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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from to

Commission File Number: 001-33609

SUCAMPO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Title of each class	Name of each exchange on which registered
Class A common stock, par value $0.01	The NASDAQ Global Market

Delaware *(State or other jurisdiction of incorporation or organization)*	30-0520478 *(I.R.S. Employer Identification No.)*
4520 East-West Highway, 3rd Floor Bethesda, MD *(Address of principal executive offices)*	20814 *(Zip Code)*

(301) 961-3400
(Registrant's telephone number, including area code)

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

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

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

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

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

As of October 31, 2014, there were 44,349,465 shares of the registrant's class A common stock outstanding.

Sucampo Pharmaceuticals, Inc.

Form 10-Q Index

		Page
	Part I. FINANCIAL INFORMATION	
Item 1.	Financial Statements	1
	Condensed Consolidated Balance Sheets (Unaudited) as of September 30, 2014 and December 31, 2013	1
	Condensed Consolidated Statements of Operations and Comprehensive Income (Unaudited) for the Three and Nine months ended September 30, 2014 and 2013	2
	Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited) for the Nine months ended September 30, 2014	3
	Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine months ended September 30, 2014 and 2013	4
	Notes to Condensed Consolidated Financial Statements (Unaudited)	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	37
Item 4.	Controls and Procedures	38
	Part II. OTHER INFORMATION	
Item 1.	Legal Proceedings	39
Item 1A.	Risk Factors	39
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	39
Item 3.	Defaults Upon Senior Securities	39
Item 4.	Mine Safety Disclosures	39
Item 5.	Other Information	39
Item 6.	Exhibits	40
SIGNATURES		
INDEX TO EXHIBITS		

PART I — FINANCIAL INFORMATION

Item 1. ***Financial Statements***

SUCAMPO PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets (Unaudited)
(In thousands of U.S. dollars, except share data)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,087	$ 44,102
Investments, current	8,857	16,003
Product royalties receivable	16,811	14,829
Unbilled accounts receivable	2	1
Accounts receivable, net	8,453	5,407
Prepaid and income taxes receivable	3,678	9
Deferred tax assets, current	-	2,028
Deferred charge, current	377	673
Restricted cash, current	26,114	26,115
Inventory	133	209
Prepaid expenses and other current assets	3,550	3,977
Total current assets	124,062	113,353
Investments, non-current	13,046	7,219
Property and equipment, net	882	1,156
Intangible assets, net	157	6,438
Deferred tax assets, non-current	1,436	1,212
Deferred charge, non-current	2,261	4,540
Restricted cash, non-current	2,313	2,471
Other assets	461	488
Total assets	$ 144,618	$ 136,877
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,924	$ 7,614
Accrued expenses	7,160	5,682
Deferred revenue, current	2,047	1,365
Income tax payable	-	701
Notes payable, current	26,342	26,892
Other current liabilities	2,436	358
Total current liabilities	43,909	42,612
Notes payable, non-current	21,741	25,828
Deferred revenue, non-current	5,457	6,169
Deferred tax liability, non-current	343	2,066
Other liabilities	1,512	1,233
Total liabilities	72,962	77,908
Stockholders' equity:		
Preferred stock, $0.01 par value; 5,000,000 shares authorized at September 30, 2014 and December 31, 2013; no shares issued and outstanding at September 30, 2014 and December 31, 2013	-	-
Class A common stock, $0.01 par value; 270,000,000 shares authorized at September 30, 2014 and December 31, 2013; 44,330,465 and 43,315,749 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	443	432
Class B common stock, $0.01 par value; 75,000,000 shares authorized at September 30, 2014 and December 31, 2013; no shares issued and outstanding at September 30, 2014 and December 31, 2013	-	-
Additional paid-in capital	80,897	72,109
Accumulated other comprehensive income	15,643	15,601
Treasury stock, at cost; 524,792 and 524,792 shares	(2,313)	(2,313)
Accumulated deficit	(23,014)	(26,860)
Total stockholders' equity	71,656	58,969
Total liabilities and stockholders' equity	$ 144,618	$ 136,877

