COMPOSITION	U.S.A. CA	13/274812	2011/10/17			8114890	2012/2/14	2020/9/5	Granted	
ANTI-CONSTIPATION COMPOSITION	U.S.A. CA3	14/265467	2014/4/30	2014-0235665	2014/8/21				pending	
ANTI-CONSTIPATION COMPOSITION	Argentina	P010104216	2001/9/5	030609	2003/8/27				pending	
ANTI-CONSTIPATION COMPOSITION	Argentina DIV	P20130103006	2013/8/26						pending	
ANTI-CONSTIPATION COMPOSITION	Taiwan	90121835	2001/9/4			1 305147	2009/1/11	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Canada	2419741	2001/9/4			2419741	2010/11/30	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	China	01818323.9	2001/9/4	1655776	2005/8/17	01818323.9	2007/9/5	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Korea	2003-7003261	2001/9/4	2003-0029919	2003/4/16	0901102	2009/5/29	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Korea DIV	2008-7021218	2009/8/29	2008-0091278	2009/10/9	0918223	2009/9/14	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Australia	2001282615	2001/9/4	2001282615	2008/6/22	2001282615	2008/10/12	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	New Zealand	524401	2001/9/4	524401	2004/8/27	524401	2004/12/9	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	South Africa	2003/1673	2001/9/4			2003/1673	2003/11/26	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Brazil	PI 0114042	2001/9/4	PI 0114042	2003/7/22				pending	
ANTI-CONSTIPATION COMPOSITION	Mexico	PA/A/2003/001859	2001/9/4			231553	2005/10/24	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	India	00 450/CHENP/2003	2001/9/4			223147	2008/9/4	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Israel	154534	2001/9/4	154534	2010/4/29	154534	2010/7/30	2021/9/4	Granted	

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Title	Country	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date	Exclusivity Ends	Status	EP Designated Country
ANTI-CONSTIPATION COMPOSITION	Russia	2003109622	2001/9/4	2003109622	2003/9/10	2278666	2006/6/27	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Czech	PV2003-787	2001/9/4			304740	2014/8/6	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Hungary	P0302422	2001/9/4	P0302422	2003/10/28	229319	2013/10/1	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Norway	20030996	2001/9/4		Marie Property College	332701	2012/12/10	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	EPC	01961333.0	2001/9/4	1315485	2003/6/4	1315485	2007/11/21	2021/9/4	Granted	ATBECHDESKERF/FRIGGREFTHLFT,N
ANTI-CONSTIPATION COMPOSITION	Switzerland		2010/4/12		2010/4/15	C1315485/01	2012/6/29	2024/11/15	Granted	
ANTI-CONSTIPATION COMPOSITION	EPC DIV	07016834.9	2001/9/4	1857105	2007/11/21	1857105	2010/8/11	2021/9/4	Granted	ATBECHDECKEDIUS (BOOKEISHUST) (B
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	U.S.A.	10/135397	2002/5/1	2003-73746	2003/4/17	6982283	2006/1/3	2022/12/4	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Argentina	P020101560	2002/4/29	035237	2004/5/5				pending	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Taiwan	91108513	2002/4/25			1 302100	2008/10/21	2022/4/25	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	China	02813389.7	2002/4/26	1522147	2004/8/18	02813389.7	2010/5/12	2022/4/26	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Korea	2003-7014221	2002/4/26	2004-0008168	2004/1/28	0886598	2009/2/25	2022/4/26	Granted	A stronger out of a day of both
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Australia	2002251554	2002/4/26	2002251554	2007/5/24	2002251554	2007/9/6	2022/4/26	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	New Zealand	529187	2002/4/26	529187	2005/10/28	529187	2006/2/9	2022/4/26	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Canada	2444103	2002/4/28			2444103	2010/6/8	2022/4/26	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Brazil	PI 0209327	2002/4/26	PI 0209327	2004/7/20				pending	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Mexico	PA/A/2003/010019	2002/4/26	PAW2003/010019	2004/3/24	244942	2007/4/12	2022/4/28	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Norway	20034864	2002/4/26						Allowed	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	EPC	02720623.4	2002/4/28	1392318	2004/3/3	1392318	2007/2/28	2022/4/26	Granted	AT DE,CH,DE,CH,ES,FR,OB,T,ML,PT,SI
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	U.S.A.	10/293516	2002/11/14	2003-0119898	2003/6/26	8097653	2012/1/17	2022/11/14	Granted	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	U.S.A. DIV	13/330942	2011/12/20	2012-0088824	2012/4/12	8389542	2013/3/5	2022/11/14	Granted	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	U.S.A. DIV2	13/754138	2013/1/30	2013-0143958	2013/6/8				pending	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Argentina	P020104349	2002/11/13	037524	2004/11/17				pending	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Taiwan	91133227	2002/11/13		1	1 331920	2010/10/21	2022/11/12	Granted	

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Title	Country	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date	Exclusivity Ends	Status	EP Designated Country
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Canada	2464420	2002/11/14			2464420	2011/12/13	2022/11/14	Granted	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Brazil	PI 0214075	2002/11/14	PI 0214075	2004/9/28				pending	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	EPC	02780083.8	2002/11/14	1443938	2004/8/11	1443938	2011/8/31	2022/11/14	Granted	AMERICAN DESCRIPTION OF THE PERSON OF THE PE
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	EPC DIV	10010211.0	2010/9/22	2298314	2011/3/23	2298314	2014/9/3	2022/11/14	Granted	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Hong Kong	11109944.5	2011/9/21	1155649	2012/5/25				pending	
SOFT-GELATIN CAPSULE FORMULATION	U.S.A.	11/856476	2007/1/23	2007-0172523	2007/7/28	8026393	2011/9/27	2027/10/25	Granted	
SOFT-GELATIN CAPSULE FORMULATION	U.S.A. CA	13/210556	2011/8/16		avisteriaes.	8338639	2012/12/25	2027/10/25	Granted	
SOFT-GELATIN CAPSULE FORMULATION	U.S.A. CA2	13/679005	2012/11/16	2013-0078303	2013/3/28	8779187	2014/7/15	2027/10/25	Granted	
SOFT-GELATIN CAPSULE FORMULATION	U.S.A. CA3	14/300351	2014/6/10						pending	
SOFT-GELATIN CAPSULE FORMULATION	Canada	2837274	2007/1/23			2637274	2013/6/4	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	Korea	2008-7020876	2007/1/23	2008-0090526	2008/10/8	1393944	2014/5/2	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	China	200780010579.0	2007/1/23	101410097	2009/4/15				pending	
SOFT-GELATIN CAPSULE FORMULATION	Russia	2008134489	2007/1/23	2008134489	2010/2/27	2420291	2011/8/10	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	India		2007/1/23						pending	
SOFT-GELATIN CAPSULE FORMULATION	Australia	2007208632	2007/1/23	2007208632	2012/1/19	2007208632	2012/5/3	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	New Zealand	570191	2007/1/23	570191	2010/9/30	570191	2011/1/8	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	Israel	192867	2007/1/23						pending	
SOFT-GELATIN CAPSULE FORMULATION	Brazil	PI 0707334-8	2007/1/23						pending	
SOFT-GELATIN CAPSULE FORMULATION	Mesico	MXXA/2008/009650	2007/1/23	MX/A/2008/009650	2009/1/27	289422	2011/8/16	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	EPC	0770756.4	2007/1/23	1978944	2008/10/15	1978944	2012/8/15	2027/1/23	Granted	AT DE JOHO EDW JES JAGO JE JEN, PEGE

EXHIBITS E & F INTENTIONALLY LEFT BLANK

EXHIBIT G ALTERNATIVE DISPUTE RESOLUTION

The Parties recognize that from time to time there may be a disputes arising out of or relating to either Party's rights or obligations under this Agreement ("<u>Dispute</u>"). The Parties agree that any such Dispute shall be resolved by the Alternative Dispute Resolution provisions set forth in this Exhibit, the result of which shall be binding, upon the Parties.

To begin the Alternative Dispute Resolution process, a Party first must send written notice of the Dispute to the other Party for attempted resolution by good faith negotiations between their respective presidents (or their designees) of the affected subsidiaries, divisions, or business units within twenty-eight (28) days after such notice is received (all references to "days" in this Alternative Dispute Resolution provision are to calendar days). If the matter has not been resolved within twenty-eight (28) days of the notice of dispute, or if the Parties fail to meet within such twenty-eight (28) days, either Party may initiate an Arbitration proceeding as provided herein. The Parties shall have the right to be represented by counsel in such a proceeding.

- 1. All Disputes shall be finally resolved by three arbitrators in accordance with the Rules of Arbitration of the International Chamber of Commerce. There will be three (3) arbitrators, one nominated by the initiating party in the request for arbitration, the second nominated by the other party within 30 days of receipt of the request for arbitration, and the third, who shall act as presiding arbitrator, nominated by the two party-nominated arbitrators within 30 days of the appointment of the second arbitrator. If any arbitrators are not nominated within these periods, the President of the ICC International Court of Arbitration shall make the appointment(s).
 - 2. The seat of the arbitration shall be New York, New York, USA
 - 3. The language of the arbitration shall be English.
- 4. All awards and procedural orders from the arbitral tribunal shall be final and binding. Judgment on any award may be entered in any court of competent jurisdiction.
- 5. The arbitral tribunal shall have the authority to award interim, injunctive, conservatory, or provisional measures of protection ("Provisional Relief"), declaratory relief, monetary compensation, equitable relief, and specific performance. The arbitral tribunal may not award or assess punitive or exemplary damages against either Party.
- 6. In addition to any remedy available pursuant to Article 29 of the Rules of Arbitration of the International Chamber of Commerce ("Emergency Arbitrator"), prior to the time the arbitral tribunal is constituted, Sucampo and Takeda may apply to the Specified Court for Provisional Relief. In the event that Sucampo or Takeda applies to the Specified Court for Provisional Relief, the decision of the Specified Court, and not the Emergency Arbitrator, shall prevail. If Sucampo or Takeda seeks Provisional Relief in such circumstances, such Party will not be deemed to have breached its agreement to arbitrate or to have affected the powers reserved to the arbitral tribunal.

- 7. The Parties unconditionally and irrevocably consent to the exclusive jurisdiction of the federal or state courts in the State of New York (the "Specified Court") in any action, suit or proceeding with respect to Provisional Relief, and the non-exclusive jurisdiction of the Specified Court with respect to the enforcement of any award. The Parties expressly waive any objection, and they agree not to plead or claim, that (i) the Specified Court does not possess personal jurisdiction over the Parties, (ii) any such action or proceeding has been brought in an inconvenient forum, or (iii) an injunction or other judicial order (interlocutory or final) should be issued that would have the effect (directly or indirectly) of restraining or impeding the maintenance or prosecution by either Sucampo or Takeda of the arbitration. The Parties further agree that any award may be enforced by Sucampo or Takeda against the assets of the other Party wherever those assets are located (including but not limited to New York), and that any award may be entered into and enforced by any court or tribunal of competent jurisdiction.
- 8. Sucampo, on the one hand, and Takeda, on the other hand, each hereby appoints the designated person in Section 17.3 (the "Service Process Agent") as its agent for service of process in New York in any Dispute, provided that the agent named by such Party in Section 17.3 may be replaced by another agent in New York upon thirty (30) days' written notice. Service of process on the designated agent at the designated address shall be deemed, for all purposes, to be due and effective service, and service shall be deemed completed whether or not forwarded to or received by the respective Parties. Any correspondence sent to a Party's agent for service of process shall also be copied to that Party directly pursuant to Section 17.3, provided, however that the failure to copy any Party directly shall not affect the effectiveness of any service of process.
- 9. The prevailing Party in any arbitration shall be entitled to recover its fees, costs and expenses, including administrative fees, arbitrators' fees and expenses, and attorneys' fees and expenses.
- 10. The existence of any Dispute, any settlement negotiations, the arbitration hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be kept confidential by the Parties, unless such disclosure is (i) made for purposes of a legal proceeding to enforce an arbitral award or any provision of this Agreement; (ii) required by any governmental agency; (iii) requested by any of the Parties' auditors; (iv) made by a Party to its parent corporation; (v) included as part of a securities filing, to the extent a Party's accountants, auditors or other securities advisors conclude that such information is necessary to a filing; or (vi) otherwise required to be disclosed by law. The Parties agree that they will notify each other in writing within five (5) business days of the receipt of any subpoena, court order, or administrative order requiring disclosure of information subject to this confidentiality provision and provide the other Party with a reasonable opportunity to object to the same before disclosing such information.

EXHIBIT H SUPPLY PRICE AND CONDITIONS

1 - FORM OF THE LICENSED PRODUCT

Sucampo shall supply the Licensed Product to Takeda in the following forms:

- For Development activities: Sample capsules in 2 count (ct.) alu-alu blister strips Capsules in 10 ct. alu-alu blister strips Capsules in 28 ct., 30 ct., 56 ct., or 60 ct. bottles
- For Commercialization activities
 Samples capsules in 2 count (ct.) alu-alu blister strips
 Capsules in 10 ct. alu-alu blister strips
 Capsules in 28 ct., 30 ct., 56 ct., or 60 ct. bottles
- For Commercialization activities during the Transition Period Capsules in 28 ct. or 56 ct. bottles and secondary packaged

2 - SUPPLY PRICE FOR THE LICENSED PRODUCT (including the samples)

· Supply Price of Licensed Product in connection with Development:

JPY[...***...] per capsule of the Licensed Product primary packed in alu-alu blister strip capsules or bottle

Supply Price of Licensed Product in connection with Commercialization:

JPY [...***...] per capsule of the Licensed Product primary packed in alu-alu blister strips or bottles JPY [...***...] per capsule of the Licensed Product primary packed in 2 count sample blister strip

· Supply Price of Licensed Product in connection with Commercialization during the Transition Period:

JPY [...***...] per capsule of the Licensed Product in secondary packaged form for 56 ct. bottles JPY [...***...] per capsule of the Licensed Product in secondary packaged form for 28 ct. bottles

*Confidential Treatment Requested

EXHIBIT I PRESS RELEASE





Takeda and Sucampo Enter Into Global Licensing Agreement for AMITIZA® (lubiprostone)

Takeda Gains Exclusive Rights to AMITIZA Beyond U.S. and Canada for All Markets Except Japan and China

BETHESDA, Md., October 21, 2014 and OSAKA, Japan, October 22, 2014 (GLOBE NEWSWIRE) - Sucampo Pharmaceuticals, Inc. (Sucampo) (NASDAQ: SCMP), a global biopharmaceutical company, and Takeda Pharmaceutical Company Limited (Takeda) today announced that on October 17, 2014, they entered into a global license, development, commercialization and supply agreement for AMITIZA® (lubiprostone). Through this agreement, Takeda expanded its exclusive rights beyond the United States (U.S.) and Canada to further develop and commercialize AMITIZA in all global markets, except Japan and the People's Republic of China.

"Takeda is committed to being patient and customer-centric, making quality health products available to the patients who need them. Through this agreement, AMITIZA can now be made available to patients worldwide," said Shinji Honda, Senior Managing Director and Corporate Strategy Officer. "Takeda forms partnerships to advance science and to provide innovative treatment options for patients, and this global agreement is an excellent example. This global collaboration leverages the expertise we have established through our gastroenterology portfolio of products."

"The expansion of our collaboration with Takeda represents a critical step forward with our strategic plan and is the natural evolution of our partnership with them for North America," said Peter Greenleaf, Chief Executive Officer of Sucampo. "This agreement allows Sucampo to remain focused on our strengths in drug development while allowing us to bring AMITIZA to more patients in need around the world. Through the eight years Takeda has marketed AMITIZA in the U.S., the company has garnered extensive experience with the product. Combined with their proven global infrastructure, we are confident that Takeda will build the brand in new global markets as they have done in the U.S., where AMITIZA continues to grow steadily."

Under the terms of the agreement, Sucampo will receive an upfront payment of \$14 million from Takeda and will also be eligible for up to \$35 million in additional commercial milestones contingent on the achievement of certain net sales revenue targets. Additionally, Sucampo will be the exclusive supplier of AMITIZA to Takeda at an agreed-upon supply price.

Takeda will be responsible for all development activities and costs, with Sucampo assuming responsibility for the first \$6 million in development expenses. In addition, Takeda will become the marketing authorization holder in each of the countries and will be responsible for all commercialization and regulatory activities. The agreement is effective until it expires on a country-by-country basis on the fourteenth anniversary of the date of first commercial sale in that country.

About AMITIZA (lubiprostone)

AMITIZA (lubiprostone) is a prostone and is a locally acting chloride channel activator, indicated in the United States for the treatment of chronic idiopathic constipation (CIC) in adults and opioid-induced constipation (OIC) in adults with chronic, non-cancer pain (24 mcg twice daily). The effectiveness in patients with OIC taking diphenylheptane opioids (e.g., methadone) has not been established. AMITIZA is also indicated in the U.S. for irritable bowel syndrome with constipation (IBS-C) (8 mcg twice daily) in women 18 years of age and older.

Important Safety Information

- · AMITIZA (lubiprostone) is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be thoroughly evaluated by the treating healthcare provider (HCP) to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.
- · Patients taking AMITIZA may experience nausea. If this occurs, concomitant administration of food with AMITIZA may reduce symptoms of nausea. Patients who experience severe nausea should inform their HCP.
- · AMITIZA should not be prescribed to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment. Patients should be instructed to discontinue AMITIZA and inform their HCP if severe diarrhea occurs.
- · Patients taking AMITIZA may experience dyspnea within an hour of first dose. This symptom generally resolves within three hours, but may recur with repeat dosing. Patients who experience dyspnea should inform their HCP. Some patients have discontinued therapy because of dyspnea.
- · In clinical trials of AMITIZA (24 mcg twice daily vs placebo; N=1113 vs N=316, respectively) in patients with CIC, the most common adverse reactions (incidence > 4%) were nausea (29% vs 3%), diarrhea (12% vs 1%), headache (11% vs 5%), abdominal pain (8% vs 3%), abdominal distension (6% vs 2%), and flatulence (6% vs 2%).
- · In clinical trials of AMITIZA (24 mcg twice daily vs placebo; N=860 vs N=632, respectively) in patients with OIC, the most common adverse reactions (incidence >4%) were nausea (11% vs 5%) and diarrhea (8% vs 2%).
- · In clinical trials of AMITIZA (8 mcg twice daily vs placebo; N=1011 vs N=435, respectively) in patients with IBS-C the most common adverse reactions (incidence > 4%) were nausea (8% vs 4%), diarrhea (7% vs 4%), and abdominal pain (5% vs 5%).
- · Concomitant use of diphenylheptane opioids (e.g., methadone) may interfere with the efficacy of AMITIZA.
- The safety of AMITIZA in pregnancy has not been evaluated in humans. Based on animal data, AMITIZA may cause fetal harm. AMITIZA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when AMITIZA is administered to a nursing woman. Advise nursing women to monitor infants for diarrhea.
- · Reduce the dosage in CIC and OIC patients with moderate and severe hepatic impairment. Reduce the dosage in IBS-C patients with severe hepatic impairment.

Please see the Full Prescribing Information here. For further information on AMITIZA, please visit www.sucampo.com/products.

About Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc. is focused on the development and commercialization of medicines that meet major unmet medical needs of patients worldwide. Sucampo has two marketed products – AMITIZA® and RESCULA® – and a pipeline of product candidates in clinical development. A global company, Sucampo is headquartered in Bethesda, Maryland, and has operations in Japan, Switzerland and the United Kingdom. For more information, please visit www.sucampo.com.

The Sucampo logo is the registered trademark and the tagline, The Science of Innovation, is a pending trademark of Sucampo AG. AMITIZA is a registered trademark of Sucampo AG. RESCULA is a registered trademark of R-Tech Ueno, Ltd, and has been licensed to Sucampo AG.

Follow us on Twitter (@Sucampo_Pharma). Follow us on LinkedIn (Sucampo Pharmaceuticals). <u>TwitterLinkedIn</u>

Sucampo Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, future financial and operating results, and other statements that are not historical facts. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; the ability of Sucampo to develop and commercialize existing and pipeline products; Sucampo's ability to accurately predict future market conditions; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally; the effects of competitive products on Sucampo's products; and the exposure to litigation and/or regulatory actions.

No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 10-K as filed with the Securities and Exchange Commission on March 12, 2014 as well as its filings with the Securities and Exchange Commission on Form 10-Q and 8-K, which Sucampo incorporates by reference.

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

Takeda Forward-Looking Statement

This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the U.S. and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.

The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.

Contact:
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staylor@sucampo.com

Takeda Pharmaceutical Company Limited Corporate Communications Dept. Tel: +81-3-3278-2037

Jocelyn Gerst Takeda Pharmaceuticals International, Inc. Corporate Communications Dept. Tel: +1 224 554 5542

EXHIBIT J TAKEDA'S AFFILIATES

List of Takeda Affiliates Arizona

Country	Legal Name	Registered Office
ARMENIA	The Representative Office of Takeda Austria GmbH in Armenia	0009, Teryan str. 105/1 Yerevan, Armenia
BELARUS	The Representative Office of Takeda Osteuropa Holding GmbH (Austria) in Belarus	4, Svoboda square, 220030 Minsk, Belorus
BRAZIL	Takeda Pharma Ltda.	Rua do Estilo Barroco, nº 721, Santo Amaro, CEP 04709-011, Cidade de São Paulo, Estado de São Paulo
COLOMBIA	Takeda S.A.S.	Calle 64 #93-11, Barrio Álamos Industrial, Bogotá, DC, Colombia
EGYPT	Takeda Egypt Trading and Distribution Company LLC	Apartment 101, Building No 52, Nady El Says Street, Giza, Egypt
GEORGIA	The Representative Office of Takeda Osteuropa Holding GmbH (Austria) in Gerorgia	3 Nutsubidze str., 0177 Tbilisi, Georgia
INDONESIA	PT Apex Pharma Indonesia	Office 8, 25th Floor, SCBD lot 28, Jl. Jend Sudirman kav 52-53, Jakarta 12190, Indonesia
ISRAEL	Takeda Israel Ltd.	25 Efal st., P.O. Box 4140, Kiriat Arie, Petach-Tikva, 4951125 Israel
ITALY	Takeda Italia S.p.A.	Via Elio Vittorini n.129-Rome Italy, REA RM-1365602
KAZAKHSTAN	Takeda Kazakhstan LLP	Begalina street, 136 a, 050010, Kazakhstan, Almaty
KOREA, REPUBLIC OF	Takeda Pharmaceuticals Korea Co. Ltd.	Being established.
LEBANON	Representative Office in Lebanon	Lebanon – legally existing, though not yet operating as entry into the commercial register is still outstanding
MALAYSIA	Takeda Malaysia Sdn. Bhd.	Jalan Perdana 4/3, Pandan Perdana, YL Consultancy, 12-1A (room A), 55300 Kuala Lumpur
MEXICO	Takeda México S.A. de C.V.	Avenida Primero de Mayo #130, Colonia Industrial Atoto, C.P. 53519, Naucalpan de Juárez
PHILIPPINES	Takeda Healthcare Philippines Inc.	17th floor, Zuellig Building, Makati Avenue corner Paseo de Roxas, Makati City, Metro Manila
RUSSIAN FEDERATION	Takeda Pharmaceuticals LLC	2 Usatcheva Str., Building 1, Moscow, 119048, the Russian Federation
SWITZERLAND	Takeda Pharma AG	Huobstrasse 16, 8808 Pfäffikon SZ

List of Takeda Affiliates Arizona

THAILAND	Takeda (Thailand) Ltd.	57 Park Ventures Ecoplex Building, 15th floor, Wireless Road, Lumpini, Patumwan Bangkok 10330
UKRAINE	Takeda Ukraine LLC	55-G, Chervonoarmiyska Str., Kyiv, 03150
UNITED KINGDOM	Takeda UK Ltd.	Takeda House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH
UZBEKISTAN	Takeda Osteuropa Holding GmbH (Austria)	Mustakillik 88a street, Mirzo Ulugbekskiy District, Tashkent, Uzbekistan
VENEZUELA, BOLIVARIAN REPUBLIC OF	Takeda S.R.L.	Av. Francisco de Miranda, entre Calle Mohedano y Av. El Parque, Centro Empresarial Galipán, Torre C Piso 9 Oficina 91C, Urbanización El Rosal 1060, Caracas

EXHIBIT K TAKEDA CODE OF CONDUCT



Better Health, Brighter Future



Takeda Pharmaceuticals International

Takeda Global Code of Conduct

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Takeda Global Code of Conduct 3



Introduction Fundamental Principles and Applicability

It is the steadfast commitment of Takeda Pharmaceutical Company Limited and all of its affiliates (collectively, "Takeda") to comply with all applicable laws and regulations. Our corporate philosophy, Takeda-ism, dictates more, however — we shall act with fairness and honesty and the highest ethical standards in all our business activities; upholding the highest ethical standards comes before everything else.

The Takeda Global Code of Conduct (this "Code of Conduct"), which is founded in the spirit of Takeda-ism, is designed to help us to do the right thing to meet the highest ethical standards by providing guidance in certain key areas. This Code of Conduct is applicable to all directors, officers and employees of all Takeda group companies, and therefore, the use of "we" throughout this Code of Conduct is defined to include all such individuals. This Code of Conduct cannot cover all situations or all applicable local laws and regulations, and therefore, each Takeda group company may adopt its own local code incorporating the provisions of this Code of Conduct and including additional standards. However, these local codes should not include any provision that conflicts with or that is less stringent than this Code of Conduct. Each Takeda group company will ensure that all employees read, understand and adhere to this Code of Conduct or the local code (if applicable).

All directors, officers and employees are expected to understand, comply with and implement this Code of Conduct and the local code (if applicable) in their day-to-day business activities.

Any breach of this Code of Conduct or the local code (if applicable) can result in disciplinary action in accordance with local employment laws.

This Code of Conduct is dated December 21, 2010, and may be updated from time to time.

Takeda Global Code of Conduct 5



Business with Integrity and Fairness

1. Product safety and quality / drug laws and regulations

Patient safety is the highest priority for Takeda. In our research, development, manufacture, storage, distribution and post-marketing activities, we will comply with all applicable laws and regulations, including reporting of safety information, designed to ensure the safety and quality of pharmaceutical products. We also will always adhere to our internal policies and standard operating procedures designed to protect patient safety and to ensure quality of product.

By way of example:

- (i) In our research, development and post-marketing activities, we will comply with all applicable laws and regulations and internal standards, including the Good Laboratory Practices, the Good Clinical Practices and the Good Pharmacovigilance Practices, and we will ensure that all results of research and development, including the results of clinical trials, are recorded accurately and are free from any falsification or manipulation.
- (ii) In manufacturing products, we will comply with all applicable laws and regulations and internal standards, including the Cood Manufacturing Practices, and will conduct appropriate quality control throughout all manufacturing processes.
- (iii) In our storage and distribution activities, we will comply with all applicable laws and regulations and internal standards, including the Good Distribution Practices.

2. Advertisements / promotion

Takeda is committed to complying with all applicable laws, regulations and industry codes governing promotional activities and advertising and will conduct these activities in an appropriate and ethical manner.

We will follow applicable company procedures designed to ensure that our promotional information and advertisements comply with regulatory requirements and are accurate, balanced, fair, supported by scientific evidence and not false or misleading.

We will not promote our products for a specific use in a country until the requisite approval for marketing for that use has been given in that country.

3. Relationships with healthcare professionals

Takeda is committed to complying with all applicable laws, regulations, and industry codes (including the IFPMA's Code of Pharmaceutical Marketing Practices and other codes established by regional and local industry associations) in interacting with healthcare professionals.

We will not provide, offer, or promise any money, goods, hospitality, gift or any other item of value to induce or reward favorable treatment of our products.

When we obtain consulting services, advisory board services, or any other services from healthcare professionals, we will have a legitimate business need and we will not pay more than an appropriate market value for the services rendered.

A. Business with Integrity and Fairness

4. Anti-corruption / anti-bribery

We will comply with all applicable laws and regulations prohibiting bribery of government officials as well as all applicable laws and regulations prohibiting bribery of foreign government officials.

In some countries, employees of hospitals or other institutions providing public services or funded or regulated by government entities are deemed to be government officials for the purpose of anti-bribery laws. Further, some countries prohibit bribery even of private sector employees. We will also comply with such laws and regulations.

We will not provide, offer or promise any bribe (including money, goods, hospitality, gifts or any other item of value), directly or indirectly, to government officials or foreign government officials. In addition, we will not provide any payment or benefits to private sector employees to influence them to obtain or retain a business advantage.

We will also ensure that those who act on our behalf, such as our agents, will not engage in corrupt practices.

5. Competition and anti-trust laws

We will comply with all applicable competition and anti-trust laws in all countries where we do business. In particular, we will adhere to the following:

- (i) We will not exchange information with competitors on pricing, outputs, capacity, customer selection, or exchange any other competitive information, and will not enter into any agreements on those matters (such as price fixing, market allocation, and bid rigging).
- (ii) We will not participate in trade association meetings or other meetings with competitors where we anticipate that such exchange of information or agreements will be requested. If a competitor raises any such issues, we will stop the conversation or ask the meeting chair or meeting facilitator to stop the conversation and, if the conversation does not stop, we will leave the meeting immediately. In the event of such a conversation, we will consult with Legal Department at our location or our legal counsel immediately.
- (iii) We will not impose unlawful resale price restrictions on wholesalers, distributors, licensees, sales agencies or any other party.

International trade controls

We will comply with all applicable laws and regulations in exporting and importing products, materials, machinery, technology and other items. In particular, in some countries, exportation of goods or technologies is tightly controlled by the government due to national security concerns. Employees responsible for exportation and jor importation of goods or technologies will familiarize themselves with these laws and regulations.



Protection of Assets / Information

1. Company assets

We will protect Takeda's money, property and other assets and will use them solely for the purpose of carrying out our duties to Takeda and will not misappropriate or embezzle these for ourselves or for any third party.

We will not claim or allow any fraudulent expense reimbursement.

In addition, we will promote appropriate and effective use of computers and other IT systems and will not use them unlawfully or inappropriately or for personal use, other than any incidental use permitted by applicable company policies. We will not install on our computer any unauthorized software or device, such as file-sharing software, which has a risk of inadvertently disclosing information to third parties.

2. Confidential information / intellectual property

Confidential information

During and after employment, we will keep confidential and protect all confidential information, including trade secrets and business or technical information about Takeda and its products, and we will not improperly disclose such information to any third party, nor will we use such information for any purpose other than performance of our duties to Takeda. Even within Takeda, we will not use such information for any purpose other than performance of our duties and will not disclose such information to any person other than those who need to know such information for the performance of their duties.

Intellectual property rights

All intellectual property owned, developed or obtained by Takeda through research, development, or other activities (including patents, designs, copyrights, trademarks, know-how, data and technical knowledge) are vital assets of Takeda. Therefore, we will carefully safeguard Takeda's intellectual property and fully cooperate in the establishment, protection, maintenance and defense of Takeda's intellectual property rights.

Confidential information of others

Takeda respects confidential information of third parties. Therefore, we will not obtain such information by illegal or unethical methods either directly or through the use of an agent, nor improperly disclose such information to any third party, nor misappropriate such information. In addition, we will not seek confidential information from other Takeda employees regarding their former employers.

Intellectual property rights of others

Takeda respects intellectual property rights of third parties. Therefore, we will not misappropriate or infringe upon intellectual property rights of third parties.

3. Personal information / data protection

It is Takeda's policy to respect the privacy of "personal information". (Personal information is information that can be used to identify a specific individual by name, date of birth or other description contained in that information. It can include information about employees, patients, clinical study subjects, doctors, employees of customers and others.) We will comply with all applicable laws and regulations regarding protection of personal information in countries where we do business. Although these laws and regulations vary from country to country, at a minimum, however, we will adhere to the following:

- (i) We will collect personal information only for legitimate business purposes and by lawful means, and will not disclose or use personal information for purposes other than a legitimate business purpose or as required by law.
- (ii) We will protect personal information by reasonable security safeguards against accidental loss or destruction or unauthorized access, use, modification or disclosure.



Company Records, Disclosures and Securities Transactions

1. Company records

We will comply with all applicable laws and regulations and company policies relevant to corporate accounting. We will record all transactions on the company books accurately and properly in accordance with generally accepted accounting principles, and will not make any false or artificial entries. We will maintain internal control systems to ensure that all transactions are accurately and properly recorded.

2. Disclosure

Takeda is committed to making timely and accurate disclosure of company information to investors.

We will comply with all applicable laws and regulations and company policies regarding financial disclosures. All employees involved in public disclosures will familiarize themselves with these laws and regulations and company policies.

3. Insider trading

We will comply with all securities laws and regulations restricting insider trading of securities. If, in performing our duties at Takeda, we become aware of "material non-public information" concerning Takeda or any company transacting business with Takeda, we will not buy or sell securities of Takeda or that other company, either on our own account or on behalf of Takeda or any others, nor will we provide that material non-public information to others, until it is publicly disclosed in accordance with applicable laws, regulations and company procedures.

"Material non-public information" is any non-public information that could have a material influence on investors' decisions to sell or buy securities. Examples may include issuance of shares, repurchase of shares, mergers and acquisitions, commercialization of new products, progress or failure of clinical trials, and material changes in financial forecasts.

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Workplace

1. Conflicts of interest

We will act in the best interests of Takeda and avoid any action or situation that may conflict with the interests of Takeda. If we have any actual or potential situation in which our personal interests conflict with Takeda's interests, we will consult with our manager before taking any action, and then act in the best interests of Takeda.

Relationship with suppliers and customers

We will select suppliers and customers based on fair and objective standards and without favor or preference based on any personal relationship.

Hospitality and gifts

We will not accept or solicit any illegal or inappropriate benefits (including money, goods, hospitality, gifts, or any other item of value) from suppliers, customers or others with whom we do business.

Financial or employment interests

We will not, without Takeda's permission, have any material financial interest in, or engage in the activities of, any competitor or an actual or potential supplier or customer.

Personnel issues

We will handle personnel issues impartially and fairly, and will not give any advantage to an employee based on a personal relationship in handling personnel issues such as recruitment, evaluation, transfer, or promotion.

2. Respect for diversity / no discrimination or harassment

Takeda respects diversity and the personal dignity of its employees. It is Takeda's policy to prohibit discrimination or harassment based on nationality, race, color, creed, religion, sex, age, disability, or any other legally protected status. We will not engage in sexual or any other forms of harassment, or any other behavior that could create a hostile work environment.

Takeda takes appropriate measures to prevent such discrimination and harassment.

3. Employee health and safety

Takeda is committed to providing a healthy and safe work environment for its employees. We will comply with all applicable laws, regulations and company policies regarding occupational health and safety.



Environment

Takeda is committed to minimizing the environmental impact of its products and operations.

We will comply with all applicable laws, regulations and company policies concerning environmental protection and accident prevention in all our business activities



F

Reporting Possible Violations of the Code

We are personally responsible for helping to fulfill the objectives of this Code of Conduct or the local code (if applicable) by following all of its provisions, preventing violations, and reporting all suspected violations. We have an obligation to raise our concerns about anything we think may be a violation or a potential violation of this Code of Conduct or the local code (if applicable).

It is Takeda's policy to:

- require employees who have a good faith belief that any of Takeda's employees or management are in violation of this Code of Conduct or the local code (if applicable), any law, or any company policy to report the possible violation;
- conduct a prompt investigation of any alleged violation and take appropriate corrective and for disciplinary action;
- prohibit any retaliatory action against any Takeda employee for making a good faith report of a suspected violation of this Code of Conduct or the local code (if applicable), any law, or any company policy, even if a subsequent investigation proves the report to be unfounded.

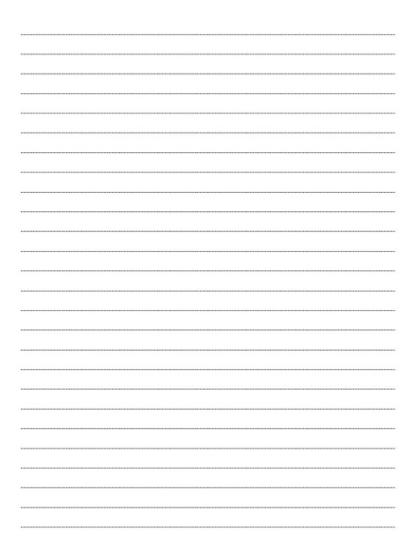
If we suspect a possible violation of this Code of Conduct or the local code (if applicable), any law, or any company policy, we should contact any of the following:

- · Our manager;
- · Another managerial employee at our location;
- · Our Human Resources manager;
- · Our compliance personnel;
- · Our Legal Department personnel;
- · Our Compliance Hotline (if available for our location).

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Notes

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EXHIBIT L

DEVELOPMENT PLAN

[...***...]

*Confidential Treatment Requested

EXHIBIT M

PAEDIATRIC INVESTIGATION PLAN

The European Medicines Agency approved the following Paediatric Investigation Plan (EMEA-000245-PIP01-08-M01):

- 1. AMITIZA® shall be developed in the paediatric population for the target indication Functional Constipation and Opioid Induced Constipation.
- 2. The subsets of paediatric patients will be from 6 years to less than 18 years of age and from 6 months to less than 6 years. The Pharmaceutical forms will be the soft capsule for the older children and adolescents, and an "age-appropriate oral liquid dosage form" for the young population
- 3. Studies to be completed are as follows:
 - a. Study 1 (Quality study): Development of an age-appropriate oral liquid dosage form dispensed in a metering pump. (this study has been completed);
 - b. Study 2 (Non-Clinical): Oral Toxicity study (study completed);
- c. Study 3 (Clinical): Multi-center, double-blinded, placebo controlled study of lubiprostone to evaluate efficacy pharmacokinetic, pharmacodynamics, in children from 6 years to less than 18 years with functional constipation, stratified according to patients age. (completion of this study is deferred);
- d. Study 4 (Clinical): Multi-center, double-blinded placebo controlled study of lubiprostone to evaluate efficacy pharmacokinetic, pharmacodynamics in children from 6 months to less than 6 years with functional constipation, stratified according to patients age. (completion of this study is deferred);
- e. Study 5 (Clinical): Multi-Center, open-labeled safety study of lubiprostone in children from 6 years to less than 18 years with functional constipation. (completion of this study is deferred);
- f. Study 6 (Clinical): Multi-Center, open-labeled safety study of lubiprostone in children from 6 months to less than 6 years with functional constipation. (completion of this study is deferred); and
- g. Study 7 (Clinical): Model-based bridging of clinical data to children and adolescents from 6 months to less than 18 years of age with opioid induced constipation. (completion of this study is deferred).

EXHIBIT N

LIST OF PATENTS TO BE PROSECUTED AND MAINTAINED BY SUCAMPO ACCORDING TO SECTION 11.2

AMITIZA Patent List

2014/10/15

Title	Country	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date	Exclusivity Ends	Status	EP Designated Country
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Taiwan	89121423	2000/10/13			I 281918	2007/6/1	2020/10/12	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Argentina	P000105407	2000/10/13	026046	2002/12/26				pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Argentina DIV	P20130100275	2013/1/30						pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Korea	2002-7004709	2000/10/13	2002-0068521	2002/8/27	0830061	2008/5/9	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Australia	76856/00	2000/10/13	780342	2005/3/17	780342	2005/7/7	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Australia DIV	2004242503	2004/12/24	2004242503	2007/6/21	2004242503	2007/10/4	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	New Zealand	518020	2000/10/13	518020	2004/2/27	518020	2004/6/8	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	South Africa	2002/2312	2000/10/13			2002/2312	2002/12/24	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Brazil	PI 0014869	2000/10/13	PI 0014869	2002/6/25				pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Mesico	PA/A/2002/003756	2000/10/13			247886	2007/8/6	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Mexico DIV	MXXA2007/005720	2007/5/11			279953	2010/10/14	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	India	NPC1002519'0-€	2000/10/13			224855	2008/10/23	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Israel	148803	2000/10/13	148803	2006/7/5	148803	2006/10/6	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Turkey	2002/01032	2000/10/13	2002/01032	2002/8/21	2002/01032	2005/10/21	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Russia	2002112984	2000/10/13	2002112984	2004/1/20	2275368	2006/4/27	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Czech	PV2002-1037	2000/10/13			303625	2012/12/5	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hungary	P0203746	2000/10/13	P0203746	2003/3/28	229547	2013/12/19	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hungary DIV	P1300369	2013/6/11						pending	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Norway	20021736	2000/10/13			330258	2011/3/14	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	EPC	00966462.4	2000/10/13	1220849	2002/7/10	1220849	2004/5/19	2020/10/13	Granted	OBTADE FLALTHER ATTERSTORE
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	EPC DIV	04005836.4	2004/3/11	1426361	2004/6/9	1426361	2008/7/30	2020/10/13	Granted	PRODEKRIJURIKARI URTI
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hong Kong	02107337.5	2002/10/7	1045693	2002/12/6	1045693	2005/1/21	2020/10/13	Granted	
BICYCLIC COMPOUNDS COMPOSITION AND METHOD FOR STABILIZING THE SAME	Hong Kong DIV	04109840.1	2004/12/6	1066792	2005/4/1	1068792	2009/4/24	2020/10/13	Granted	
ANTI-CONSTIPATION COMPOSITION	Argentina	P010104216	2001/9/5	030609	2003/8/27				pending	

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Title	Country	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date	Exclusivity Ends	Status	EP Designated Country
ANTI-CONSTIPATION COMPOSITION	Argentina DIV	P20130103006	2013/8/26						pending	
ANTI-CONSTIPATION COMPOSITION	Taiwan	90121835	2001/9/4			I 305147	2009/1/11	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Korea	2003-7003261	2001/9/4	2003-0029919	2003/4/16	0901102	2009/5/29	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Korea DIV	2008-7021218	2008/8/29	2008-0091278	2008/10/9	0918223	2009/9/14	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Australia	2001282615	2001/9/4	2001282615	2008/8/22	2001282615	2008/10/12	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	New Zealand	524401	2001/9/4	524401	2004/8/27	524401	2004/12/9	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	South Africa	2003/1673	2001/9/4			2003/1673	2003/11/26	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Brazil	PI 0114042	2001/9/4	PI 0114042	2003/7/22				pending	
ANTI-CONSTIPATION COMPOSITION	Mexico	PA/A/2003/001858	2001/9/4			231553	2005/10/24	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	India	00460/CHENP/2003	2001/9/4			223147	2008/9/4	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Israel	154534	2001/9/4	154534	2010/4/29	154534	2010/7/30	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Russia	2003109622	2001/9/4	2003109622	2003/9/10	2278666	2006/6/27	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Czech	PV2003-787	2001/9/4						Allowed	
ANTI-CONSTIPATION COMPOSITION	Hungary	P0302422	2001/9/4	P0302422	2003/10/28	229319	2013/10/1	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	Norway	20030996	2001/9/4			332701	2012/12/10	2021/9/4	Granted	
ANTI-CONSTIPATION COMPOSITION	EPC	01961333.0	2001/9/4	1315485	2003/6/4	1315485	2007/11/21	2021/9/4	Granted	ATBECKSESKESKUR HOORERRUPT.SE
ANTI-CONSTIPATION COMPOSITION	Switzerland		2010/4/12		2010/4/15	C1315485/01	2012/8/29	2024/11/15	Granted	
ANTI-CONSTIPATION COMPOSITION	EPC DIV	07016834.9	2001/9/4	1857105	2007/11/21	1857106	2010/8/11	2021/9/4	Granted	ATBECHDE ON ESTATE OR OR ESTAN PT.SE
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Argentina	P020101560	2002/4/29	035237	2004/5/5				pending	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Taiwan	91108513	2002/4/25			1 302100	2008/10/21	2022/4/25	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Korea	2003-7014221	2002/4/26	2004-0008168	2004/1/28	0886598	2009/2/25	2022/4/26	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Australia	2002251554	2002/4/28	2002251554	2007/5/24	2002251554	2007/9/6	2022/4/28	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	New Zealand	529187	2002/4/26	529187	2005/10/28	529187	2006/2/9	2022/4/26	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Brazil	PI 0209327	2002/4/26	PI 0209327	2004/7/20				pending	

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Title	Country	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date	Exclusivity Ends	Status	EP Designated Country
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Mexico	PA/A/2003/010019	2002/4/26	PA/A/2003/010019	2004/3/24	244942	2007/4/12	2022/4/26	Granted	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	Norway	20034864	2002/4/26						Allowed	
COMPOSITION FOR TREATING DRUG-INDUCED CONSTIPATION	EPC	02720623.4	2002/4/26	1392318	2004/3/3	1392318	2007/2/28	2022/4/26	Granted	AT DE CHOECKES/ROBITALPT, SE
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Argentina	P020104349	2002/11/13	037524	2004/11/17	CHECK LOCAL		Anconsolut	pending	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Taiwan	91133227	2002/11/13			I 331920	2010/10/21	2022/11/12	Granted	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Brazil	PI 0214075	2002/11/14	PI 0214075	2004/9/28				pending	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	EPC	02780083.8	2002/11/14	1443938	2004/8/11	1443938	2011/8/31	2022/11/14	Granted	MRECKESSESKEIFURGIGKEIKERIN
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	EPC DIV	10010211.0	2010/9/22	2298314	2011/3/23	2298314	2014/9/3	2022/11/14	Granted	
PROSTAGLANDIN ANALOGS FOR TREATING CONSTIPATION	Hong Kong	11109944.5	2011/9/21	1155649	2012/5/25				pending	
SOFT-GELATIN CAPSULE FORMULATION	Korea	2008-7020676	2007/1/23	2008-0090526	2008/10/8	1393944	2014/5/2	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	Russia	2008134489	2007/1/23	2008134489	2010/2/27	2420291	2011/6/10	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	India		2007/1/23						pending	
SOFT-GELATIN CAPSULE FORMULATION	Australia	2007208632	2007/1/23	2007208632	2012/1/19	2007208632	2012/5/3	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	New Zealand	570191	2007/1/23	570191	2010/9/30	570191	2011/1/8	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	Israel	192867	2007/1/23						pending	
SOFT-GELATIN CAPSULE FORMULATION	Brazil	PI 0707334-8	2007/1/23						pending	
SOFT-GELATIN CAPSULE FORMULATION	Mexico	MX/A/2008/009650	2007/1/23	MX/A/2008/009650	2009/1/27	289422	2011/8/16	2027/1/23	Granted	
SOFT-GELATIN CAPSULE FORMULATION	EPC	0770758.4	2007/1/23	1978944	2008/10/15	1978944	2012/8/15	2027/1/23	Granted	AT DE J. H, DE DH. J.S. J. A, DB. JE JT JHL. PT. SE

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FORECAST

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*Confidential Treatment Requested

EXHIBIT P

INVENTORY

[...***...]

*Confidential Treatment Requested

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), dated as of October 21, 2014, is hereby entered into in the State of Maryland by and between SUCAMPO PHARMA AMERICAS, LLC., a Delaware limited liability company (the "Company"), and Peter Kiener ("Executive").

WHEREAS, Executive was hired as the Chief Scientific Officer of the Company as of October 27, 2014;

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 Scientific Officer as of October 27, 2014 and Executive desires to obtain such employment.

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

Employment and Duties

1.1 The Company offers and Executive hereby accepts employment with the Company for the Term (as hereinafter defined) as its Chief Scientific Officer, and in connection therewith, to perform such duties as Executive shall reasonably be assigned by Executive's supervisor and/or by the Company's Board of Directors and to enter into this Agreement.

- 1.2 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.
- 1.3 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).
- 1.4 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.

2. Employment Term

2.1 <u>Term</u>

The term of Executive's employment hereunder (the "Term") shall commence on October 27, 2014 and shall end on October 27, 2015, 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 date on which it would otherwise expire 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 Survival on Merger or Acquisition

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

3. Compensation and Benefits

3.1 Compensation

(a) <u>Base Salary</u>. The Company shall pay Executive a salary at an annual rate that is not less than Three Hundred and Ninety Thousand and 00/100 dollars (\$390,000), to be paid in bi-weekly installments, in arrears (the "<u>Base Salary</u>"). 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, 300,000 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 four (4) year period. Additionally, at least annually for the Term of this Agreement, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the Amended and Restated 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.

- (ii) Effect of Termination of Employment. 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 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 of its assets, and in advance of the closing of such transaction or within twelve (12) months thereafter the Executive is terminated without Cause, or terminates his or her employment for Good Reason or because this Agreement is not assumed by the successor corporation (or affiliate thereto), 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 and any unvested stock options under the Plan with a performance condition 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) <u>Bonuses</u>. Executive shall be eligible to receive an annual cash bonus award targeted at 40% of annual base earnings in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified from time to time. Recommendations concerning the decision to make an award and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.

(d) <u>Taxes</u>. 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.

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 Professional Organizations

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

3.5 Parking

During the Term 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.

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 Section 4.4(a) or (ii) the eighteen (18) 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(b), 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 of Directors that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; provided, however, that Cause shall not exist if such refusal arises from Executive's reasonable, good faith belief that such failure or refusal is required by law.

- (c) "Date of Termination" shall mean the date specified in the Notice of Termination (as hereinafter defined) (except in the case of Executive's death, in which case the Date of Termination shall be the date of death); provided, however, that if Executive's employment is terminated by the Company other than for Cause, the date specified in the Notice of Termination shall be at least thirty (30) days from the date the Notice of Termination is given to Executive.
- (d) "Notice of Termination" shall mean a written notice from the Company to Executive that indicates Section 2 or the specific provision of Section 4 of this Agreement relied upon as the reason for such termination or nonrenewal, the Date of Termination, and, in the case of termination or non-renewal by the Company for Cause, in reasonable detail, the facts and circumstances claimed to provide a basis for termination or nonrenewal.
- (e) "Good Reason" shall mean:
- i. Company effects a material diminution of Executive's position, authority or duties;
- ii. any requirement that Executive, without his/her consent, move his/her regular office to a location more than fifty (50) miles from Company's executive offices:
- iii. the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
- iv. any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within thirty (30) days, and Executive resigns within sixty (60) days thereafter.

(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 Termination upon Death or Disability

This Agreement and Executive's employment hereunder, shall terminate automatically and without the necessity of any action on the part of the Company upon the death of Executive. In addition, 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 Termination.

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

4.4 Compensation Upon Termination

Severance.

(a) In the event (1) the Company terminates Executive's employment without Cause; or (2) this Agreement terminates pursuant to Section 4.2 due to the death or disability of Executive, or (3) the Company elects not to renew this Agreement under circumstances where Executive is willing and able to execute a new agreement providing terms and conditions substantially similar to those in this Agreement, or (4) the Executive terminates this Agreement for Good Reason, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to twelve (12) months of Executive's then 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 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-1(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) Change in Control. In the event that Executive in advance of the closing or within twelve (12) months following the occurrence of a "Change in Control" of the Company (1) is terminated other than for Cause, or (2) terminates for Good Reason, or (3) terminates because this Agreement is not assumed by the successor corporation (or affiliate thereto) as the result of a Change in Control, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to eighteen (18) months of Executive's then 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 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 the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (the "Code"). If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code, 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 A 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.

5. Employment Covenants

5.1 <u>Definitions</u>

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, licensors, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii) Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.

- (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 Nondisclosure and Nonuse

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

5.3 Other Confidentiality Obligations

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

5.4 Return of Confidential Information

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

5.5 Confidential Information of Others

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

5.6 Other Obligations

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

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 Inventions, Intellectual Property and Equipment Not Transferred

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

5.10 Exclusivity of Employment

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

5.11 Covenant Not to Compete

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

- (b) <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:

"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 material to the Company's business 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.

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

5.12 Non-Solicitation

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

5.13 Judicial Enforcement

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

6. Miscellaneous

6.1 Notices

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

To Company: Sucampo Pharma Americas, LLC

4520 East West Highway, Third Floor

Bethesda, Maryland 20814

Attention: Executive Vice President, Human Resources

Copy to: Corporate Secretary

To Executive: Peter Kiener

14017 Gorky Drive Potomac, Maryland 20854

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

6.2 Headings

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

6.3 Modifications; Waiver

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

6.4 Entire Agreement

This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, the offer letter between Executive and the Company dated October 27, 2014.

6.5 Severability

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

6.6 Controlling Law

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

6.7 Arbitration

Any controversy, claim, or breach arising out of or relating to executive's employment or termination of employment, 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. All other disputes or any nature related to executive's employment or this agreement will be resolved by arbitration. 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. Counterparts

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 PHARMA AMERICAS, LLC

By: /s/ Peter Greenleaf
Peter Greenleaf
Chief Executive Officer

/s/ Peter Kiener
EXECUTIVE

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), dated as of October 21, 2014, is hereby entered into in the State of Maryland by and between SUCAMPO PHARMA AMERICAS, LLC., a Delaware limited liability company (the "Company"), and Matthias Alder ("Executive").

WHEREAS, Executive was hired as the Executive Vice President, Business Development & Licensing of the Company as of October 27, 2014;

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 Executive Vice President, Business Development & Licensing as of October 27, 2014 and Executive desires to obtain such employment.

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

Employment and Duties

1.1 The Company offers and Executive hereby accepts employment with the Company for the Term (as hereinafter defined) as its Executive Vice President, Business Development & Licensing, and in connection therewith, to perform such duties as Executive shall reasonably be assigned by Executive's supervisor and/or by the Company's Board of Directors and to enter into this Agreement.

- 1.2 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.
- 1.3 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).
- 1.4 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.

2. Employment Term

2.1 <u>Term</u>

The term of Executive's employment hereunder (the "Term") shall commence on October 27, 2014 and shall end on October 27, 2015, 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 date on which it would otherwise expire 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 Survival on Merger or Acquisition

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

3. Compensation and Benefits

3.1 Compensation

(a) <u>Base Salary</u>. The Company shall pay Executive a salary at an annual rate that is not less than Three Hundred and Eighty Thousand and 00/100 dollars (\$380,000), to be paid in bi-weekly installments, in arrears (the "<u>Base Salary</u>"). 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, 300,000 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 four (4) year period. Additionally, at least annually for the Term of this Agreement, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the Amended and Restated 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.
- (ii) Effect of Termination of Employment. 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 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 of its assets, and in advance of the closing of such transaction or within twelve (12) months thereafter the Executive is terminated without Cause, or terminates his or her employment for Good Reason or because this Agreement is not assumed by the successor corporation (or affiliate thereto), 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 and any unvested stock options under the Plan with a performance condition 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) <u>Bonuses</u>. Executive shall be eligible to receive an annual cash bonus award targeted at 40% of annual base earnings in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified from time to time. Recommendations concerning the decision to make an award and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.
- (d) <u>Taxes</u>. 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.

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 Professional Organizations

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

3.5 Parking

During the Term 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.

4. Termination of Employment

4.1 <u>Definitions</u>

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 Section 4.4(a) or (ii) the eighteen (18) 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(b), 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 of Directors that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; provided, however, that Cause shall not exist if such refusal arises from Executive's reasonable, good faith belief that such failure or refusal is required by law.
- (c) "<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>, <u>however</u>, 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) "Good Reason" shall mean:
- i. Company effects a material diminution of Executive's position, authority or duties;
- ii. any requirement that Executive, without his/her consent, move his/her regular office to a location more than fifty (50) miles from Company's executive offices;
- iii. the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
- iv. any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within thirty (30) days, and Executive resigns within sixty (60) days thereafter.

(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 Termination.

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>

Severance.

(a) In the event (1) the Company terminates Executive's employment without Cause; or (2) this Agreement terminates pursuant to Section 4.2 due to the death or disability of Executive, or (3) the Company elects not to renew this Agreement under circumstances where Executive is willing and able to execute a new agreement providing terms and conditions substantially similar to those in this Agreement, or (4) the Executive terminates this Agreement for Good Reason, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to twelve (12) months of Executive's then 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 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-1(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) Change in Control. In the event that Executive in advance of the closing or within twelve (12) months following the occurrence of a "Change in Control" of the Company (1) is terminated other than for Cause, or (2) terminates for Good Reason, or (3) terminates because this Agreement is not assumed by the successor corporation (or affiliate thereto) as the result of a Change in Control, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to eighteen (18) months of Executive's then 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 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 the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (the "Code"). If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code, 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 A 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.

5. Employment Covenants

5.1 <u>Definitions</u>

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, licensors, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii) Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.

(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 Nondisclosure and Nonuse

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

5.3 Other Confidentiality Obligations

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

5.4 Return of Confidential Information

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

5.5 Confidential Information of Others

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

5.6 Other Obligations

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

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

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

5.8 Representations

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

5.9 Inventions, Intellectual Property and Equipment Not Transferred

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

5.10 Exclusivity of Employment

During the Term, and without prior approval of the Board of Directors, Executive shall not directly or indirectly engage in any activity competitive with or adverse to the Company's business or welfare or render a material level of services of a business, professional or commercial nature to any other person or firm, whether for compensation or otherwise; provided, however, that subject to Executive's performance of his obligations under this Agreement, Executive may perform wind-down activities for Cytos Biotechnology AG until February 28, 2015 not to exceed eight (8) hours per week; and provided further, that Executive may accept up to two concurrent engagements as a board member or board advisor of a third party.

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

- (b) <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:

"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 material to the Company's business 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.

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

5.12 Non-Solicitation

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

5.13 Judicial Enforcement

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

6. Miscellaneous

6.1 Notices

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

To Company: Sucampo Pharma Americas, LLC

4520 East West Highway, Third Floor

Bethesda, Maryland 20814

Attention: Executive Vice President, Human Resources

Copy to: Corporate Secretary

To Executive: Matthias Alder

4424 18th Street N Arlington, Virginia 22207

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

6.2 Headings

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

6.3 Modifications; Waiver

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

6.4 Entire Agreement

This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, the offer letter between Executive and the Company dated October 27, 2014.

6.5 Severability

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

6.6 Controlling Law

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

6.7 Arbitration

Any controversy, claim, or breach arising out of or relating to executive's employment or termination of employment, 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. All other disputes or any nature related to executive's employment or this agreement will be resolved by arbitration. 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. Counterparts

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 PHARMA AMERICAS, LLC

By: /s/ Peter Greenleaf
Peter Greenleaf
Chief Executive Officer

/s/ Matthias Alder EXECUTIVE

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), dated as of October 21, 2014, is hereby entered into in the State of Maryland by and between SUCAMPO PHARMA AMERICAS, LLC., a Delaware limited liability company (the "Company"), and Steve Caffé ("Executive").

WHEREAS, Executive was hired as the Senior Vice President, Regulatory of the Company as of October 27, 2014;

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 Senior Vice President, Regulatory as of October 27, 2014 and Executive desires to obtain such employment.

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

Employment and Duties

1.1 The Company offers and Executive hereby accepts employment with the Company for the Term (as hereinafter defined) as its Senior Vice President, Regulatory, and in connection therewith, to perform such duties as Executive shall reasonably be assigned by Executive's supervisor and/or by the Company's Board of Directors and to enter into this Agreement.

- 1.2 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.
- 1.3 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).
- 1.4 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.

2. Employment Term

2.1 <u>Term</u>

The term of Executive's employment hereunder (the "Term") shall commence on October 27, 2014 and shall end on October 27, 2015, 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 date on which it would otherwise expire 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 Survival on Merger or Acquisition

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

3. Compensation and Benefits

3.1 Compensation

(a) <u>Base Salary</u>. The Company shall pay Executive a salary at an annual rate that is not less than Three Hundred and Twenty Five Thousand and 00/100 dollars (\$325,000), to be paid in bi-weekly installments, in arrears (the "<u>Base Salary</u>"). 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, 200,000 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 four (4) year period. Additionally, at least annually for the Term of this Agreement, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the Amended and Restated 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.
- (ii) Effect of Termination of Employment. 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 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 of its assets, and in advance of the closing of such transaction or within twelve (12) months thereafter the Executive is terminated without Cause, or terminates his or her employment for Good Reason or because this Agreement is not assumed by the successor corporation (or affiliate thereto), 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 and any unvested stock options under the Plan with a performance condition 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) <u>Bonuses</u>. Executive shall be eligible to receive an annual cash bonus award targeted at 40% of annual base earnings in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified from time to time. Recommendations concerning the decision to make an award and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.
- (d) <u>Taxes</u>. 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.

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 Professional Organizations

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

3.5 Parking

During the Term 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.

4. Termination of Employment

4.1 <u>Definitions</u>

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 Section 4.4(a) or (ii) the eighteen (18) 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(b), 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 of Directors that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; provided, however, that Cause shall not exist if such refusal arises from Executive's reasonable, good faith belief that such failure or refusal is required by law.
- (c) "<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>, <u>however</u>, 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) "Good Reason" shall mean:
- i. Company effects a material diminution of Executive's position, authority or duties;
- ii. any requirement that Executive, without his/her consent, move his/her regular office to a location more than fifty (50) miles from Company's executive offices;
- iii. the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
- iv. any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within thirty (30) days, and Executive resigns within sixty (60) days thereafter.

(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 Termination upon Death or Disability

This Agreement and Executive's employment hereunder, shall terminate automatically and without the necessity of any action on the part of the Company upon the death of Executive. In addition, 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 Termination.

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>

Severance.

(a) In the event (1) the Company terminates Executive's employment without Cause; or (2) this Agreement terminates pursuant to Section 4.2 due to the death or disability of Executive, or (3) the Company elects not to renew this Agreement under circumstances where Executive is willing and able to execute a new agreement providing terms and conditions substantially similar to those in this Agreement, or (4) the Executive terminates this Agreement for Good Reason, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to twelve (12) months of Executive's then 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 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-1(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) Change in Control. In the event that Executive in advance of the closing or within twelve (12) months following the occurrence of a "Change in Control" of the Company (1) is terminated other than for Cause, or (2) terminates for Good Reason, or (3) terminates because this Agreement is not assumed by the successor corporation (or affiliate thereto) as the result of a Change in Control, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to eighteen (18) months of Executive's then 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 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 the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (the "Code"). If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code, 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 A 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.

5. Employment Covenants

5.1 <u>Definitions</u>

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, licensors, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii) Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.

- (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 Nondisclosure and Nonuse

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

5.3 Other Confidentiality Obligations

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

5.4 Return of Confidential Information

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

5.5 Confidential Information of Others

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

5.6 Other Obligations

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

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

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

5.8 Representations

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

5.9 Inventions, Intellectual Property and Equipment Not Transferred

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

5.10 Exclusivity of Employment

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

5.11 Covenant Not to Compete

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

- (b) <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:

"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 material to the Company's business 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.

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

5.12 Non-Solicitation

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

5.13 Judicial Enforcement

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

6. Miscellaneous

6.1 Notices

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

To Company: Sucampo Pharma Americas, LLC

4520 East West Highway, Third Floor

Bethesda, Maryland 20814

Attention: Executive Vice President, Human Resources

Copy to: Corporate Secretary

Steve Caffé
To Executive: 206 Woodhaven Lane
Barrington Hills, IL 60010

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

6.2 Headings

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

6.3 Modifications; Waiver

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

6.4 Entire Agreement

This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, the offer letter between Executive and the Company dated October 27, 2014.

6.5 Severability

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

6.6 Controlling Law

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

6.7 Arbitration

Any controversy, claim, or breach arising out of or relating to executive's employment or termination of employment, 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. All other disputes or any nature related to executive's employment or this agreement will be resolved by arbitration. 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. Counterparts

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 PHARMA AMERICAS, LLC

By: /s/ Peter Greenleaf
Peter Greenleaf
Chief Executive Officer

/s/ Steve Caffé
EXECUTIVE

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), dated as of October 21, 2014, is hereby entered into in the State of Maryland by and between SUCAMPO PHARMACEUTICALS, INC., a Delaware limited liability company (the "Company"), and Thomas Knapp ("Executive").

WHEREAS, Executive has been employed by the Company under a certain Employment Agreement dated December 31, 2012;

WHEREAS, Executive has been the Executive Vice President, Chief Legal Officer & Corporate Secretary since March 5, 2012;

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 continue to employ Executive as the Executive Vice President, Chief Legal Officer & Corporate Secretary as of October 21, 2014 (the "Effective Date") and Executive desires to continue such employment.

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

1. Employment and Duties

- 1.1 The Company offers and Executive hereby accepts employment with the Company for the Term (as hereinafter defined) as its Executive Vice President, Chief Legal Officer & Corporate Secretary, and in connection therewith, to perform such duties as Executive shall reasonably be assigned by Executive's supervisor and/or by the Company's Board of Directors and to enter into this Agreement.
- 1.2 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.
- 1.3 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).
- 1.4 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.

2. Employment Term

2.1 <u>Term</u>

The term of Executive's employment hereunder (the "Term") shall commence on October 21, 2014 and shall end on October 21, 2015, 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 date on which it would otherwise expire 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 Survival on Merger or Acquisition

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

3. Compensation and Benefits

3.1 Compensation

(a) <u>Base Salary</u>. The Company shall pay Executive a salary at an annual rate that is not less than Three Hundred Forty Three Thousand Seven Hundred and Ten and 00/100 dollars (\$343,710.00), to be paid in bi-weekly installments, in arrears (the "<u>Base Salary</u>"). 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) <u>Awards</u>. At least annually for the Term of this Agreement, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the Amended and Restated 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.
- (ii) Effect of Termination of Employment. 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 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 of its assets, and in advance of the closing of such transaction or within twelve (12) months thereafter the Executive is terminated without Cause, or terminates his or her employment for Good Reason or because this Agreement is not assumed by the successor corporation (or affiliate thereto), 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 and any unvested stock options under the Plan with a performance condition 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) <u>Bonuses</u>. Executive shall be eligible to receive an annual cash bonus award targeted at 40% of annual base earnings in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified from time to time. Recommendations concerning the decision to make an award and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.
- (d) <u>Taxes</u>. 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.

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 Professional Organizations

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

3.5 Parking

During the Term 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.

4. Termination of Employment

4.1 <u>Definitions</u>

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 Section 4.4(a) or (ii) the eighteen (18) 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(b), 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 of Directors that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; provided, however, that Cause shall not exist if such refusal arises from Executive's reasonable, good faith belief that such failure or refusal is required by law.
- (c) "<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>, <u>however</u>, 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) "Good Reason" shall mean:
- i. Company effects a material diminution of Executive's position, authority or duties;
- ii. any requirement that Executive, without his/her consent, move his/her regular office to a location more than fifty (50) miles from Company's executive offices;
- iii. the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
- iv. any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within thirty (30) days, and Executive resigns within sixty (60) days thereafter.

(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 Termination.

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>

Severance.

(a) In the event (1) the Company terminates Executive's employment without Cause; or (2) this Agreement terminates pursuant to Section 4.2 due to the death or disability of Executive, or (3) the Company elects not to renew this Agreement under circumstances where Executive is willing and able to execute a new agreement providing terms and conditions substantially similar to those in this Agreement, or (4) the Executive terminates this Agreement for Good Reason, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to twelve (12) months of Executive's then 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 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-1(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) Change in Control. In the event that Executive in advance of the closing or within twelve (12) months following the occurrence of a "Change in Control" of the Company (1) is terminated other than for Cause, or (2) terminates for Good Reason, or (3) terminates because this Agreement is not assumed by the successor corporation (or affiliate thereto) as the result of a Change in Control, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to eighteen (18) months of Executive's then 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 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 the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (the "Code"). If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code, 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 A 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.

5. Employment Covenants

5.1 <u>Definitions</u>

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, licensors, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii) Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.
- (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 Nondisclosure and Nonuse

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

5.3 Other Confidentiality Obligations

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

5.4 Return of Confidential Information

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

5.5 Confidential Information of Others

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

5.6 Other Obligations

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

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

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

5.8 Representations

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

5.9 Inventions, Intellectual Property and Equipment Not Transferred

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

5.10 Exclusivity of Employment

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

5.11 Covenant Not to Compete

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

- (b) <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:

"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 material to the Company's business 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.

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

5.12 Non-Solicitation

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

5.13 Judicial Enforcement

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

6. Miscellaneous

6.1 Notices

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

To Company: Sucampo Pharma Americas, LLC

4520 East West Highway, Third Floor

Bethesda, Maryland 20814

Attention: Executive Vice President, Human Resources

Copy to: Corporate Secretary

To Executive: Thomas Knapp

7116 Darby Road Bethesda, Maryland 20817

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

6.2 Headings

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

6.3 Modifications; Waiver

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

6.4 Entire Agreement

This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, the offer letter between Executive and the Company dated October 21, 2012.

6.5 Severability

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

6.6 Controlling Law

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

6.7 <u>Arbitration</u>

Any controversy, claim, or breach arising out of or relating to executive's employment or termination of employment, 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. All other disputes or any nature related to executive's employment or this agreement will be resolved by arbitration. 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. Counterparts

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 PHARMA AMERICAS, LLC

By: /s/ Peter Greenleaf
Peter Greenleaf
Chief Executive Officer

/s/ Thomas Knapp EXECUTIVE

EMPLOYMENT AGREEMENT

between

Sucampo AG, Baarerstrasse 22, 6300 Zug, Switzerland

("Company")

and

Peter Lichtlen, Seehaldenstrasse 83, CH-8800, Thalwil, Switzerland

("Executive")

1. POSITION AND RESPONSIBILITIES

1.1 The Company hereby employs Executive and Executive accepts employment as Chief Medical Officer.

1.2

Executive's responsibilities are specified by his superior and the Company's Board of Directors ("Board"). Executive's responsibilities may, from time to time, be modified by the Board to perform other assignments or assume further responsibilities. Executive's other rights and obligations shall not be affected by such modification.

The tasks as well as the obligations of Executive are set out in detail in the Company's management regulations. Executive has to perform his tasks and his obligations in accordance with the management regulations and the instructions given by the Board. The job description is attached hereto as Exhibit A.

1.3 Place of work is Zug. The Company reserves the right to relocate Executive to another appropriate place of work but without lowering Executive's salary entitlement. It is understood that the above mentioned position of Executive includes a high level of travel activities.

2. REMUNERATION

2.1 Salary

Executive shall receive an annual gross base salary of CHF 336,000 paid in equal monthly installments which shall be paid on the final business day of each month. The Base Salary will be reviewed by the Compensation Committee of the board of SPI ("Compensation Committee") at least annually, and the Committee's recommendation shall be reviewed and approved by the Board of SPI. The Base Salary may, in the sole discretion of the Board of SPI, be increased, but not decreased (unless mutually agreed by Executive and the Company).

2.2 Bonus Payments

Executive may be eligible to receive an annual bonus award based upon both the Executive's performance and the Company and SPI's performance pursuant to SPI's management incentive bonus program as it may be amended or modified from time to time. Recommendations concerning the decision to make an award and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of SPI.

2.3 Employee Stock Incentive Plan

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 B and generally described herein, the right and option to purchase, in whole or in part, 78,200 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 four (4) year period. Additionally, at least annually for the Term of this Agreement, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the Amended and Restated 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors. In the event that, during the Term (i) the Company terminates Executive's employment by not renewing this Agreement, without Cause or Executive resigns for Good Reason, in any of these cases on or after the Company is acquired or is the non-surviving party in a merger, or the Company sells all or substantially all of its assets, or (ii) there is the death of Executive, all unvested restricted stock awards and incentive stock options having previously been awarded to Executive shall immediately vest and may be exercised in accordance with the terms of the Plan and the Executive's grant award.

2.4 Deductions

The salary and bonus payments are gross payments. Executive's share in the prevailing premiums for social security insurances mandatory under Swiss law such as, in particular, "AHV", "IV", "ALV", "EO", source taxes, if applicable.

2.5 Further Payments

Unless otherwise expressly agreed upon in writing, the payment of any other gratuities, profit shares, premiums or other extra payments shall be on a voluntary basis. Even repeated payments without the reservation of their voluntary nature shall not create any legal claim for Executive, either in respect to their cause or their amount, either for the past or for the future.

2.6 Repayment Obligation

Should Executive have received any payment in excess of his actual entitlement Executive shall, upon the Company's first request, pay back such excessive amount to the Company. Payments that the Company, without being in any error, declares as voluntary, shall not be covered by this repayment obligation.

3. EXPENSES

- 3.1 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's travel to SPI's headquarters and associated lodging and meals shall be reimbursed. Executive shall provide to the Company detailed and accurate records of such expenses for which payment or reimbursement is sought, and Company payments shall be in accordance with the regular policies and procedures maintained by the Company from time to time.
- 3.2 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.
- 3.3 The Company shall either provide parking for Executive's automobile at the office at the Company's expense or reimburse Executive for such expense.

4. PENSION FUND

Employee shall be covered by the Company's pension fund in accordance with the pension fund regulations as in force from time to time.

5. SICKNESS

- 5.1 If Executive is prevented from work due to sickness or accident, he shall inform the Company without delay and, at the Company's request, submit a medical certificate.
- 5.2 The Company shall, at any time, be entitled to demand a physical exam by a medical referee and Executive shall release such doctor from his or her secrecy obligation to the extent required to assess Executive's ability to work and claims.
- 5.3 If Executive is, by no fault of his own and due to reasons inherent in the Executive's person, such as for example sickness, accident or military service, prevented from performing work, the Company will, after the first three months of employment and for as long as this Agreement is in force, continue to pay Executive's salary according to the "Zürcher Skala" according to Executive's years of service:

during the first year of service 3 weeks during the second year of service 8 weeks during the third year of service 9 weeks during the fourth year of service 10 weeks during the fifth year of service 11 weeks

(to be further increased in subsequent years of service according to the following formula: years of service plus six weeks)

OR (BUT ONLY IF LOSS OF EARNINGS INSURANCE DOES EXIST):

After the expiry of the probation period Executive will be insured against the risk of sickness (loss of earnings insurance; Krankentaggeldversicherung). The insurance coverage shall replace the statutory sick pay rules.

In cases that are covered by the loss of earnings insurance basically 80% of the base salary will be paid for a maximum period of up to 720 days (minus a 30 day waiting period). The insurance conditions that apply from time to time are explicitly reserved and will be disclosed to Executive upon request. During the 30 day waiting period the Company will pay 80% of the salary.

The premium for the loss of earning insurance will be borne by the Company.

In case the insurance benefits will be reduced or refused due to pre-existing diseases or other reasons Executive's claim to sick pay shall be reduced to the statutory payments.

In cases that are neither covered by the loss of earning insurance nor by any other insurance (such as, e.g. the accident insurance) the following shall apply:

If the employee is by no fault of his own and due to reasons inherent in Executive's person, prevented from performing work, the Company will, after the first three months of employment and for as long as this Agreement is in force, continue to pay Executive's salary according to the "Zürcher Skala" according to Executive's years of service:

during the first year of service 3 weeks during the second year of service 8 weeks during the third year of service 9 weeks during the fourth year of service 10 weeks during the fifth year of service 11 weeks

(to be further increased in subsequent years of service according to the following formula: years of service plus six weeks).

6. WORKING HOURS / VACATIONS

- 6.1 Executive agrees to exercise his best efforts to successfully and carefully accomplish the duties assigned to him and further agrees that he shall devote at least 40 hours per week to service on behalf of the Company. Executive acknowledges that the proper discharge of his duties will require a considerable amount of overtime and agrees to perform such overtime work to the extent necessary to properly fulfill his employment duties.
- 6.2 If Executive performs overtime work he shall neither be entitled to a financial compensation nor to any compensation by free time.
- 6.3 Executive shall be entitled to 4 weeks of paid vacations per calendar year.

7. DUTIES OF LOYALTY AND CONFIDENTIALITY

7.1 Executive shall devote his efforts exclusively to the Company in furtherance of the Company's interests. Any engagement in additional occupations for remuneration or any participation in any kind of enterprise requires the written consent of the Company. This shall not apply to the usual acquisition of shares or other stocks for investment purposes. Membership in the board of directors or supervisory board of other companies shall also require the written approval of the Company. 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 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.

7.2 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 SPI or 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 SPI or the Company in writing. Confidential Information shall mean all confidential and proprietary information of SPI, 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 SPI or the Company's current and prospective consultants, customers, licensors, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii) Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to SPI or the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify SPI and the Company; (b) at SPI or the Company's expense, take all reasonable necessary steps requested by SPI or the Company to defend against the enforcement of such court order or other government process, and permit SPI or 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. 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.

- 7.3 Executive acknowledges that SPI, its Affiliates, or 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 SPI, its Affiliates, or the Company thereunder, including, without limitation, signing any confidentiality or other agreements required by such third parties.
- 7.4 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 SPI or the Company's business premises or deliver any of the Company Materials to any person or entity outside of SPI or 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 C attached hereto.
- 7.5 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 non-use, and Executive shall not disclose to SPI, its Affiliates, or the Company or cause SPI, its Affiliates, or 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 SPI, its Affiliates, or the Company or use at SPI, its Affiliates, or 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.
- 7.6 The terms of this Section 7 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.

7.7 During the term of his employment and 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 SPI, its Affiliates, or 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 SPI, its Affiliates, or the Company, or induce any such employee to terminate his or her employment with SPI, its Affiliates, or the Company. Upon each violation of his obligations under this section 7.7, Executive shall pay to the Company liquidated damages in the amount of CHF 100'000. Payment of the liquidated damages does not relieve Executive from his obligations under this section 7.7. The Company is, furthermore, entitled to seek judicial enforcement of Executive's obligations under this section 7.7 and/or to claim damages exceeding the amount of the liquidated damages.

8. INTELLECTUAL PROPERTY RIGHTS

- 8.1. All rights, title and interest in all intellectual property including but not limited to patent applications, trade secrets, design rights, copyrights and related rights, software, database rights, trademark rights and chip rights as well as any rights in know how associated with the Executive Work Product and/or Confidential Information (the "Intellectual Property Rights"), shall exclusively vest in the Company and Executive acknowledges and agrees that all Executive Work Product is "work made for hire". 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 SPI, its Affiliates or 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 SPI, the Company or any of its Affiliates. 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.
- 8.2. Insofar as Intellectual Property Rights are not vested in the Company by operation of law or based on section 8.1 above, the Executive covenants that he will transfer and, insofar as possible, hereby transfers to the Company such rights provided, however, that the Company may renounce such transfer or transfer back to the Executive any such Intellectual Property Rights at any time. 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. If a transfer should not be possible under the applicable law, then the Executive shall grant to the Company a worldwide, perpetual, transferable, sub-licensable, royalty-free license to use and exploit such Intellectual Property Rights in any way the Company sees fit.

- 8.3. The Executive shall promptly disclose to the Company in writing all Executive Work Products and acknowledges that his salary includes reasonable compensation for the loss of Intellectual Property Rights.
- 8.4 Executive represents that, to the best of his 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.
- 8.5 Executive has set forth on Exhibit D attached hereto a complete list and brief description of all Inventions, intellectual property and equipment located at SPI, its Affiliates, or 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.
- 8.6 The Company is entitled to transfer the Intellectual Property Rights in full or in part to any third party. The Company and such third parties are not obliged to mention the Executive as the author if they publish any inventions, computer programs or other works. They are free to make any modifications, translations and/or other adaptations and/or can refrain from making any publications.

9. DATA PROTECTION

By signing this Agreement, Executive agrees that the Company may process personal data concerning Executive to the extent such data relates to the Executive's suitability for the employment or is necessary to perform the employment relationship. Executive agrees that personal data may be transferred to companies outside Switzerland affiliated with the Company, in particular to Sucampo Pharmaceuticals, Inc. in the United States of America and to other countries which may not provide for a data protection level equivalent to Switzerland.

10. NON-COMPETITION

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 services, directly or indirectly, anywhere in the world in connection with any Conflicting Product, 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.

For the purposes of this section 10, the following definitions apply:

Conflicting Product means any product, method or process, system or service of any person or organization other than SPI, its Affiliates, or 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 SPI, its Affiliates, or the Company at the time Executive's employment with the Company terminates, or about which Executive acquired any Confidential Information or developed any Executive Work Product.

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.

Executive understands that a violation of the obligations under this section 10 might cause serious damage to the Company. In the event Executive violates an obligation under this section 10, the Company shall be entitled to seek judicial enforcement of such obligation. Furthermore, Executive agrees to pay to the Company an amount equal to Executive's last annual gross Base Salary as liquidated damages upon each violation of an obligation under this section 10. The payment of the liquidated damages does not relieve Executive from the obligations under this section 10. The Company's right to claim damages exceeding the amount of liquidated damages is expressly reserved.

11. DURATION AND TERMINATION

- 11.1 This Employment Agreement shall be effective as of June 16, 2014 and last for a maximum period of two years. This means that this Employment Agreement will automatically end, without any notice being required, on June 16, 2016.
- 11.2 There shall be no probationary period.
- 11.3 This Agreement may be terminated by either party by respecting a notice period of three months with effect to any calendar day.
- 11.4 In the event the Company terminates Executive's employment without Cause or in the event Executive terminates employment for Good Reason, Executive shall be entitled to receive a lump sum severance payment equal to seven (7) months of Executive's then current Base Salary. Any payments that the Executive receives for the period subsequent to the notice of termination as well as any pro rata payments for the year in which his employment ends, if any at all, shall be offset against this lump sum severance amount which shall be made not later than ten (10) business days following the day on which the Company received the duly signed Release and all conditions for the payment are met.

Cause in the sense of this section 11.4 and of section 11.5 shall mean any of the following:

- (i) the gross neglect or willful failure or refusal of Executive to perform Executive's duties hereunder;
- (ii) perpetration of an intentional and knowing fraud against or affecting the SPI, its affiliates, 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 SPI, its affiliates, the Company or Executive's reputation or business relationships;

- (iv) (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 Articles 7 and 10 of this Agreement); or
- (vi) the failure or continued refusal to carry out the directives of Executive's supervisor or the Company's 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.

Good Reason in the sense of this section 11.4 shall mean any of the following:

- (i) SPI or the Company effects a material diminution of Executive's position, authority or duties;
- (ii) any requirement that Executive, without his consent, move his regular office to a location more than fifty (50) miles from Company's executive offices;
- (iii) the material failure by Company 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 only if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within twenty-one (21) days. If either condition is not met, Executive shall not have a Good Reason to terminate Executive's employment.

11.5 In the event that Executive is terminated other than for Cause within eighteen (18) months following the occurrence of a Change in Control of SPI, then Executive shall, rather than receiving the severance payment set forth under section 11.4 above, be entitled to a severance payment in an amount equal to fourteen (14) months of Executive's then current Base Salary. Any payments that the Executive receives for the period subsequent to the notice of termination shall be offset against this lump sum severance amount which shall be made not later than ten (10) business days following the day on which the Company received the duly signed Release and all conditions for the payment are met.

Change in Control in the sense of this section 11.5 shall mean any of the following:

- (i) the acquisition by any person of beneficial ownership of fifty percent (50%) or more of the outstanding shares of SPI's voting securities; or
- (ii) SPI is the non-surviving party in a merger; or
- (iii) SPI 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 SPI or as a result of SPI's insolvency or the appointment of a conservator; or
- (iv) the Compensation Committee of SPI, 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 SPI's voting securities to constitute a change of effective ownership or control of SPI.
- 11.6 Anything to the contrary contained herein notwithstanding, as a condition to Executive receiving severance benefits to be paid pursuant to Sections 11.4 or 11.5, Executive shall execute and deliver to SPI and the Company a general release in the form attached hereto as Exhibit A. The Company shall have no obligation to provide any severance benefits to Executive until it has received the general release from Executive (which must not have been paid earlier than the lapse of a one month period following the last date of employment) and any revocation or rescission period applicable to the Release shall have expired without revocation or rescission.
- 11.7 This Agreement terminates without notice and without any severance being due at the end of the month on which the Executive reached the ordinary retirement age.
- 11.8 The Company has at any time the right to relieve Executive from his obligation to work at full pay provided, however, that any income that Executive receives from any activity during such release period shall be deducted. Executive shall compensate any vacation during such release period and shall not engage in any competing activity.

12 MISCELLANEOUS

- 12.1 This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, the offer letter between Executive and the Company dated June 16, 2014.
- 12.2 Amendments and additions to this Agreement including this clause must be in writing to be effective. This form requirement does not apply to the notice of termination which does not require a particular form.
- 12.3 Should one or several provisions of this Agreement prove invalid, in part or in whole, such invalid provision(s) shall not affect the validity of the other provisions in this Agreement. The invalid provision(s) shall be replaced by such valid provision(s) that best meet(s) the parties' intention when agreeing on the invalid provision(s).

12.4 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 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.

12.5 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, or sent by courier or mail, postage prepaid, addressed to such party at the address set forth above or such other address as may thereafter be designated in a written notice from such party to the other party provided, however, that Executive shall send a copy of any notice or other communication addressed to the Company to the following address:

Sucampo Pharmaceuticals, Inc. 4520 East West Highway, Third Floor Bethesda, Maryland 20814 Attention: Human Resources

by: Thomas Knapp, Secretary & Director

13. APPLICABLE LAW

13.1 This Employment Agreement shall be governed by Swiss law.
Place and date
/s/ Peter Lichtlen
The Company Executive
Sucampo AG
/s/ Thomas Knapp

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), dated as of October 21, 2014, is hereby entered into in the State of Maryland by and between SUCAMPO PHARMACEUTICALS, INC., a Delaware limited liability company (the "Company"), and Stanley Miele ("Executive").

WHEREAS, Executive has been employed by the Company under a certain Employment Agreement dated December 31, 2012;

WHEREAS, Executive has been the Senior Vice President, Sales & Marketing & President, SPA since February 27, 2006;

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 continue to employ Executive as the Senior Vice President, Sales & Marketing & President, SPA as of October 21, 2014 (the "Effective Date") and Executive desires to continue such employment.

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

1. Employment and Duties

- 1.1 The Company offers and Executive hereby accepts employment with the Company for the Term (as hereinafter defined) as its Senior Vice President, Sales & Marketing & President, SPA, and in connection therewith, to perform such duties as Executive shall reasonably be assigned by Executive's supervisor and/or by the Company's Board of Directors and to enter into this Agreement.
- 1.2 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.
- 1.3 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).
- 1.4 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.

2. Employment Term

2.1 <u>Term</u>

The term of Executive's employment hereunder (the "Term") shall commence on October 21, 2014 and shall end on October 21, 2015, 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 date on which it would otherwise expire 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 Survival on Merger or Acquisition

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

3. Compensation and Benefits

3.1 Compensation

(a) <u>Base Salary</u>. The Company shall pay Executive a salary at an annual rate that is not less than Two Hundred Forty Eighty Thousand One Hundred and Sixty and 02/100 dollars (\$248,160.02), to be paid in bi-weekly installments, in arrears (the "<u>Base Salary</u>"). 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) <u>Awards</u>. At least annually for the Term of this Agreement, Executive shall be eligible for consideration to receive restricted stock grants, incentive stock options or other awards in accordance with the Amended and Restated 2006 Stock Incentive Plan. Recommendations concerning the decision to make an award pursuant to that Plan and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.
- (ii) Effect of Termination of Employment. 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 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 of its assets, and in advance of the closing of such transaction or within twelve (12) months thereafter the Executive is terminated without Cause, or terminates his or her employment for Good Reason or because this Agreement is not assumed by the successor corporation (or affiliate thereto), 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 and any unvested stock options under the Plan with a performance condition 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) <u>Bonuses</u>. Executive shall be eligible to receive an annual cash bonus award targeted at 40% of annual base earnings in recognition of Executive's contributions to the success of the Company pursuant to the Company's management incentive bonus program as it may be amended or modified from time to time. Recommendations concerning the decision to make an award and the amount of any award are entirely discretionary and shall be made initially by the Compensation Committee, subject to review and approval by the Board of Directors.
- (d) <u>Taxes</u>. 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.

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 Professional Organizations

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

3.5 Parking

During the Term 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.

4. Termination of Employment

4.1 <u>Definitions</u>

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 Section 4.4(a) or (ii) the eighteen (18) 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(b), 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:
- $i. \ the gross \ neglect \ or \ will full \ failure \ or \ refusal \ of \ Executive \ to \ perform \ Executive's \ duties \ hereunder \ (other \ than \ as \ a \ result \ of \ Executive's \ death \ or \ Disability);$
- 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 of Directors that are consistent with Executive's duties and responsibilities under this Agreement which is not cured within thirty (30) days after receipt of written notice from the Company specifying the nature of such failure or refusal; provided, however, that Cause shall not exist if such refusal arises from Executive's reasonable, good faith belief that such failure or refusal is required by law.

- (c) "Date of Termination" shall mean the date specified in the Notice of Termination (as hereinafter defined) (except in the case of Executive's death, in which case the Date of Termination shall be the date of death); provided, however, that if Executive's employment is terminated by the Company other than for Cause, the date specified in the Notice of Termination shall be at least thirty (30) days from the date the Notice of Termination is given to Executive.
- (d) "Notice of Termination" shall mean a written notice from the Company to Executive that indicates Section 2 or the specific provision of Section 4 of this Agreement relied upon as the reason for such termination or nonrenewal, the Date of Termination, and, in the case of termination or non-renewal by the Company for Cause, in reasonable detail, the facts and circumstances claimed to provide a basis for termination or nonrenewal.
- (e) "Good Reason" shall mean:
- i. Company effects a material diminution of Executive's position, authority or duties;
- ii. any requirement that Executive, without his/her consent, move his/her regular office to a location more than fifty (50) miles from Company's executive offices:
- iii. the material failure by Company, or its successor, if any, to pay compensation or provide benefits or perquisites to Executive as and when required by the terms of this Agreement; or
- iv. any material breach by Company of this Agreement.

The Executive shall have Good Reason to terminate Executive's employment if (i) within twenty-one (21) days following Executive's actual knowledge of the event which Executive determines constitutes Good Reason, Executive notifies the Company in writing that Executive has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within thirty (30) days, and Executive resigns within sixty (60) days thereafter.

(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 Termination.

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>

Severance.

(a) In the event (1) the Company terminates Executive's employment without Cause; or (2) this Agreement terminates pursuant to Section 4.2 due to the death or disability of Executive, or (3) the Company elects not to renew this Agreement under circumstances where Executive is willing and able to execute a new agreement providing terms and conditions substantially similar to those in this Agreement, or (4) the Executive terminates this Agreement for Good Reason, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to twelve (12) months of Executive's then 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 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-1(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) Change in Control. In the event that Executive in advance of the closing or within twelve (12) months following the occurrence of a "Change in Control" of the Company (1) is terminated other than for Cause, or (2) terminates for Good Reason, or (3) terminates because this Agreement is not assumed by the successor corporation (or affiliate thereto) as the result of a Change in Control, Executive (or his estate) shall be entitled to receive: (i) Executive's Base Salary through the Date of Termination, (ii) reimbursement for the duration of the Benefit Period of (1) any COBRA continuation premium payments made by Executive and (iii) a lump sum severance payment equal to eighteen (18) months of Executive's then 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 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 the event that Executive shall become entitled to a Change in Control Severance Payment as provided herein, the Company shall cause its independent auditors promptly to review, at the Company's sole expense, the applicability to those payments of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (the "Code"). If the auditors determine that any payment of the Change in Control Severance Payment would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, then such payment owed to Executive shall be reduced by an amount calculated to provide to Executive the maximum Change in Control Severance Payment which will not trigger application of Sections 280G and 4999 of the Code, 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 A 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.

5. Employment Covenants

5.1 <u>Definitions</u>

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, licensors, licensees, investors and personnel, including their names, addresses, duties and other personal characteristics. Confidential Information does not include information that (i) is in the public domain, other than as a result of an act of misappropriation or breach of an obligation of confidentiality by any person; (ii) Executive can verify by written records kept in the ordinary course of business was in Executive's lawful possession prior to its disclosure to Executive; (iii) is received by Executive from a third party without a breach of an obligation of confidentiality owed by the third party to the Company and without the requirement that Executive keep such information confidential; or (iv) Executive is required to disclose by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction. If Executive is required to make disclosure pursuant to clause (iv) of the preceding sentence as a result of the issuance of a court order or other government process, Executive shall (a) promptly, but in no event more than 72 hours after learning of such court order or other government process, notify, pursuant to Section 6.1 below, the Company; (b) at the Company's expense, take all reasonable necessary steps requested by the Company to defend against the enforcement of such court order or other government process, and permit the Company to intervene and participate with counsel of its choice in any proceeding relating to the enforcement thereof; and (c) if such compelled disclosure is required, Executive shall disclose only that portion of the Confidential Information that is necessary to meet the minimum legal requirement imposed on Executive.

(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 Nondisclosure and Nonuse

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

5.3 Other Confidentiality Obligations

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

5.4 Return of Confidential Information

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

5.5 Confidential Information of Others

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

5.6 Other Obligations

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

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

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

5.8 Representations

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

5.9 Inventions, Intellectual Property and Equipment Not Transferred

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

5.10 Exclusivity of Employment

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

5.11 Covenant Not to Compete

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

- (b) <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:

"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 material to the Company's business 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.

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

5.12 Non-Solicitation

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

5.13 Judicial Enforcement

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

6. Miscellaneous

6.1 Notices

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

To Company: Sucampo Pharma Americas, LLC

4520 East West Highway, Third Floor

Bethesda, Maryland 20814

Attention: Executive Vice President, Human Resources

Copy to: Corporate Secretary

To Executive: Stanley Miele

1955 Bells Ferry Road Marietta, GA 30066

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

6.2 Headings

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

6.3 Modifications; Waiver

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

6.4 Entire Agreement

This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all other agreements, oral or written, heretofore made with respect thereto including, without limitation, the offer letter between Executive and the Company dated October 21, 2012.

6.5 Severability

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

6.6 Controlling Law

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

6.7 Arbitration

Any controversy, claim, or breach arising out of or relating to executive's employment or termination of employment, 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. All other disputes or any nature related to executive's employment or this agreement will be resolved by arbitration. 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. Counterparts

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 PHARMA AMERICAS, LLC

By: /s/ Peter Greenleaf
Peter Greenleaf
Chief Executive Officer

/s/ Stanley Miele
EXECUTIVE

EXHIBIT 10.88

*** TEXT OMITTED AND FILED SEPARATELY
CONFIDENTIAL TREATMENT REQUESTED
UNDER 17 C.F.R. §§ 200.80(b)(4) AND 240.24b-2

STIPULATION AND LICENSE AGREEMENT

THIS STIPULATION AND LICENSE AGREEMENT (this "Agreement") is made and entered into as of February 5, 2015 (the "Effective Date") by and between, on the one hand, Sucampo AG and Sucampo Pharmaceuticals, Inc. (collectively, "Sucampo") and R-Tech Ueno, Ltd. ("RTU"), and on the other hand, Par Pharmaceutical, Inc. ("Par"). Each of Sucampo, RTU, and Par is a "Party" and, together, are the "Parties" with respect to the following:

WHEREAS, the United States Patent & Trademark Office has lawfully granted the Sucampo Patents (as defined below) providing for the exclusive right to exclude others from making, using, offering for sale, or selling any of the inventions described in the Sucampo Patents;

WHEREAS, RTU is the owner of the right, title and interest to the Sucampo Patents;

WHEREAS, Sucampo is the exclusive licensee of the Sucampo Patents;

WHEREAS, RTU has manufactured and Sucampo has marketed Rescula® brand (unoprostone isopropyl) ophthalmic solution/drops for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension (the "Rescula® Product") approved under New Drug Application No. 21-214 (the "Rescula® NDA");

WHEREAS, Par has submitted an Abbreviated New Drug Application No. 206893 (as amended or supplemented, the "Par ANDA"), including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") asserting, alternatively, the invalidity, unenforceability, and/or non-infringement of U.S. Patent No. 6,458,836 ("the '836 patent") and U.S. Patent No. 6,770,675 ("the '675 patent") (collectively, "the Sucampo Patents"), to the United States Food and Drug Administration (the "FDA") to obtain approval to market Par's ANDA Product (defined below);

WHEREAS, on December 19, 2014, Par sent a Notice Letter to Sucampo, informing Sucampo of the filing of Par's ANDA, accompanied by a Paragraph IV Certification directed to the '836 patent and the '675 patent;

WHEREAS, the current expiration dates for the Sucampo Patents which are the subject of this Agreement are:

- · U.S. Patent No. 6,458,836 currently expires on July 9, 2021;
- · U.S. Patent No. 6,770,675 currently expires on November 24, 2018;

WHEREAS, in connection with the Notice Letter, Sucampo is entitled to initiate an Action (the "Lawsuit");

WHEREAS, Rescula® NDA generated total net sales of less than \$1 million in the 2014 calendar year; manufacturing of the Rescula® Product has already ended; and Sucampo's current inventory expires March 31, 2015;

WHEREAS, as a result of the weak and decreasing sales of the Rescula® Product, Sucampo's expected litigation costs would very likely exceed its sales, and the avoidance of litigation will enable Sucampo to focus its finite resources on more productive, procompetitive activities;

WHEREAS, Sucampo and RTU agrees herein to permanently resolve the issues of liability by granting to Par a license to the Sucampo Patents;

WHEREAS, the Parties agree their purpose and intent in entering this Stipulation and License Agreement is to enable a procompetitive resolution and license;

WHEREAS, without any admission of fault by any Party and prior to the commencement of any legal action in connection with Par's ANDA, the Notice Letter or Par's ANDA Product, Sucampo, RTU, and Par desire to resolve, without litigating or defending the Lawsuit, any and all outstanding issues between them on a worldwide basis relating to Par's importation, exportation, manufacture, use, distribution, offer for sale and sale of Par's ANDA Product, on the terms set forth below; and

WHEREAS, this Stipulation and License Agreement reflects the entirety of the parties' agreement with respect to the Rescula® Product and PAR's ANDA, and is independent of any other agreement or understanding between the parties.

NOW, THEREFORE, for and in consideration of the mutual covenants, agreements, and undertakings set forth in this Agreement, and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties, on behalf of themselves, and their respective officers, directors, agents, employees, representatives, heirs, assigns, predecessors and successors ("Related Parties"), agree as follows:

1. DEFINITIONS AND RULES OF CONSTRUCTION

(a) **Definitions**.

- (i) "Action" means any legal action or proceeding that may be brought or instituted by either Sucampo or Par in connection with Par's ANDA (including the filing thereof with the FDA), any Paragraph IV Certification included therewith, any Notice Letter sent by Par to Sucampo in connection therewith or any of Par's ANDA Product.
- (ii) "Affiliate" means, with respect to a Party, any Person that directly or indirectly controls, is controlled by, or is under common control with such Party. For purposes of the foregoing definition only, the term "control" (including, with correlative meaning, the terms "controlling", "controlled by", and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through ownership of interests representing equity securities, or partnership interests or by contract, or otherwise.

Ownership of more than fifty percent (50%) of such equity securities or partnership interests in a Person shall, without limitation, be deemed to be control for purposes of this definition. Any venture capital fund or private equity fund, or any Person that directly or indirectly is controlled thereby, that otherwise would be considered an "Affiliate" shall not, for purposes of this Agreement, be considered an Affiliate, except that in the case of Par, Sky Growth Holdings Corporation and its direct and indirect subsidiaries as well as any successor entity to Sky Growth Holdings Corporation and the successor entity's direct and indirect subsidiaries, shall be considered an Affiliate of Par. For the avoidance of doubt Sucampo and RTU are not Affiliates of each other.

- (iii) "Authorized Generic" means unoprostone isopropyl ophthalmic solution/drops product sold in the Territory pursuant to the Rescula® NDA but not under the Rescula® trademark.
- (iv) "Commercial[ly] Market[ing]" is defined consistent with 21 C.F.R. 314.107(c)(4) and means the first date of introduction or delivery for introduction into interstate commerce outside the control of the manufacturer of a drug product, but does not include transfer of the drug product for reasons other than a sale within the control of the manufacturer or application holder.
- (v) "Final Court Decision" means a decision of a United States Court, including any settlement order, consent decree, consent judgment, or similar form of judgment entered by such court, from which no appeal has been or can be taken, other than a petition to the Supreme Court for a review of certiorari.
- (vi) "Fully Loaded Manufacturing Cost" means the Party's direct out-of-pocket costs actually incurred for the manufacturing, labeling, and packaging of a Rescula® Product, including API, excipients, packaging components, labeling components, internal direct labor, and quality control and assurance testing that are a necessary part of manufacturing.
- (vii) "Generic Equivalent" means any pharmaceutical product that has received FDA approval for marketing in the Territory as an ABrated generic version of Rescula® Product, whether pursuant to an ANDA, a 505(b)(2) application, or the Rescula® NDA.
 - (viii) "Gross Profits" means [...***...].
 - (ix) "License Launch Date" means the earliest to occur of the following dates:
 - A. provided that Par has not forfeited its 180-day exclusivity pursuant to 21 U.S.C. § 355(J)(5)(D), the date of a Final Court Decision in an action brought against or by a Third Party that causes the 75-day period of 21 U.S.C. § 355(J)(5)(D)(i)(I)(bb)(AA) to begin; in the event of such forfeiture, the date following the entry of such Final Court Decision on which such Third Party begins to Commercially Market a Generic Equivalent; or

- B. the date of a Final Court Decision holding all claims of the '836 and '675 patents asserted against a third party to be invalid or unenforceable; or
- C. the date on which (x) Sucampo, RTU or any of their respective Affiliates or (y) a third party, pursuant to a license or authorization, directly or indirectly, by Sucampo or RTU (or any of their respective Affiliates), launches or sells a Generic Equivalent, provided that Par has secured final approval of Par's ANDA from the FDA; or
- D. the date on which a third party, without license or authorization from Sucampo, RTU, or its Affiliates, directly or indirectly, launches or sells a Generic Equivalent, provided that Par has secured final approval of Par's ANDA from the FDA.
- (x) "Net Sales" means the gross sales of Par's ANDA Product by Par or its Affiliate in arm's-length transactions with third parties in the Territory, less all applicable deductions, to the extent accrued, paid or allowed are in accordance with GAAP and in the ordinary course of business with respect to the sale of Par's ANDA Product, including:
 - A. cash discounts, quantity discounts, promotional discounts, stocking or other promotional allowances;
 - B. sales and excise taxes, customs and any other taxes, all to the extent added to the sale price and paid and not refundable in accordance with applicable law (but not including taxes assessed against the income derived from such sale);
 - C. returns, recalls and returned goods allowances;
 - D. retroactive corrections, including price adjustments (including those on customer inventories following price changes) and corrections for billing errors or shipping errors;
 - E. chargebacks, rebates, administrative fees, any other allowances actually granted or allowed to any person or entity, including group purchasing organizations, managed health care organizations and to governments, including their agencies, or to trade customers, in each case that are not Affiliates of Par, and that are directly attributable to the sale of Par's ANDA Product;

- F. redistribution center (RDC) fees, information service agreement (ISA) fees, and like fees that are customary in the industry that are passed from wholesalers, retailers, distributors, and other customers back to Par; and
- G. any failure-to-supply penalties that Par may incur from any third party customer purchasing Par ANDA Product pursuant to a written agreement between Par and such third party.

In no event will any particular amount, identified above, be deducted more than once in calculating Net Sales (i.e., no "double counting" of reductions). Sales of any of Par's ANDA Product between Par and its Affiliates or sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of Par's ANDA Product to a Third Party shall be included within the computation of Net Sales. If any of Par's ANDA Product is sold or transferred for consideration other than cash, the Net Sales from such sale or transfer shall be deemed the then fair market value of such Par's ANDA Product.

For purposes of determining Net Sales with respect to a unit of product that is sold in a Bundled Sale (as defined below), the gross sales deemed to have been invoiced shall be the average gross sales invoiced for a unit of Par's ANDA Product during the immediately preceding thirty (30)-day period, and the total amount of any deductions made from such gross amount with respect to each such unit pursuant to this definition shall be no greater than the average total amount deducted for a unit of Par's ANDA Product during the immediately preceding thirty (30)-day period. For purposes of this definition of Net Sales, the term "Bundled Sale" shall mean the sale of any other product with Par's ANDA Product, where discounts, credits, allowances, charge backs, rebates, and other deductions are granted wholly or partially by Par in consideration of a Third Party's agreement to purchase such other product (other than "across the board" discounts, credits, allowances, chargebacks, rebates, and other deductions that would otherwise be applied independently to the sale of Par's ANDA Product and such other product).

- (xi) "Par's ANDA Product" means any existing formulation of a product that is the subject of Par's ANDA whose ability to be marketed in the United States is contingent upon the FDA approving Par's ANDA. Par's ANDA Product does not mean or include any product that is not the subject of Par's ANDA and does not include any products for any indication other than the currently-approved indications for the Rescula® Product.
- (xii) "Person" means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, governmental authority, or other entity or organization.
- (xiii) "Sucampo IP Rights" means the '836 Patent and the '675 Patent, and (A) any patents (issued or that may issue in the future) owned by or licensed to Sucampo, RTU, and/or any of their Affiliates purporting to cover the Rescula® Product, including, but not limited to, any continuations, continuations-in-part, divisionals, reissues or reexaminations of the '836 Patent or '675 Patent.

- (xiv) "**Term**" means the period commencing on the Effective Date and expiring on the date of expiration of the last-to-expire of the Sucampo IP Rights.
- (xv) "Territory" means the United States of America, and its commonwealths, territories, districts and possessions, including the District of Columbia, Commonwealth of Puerto Rico; any installation, territory, location or jurisdiction under the purview of the FDA or control of the United States government; and any United States military bases and installations worldwide.
 - (xvi) "Third Party" means any Person other than Sucampo, RTU, Par, their Affiliates, and their subsidiaries.
- (xvii) "Valid Claim" means a claim of an issued patent or pending patent application that has not (A) lapsed or become permanently abandoned, (B) been held permanently revoked, unenforceable, invalid, or unpatentable (as the case may be) by a final decision of a court or other governmental agency of competent jurisdiction, which decision is unappealable or not appealed within the time allowed for appeal, and (C) been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

(b) Rules of Construction.

- (i) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Neutral pronouns and any variations thereof shall be deemed to include the feminine and masculine and all terms used in the singular shall be deemed to include the plural, and vice versa, as the context may require. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The word "any" shall mean "any and all" unless otherwise clearly indicated by context. Where either Party's consent is required hereunder, except as otherwise specified herein, such Party's consent may be granted or withheld in such Party's sole discretion. Derivative forms of any capitalized term defined herein shall have meanings correlative to the meaning specified herein.
- (ii) Unless the context requires otherwise: (1) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (2) any reference to any laws herein shall be construed as referring to such laws as from time to time enacted, repealed or amended, (3) any reference herein to any person or entity shall be construed to include such person's or entity's successors and permitted assigns, and (4) the words "herein", "hereof' and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof.

2. STIPULATION AND LICENSE

- (a) Par, on behalf of itself, its Affiliates, and Related Parties, stipulate that they shall not make, have made, import into, distribute, offer to sell or sell in the Territory Par's ANDA Product prior to the expiration date of the '836 patent, including any patent term adjustment or patent term extension, except as provided by Section 2(b). Par agrees that any breach by it, or its Affiliates and/or Related Parties, of this Section 2 shall cause irreparable harm to Sucampo and RTU, and Par, its Affiliates and its Related Parties consent irrevocably and unconditionally to specific performance, or immediate entry of a temporary restraining order, preliminary injunction, and permanent injunction, to enforce this Section 2(a). Notwithstanding anything to the contrary, Par, its Affiliates and its Related Parties consent irrevocably and unconditionally to personal jurisdiction and venue in the United States District Court for the District of Delaware for the purpose of enforcing this provision. Notwithstanding the foregoing, Par and its Affiliates and Related Parties shall have the right to engage in certain pre-marketing activities, as set forth in Section 2(d), prior to the License Launch Date.
- (b) Notwithstanding Section 2(a), if a License Launch Date occurs, Sucampo and RTU hereby grant to Par a non-exclusive license with respect to the Sucampo Patents with the right to grant sublicenses to Affiliates, (i) to make, have made, use, promote, offer to sell, sell, import, or otherwise dispose of Par's ANDA Product in the Territory, and (ii) to make and have made Par's ANDA Product outside the Territory only for use, sale and importation in the Territory.
- (c) With respect only to Par's ANDA Product, each of Sucampo and RTU (and their respective Affiliates) covenants not to sue Par or any of Par's Affiliates, Related Parties, or any of their importers, suppliers, distributors, or customers, or support or encourage any Third Party to sue, for infringement of any Sucampo IP Rights based on the making, using, selling, or offering for sale in the Territory, or making or having made only for importation, use, sale or offering for sale into or for the Territory, Par's ANDA Product. Sucampo and RTU, on behalf of themselves and their Affiliates, will impose the license grants, covenants, waivers and other obligations contained in this Article 2 and elsewhere in this Agreement on any Person to whom Sucampo and RTU or their Affiliates may assign or otherwise transfer title or interest in or to the Rescula® NDA and/or the Sucampo Patents.
- (d) Commencing [...***...] ([...***...]) days prior to the License Launch Date or the '836 patent expiry, whichever is earlier, Par and its Affiliates may [... ***...] but solely for the purpose of preparing for the commercial launch thereof on the License Launch Date; provided, however, that neither Par nor any of its Affiliates shall be allowed to engage in taking orders before the License Launch Date; and providedfurther, however, that other reasonably associated pre-marketing activities, including but not limited to offers to the trade that communicate information regarding the products offered for sale, may be conducted within [...***...] ([... ***...]) days prior to the License Launch Date. For the avoidance of any doubt, and notwithstanding anything to the contrary herein, the option to Commercially Market an Authorized Generic is not exclusive to Par, and Sucampo reserves all rights to market and sell an Authorized Generic and to license to third parties the right to market and sell an Authorized Generic.

(e) Par shall have the option to Commercially Market an Authorized Generic if a License Launch Date occurs. In the event that Par or its Affiliates wishes to Commercially Market an Authorized Generic, Par shall first notify Sucampo of its desire to purchase an Authorized Generic product to resell, which Authorized Generic product shall be supplied to Par at Sucampo's and/or RTU's [...***...] (the "Authorized Generic Supply Cost") and pursuant to such other terms and provisions as set forth in the Manufacturing and Supply Agreement set forth on Exhibit A hereto. Except as stated above in this Section 2(e), all terms in this Agreement that apply to Par's ANDA Product shall apply equally to the Authorized Generic product manufactured for, and supplied to Par, including the payment of royalties pursuant to Section 5, as though Par were Commercially Marketing its ANDA Product.

3. MUTUAL RELEASE AND OBLIGATIONS

- (a) Upon execution of this Agreement by each of the Parties, and subject to the terms of this Agreement, each of Sucampo and RTU, for themselves and on behalf of their Related Parties and all persons and entities claiming by, through and under them, does hereby fully, finally release and forever discharge, relinquish and acquit, Par, and its shareholders, employees, agents, officers, directors, successors, assigns, representatives, customers, suppliers, manufacturers, partners and distributors, from any and all claims, rights, causes of action, counterclaims, defenses and liabilities whatsoever that in each case accrued prior to the Effective Date, whether based on federal, state, local, statutory or common law or any other law, rule or regulation, whether known or unknown, that relate to (i) Par's ANDA Product and could have been asserted in an Action now or upon the approval of Par's ANDA Product or (ii) any activities in respect of Par's ANDA Product that were engaged in by Par or its Affiliates prior to the Effective Date and that would have given rise to a claim of infringement of any of the Sucampo IP Rights. Nothing in this release shall preclude Par or any of its Affiliates from asserting the invalidity, unenforceability or non-infringement of the Sucampo IP Rights in any future litigation concerning any product that is not Par's ANDA Product.
- (b) Upon execution of this Agreement by each of the Parties, and subject to the terms of this Agreement, Par for itself and on behalf of its shareholders, officers, directors, agents, representatives and all persons and entities claiming by, through and under them, does hereby fully, finally release and forever discharge, relinquish and acquit, Sucampo and RTU, and their respective shareholders, employees, agents, officers, directors, successors, assigns, representatives, customers, suppliers, manufacturers, partners and distributors, from any and all claims, rights, causes of action, counterclaims, defenses and liabilities whatsoever that in each case accrued prior to the Effective Date, whether based on federal, state, local, statutory or common law or any other law, rule or regulation, whether known or unknown, that relate to Par's ANDA Product and could have been asserted in an Action now or upon the approval of Par's ANDA Product. Nothing in this release shall preclude Sucampo or RTU, or any of their respective Affiliates, from asserting the Sucampo IP Rights in any future litigation concerning any product that is not Par's ANDA Product.

 Nothing in this release shall preclude Sucampo, RTU, or any of their respective Affiliates from asserting the Sucampo IP Rights in any future litigation concerning any product that is not Par's ANDA Product.

(c) Each party shall be solely responsible for its own attorney's fees and costs. No payment shall be made by Sucampo or RTU to Par as consideration for this Stipulation and License Agreement.

4. PAR'S OBLIGATIONS TO SUCAMPO

- (a) Except to the extent required by law or order of a court or administrative agency of competent jurisdiction, Par, its Affiliates, and its Related Parties stipulate not to (1) challenge the validity or enforceability of, or assert the noninfringement of, any of the Sucampo IP Rights; and/or (2) cause its Affiliates, Related Parties, subsidiaries and their respective counsel (specifically including but not limited to the counsel who have advised or represented Par in connection with the Action or this Agreement), to assist, encourage, finance, or otherwise provide any information to any Third Party attacking or who may attack, the validity or enforceability of, or assert the noninfringement of, any of the Sucampo IP Rights; provided, however, that the foregoing shall not prevent or otherwise prohibit Par, its Affiliates, or its Related Parties from such challenge or assertion solely to the extent that such challenge or assertion involves any subsequent submission by Par of an ANDA or 505(b) (2) application that does not reference NDA No. 21-214. Furthermore, any additional certification or statement required by FDA of Par with respect to the Par ANDA in light of any future patent information submission or Orange Book listing by Sucampo or RTU for NDA No. 21-214 shall not be deemed a violation of this section.
- (b) Solely for the purposes of the enforcement of this Agreement, and only to the extent that it pertains to the Rescula® Product approved under the Rescula® NDA (and for no other purpose or product), Par acknowledges that the Sucampo IP Rights are valid and enforceable and that Par's ANDA Product would infringe one or more Valid Claims of the Sucampo IP Rights, with such acknowledgement having no estoppel or other preclusive effect on future litigation should this Agreement be breached by either Party.
- (c) If Par acquires the right, title, or interest to another ANDA for unoprostone isopropyl 0.15% ophthalmic solution products that references the Rescula® NDA and that ANDA contains a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '836 patent and/or the '675 patent and seeks approval to market generic versions of unoprostone isopropyl 0.15% ophthalmic solution products before the expiration of the '836 patent and/or the '675 patent, the terms of this Agreement shall apply equally to that ANDA and its products as they do to Par's ANDA and its products.

5. ROYALTY PAYMENTS AND REPORTING

(a) Beginning on any License Launch Date that is prior to the date specified in Section 2(a), Par shall pay Sucampo [...***...] of Par's ANDA Product sold during the term of this Agreement for all such Gross Profits [...***...], which term continues until each of the Sucampo Patents has expired, or each has been dedicated to the public or disclaimed pursuant to 35 USC § 253, or every claim that was asserted against Par in the Patent Litigation has been held invalid or unenforceable in a Final Court Decision, unless otherwise provided by this Section 5.

- (b) During any period after a License Launch Date occurs where, in addition to Par Commercially Marketing a Generic Equivalent, one Third Party is Commercially Marketing a Generic Equivalent or Authorized Generic in the Territory (or Sucampo, RTU, and/or an Affiliate is Commercially Marketing an Authorized Generic in the Territory) the royalty rate provided for in Section 5(a) shall be [...***...] of Gross Profits [...***...].
- (c) During any period after a License Launch Date occurs where, in addition to Par Commercially Marketing a Generic Equivalent, two or more Third Parties are Commercially Marketing a Generic Equivalent or Authorized Generic in the Territory (or one or more Third Parties is Commercially Marketing a Generic Equivalent and Sucampo, RTU, and/or an Affiliate is Commercially Marketing Authorized Generics in the Territory), the royalty rate provided for in Section 5(a) shall be [...***...].
- (d) Within thirty (30) calendar days after the close of each calendar quarter for which royalties are due hereunder, Par shall deliver to Sucampo a report of the amount of Gross Profits and Net Sales of Par's ANDA Product sold by Par or its Affiliates in the quarter listing the amount of royalties due for the quarter and the details of the calculation performed by Par to arrive at the amount of royalties due, and shall remit to Sucampo payment of said royalties in United States Dollars by wire transfer to such bank account as Sucampo may from time to time designate in writing.
- (e) Par shall maintain accurate books and records in sufficient detail to enable the payments due hereunder to be determined. Such records shall be available on request by Sucampo for inspection, during normal business hours, by Sucampo's independent certified public accountant for up to three (3) years after the calendar year to which they pertain, for purposes of verifying the accuracy of the reports and payments made by Par. If the audit reveals a deficiency in the calculation of payments resulting from any underpayment to Sucampo, Par shall promptly pay (but in all cases within thirty (30) days of such determination) Sucampo the amount remaining to be paid and, if such underpayment is five percent (5%) or more, Par shall also pay Sucampo the reasonable out-of-pocket expenses paid to a Third Party for such audit. If the accountant determines that Par has overpaid Sucampo, Sucampo shall pay such amounts to Par within thirty (30) calendar days of the result of the audit.
- (f) Any amount due hereunder from a Party and not paid timely under the terms of this Agreement shall bear interest from the date due at the then-prevailing prime rate.

(g) Sucampo, RTU, and Par acknowledge that any expenses or costs deducted from Net Sales under this Agreement may be based upon accruals or estimates, which accruals or estimates will be compliant with Par's standard practices consistently applied; provided that such accruals or estimates shall be reconciled to actual amounts at least quarterly and when known relative to any accrued or estimated amount, and any difference between the actual results and the accrual or estimate shall be reported and accounted for. To the extent that the difference between such accruals or estimates and the actual results has led to an underpayment, the amount of such underpayment to Sucampo, that amount may set-off such overpayments against subsequent payments. Within one (1) year of the termination or expiration of this Agreement, a "contract-end" reconciliation shall be performed (and a written report of such reconciliation shall be provided) of the deductions made, pursuant to the definition of Net Sales, and of the amounts payable. The reconciliation shall be based on all actual amounts known through the date that is ten (10) months following the applicable termination or expiration date versus prior accruals or estimates. No further reconciliations shall be made. If any reconciliation under this Section 5(g) following the termination or expiration of this Agreement shows either an underpayment or an overpayment, the respective party shall pay the amount of the difference to the other within thirty (30) days of the date of delivery of the report of such reconciliation.

6. REPRESENTATIONS AND WARRANTIES

- (a) Each Party hereby warrants and represents to the other Party that (i) it has the right to enter into this Agreement and perform its obligations and duties under this Agreement, (ii) all factual statements made herein are true, (iii) the undersigned representative is duly authorized to execute and deliver this Agreement on behalf of such Party, and (iv) such Party has provided its undersigned representative with the full and necessary authority to bind it with respect to the subject matter herein
- (b) Sucampo and RTU hereby represent and warrant that they have all rights, title and authority necessary to grant to Par the release and covenants not to sue granted hereunder.
- (c) Each Party hereby represents and warrants that neither this Agreement, nor any of its terms or provisions, nor any of the negotiations or proceedings connected with it, shall be construed as an admission or concession by either Party of any liability, fault, or wrongdoing of any kind.

7. CONFIDENTIALITY

- (a) The terms of this Agreement are confidential, and shall not be disclosed to any third party without the prior written consent of all Parties. Any press release regarding this Agreement must be approved by all Parties.
 - (b) Notwithstanding the foregoing, the Parties may disclose the terms of this Agreement if the disclosure is:
 - (i) of matters contained in the public record,
 - (ii) as required by any court or other governmental body,
 - (iii) to any regulatory agency, including disclosure required by securities laws or regulations,
 - (iv) in confidence to the Parties' attorneys, insurers, accountants, or financial advisors,

- (v) as required to assert the Parties' rights hereunder, and
- (vi) as otherwise agreed to in writing by the Parties, or required by law.

8. GOVERNMENT NOTIFICATIONS AND GOVERNMENT PROCEEDINGS

- (a) Within ten (10) business days following the Effective Date, and pursuant to current statutory law, the Parties shall file or cause to be filed this Agreement with the U.S. Federal Trade Commission Bureau of Competition ("FTC"), the Assistant Attorney General for the Antitrust Division of the U.S. Department of Justice ("DOJ"), and any other applicable state or federal governmental agency, and, in each case, shall request that this Agreement be treated as confidential to the fullest extent permitted under the law.
- (b) If, within thirty (30) days of receipt of this Agreement by the FTC and DOJ, the FTC and/or DOJ object to, respond to, or otherwise comment on such submission, the Parties shall use best efforts to resolve such objection, response or comment, without making any material change to the rights and obligations of the Parties under this Agreement, except as the Parties may mutually agree.

9. MISCELLANEOUS PROVISIONS

(a) <u>Interpretation</u>. The Parties are equally responsible for the negotiation and preparation of this Agreement, and in any judicial proceeding the terms hereof shall not be more strictly construed against one Party than the other Party.

(b) Notice.

- (i) Any notice or other communication to be given under this Agreement by any Party to the other Party shall be in writing and shall be either (A) personally delivered, (B) mailed by registered or certified mail, postage prepaid with return receipt requested, (C) delivered by overnight express delivery service or same-day local courier service, or (D) delivered by facsimile transmission (followed by a copy by the preceding methods in clause (A), (B) or (C)), to the address of the applicable Party as set forth below, or to such other address as may be designated by the Parties from time to time in accordance with this Section 8(b).
- (ii) Notices delivered personally, by overnight express delivery service or by local courier service shall be deemed given as of actual receipt. Mailed notices shall be deemed given five (5) business days after mailing. Notices delivered by facsimile transmission shall be deemed given upon receipt by the sender of the transmission confirmation (in the case of a facsimile transmission) if transmitted before 5:00 p.m. (recipient's local time) on a business day, and otherwise on the following business day.

If to Par: Par Pharmaceutical, Inc.

One Ram Ridge Road Chestnut Ridge, NY 10977 Attention: General Counsel Facsimile Number: (201) 802-4600 If to Sucampo: Sucampo Pharmaceuticals, Inc.

4520 East West Highway, 3rd Flr.

Bethesda, MD 20814

Attention: Chief Legal Officer Facsimile Number: (301) 961-3440

If to RTU: R-Tech Ueno, Ltd.

NBF Hibiya Bldg. 10F, 1-1-7, Uchisaiwai-cho,

Chiyoda-ku, Tokyo, 100-0011, Japan, Attention: Director, Office of the President

Fax No. +81-3-3596-8023

(c) Governing Law. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the parties hereunder, shall be construed under and governed by the laws of the State of Delaware, without regard to its choice of law rules.

- (d) <u>Dispute Resolution</u>. In the event of any dispute, controversy or claim arising from, out of, or in connection with or relating to this Agreement or any breach or alleged breach of this Agreement (each, a "**Dispute**"), a Party shall notify the other Party of such Dispute in writing and the Parties shall meet to discuss and attempt to resolve in good faith such Dispute. If such Dispute is not resolved by the Parties within thirty (30) days of such notice, either Party may commence action in a court of competent jurisdiction.
- (e) Entire Agreement. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and shall not be modified, amended, or terminated except as herein provided or except by another agreement in writing executed by the Parties hereto. This agreement is not contingent upon or related to any agreement, promise, or understanding except as expressly set forth herein.
- (f) <u>Severability</u>. If any provision of this Agreement is held to be invalid or unenforceable, such provision shall be limited or eliminated to the minimum extent necessary so that the remainder of this Agreement will continue in full force and effect and be enforceable. The parties agree to negotiate in good faith an enforceable substitute provision for any invalid or unenforceable provision that best achieves the intent of such provision.
 - (g) <u>Headings</u>. The headings used herein are for reference and convenience only, and shall not enter into the interpretation of this Agreement.
 - (h) <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which shall constitute one and the same document.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Agreement to be executed in duplicate originals by these duly authorize representatives.
SUCAMPO AG

			Name
			Title
		SU	UCAMPO PHARMACEUTICALS, INC.
		Ву	Name
			Title
		R-	-Tech Ueno, Ltd.
		Ву	iv
		-,	Name Title
		P.A	AR PHARMACEUTICAL, INC.
		Ву	Name
			Title
Ву	Name		
	Title		
R-Tech Ueno, By			
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PAR PHARM By	IACEUTICAL, INC.		
Dy.	Name Title		
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*** Text Omitted and Filed Separately Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2

MANUFACTURING AND SUPPLY AGREEMENT

BY AND BETWEEN

SUCAMPO AG

AND

PAR PHARMACEUTICAL, INC.

DATED AS OF FEBRUARY 5, 2015

MANUFACTURING AND SUPPLY AGREEMENT

Manufacturing and Supply Agreement (this "Agreement") is hereby entered into and effective as of February 5, 2015 (the "Effective Date") by and between Sucampo AG ("Sucampo") and Par Pharmaceutical, Inc. ("Par"). Each of Sucampo and Par are referred hereto as the "Parties" or, individually, as a "Party").

WHEREAS, Sucampo is a pharmaceutical company engaged in the marketing, sales and distribution of pharmaceutical products;

WHEREAS, Par is a pharmaceutical company engaged in the manufacture, marketing, sales and distribution of pharmaceutical products;

WHEREAS, the Parties have independently determined this Agreement reflects fair value with regard to their respective business considerations;

WHEREAS, Par and Sucampo, among other parties, have entered into that certain Stipulation and License Agreement dated February 5, 2015 (the "License Agreement") related to the Product (as defined below); and

WHEREAS, pursuant to the terms and conditions of this Agreement and the License Agreement, Par desires Sucampo to supply to Par commercial quantities of the Product to be marketed and distributed by Par in the Territory.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises, covenants and agreements hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Sucampo and Par hereby agree as follows:

ARTICLE 1. DEFINITIONS

- 1.1 "Affiliate" means, with respect to either Party, any Person that directly or indirectly controls, is controlled by, or is under common control with such Party. For purposes of the foregoing definition only, the term "control" (including, with correlative meaning, the terms "controlling", "controlled by", and "under common control with") means the possession, directly or indirectly, of the power to direct of cause the direction of the management and policies of such Person, whether through ownership of interests representing equity securities, or partnership interests or by contract, or otherwise. Ownership of more than fifty percent (50%) of such equity securities or partnership interests in a Person shall, without limitation, be deemed to be control for purposes of this definition. Any venture capital fund or private equity fund, or any Person that directly or indirectly is controlled thereby, that otherwise would be considered an "Affiliate" shall not, for purposes of this Agreement, be considered an Affiliate, except that in the case of Par, Sky Growth Holdings Corporation and its direct and indirect subsidiaries as well as any successor entity to Sky Growth Holdings Corporation and the successor entity's direct and indirect subsidiaries, shall be considered an Affiliate of Par.
 - **1.2** "Agreement" has the meaning given in the introductory paragraph hereof.

- **1.3** "API" means the active pharmaceutical ingredient known as Unoprostone.
- 1.4 "Applicable Laws" means all laws, rules, regulations and guidelines of any Governmental Authority with jurisdiction over the development, manufacturing, exportation, importation, promotion, marketing, sale or distribution of the API and/or the Product, including specifically, but without limitation, all cGMP or similar standards or guidelines of the FDA and compendial guidelines (e.g. United States Pharmacopeia), where applicable, as well as the U.S. export control laws and the U.S. Foreign Corrupt Practices Act, in each case to the extent applicable to the performance of a Party's obligations under this Agreement.
- 1.5 "Authorized Generic Launch" means the first commercial sale of the Product in the Territory by Par pursuant to the terms of this Agreement and the License Agreement.
 - 1.6 "Calendar Quarter" means each three (3) consecutive month period ending on March 31, June 30, September 30 or December 31.
- 1.7 "Certificate of Analysis" means a certificate of analysis provided by Sucampo to Par with each shipment of the Product that sets forth: (a) the results of any quality assurance testing and (b) the manufacturing date.
- 1.8 "Certificate of Product Conformance" means a certificate of product conformance indicating that such Product was manufactured materially in accordance with cGMP requirements, certified by quality assurance personnel of Sucampo or its contractor.
- 1.9 "cGMP" means quality systems and current good manufacturing practices as required by the rules, guidelines and regulations of the FDA as applicable to the manufacture, Labeling, Packaging, handling, storage and transport of the API and Product in the Territory, as set forth in 21 USC § 351(a)(2)(B) and 21 CFR Parts 210 and 211, or any successor provisions and any update thereto.
- 1.10 "Commercially Reasonable Efforts" means, with respect to each Party, efforts and commitment of resources, consistent with Applicable Laws, in accordance with such Party's reasonable business, legal, medical, and scientific judgment that are consistent with the efforts and resources such Party customarily uses to accomplish a similar objective under similar circumstances for other similar products owned by it or to which it has similar rights, which are of similar market potential and at a similar stage in their life cycle, taking into account the competitiveness of the marketplace, the regulatory structure involved, the profitability of the applicable products and other relevant factors, including any royalties, product sales and other payments required under this Agreement, technical, legal, scientific, medical, sales performance, and/or marketing factors, including the reasonable performance of any associated commitments under this Agreement.

- 1.11 "Confidential Information" means, with respect to a Party (as the "Disclosing Party"), all non-public information of any kind whatsoever (including without limitation, data, materials, compilations, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies, techniques and all non-public Intellectual Property as defined herein), and all tangible and intangible embodiments thereof of any kind whatsoever (including without limitation, materials, samples, apparatus, compositions, documents, drawings, machinery, patent applications, records and reports), which are disclosed by the Disclosing Party to another Party (as the "Receiving Party") including any and all copies, replication or embodiments thereof. Notwithstanding the foregoing, Confidential Information of a Disclosing Party shall not include information to the extent that the Receiving Party can establish by competent proof (a) to have been publicly known prior to disclosure of such information by the Disclosing Party to the Receiving Party, (b) to have become publicly known, without fault on the part of the Receiving Party, subsequent to disclosure of such information by the Disclosing Party to the Receiving Party, (c) to have been received by the Receiving Party free of an obligation of confidentiality from a source rightfully having possession of and the right to disclose such information free of an obligation of confidentiality from a source rightfully having possession of and the right to disclose such information free of an obligation of Party, as substantiated by reasonable documentation in support thereof, or (e) to have been independently developed by employees or agents of the Receiving Party without the use of Confidential Information of the Disclosing Party. For the avoidance of doubt and without limiting the generality of the foregoing, "Confidential Information" of Sucampo shall include without limitation all non-public Intellectual Property and T
- 1.12 "Direct Manufacturing Cost" means the direct out-ofpocket costs actually incurred by Sucampo or its Third Party contract manufacturer for the manufacturing, Labeling and Packaging of the Product, including API, excipients, Packaging and Labeling components, internal direct labor, and quality control and assurance testing that are a necessary part of manufacturing.
 - 1.13 "Dollar" means the United States dollar.
 - 1.14 "Effective Date" has the meaning given to such term in the introductory paragraph of this Agreement.
 - 1.15 "FDA" means the United States Food and Drug Administration and any successor agency thereto.
 - **1.16** "Forecast Period" has the meaning set forth in Section 3.2.
 - **1.17 "Force Majeure Event"** has the meaning set forth in Section 13.13.
 - **1.18** "Forecast Period" has the meaning set forth in Section 3.2.
 - 1.19 "GAAP" means generally accepted accounting principles as in effect in the United States from time to time, consistently applied.
 - **1.20** "GDEA" has the meaning set forth in Section 9.1.5.
- 1.21 "Governmental Authority" means any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country, or (ii) a federal, state, province, county, city or other political subdivision thereof.

- **1.22** "Indemnitee" has the meaning set forth in Section 10.3.
- **1.23** "Indemnitor" has the meaning set forth in Section 10.3.
- 1.24 "Intellectual Property" means, without limitation, all of the following: (i) all patent rights and all rights, title and interests in and to all patent applications, continuation-in-part applications, divisional applications, and United States patents corresponding to any of the foregoing that may grant or may have been granted on any of the foregoing, including without limitation reissues, re-examinations and extensions, or the like; (ii) all copyrights and all rights, title and interests in and to all copyrightable works, copyright applications, registrations and renewals; (iii) all rights, title and interests in and to all trade secrets and trade secret rights arising under common law, state law, federal law or laws of foreign countries; (iv) logos, trademarks, service marks, and all rights, title and interest in and to all applications and registrations relating thereto; (v) any other intellectual or proprietary rights anywhere in the world; (vi) any rights, title and interest in and to abbreviated new drug applications or other applications to market (including right of reference thereto); and (vii) any regulatory exclusivities, patent extensions, supplemental protection certificates or the like.
- 1.25 "Labeled" or "Labeling" refers to such labels and other written, printed or graphic matter, (i) upon the Product or any container or wrapper utilized with the Product, or (ii) accompanying the Product, including without limitation, package inserts.
- 1,26 "Latent Defect" means a defect in any Product not conforming to Sucampo's warranty for such Product as set forth in Section 5.1 such that (a) the non-conformance of such Product with the warranty set forth in Section 5.1 is not readily discoverable or not reasonably expected to be readily discoverable based on Par's or Par's designee's normal, incoming-goods inspections and (b) such non-conformance was not caused directly or indirectly by any acts or omissions of Par, its Affiliates or any Third Parties for whom Par is responsible.
 - **1.27** "**License Agreement**" has the meaning set forth in the fourth recital hereof.
 - **1.28** "Losses" has the meaning set forth in Section 10.1.
 - **1.29** "Objection Notice" has the meaning set forth in Section 3.6.3.
- 1.30 "Order" means, with respect to commercial supply of Product hereunder, a written communication from Par to Sucampo of Par's order of Product for a particular supply period, issued in accordance with Article 3.
- 1.31 "Packaged" or "Packaging" means all primary containers, including bottles, cartons, shipping cases or any other like matter used in packaging or accompanying the Product.
 - **1.32** "Par Parties" has the meaning set forth in Section 10.2.
- 1.33 "Patent Defect" means a defect in any Product not conforming to Sucampo's warranty for such Product as set forth in Section 5.1 such that (a) the non-conformance of such Product with the warranty set forth in Section 5.1 may be readily discovered or should be reasonably expected to be readily discoverable based on Par's or Par's designee's normal, incoming-goods inspections and (b) such non-conformance was not caused directly or indirectly by any acts or omissions of Par, its Affiliates or any Third Parties for whom Par is responsible.

- 1.34 "Permitted Variance" has the meaning set forth in Section 3.2.
- 1.35 "Person" means an individual, corporation, partnership, limited liability company, firm, association, joint venture, estate, trust, governmental or administrative body or agency, or any other entity.
- 1.36 "Product" means a generically labeled (and not under the Rescula® trademark) version of (Unoprostone isopropyl) ophthalmic solution/drops for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension, which is the subject of the Product NDA, including all dosage strengths and packaging configurations, and which is supplied by Sucampo to Par pursuant to this Agreement and subject to the terms of the License Agreement.
 - 1.37 "Product Liability Litigation" has the meaning set forth in Section 10.4.
 - 1.38 "Product NDA" means New Drug Application No. 21-214, as may be amended or supplemented.
- 1.39 "Product Specifications" means the applicable specifications set forth in the Product NDA, including any statements of pharmaceutical manufacturing, filling, storage and quality control procedures, submission batch specifications, and Labeling and Packaging specifications.
- 1.40 "Product Supply Price" means, in Dollars, the Direct Manufacturing Cost for the supplied Product plus [...***...] percent ([...***...]%) thereof or such other price as the Parties may subsequently agree in a writing signed by both Parties.
 - **1.41** "Quality Agreement" has the meaning set forth in Section 5.3.
 - **1.42** "Recall" has the meaning set forth in Section 5.2.
- 1.43 "Regulatory Approval" means any and all approvals, licenses (including product and establishment licenses), registrations, or authorizations of any Governmental Authority necessary to develop, manufacture, commercialize, promote, distribute, transport, store, use, sell or market the Product, and all applicable product and/or establishment licenses, registrations, permits or other authorizations as may be necessary in connection with the Product and API, and which are necessary for the commercial manufacture, commercialization, use, storage, importation, transport, promotion, pricing, distribution or sale of such Product in the Territory.
 - **1.44** "**Rejection Notice**" has the meaning set forth in Section 3.6.2.
 - **1.45** "Responsible Party" has the meaning set forth in Section 5.2.3.

- 1.46 "SKU(s)" means Stock Keeping Unit(s) in different product formats used as the smallest unit of measure to identify manufacturing and distribution of the Product.
 - **1.47** "Sucampo Parties" has the meaning set forth in Section 10.1.
- 1.48 "Technology" means any and all proprietary information, ideas, concepts, compositions, formulas, techniques, procedures, practices, protocols, methods, samples, models, technology, work product, trade secrets, inventions, designs, discoveries, developments, drawings, notes, documents, descriptions, specifications, knowledge, know-how, skill, experience, test data and results (including without limitation pharmacological, toxicological and clinical test data and results), analytical and quality control data and other data, results or descriptions, other copyrightable subject matter and any other information or technology, in each of the foregoing cases, whether in written, electronic, graphic or any other form and whether patentable or not, including without limitation, the following confidential proprietary information to the extent related to the Product (including all embodiments thereof): manufacturing information, protocols and methods, Product formulations, Product and process specifications, processes, Product designs, plans, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, quality assurance, quality control and clinical data, technical information, data and research records.
- 1.49 "Territory" means the United States of America and its territories, districts and possessions, including the Commonwealth of Puerto Rico and any installation, territory, location or jurisdiction under the purview of the FDA or control of the United States government.
 - 1.50 "Third Party" or "Third Parties" means any Person other than a Party or its Affiliates.
 - **1.51** "Unoprostone" means the compound described in more detail in Appendix A.

ARTICLE 2. COMMERCIAL MANUFACTURING & SUPPLY

2.1 Supply. Subject to Par providing written notice to Sucampo pursuant to Section 2(e) of the License Agreement, Sucampo shall, or shall cause its Third Party contract manufacturer to, commercially manufacture for, and Sucampo shall supply to, Par on a non-exclusive basis during the Term, with such amounts of Product in material compliance with the Product Specifications and in fully finished, Packaged and Labeled form, as Par may order pursuant to and in accordance with Article 3 below and accepted by Sucampo pursuant to Section 3.6.1 below, and Par shall purchase such amounts of Product pursuant to and in accordance with Article 3 below. For the avoidance of doubt, nothing in this Agreement or otherwise as between Par and Sucampo shall restrict, limit or prevent Sucampo from manufacturing, supplying, marketing, or selling to or for others, Rescula® (Unoprostone isopropyl) ophthalmic solution/drops or other Unoprostone products under the Rescula® trademark in the Territory, or generic versions thereof to any Person in or outside of the Territory. For the avoidance of doubt, notwithstanding any other provision of this Agreement, the Authorized Generic Launch shall not occur earlier than [...***...].

- 2.2 Raw Materials. In connection with commercial supply of Product to Par hereunder, Sucampo or its Third Party contract manufacturer shall procure all raw materials, including API, necessary to produce commercial quantities of Product, including all Packaging and Labeling material, and shall process and test all such materials as required by the Product Specifications.
- 2.3 Labeling and Packaging. Par shall provide to Sucampo all applicable information for the Labeling and Packaging, including applicable artwork. The information shall be in accordance and in compliance with the Product Specifications for the Labeling and Packaging, any applicable Regulatory Approval and Applicable Law.
- 2.4 Product Specifications. Sucampo shall not make any change to the Product Specifications that would adversely affect the Product, or the Packaging or Labeling for the Product, without first obtaining Par's written consent prior to any such change, which consent shall not be unreasonably withheld or delayed; provided, however, that notwithstanding the foregoing, Par's consent will not be required if such changes are necessary to comply with any Applicable Law, Regulatory Approval or the requirements, orders, regulations or other instructions of any applicable Governmental Authority, in which case Sucampo shall use Commercially Reasonable Efforts to provide Par with as much prior written notice of such change as practicable.

ARTICLE 3. COMMERCIAL LOGISTICS

3.1 General.

- **3.1.1** Except as otherwise expressly provided for in this Agreement, Par's commercial purchases of Product shall be made pursuant to Orders issued pursuant to Sections 3.3 and 3.4 below that will specify for each month of the applicable period covered by the Order the quantity (by SKU, Packaging and size of Product), delivery dates and the delivery locations, each in accordance with this Section 3.1.
- **3.1.2** All purchases of the Product shall be pursuant to written Orders consistent with Section 3.4 and the earliest delivery date in any given Order shall not be less than ninety (90) days following the date such Order is received by Sucampo. Each Order will be consistent in all respects with the Firm Order Period (defined in Section 3.2 below) of the most recent rolling forecast plus or minus the Permitted Variance (as defined Section 3.2 below).
- 3.1.3 The Parties shall cooperate in good faith to prepare for an Authorized Generic Launch, including making any adjustments to Orders, forecasts and associated delivery dates, as and to the extent requested by Par and agreed upon by Sucampo in writing in its sole discretion in accordance with the following procedure:
 - (a) In the event that Par wishes to adjust any Orders, forecast or associated delivery dates, it shall promptly submit a written request with respect to the same to Sucampo, including without limitation a detailed reason for such change

(b) Each change will be considered by Sucampo on a case-by-case basis in its sole discretion, including after taking into account Sucampo's timing requirements and reasonable manufacturing lead times. In addition to and without limiting the generality of the foregoing, in no event will Sucampo be obligated to: (i) deliver the Products in less than ninety (90) days; (ii) accept any quantities ordered in any particular month in excess of the amount forecasted for such month plus the Permitted Variance as expressly set forth in Section 3.2 below; and/or (iii) accept any quantities ordered in any particular month that are less than the amounts forecasted for the Firm Order Period of the rolling forecast less the Permitted Variance as expressly set forth in Section 3.2 below.

(c) In the event that Sucampo agrees in writing and in its sole discretion to a change in excess of the Permitted Variance, Par shall be responsible for all costs and expenses incurred by Sucampo but only to the extent necessary to implement such change, including any costs for expediting shipping to meet an earlier delivery date and any cancellation fees associated with cancelling all or any portion of an Order after Sucampo has commenced actual manufacturing of the Product. For the avoidance of doubt, Sucampo shall not be obligated to proceed with any requested change in excess of the Permitted Variance unless and until it agrees to such change in writing and in its sole discretion, Par has agreed to pay all costs and expenses in connection with implementing such change (after having received an accurate estimate thereof, including any documentation in reasonable support thereof) and the Parties have documented agreement to such change pursuant to a written change order. All executed change orders will be subject to the terms and conditions of this Agreement.

The Parties shall communicate with one another, on an ongoing basis, developments that may reasonably affect the timing of any Authorized Generic Launch.

3.1.4 Any terms and conditions of an invoice, Order, acknowledgement or similar document provided by Sucampo or Par to another Party for the Product that are inconsistent with the terms of this Agreement shall be null and void.

3.2 Rolling Forecasts. Beginning no less than [...***...] ([...**...]) days before the scheduled Authorized Generic Launch (provided that Sucampo has provided Par with notice of the License Launch Date) and within [...***...] ([...***...]) business days prior to the last day of each Calendar Quarter thereafter during the Term, Par shall deliver to Sucampo a written rolling [...***...] ([...***...]) month forecast (or, if shorter, a forecast for the remainder of the Term) of its anticipated requirements for the Product for the [...***...] ([...***...]) month period beginning on the first day of the following month or, in the case of each forecast prior to an Authorized Generic Launch, the [...***...] ([...***...]) months following such Authorized Generic Launch (the "Forecast Period"). The Product supply requirements specified for the first [...***...] ([...***...]) months of the Forecast Period of any rolling forecast provided to Sucampo (such [...***...]) months, the "Firm Order Period") shall be a firm order from Par for such quantity of Product and Par will be obligated to submit an Order for, and purchase and take delivery of such quantity of Product. If Par does not timely submit an Order for the Product supply requirements for any Firm Order Period pursuant to the terms of this Agreement, the most recent forecast covering such Firm Order Period shall be deemed to be, and shall be, an Order for such amount. All months of the Forecast Period of any rolling forecast provided to Sucampo, other than the Firm Order Period therein, will set forth Par's good faith estimate of its Product supply requirements, and the Product supply requirements for months [...***...] ([...***...]) through [...***...]) of each Forecast Period will not be binding. The rolling forecast for months [... ***...] ([...***...]) through [...***...] ([...***...]) of each Forecast Period shall not increase or decrease in the following forecast in the aggregate by more than [... ***...] percent ([...***...]%) on a month-to-month basis or more than [...***...] percent ([...***...]%) on a year-to-year basis ("**Permitted Variance**"); provided that any increases or decreases greater than [...***...] percent ([...***...]%) or [...***...] percent ([...***...]%), as applicable, may, in each case, be accepted by Sucampo on a case-by-case basis in its sole discretion. For example, a rolling forecast delivered [...***...] business days prior to [...***...] would be for Par's Product supply requirements for [...***...] through [...***...], and the Product supply requirements specified for the Firm Order Period of such forecast (i.e. [...***...] to [...***...]) shall be binding. Par shall use Commercially Reasonable Efforts to ensure that the Product supply requirement for months [...***...] ([...***...]) through [...***...] ([...***...]) of the Forecast Period under each of its forecasts are accurate. Each forecast shall also specify, for each month of the Forecast Period and consistent with the quantity limitations set forth in this Section 3.3, Par's anticipated delivery requirements for such month, including the quantity (by SKU, Packaging and size of Product), the corresponding delivery date, and the delivery location. For purposes of clarity, for each forecast delivered before the Authorized Generic Launch, it is anticipated that the only amounts expected to be forecast for delivery before Authorized Generic Launch shall be the initial order (or the expected initial order) to be made pursuant to Section 3.3.

- 3.3 Initial Order. Par shall place an Order for the first month to be used for an Authorized Generic Launch, including the quantity (by SKU, Packaging and size of Product), contemporaneously with an initial forecast provided under Section 3.2 approximately one hundred twenty (120) days before the scheduled Authorized Generic Launch of the Product.
- 3.4 Future Orders. On or about the first business day of each month, Par shall submit to Sucampo an Order that (a) specifies those quantities that Par is obligated to purchase for that month pursuant to the Rolling Forecast, subject to the Permitted Variances as set forth in Section 3.2 above, (b) identifies the ordered Product by SKU, Packaging and size of Product, and (c) specifies the delivery date(s) and delivery location(s) for Product, in each case consistent with terms and conditions of this Agreement and, subject to the Permitted Variances, the applicable quantities in the Firm Order Period. The Product supply requirements for the Firm Order Period of any Forecast Period shall not exceed one hundred percent (100%) of the aggregate amounts set forth in the most recent previous forecast for the same six (6) calendar months; provided, however, that notwithstanding the foregoing, (i) Sucampo shall have no firm obligation to supply any amounts in any particular month in excess of the amount forecasted for such month in any Firm Order Period plus the Permitted Variance but shall use Commercially Reasonable Efforts to supply such additional amounts above such Permitted Variance, and (ii) Sucampo shall use

Commercially Reasonable Efforts to notify Par within fifteen (15) business days of receipt of any Order where the total quantity of Product ordered for a particular month exceeds the amounts forecasted plus the Permitted Variance, whether and/or to what extent it accepts and is able to deliver such additional amounts to Par.

3.5 Shipment and Delivery. Sucampo shall deliver all amounts ordered by Par pursuant to Orders in conformance with the forecast provisions set forth in Sections 3.2 and 3.4 and other terms and conditions of this Agreement to Par within fifteen (15) days of the delivery date specified in the applicable Order. Sucampo shall notify Par if Sucampo believes that it will not be able to deliver the ordered amounts in accordance with the terms set forth in Sections 3.1 and 3.2, and the Parties will thereafter confer in good faith to resolve any delivery issues. Delivery of Product shall be CIP (Incoterms 2012) Sucampo or its contractor's facility. The quantity of Product actually delivered with respect to each accepted Order shall not exceed a range of minus two percent (2%) up to plus five percent (5%) of the quantity of the Product specified in the Order, unless otherwise agreed to in writing by Par. Delivery documents shall include the applicable Order, quantity, copy of the Certificate of Analysis, Certificate of Product Conformance, items codes and description, lot number, expiry date of Products, number of shippers, weight, and number of pallets. Title and risk of loss shall pass to Par at the time the goods are delivered to Par or its designee at Sucampo or its Third Party contractor's facility in accordance with this Section 3.5, and Par shall assume all responsibility for all costs associated with the goods upon such delivery.

3.6 Acceptance and Rejection of Product.

- **3.6.1** Sucampo shall have fifteen (15) business days from receipt of an Order from Par to reject or propose to modify an Order. Sucampo may only reject an Order that (a) lists products that are not covered by this Agreement, or (b) that is in excess of, or less than, the amount forecasted for a particular month in any Firm Order Period plus or minus the Permitted Variance permitted by Sections 3.1.2 and 3.2.
- 3.6.2 Par may reject any shipment, or portion of a shipment, of Product as defective if the applicable Product contains a Patent Defect or Latent Defect. Par shall deliver written notice of any such rejection (a "Rejection Notice") to Sucampo (i) in the case of Patent Defects within thirty (30) days after actual receipt of the Product by Par or Par's designee, and (ii) in the case of Latent Defects promptly and in any event within thirty (30) days after the date that Par discovers such Latent Defect; provided, however, that in no event shall Par be entitled to deliver a Rejection Notice in respect of a Latent Defect in respect of any Product more than one hundred twenty (120) days following delivery of such Product to Par or Par's designee in accordance with Section 3.5 Any such Rejection Notice shall state in reasonable detail the reason why Par believes such Product contains a Patent Defect or Latent Defect and shall include a sample of the Product being rejected and copies of written reports relating to tests, studies or investigations performed to date by or on behalf of Par on the Product being rejected.

- 3.6.3 Par's test results or basis for rejection shall be conclusive, unless Sucampo notifies Par in writing, within thirty (30) days of receipt by Sucampo of the Rejection Notice that Sucampo disagrees with such test results or basis for rejection (an "Objection Notice"). If Sucampo and Par fail, within ten (10) business days after delivery of the Objection Notice to Par, to agree as to whether the Product identified in the Rejection Notice is defective, representative samples of the batch of Product in question shall be submitted to a mutually acceptable qualified and reputable independent laboratory or consultant for analysis or review and a determination shall be made by such independent laboratory or consultant within thirty (30) days of such submission unless otherwise agreed by both Parties in writing. The results of such evaluation shall be binding upon the Parties. The Parties shall share equally the out-of-pocket cost of such evaluation, except that (a) if such independent laboratory or consultant determines that the Product shipment in question did not contain a Patent Defect or a Latent Defect, Par will: (i) be responsible for and pay any out-of-pocket costs and expenses of: (x) shipping the Product samples to Sucampo and shipping the Product to and from the independent laboratory or consultant in connection with that determination and (b) if such independent laboratory or consultant confirms that such Product shipment did contain a Patent Defect or a Latent Defect, Sucampo will: (i) be responsible for and pay the out-of-pocket costs and expenses of: (x) Par's shipping the Product samples to Sucampo and shipping the Product to and from the independent laboratory and consultant and (y) any analysis and review of such independent laboratory or consultant and (ii) promptly reimburse Par for any out-of-pocket amounts previously paid for shipping or to the independent laboratory or consultant in connection with that determination.
- **3.6.4** If any shipment of Product is rejected by Par in accordance with Section 3.6.2, Par's duty to pay any and all amounts payable to Sucampo in respect of such shipment shall be suspended, unless and until there is a determination by the independent laboratory or consultant in support of Sucampo's Objection Notice in accordance with Section 3.6.3. If only a portion of a shipment is rejected, Par's duty to pay shall be suspended only as to the rejected portion thereof.
- 3.6.5 If Sucampo or the independent laboratory or consultant confirms that a shipment or partial shipment of a Product contained a Patent Defect or a Latent Defect pursuant to the provisions of this Section 3.6, Par shall return to Sucampo, at Sucampo's request and expense (or, at the election and expense of Sucampo, destroy and provide evidence of such destruction to Sucampo), any such available rejected Product. Sucampo will bear all of Par's reasonable direct and documented out-of-pocket expenses of such return or destruction. In the event that the Product contained a Patent Defect or Latent Defect, Sucampo shall also (i) credit the original invoice or, upon any expiration or termination of this Agreement, refund Par in respect of the amounts actually paid and received by Sucampo for such defective Product, and (ii) adjust the invoice to Par to reflect the amount of the Product that was not rejected, payment of which is due in accordance with the terms of this Agreement. The remedies available to Par under Section 3.6.3 and this 3.6.5 (and any deductions permitted in connection with any royalties payable under the License Agreement) shall be Par's sole and exclusive remedy, and Sucampo's sole liability, under this Agreement in respect of any Patent Defect or Latent Defect of the Product.

3.6.6 During the pendency of any rejection discussions, upon Par's request, Sucampo shall use Commercially Reasonable Efforts to promptly, but in no event sooner than ninety (90) days from the date of the Rejection Notice and subject to the Permitted Variance set

forth in Section 3.2 above, supply Par with additional Product in an amount equal to the quantity of Product that is the subject of the rejection discussions.

3.7 Continuity of Supply. In the event there is a short supply of the Product, including if Sucampo's Third Party contract manufacturer is unable to supply the Product, Sucampo shall use Commercially Reasonable Efforts to allocate available Product to Par in each month that such short supply exists (and in each month thereafter during the period of any short supply) in an amount of the Product equal to the factor obtained by multiplying (a) the amount of available Product for that month by (b) a fraction, (i) the numerator of which is the aggregate of firm Orders made by Par over the immediately prior twelve (12) month period (or such shorter period if Par has purchased Product for less than twelve (12) months) and (ii) the denominator of which is the sum of (x) the aggregate quantity of firm Orders made by Par over the immediately prior twelve (12) month period (or such shorter period) and (y) the aggregate quantity of any product comprising the API (whether as a sole active ingredient or in combination with one or more other active ingredients) purchased by other of Sucampo's internal and external customers over the same twelve (12) month period (or such shorter period); provided, however, that any failure of Sucampo to supply Par during the period of any supply constraint shall not be, and shall not be deemed to be, a breach of this Agreement.

ARTICLE 4. COMMERCIAL FINANCIAL PROVISIONS

- **4.1 Product Supply Price.** Sucampo shall provide to Par an invoice for the Product Supply Price for such units of Product supplied hereunder upon delivery thereof in accordance with Section 3.5. Par shall pay such invoiced amounts within forty-five (45) days after the date that Sucampo delivers such invoice.
- **4.2 Direct Manufacturing Costs and Product Supply Price.** The Parties shall confer every year on the anniversary of the Authorized Generic Launch to review and discuss the Product Supply Price in light of changes in material, direct costs and competitive market conditions; provided, however, that (a) in the event the Parties do not agree to any adjustments in the Product Supply Price, [...***...] and (b) notwithstanding the foregoing, Sucampo shall have the right, in its sole discretion, to adjust its Direct Manufacturing Costs to the extent affected by (i) changes in material costs, including, but not limited to, API, excipients and other raw materials, Packaging and Labeling materials; and (ii) other substantial changes in manufacturing and testing costs, each of which types of changes (clause (i) and/or (ii)) is substantiated through written records provided to Par prior to reflecting such changes in the Product Supply Price.
- 4.3 Taxes. Par shall be solely responsible for, and shall pay, all taxes (including but not limited to sales, use, value-added and withholding taxes), customs and excise duties, and import or export tariffs with respect to the sale, disposition, importation or use of the Product (including with respect to the delivery of Product to Par hereunder and the sale by Par of such Products to Third Parties). All amounts payable hereunder by Par to Sucampo shall be paid without deduction or withholding for or on account of any present or future tax, levy, impost, fee, assessment, deduction or charge by any taxing authority, unless otherwise required by Applicable Law. If Par is required by Applicable Law to deduct or withhold any taxes, levies, imposts, fees, assessments, deductions or charges from or in respect of any amount payable hereunder to Sucampo, (a) Par shall pay the relevant taxation authority the minimum amount necessary to comply with the Applicable Law and (b) Par shall make such payment prior to the date on which interest or penalty is attached thereto.

4.4 Sucampo Records and Audit. Sucampo, and its Affiliates, shall keep and maintain or cause to be maintained books and records pertaining to the Product Supply Price and the calculation of Direct Manufacturing Costs for the period of time required by Applicable Laws, or if there is no period of time specified by such Applicable Laws, for three (3) years following the respective dates of records. Such books and records shall be maintained in accordance with GAAP and with all records and details reasonably necessary to enable Par to verify the foregoing. All factors included in the determination of the Product Supply Price shall be specific to the Product, fully documented, and available for independent audit purposes. Par shall have the right once per calendar year, at its own expense, during the Term and for a period of six (6) months thereafter, to have an independent public accountant, acceptable to Sucampo acting reasonably, audit the relevant financial books and records of account of Sucampo only pertaining to the provision of this Agreement during normal business hours, upon reasonable advance notice, solely to determine or verify the Product Supply Price; provided that in no event will Par or the independent public accountant be entitled to review or have access to any information subject to a confidentiality obligation by Sucampo to a Third Party (including any confidential documentation or pricing related to the Third Party contract manufacturer). All results of such review and audit shall be the Confidential Information of Sucampo. If errors or discrepancies in the Product Supply Price are found, any deficiency shall be paid immediately, and if errors or discrepancies exceeding the greater of [...***...] percent ([...***...]%) of the total amount payable under the applicable Order and [...***...] Dollars (\$[...***...]) for the period audited in Par's favor are discovered as a result of such audit, Sucampo shall reimburse Par for the reasonable out-of-pocket expense of such audit.

ARTICLE 5. OTHER AGREEMENTS

- **5.1 Product Warranties.** Sucampo hereby represents, warrants, covenants and agrees that:
- 5.1.1 all Product that is delivered to Par by Sucampo hereunder, as and in the form delivered to Par, but excluding ay Labelling or Packaging texts or other Labelling or Packaging information specified or provided by or for Par for the Product, shall: (a) materially comply with the Product Specifications, and (b) materially conform with the information shown on the Certificate of Analysis and Certificate of Product Conformance provided with any particular shipment of Product;
- 5.1.2 no Product that is delivered to Par by Sucampo hereunder, as and in the form delivered to Par, shall be adulterated or misbranded within the meaning of Applicable Law, as amended and in effect at the time of shipment; provided, however, that this paragraph shall not apply to, and Sucampo shall have no responsibility for, misbranding caused by Par as a result of Labelling or Packaging texts or other Labelling or Packaging information specified or provided by or for Par for the Product; and Sucampo shall have no responsibility for issues of regulatory and legal compliance that are the responsibility of Par, including but not limited to ensuring that the Product is stored and distributed in the Territory in a manner that does not result in its becoming adulterated, misbranded, or otherwise in violation of Applicable Laws; and

5.1.3 at the time of delivery to Par, the Product shall have a minimum shelf life of at least either percent ([...***...]%) of the shelf life set forth in the Product Specifications if the order therefor is for a minimum number of Product units of [...***...] ([...***...]) bottles.

5.2 Recall.

- 5.2.1 In the event that any Party believes reasonably and in good faith that it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to the Product (a "Recall"), such Party shall promptly notify the other and Sucampo and Par shall promptly consult with each other as to how best to proceed, it being understood and agreed that no Party shall be prohibited hereunder from taking any action that it is required to take by Applicable Law. In addition to and not in lieu or limitation of the foregoing, in the event that Sucampo and Par are unable to agree whether or not to voluntarily implement a Recall of the Product in the Territory, notwithstanding anything herein to the contrary, Sucampo shall make the final determination.
- **5.2.2** In the event of any Recall of the Product in the Territory, each Party shall provide, and cause its Affiliates to provide, any and all information, assistance and support required by Applicable Law in the Territory, or reasonably requested by the other Party; provided that for clarification, Par shall be responsible for initiating such Recall after the final determination is made that a Recall should be implemented in accordance with Section 5.2.1 above.
- 5.2.3 The cost of any Recall of Product manufactured under this Agreement, including expenses and other costs or obligations of Third Parties, the cost and expense of notifying customers, the costs and expenses associated with the Recall of the Product in the Territory and the cost and expenses of destroying the Product recalled from such Territory, if necessary, shall be borne solely by Par except to the extent that the Recall was caused by (a) Sucampo's failure to comply with the warranties in Section 5.1 to the extent that the defect that resulted in the Recall existed prior to delivery to Par, or (b) Sucampo's sole determination to implement a voluntary Recall after the Parties are unable to agree on a Recall and it is later determined that the Recall was unnecessary, or (c) in the event that a Recall is required by any Governmental Authority, in which case Sucampo shall be responsible for any direct, documented out-of-pocket costs and expenses for such Recall to the extent that such Recall was conducted pursuant to clause (a), (b) or (c) of this Section 5.2.3. To the extent that one Party incurs out-of-pocket expenses in connection with a Recall that is required to be at the sole expense of the other Party under this Section 5.2 (the "Responsible Party"), the Responsible Party shall pay that Party's documented reasonable out-of-pocket expenses within thirty (30) days of receiving an invoice therefor.
- 5.3 Quality Agreement. Within ninety (90) days from the Effective Date, the Parties shall enter into an agreement that details the quality assurance obligations of each Party (the "Quality Agreement"). Notwithstanding the foregoing, the Quality Agreement, nor the absence of a Quality Agreement, shall affect the rights and obligations of the Parties in this Agreement, and this Agreement shall govern in the event of any inconsistencies between the Quality

Agreement and this Agreement (unless expressly provided otherwise in the Quality Agreement). The Parties shall amend the Quality Agreement from time to time as the Parties deem necessary. If the Parties enter into a Quality Agreement, all Product supplied to Par shall be supplied in accordance with the Quality Agreement (as well as this Agreement).

ARTICLE 6. AUDITS AND INSPECTION RIGHTS

- 6.1 Inspections by Governmental Authorities. During the Term, each Party shall promptly notify the other Party in writing of (i) any Governmental Authority visits to facilities that manufacture, store, transport or handle the Product, or (ii) written inquiries about any procedures for the manufacture, storage, transportation, or handling of the Product, in either case of which it becomes aware. The Party subject to the visits or inquiries shall furnish written notice thereof and a summary of the interaction with such Governmental Authority to the other Party within a reasonable time period after receipt of any report or correspondence issued by or provided to the Governmental Authority in connection with such visit or inquiry. Each Party shall, if applicable, permit the relevant Governmental Authorities to inspect their facilities and records in connection with the activities contemplated by this Agreement.
- 6.2 Inspections by Par. Sucampo shall permit Par, or cause Par to be permitted, to inspect the applicable manufacturing facility for the Product for regulatory or quality control purposes only at reasonable times during normal business hours, provided that Par gives Sucampo as much advance written notice as possible and, in any event, not less than thirty (30) days' prior written notice and the inspection by Par shall be within the scope of inspection that is allowed under Applicable Law. During any such inspection, and subject to all Applicable Laws, Sucampo shall permit, or cause to be permitted, Par or its authorized representatives to (i) inspect the manufacturing facilities, (ii) inspect the quality control procedures and/or (iii) review any records and reports pertinent to the manufacture, disposition or transport of the Product, as may be necessary to evidence material compliance with all applicable regulations in connection with activities associated with the Product, including without limitation, material compliance with cGMP; provided that in no event will Par be entitled to review or have access to any information subject to a confidentiality obligation to a Third Party. All results of such inspection shall, as and between the Parties, be the Confidential Information of Sucampo.

ARTICLE 7. INTELLECTUAL PROPERTY AND TECHNOLOGY

- 7.1 General Ownership. Sucampo shall retain sole ownership of any and all Intellectual Property and Technology developed or conceived by or for Sucampo, whether solely and independently or jointly with others, that is related to or associated with the Product, including any and all improvements or modifications to any of the foregoing.
- 7.2 Cooperation. Each Party shall promptly notify the other Party of any potential infringement of Intellectual Property rights of a Third Party by the making, using or selling of the Product in the Territory, as it may become aware of such potential infringement, and to cooperate in addressing such potential infringement issues upon the reasonable request of the other Party. Each Party shall also promptly notify the other of any potential infringement of Sucampo's Intellectual Property rights or Sucampo's Technology related to or associated with the Product, including any notice, suit, or threatened suit, by a Third Party as it may become aware of such infringement, and to cooperate in addressing such infringement issues upon the reasonable request of the other Party. In the event of any such infringement, Sucampo and its Affiliates shall have the right and option to initiate or defend legal proceedings, through counsel of its choosing, or take other reasonable steps in good faith regarding such infringement and, to the extent reasonably practicable and subject to Applicable Law, in reasonable consultation with Par. To the extent reasonably practical and subject to Applicable Law, Sucampo shall use Commercially Reasonable Efforts to inform and reasonably consult with Par in advance of any due dates; provided, however, Sucampo and its Affiliates shall make the final decision as to the enforcement or defense strategy.

ARTICLE 8. CONFIDENTIALITY AND PUBLIC DISCLOSURE

8.1 Confidential Information.

- **8.1.1** No Receiving Party shall disclose to any Third Party (other than its outside counsel and applicable Affiliates or, in the case of Sucampo, its applicable Third Party contractor, in each of the foregoing cases, who have a need to know and who are bound by written obligations of confidentiality and non-use at least as protective of the Confidential Information of the Disclosing Party as those contained herein) any Confidential Information of any Disclosing Party received hereunder or use any such Confidential Information for its own benefit or otherwise, except as necessary to fulfil its obligations hereunder, without the written consent of the Disclosing Party. Each Receiving Party shall protect Confidential Information received from a Disclosing Party with at least the same degree of care that it uses to protect its own proprietary and confidential information, but no less than reasonable care under the circumstances.
- **8.1.2** Without limitation to Section 8.1.1, each Receiving Party shall bind all persons having access through it to any Confidential Information of the Disclosing Party to written obligations of confidentiality and non-use at least as protective of the Confidential Information of the Disclosing Party as those contained herein. Each Receiving Party will be responsible for the acts and omissions of any officer or employee of such Receiving Party, Affiliate of such Receiving Party or other Third Party receiving the Confidential Information from such Receiving Party with respect to such confidentiality and non-use obligations.
- **8.1.3** Each Receiving Party, at the request of the Disclosing Party, shall return or destroy all Confidential Information of the Disclosing Party disclosed to it hereunder, in whatever form contained, including all notes or memoranda made by its employees, agents, or representatives obtained or derived from any such Confidential Information, except that one copy of the Confidential Information may be retained by each Receiving Party's general counsel to maintain a record of the same solely to the extent required to comply with any Applicable Laws pertaining to its activities under this Agreement; provided that such copy shall continue to be subject to the confidentiality and non-use obligations set forth in this Article 8.

- **8.2 Required Disclosures.** Notwithstanding anything to the contrary in this Agreement, the Parties understand and agree that any Party, as the Receiving Party of Confidential Information from the Disclosing Party, may, if so required, disclose some or all of the information included in this Agreement or other Confidential Information of the Disclosing Party (i) in order to comply with its obligations under law, including the United States Securities Act of 1933, the United States Securities Exchange Act of 1934, and the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market or other similar laws of a Governmental Authority, (ii) to respond to an inquiry of a Governmental Authority, or (iii) in connection with a judicial, administrative or arbitration proceeding. In any such event the Receiving Party making such disclosure shall (A) provide the Disclosing Party with as much advance notice as reasonably practicable of the required disclosure, (B) cooperate with the Disclosing Party in any attempt to prevent or limit the disclosure, and (C) limit any disclosure to the specific purpose at issue.
- **8.3 Press Release.** Each Party shall have the right to issue press releases related to this Agreement, <u>provided</u> that the issuing Party provides the other Parties with a written draft of the proposed press release not less than three (3) business days prior to the issuance and considers in good faith and incorporates, to the extent reasonable, any revisions requested and comments made by the non-issuing Parties; <u>provided, however</u>, that nothing herein shall interfere with a Party's disclosure obligations under applicable laws, including the United States Securities Act of 1933, the United States Securities Exchange Act of 1934, and the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market or other similar laws of a Governmental Authority. Nothing herein shall limit a Party's ability to make comments on a press release or announcement that are consistent with such press release or announcement.

ARTICLE 9. REPRESENTATIONS AND WARRANTIES

- **9.1 Par Representations.** Par hereby represents, warrants and covenants that:
 - 9.1.1 Par is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation;
- **9.1.2** Par has the corporate power and authority to enter into and be bound by the terms and conditions of this Agreement and to perform its obligations hereunder and to execute this Agreement on behalf of itself and its Affiliates and to so bind itself and its Affiliates to the terms and conditions of this Agreement;
- 9.1.3 Par has taken all necessary action on its part to authorize the execution and delivery of this Agreement and this Agreement has been duly executed and delivered on behalf of Par and its Affiliates and constitutes a legal, valid, binding obligation, enforceable against Par and its Affiliates in accordance with its terms;
- **9.1.4** Par is subject to no legal, contractual or other restrictions, limitations or conditions which conflict with its rights and obligations under this Agreement or which would reasonably be expected to affect adversely its ability to perform hereunder; and
- 9.1.5 Par is not prohibited by any Applicable Law from selling the Product or other pharmaceutical products within the Territory, and Par and Par's employees have never been (i) debarred or (ii) convicted of a crime for which a person can be debarred, under Section 306(a) or (b) of the Generic Drug Enforcement Act (the "GDEA") or (iii) threatened to be debarred or (iv) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under Section 306(a) or (b) of the GDEA; and Par shall promptly notify Sucampo upon learning of any such debarment, conviction, threat or indictment and shall take all appropriate action.

- **9.2** Sucampo Representations. Sucampo hereby represents, warrants and covenants that:
 - 9.2.1 Sucampo is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation;
- **9.2.2** Sucampo has the corporate power and authority to enter into and be bound by the terms and conditions of this Agreement and to perform its obligations hereunder;
- **9.2.3** Sucampo has taken all necessary action on its part to authorize the execution and delivery of this Agreement and this Agreement has been duly executed and delivered on behalf of Sucampo and constitutes a legal, valid, binding obligation, enforceable against Sucampo in accordance with its terms;
- **9.2.4** Sucampo is subject to no legal, contractual or other restrictions, limitations or conditions which conflict with its rights and obligations under this Agreement or which would reasonably be expected to affect adversely its ability to perform hereunder; and
- 9.2.5 Sucampo is not prohibited by any Applicable Law from selling the Product or other pharmaceutical products within the Territory, and Sucampo and Sucampo's employees have never been (i) debarred or (ii) convicted of a crime for which a person can be debarred, under Section 306(a) or (b) of the GDEA or (iii) threatened to be debarred or (iv) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under Section 306(a) or (b) of the GDEA; and Sucampo shall promptly notify Par upon learning of any such debarrent, conviction, threat or indictment and shall take all appropriate action.
- 9.3 Warranty Disclaimer. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT OR THE LICENSE AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT, ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY EXPRESSLY AND SPECIFICALLY DISCLAIMS ALL WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

9.4 Limited Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, EXCEPT WITH RESPECT TO EACH PARTY'S INDEMNIFICATION OBLIGATIONS SET FORTH IN ARTICLE 10, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, (I) NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, LOST PROFITS OR LOST REVENUES, OR COST AND EXPENSE OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY AND (II) EACH PARTY'S MAXIMUM AGGREGATE LIABILITY UNDER THIS AGREEMENT SHALL NOT EXCEED THE AGGREGATE AMOUNTS PAID AND PAYABLE OR DUE UNDER OR IN CONNECTION WITH THIS AGREEMENT IN THE TWELVE (12) MONTHS PRIOR TO THE INCIDENT GIVING RISE TO SUCH LIABILITY AND RELATED CAUSE OF ACTION.

ARTICLE 10. INDEMNIFICATION

- 10.1 Par Indemnification. Par shall at all times during the Term and thereafter indemnify, defend and hold Sucampo, and its Affiliates, and its Third Party contract manufacturer of the Product and their respective officers, directors, employees and agents, and the successors and permitted assigns of the foregoing (collectively, "Sucampo Parties"), harmless from and against all expenses, damages, costs and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys' fees, as a result of a Third Party claim, Third Party suit, or Third Party cause of action (collectively, "Losses") to the extent resulting from or arising out of (i) a material breach by Par of any representation, warranty, covenant, obligation or agreement of Par under this Agreement, (ii) a failure of Par, or its Affiliates, to comply with all Applicable Laws during the Term, (iii) the negligence or willful misconduct of Par, or (iv) the administration, use, Labeling, Packaging, sale, marketing, promotion, advertising, storage, handling, distribution and commercialization of the Product by Par, except, in each case (clause (i), (ii), (iii) or (iv)), for those Losses for which Sucampo has an obligation to indemnify the Par Parties pursuant to Section 10.2, as to which Losses Sucampo shall indemnify Par Parties to the extent of its respective liabilities for such Losses.
- 10.2 Sucampo Indemnification. Sucampo shall at all times during the Term and thereafter indemnify, defend and hold Par and its officers, directors, employees and agents, and the successors and permitted assigns of the foregoing (collectively, "Par Parties"), harmless from and against any and all Losses to the extent resulting from or arising out of (i) a material breach by Sucampo of any representation, warranty, covenant, obligation or agreement of Sucampo under this Agreement, (ii) a failure of Sucampo, or its Affiliates, to comply with all Applicable Laws during the Term, or (iii) Product that does not meet the Product Specifications or (iv) the negligence or willful misconduct of Sucampo, except, in each case (clause (i), (ii), (iii) or (iv)), for those Losses for which Par has an obligation to indemnify the Sucampo Parties pursuant to Section 10.1, as to which Losses Par shall indemnify Sucampo Parties to the extent of its respective liabilities for such Losses.

- 10.3 Notice and Procedures. If a Par Party or Sucampo Parties (the "Indemnitee") intend to claim indemnification under this Article 10, it shall promptly notify the other Party (the "Indemnitor") in writing of any such Losses. In the event that the Indemnitor does not assume and pursue in a timely and diligent manner the defense of any Third Party claim (but in no event later than thirty (30) days, or such shorter period as required under Applicable Laws), then the Indemnitor shall be deemed to have ceded control of such claim and the Indemnitee shall be entitled to appoint counsel of its own choice for such defense, at the cost and expense of the Indemnitor. In the event that the Indemnitor assumes such defense, the Indemnitor shall have the right to control the defense of such claim with counsel of its choice; and provided further that any Indemnitee shall have the right to retain its own counsel at its own expense, for any reason, including if representation of any Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other Party reasonably represented by such counsel in such proceeding. The Indemnitee, and its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any Losses covered by this Article 10. The obligations of this Section 10.3 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the written consent of the Indemnitor (unless the Indemnitor is deemed to have ceded control of the applicable third Party claim under this Section 10.3). The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such claim, demand or action shall not relieve the Indemnitor of any obligation to the Indemnitee under this Section 10.3, unless and to the extent that the Indemnitor is materially prejudiced by such delay. Indemn
- 10.4 Other Product Liability Claims. To the extent that any Third Party asserts a claim or institutes a lawsuit based on a product liability claim with respect to the Product for which no Party has an indemnity obligation under Section 10.1 or 10.2 and subject to Section 10.4.2 below, Par shall have sole responsibility and control in addressing, defending, managing and conducting such claims or lawsuits, any related litigation and any settlement or settlement negotiations thereof (collectively, "Product Liability Litigation"), using counsel of their choice; provided, however, that (a) Par shall not settle any Product Liability Litigation without Sucampo's prior written consent, which consent shall not be unreasonably withheld or delayed and (b) if Sucampo is a named party in any Product Liability Litigation, Sucampo shall have sole responsibility and control in addressing, defending, managing and conducting such Product Liability Litigation using counsel of its choice. Each Party shall keep the other Party informed about all product liability claims and the controlling Party's plans to mitigate such claims.
- 10.4.1 At Sucampo's request, the Parties shall enter into a Joint Defense Agreement, including a waiver with such legal counsel (signed by Par) reflecting Sucampo's responsibility and right to control such Product Liability Litigation; provided that Sucampo shall not settle any such Product Liability Litigation without Par's prior written consent, which consent shall not be unreasonably withheld or delayed.
- 10.4.2 Each Party shall be solely liable for any settlement amounts that it agrees to pay or any damages that it is ordered to pay in order to resolve any Product Liability Litigation.
- 10.5 Exclusive Remedy. The rights of the Par Parties and the Sucampo Parties under this Article 10 shall be the sole and exclusive remedy of the Par Parties and the Sucampo Parties, as the case may be, with respect to matters covered hereunder.

ARTICLE 11. TERM AND TERMINATION

- 11.1 Term. Unless earlier terminated pursuant to the terms hereof, the term of this Agreement (the "Term") shall continue from the Effective Date until the date that is three (3) years following the Authorized Generic Launch. The Term of this Agreement may be renewed upon mutual written agreement on an annual basis thereafter. If it is not so renewed, it shall be deemed to have been expired without fault at the end of the applicable term, and the termination provisions relating thereto shall apply.
- 11.2 Termination for Breach. Any Party may terminate this Agreement, or suspend performance under this Agreement upon written notice to the other Parties at any time during the Term, if another Party is in material breach of the terms and provisions of this Agreement and such other Party has not cured such material breach within thirty (30) days after notice requesting cure of the breach; provided, however, that if such breach is not capable of cure within thirty (30) days, but is capable of cure, and the breaching Party has promptly commenced during such thirty (30) day period, and is and continues diligently pursuing in good faith the remedy of any such breach, then such cure period shall be extended for such period as may be reasonably required to effectuate such cure; provided further, however, that if such breach is not capable of cure, a non-breaching Party may terminate this Agreement, or suspend performance under this Agreement immediately by delivery of written notice thereof to such breaching Party.
 - 11.3 Termination Costs. In the event of termination by Sucampo under Section 11.2, Par shall pay the following cancellation charges:
- 11.3.1 for Product ordered by Par that has already been completely manufactured by Sucampo, one hundred percent (100%) of the Product Supply Price of the Product being cancelled and Par shall take delivery of all such Product in accordance with Section 3.5; and
- 11.3.2 for Product ordered by Par that has been cancelled prior to complete manufacture, (i) the cost of nonreusable raw materials on order which cannot be cancelled, despite Sucampo's Commercially Reasonable Efforts, that are unique to the ordered Product being cancelled, or not usable for orders of other customers of Sucampo, despite Sucampo's Commercially Reasonable Efforts, (ii) the cost of non-reusable raw material inventory ordered by Sucampo with regard to Par's issued Orders, including any work-in-progress, that are unique to the Product being cancelled, not returnable to the vendor, or not usable for orders of other customers of Sucampo, in each case, despite Sucampo's Commercially Reasonable Efforts, (iii) reasonable vendor cancellation charges incurred with respect to raw materials cancelled or returned to the vendor in respect of Product ordered by Par, and (iv) reasonable charges for nonrecurring services associated with work stoppage on Product ordered by Par.
- 11.4 Accrued Rights and Surviving Obligations. The termination of this Agreement for any reason or expiration of the Term shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination or expiration, including any damages arising from any breach hereunder. Such termination or expiration shall not relieve any Party from obligations that are expressly indicated to survive such termination or expiration. Articles 1, 5, 6, 7, 8, 10, 12 and 13, and Sections 2.4, 3.6 and 4.1, 11.3 and this Section 11.4 and any other provisions necessary and proper to give effect to the intention of the Parties as to the effect of the Agreement after termination shall survive such termination or expiration.

ARTICLE 12. INSURANCE

12.1 Insurance.

- 12.1.1 Each Party shall, at its own cost and expense, obtain and maintain in full force and effect at all times during the Term, and for a period of three (3) years thereafter:
- (i) commercial general liability insurance covering bodily injury and property damage with limits of [...***...] Dollars ([...***...]) per occurrence and [...***...] Dollars ([...***...]) in the aggregate;
- (ii) products and completed operations liability insurance (including coverage for Product used in clinical trials) with limits of (i) [...***...] Dollars (\$[...***...]) per occurrence and [...***...] Dollars (\$[...***...]) in the aggregate prior to the Authorized Generic Launch and (ii) [...***...] Dollars (\$[...***...]) per occurrence and [...***...] Dollars (\$[...***...]) in the aggregate upon the Authorized Generic Launch;
- (iii) workers compensation with statutory limits as required by law and employers liability insurance with a limit of [...***...] Dollars (\$[...***...]) per accident; and
- (iv) commercial automobile liability insurance covering owned, hired and non-owned vehicles, and covering uninsured and underinsured motorists, with limits of [...***...] Dollars (\$[...***...]) combined single limit (bodily injury and property damage).
- 12.1.2 All of the foregoing insurance policies shall be obtained from an insurance carrier or carriers having a current A.M. Best rating of at least A-Class VIII.
- 12.1.3 Upon execution of this Agreement and annually thereafter, each Party shall provide the other Parties with a certificate of insurance evidencing such coverage and including such other Parties and its Affiliates as additional insureds. Each Party shall provide the other Parties with written notice within thirty (30) days' of any material change in the terms or coverage of such insurance policies or their lapse, cancellation or termination.
- 12.1.4 All insurance policies obtained by any Party pursuant to this Agreement shall be primary and not contributing to any other insurance, self-insurance or captive insurance maintained by another party to the extent of such Party's indemnification obligations hereunder; provided, however, that notwithstanding the foregoing, the insurance policies required under Section 12.1.1 shall not be construed to limit either Party's liability with respect to its indemnification obligations under this Agreement.

ARTICLE 13. MISCELLANEOUS

- 13.1 Interpretation and Construction. Unless the context of this Agreement otherwise requires, (i) the terms "include," "includes," or "including" shall be deemed to be followed by the words "without limitation" unless otherwise indicated; (ii) the terms "hereof,"
- "herein," "hereby," and derivative or similar words refer to this entire Agreement; and (iii) the terms "Article" and "Section" and refer to the specified Article and Section of this Agreement. Whenever this Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days. The headings and paragraph captions in this Agreement are for reference and convenience purposes only and shall not affect the meaning or interpretation of this Agreement. This Agreement shall not be interpreted or constructed in favor of or against either Party because of its effort in preparing it.
- 13.2 Independent Contractor Status. It is understood and agreed that nothing in this Agreement nor any agreements related hereto is intended to nor shall create a partnership between the Parties. The Parties are independent contractors and are engaged in the operation of their own respective businesses, and no Party is to be considered the agent, partner, joint venturer or employee of another Party for any purpose whatsoever and no Party shall have any authority to enter into any contracts or assume any obligations for another Party nor make any warranties or representations on behalf of that other Party.
- 13.3 Performance by Affiliates. The Parties recognize that each Party may perform some or all of its obligations under this Agreement through one (1) or more of its Affiliates; provided, however, that each Party shall remain responsible for and shall guarantee such performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Each Party hereby expressly waives any requirement that another Party exhaust any right, power or remedy, or proceed against an Affiliate for any obligation or performance hereunder prior to proceeding directly against such Party.
- 13.4 Waiver. The waiver by any Party of a breach of any provision contained herein shall be in writing and shall in no way be construed as a waiver of any succeeding breach of such provision or the waiver of the provision itself.
- 13.5 Assignment. This Agreement shall be binding upon and inure to the benefit of each of the Parties hereto and their respective successors and approved assigns; provided, however, that no Party may assign or transfer this Agreement whether by operation of law or otherwise without the prior written consent of the other Parties, except that no consent shall be required if such assignment or transfer is (i) to an Affiliate or (ii) in connection with a merger or acquisition or sale of all or substantially all of the assets of the assigning Party. Any assignment or transfer in contravention of this Agreement shall be null and void *ab initio*.
 - 13.6 Modification. This Agreement may not be changed, modified, amended or supplemented except by an express written instrument signed by all Parties.
- 13.7 Severability. If any provision of this Agreement shall be held illegal or unenforceable, that provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.
- 13.8 Further Assurances. Each Party hereto agrees to execute, acknowledge and deliver such further instruments and documents, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

- 13.9 Use of Party's Name. Except as required by Applicable Laws or as to Labeling activities, no right, express or implied, is granted by this Agreement to any Party to use in any manner the name of the other or any other trade name or trademark of the other in connection with the performance of this Agreement. For clarity, it is understood that nothing herein shall prohibit either Party from using the name of another Party (i) in certain of such Party's disclosure documents, including those filed or disclosed in order to comply with its obligations under Applicable Laws or the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market or other similar laws of a governmental authority, (ii) to respond to an inquiry of a Governmental Authority, or (iii) in a judicial, administrative or arbitration proceeding, or from disclosing the fact that it has granted or obtained a license to any Intellectual Property of the other Party so long as such use of the other's name is limited to statements of fact and is not done in a manner to suggest or imply endorsement by the other Party.
- 13.10 Notices. Any notice or other communication to be given under this Agreement by any Party to any other Party shall be in writing and shall be either (a) personally delivered, (b) mailed by registered or certified mail, postage prepaid with return receipt requested, (c) delivered by overnight express delivery service or same-day local courier service, or (d) delivered by telex or facsimile transmission (followed by a copy by the preceding (a), (b) or (c)), to the address of the applicable Party as set forth below, or to such other address as may be designated by the Parties from time to time in accordance with this Section 13.10. Notices delivered personally, by overnight express delivery service or by local courier service shall be deemed given as of actual receipt. Mailed notices shall be deemed given five (5) business days after mailing. Notices delivered by telex or facsimile transmission shall be deemed given upon receipt by the sender of the answerback (in the case of a telex) or transmission confirmation (in the case of a facsimile transmission) if transmitted before 5:00 p.m. (recipient's local time) on a business day, and otherwise on the following business day.

If to Sucampo: Sucampo Pharmaceuticals, Inc.

4520 East West Highway, 3rd Flr.

Bethesda, MD 20814

Attn: Chief Legal Officer

Facsimile Number: (301) 961-3440

If to Par: Par Pharmaceutical, Inc.

300 Tice Boulevard

Woodcliff Lake, NJ 07677

Attention: General Counsel

Facsimile Number: (201) 802-4600

13.11 Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of New York. The Parties irrevocably agree that the State and Federal Courts located in New York shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this Agreement and that venue is proper in such Courts. Each Party hereby expressly consents and submits to the personal jurisdiction of Federal and State Courts in New York.

- 13.12 Equitable Relief. Par recognizes that the covenants contained in Articles 7 and 8 hereof are reasonable and necessary to protect the legitimate interests of Sucampo, that Sucampo would not have entered into this Agreement in the absence of such covenants, and that Par's breach or threatened breach of such covenants shall cause Sucampo irreparable harm and significant injury, the amount of which shall be extremely difficult to estimate and ascertain, thus, making any remedy at law or in damages inadequate. Therefore, Par agrees that Sucampo shall be entitled, without the necessity of posting of any bond or security, to the issuance of injunctive relief by any court of competent jurisdiction enjoining any breach or threatened breach of such covenants and for any other relief such court deems appropriate. This right shall be in addition to any other remedy available to Sucampo at law or in equity.
- 13.13 Force Majeure. A Party shall not be liable for nonperformance or delay in performance, except for defaulted obligations of payment, to the extent that and solely for so long as such nonperformance or delay in performance is caused by any event reasonably beyond the control of such Party, including wars, hostilities, revolutions, riots, civil commotion, national emergency, strikes, lockouts, unavailability of supplies, epidemics, fire, flood, earthquake, force of nature, explosion, terrorist act, embargo, or any other Act of God, or any law, proclamation, regulation, ordinance, or other act or order of any court, Governmental Authority (each, a "Force Majeure Event"). In the event of any such delay, the delayed Party may defer its performance for a period equal to the time of such delay, provided that the delayed Party gives the other Party written notice thereof promptly and, in any event, within thirty (30) calendar days of discovery thereof, and uses its good faith efforts to cure the excused breach. If either Party is unable to perform its obligations hereunder as a result of a Force Majeure Event for a period of three (3) months or greater, then the other Party shall have the right, upon its issuance of notice to the other Parties, to terminate this Agreement.
- 13.14 Entire Agreement. This Agreement and the License Agreement constitute the entire agreement between Par, on the one hand, and Sucampo, on the other hand, with respect to the subject matter hereof and supersedes all prior representations, understandings and agreements with respect thereto. In the event of any conflict between the terms of the License Agreement and this Agreement, the terms of the License Agreement will control.
- 13.15 Counterparts. This Agreement may be executed in one or more counterparts, including by transmission of facsimile or PDF copies of signature pages, each of which shall for all purposes are deemed to be an original and all of which shall constitute on instrument.
- 13.16 Third Party Beneficiaries. Except as provided in Section 10.1 and 10.2, (i) no term or provision of this Agreement is intended to be, or shall be, for the benefit of any Person (including any sub-contractor, or any individual member of the control group utilized for the bioequivalence studies) that is not a party hereto, and (ii) no such other Person shall have any right or cause of action hereunder.

13.17 Cumulative Rights. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law.
[Remainder of this page intentionally left blank]

[Signature Page of Manufacturing and Supply Agreement]

IN WITNESS WHEREOF, the Parties hereto have executed this Manufacturing and Supply Agreement to be effective as of the Effective Date.

SUCAMPO AG

By:

Name:
Title:

PAR PHARMACEUTICAL, INC.

By:

Name:
Title:

Name:
Title:

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*Confidential Treatment Requested

APPENDIX A

Description of Compound

Generic Name: unoprostone

Chemical names: [...***...]

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SUBSIDIARIES OF COMPANY

SubsidiaryState or other jurisdiction of incorporation or organizationSucampo Pharma Americas, LLCDelawareSucampo LLCDelawareSucampo AGSwitzerlandSucampo Pharma, LLCJapanSucampo Pharma Europe Ltd.United Kingdom

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-147420) and Form S-3 (Nos. 333- 185635 and 333- 201566) of Sucampo Pharmaceuticals, Inc. of our report dated March 9, 2015 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland March 9, 2015

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 9, 2015 /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, Andrew P. Smith, certify that:

- 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 9, 2015 /s/ Andrew P. Smith

Andrew P. Smith (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, 2014 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 9, 2015 /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, 2014 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 9, 2015 /s/ Andrew P. Smith

Andrew P. Smith

(Principal Financial Officer)