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

SUCAMPO PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Income (Unaudited)
(In thousands of U.S. dollars, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Research and development revenue	$ 1,797	$ 2,027	$ 5,281	$ 16,288
Product royalty revenue	16,811	13,595	44,200	37,271
Product sales revenue	11,717	5,378	25,572	10,994
Co-promotion revenue	936	-	2,021	61
Contract and collaboration revenue	202	163	619	490
Total revenues	31,463	21,163	77,693	65,104
Costs and expenses:				
Costs of goods sold	4,974	6,267	12,163	9,457
Intangible assets impairment	5,631	-	5,631	-
Research and development	5,297	4,474	14,684	14,528
General and administrative	8,117	5,440	23,571	18,635
Selling and marketing	3,801	6,026	11,461	15,967
Total costs and expenses	27,820	22,207	67,510	58,587
Income (loss) from operations	3,643	(1,044)	10,183	6,517
Non-operating income (expense):				
Interest income	26	20	106	63
Interest expense	(384)	(461)	(1,176)	(1,449)
Other income (expense), net	519	183	143	2,203
Total non-operating income (expense), net	161	(258)	(927)	817
Income (loss) before income taxes	3,804	(1,302)	9,256	7,334
Income tax (provision) benefit	(2,324)	2,825	(5,410)	(2,641)
Net income	$ 1,480	$ 1,523	$ 3,846	$ 4,693
Net income per share:				
Basic	$ 0.03	$ 0.04	$ 0.09	$ 0.11
Diluted	$ 0.03	$ 0.04	$ 0.09	$ 0.11
Weighted average common shares outstanding:				
Basic	43,796	41,863	43,613	41,644
Diluted	43,796	42,787	43,613	42,662
Comprehensive income:				
Net income	$ 1,480	$ 1,523	3,846	$ 4,693
Other comprehensive income (loss):				
Unrealized gain (loss) on investments, net of tax effect	(5)	18	-	(16)
Foreign currency translation	287	(253)	42	(387)
Comprehensive income	$ 1,762	$ 1,288	$ 3,888	$ 4,290

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

SUCAMPO PHARMACEUTICALS, INC.
Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited)
(In thousands of U.S. dollars, except share data)

	Class A Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Treasury Stock		Retained Earnings (Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Shares	Amount	Deficit)	Equity
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	-	-	1,379	-	-	-	-	1,379
Stock issued under exercise of stock options	472,640	5	2,162	-	-	-	-	2,167
Stock issued under employee stock purchase plan	3,555	-	23	-	-	-	-	23
Stock issued under "at-the-market" offering	538,521	6	5,321	-	-	-	-	5,327
Foreign currency translation	-	-	-	42	-	-	-	42
Windfall tax benefit from stock-based compensation	-	-	(97)	-	-	-	-	(97)
Net income	-	-	-	-	-	-	3,846	3,846
Balance at September 30, 2014	44,330,465	$ 443	$ 80,897	$ 15,643	524,792	$ (2,313)	$ (23,014)	$ 71,656

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

SUCAMPO PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Cash Flows (Unaudited)
(In thousands of U.S. dollars)

	Nine Months Ended September 30,	
	2014	**2013**
Cash flows from operating activities:		
Net income	$ 3,846	$ 4,693
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	984	1,117
Intangible assets impairment	5,631	-
Deferred tax provision	48	(201)
Deferred charge	2,576	504
Stock-based compensation	1,379	1,376
Amortization of premiums on investments	69	81
Unrealized currency translations	(301)	(815)
Changes in operating assets and liabilities:		
Accounts receivable	(3,047)	(1,334)
Unbilled accounts receivable	(2)	732
Product royalties receivable	(1,982)	581
Inventory	74	(218)
Prepaid and income taxes receivable and payable, net	(4,091)	(2,159)
Accounts payable	(1,682)	(2,428)
Accrued expenses	1,501	(4,231)
Deferred revenue	18	(3,039)
Accrued interest payable	304	395
Other assets and liabilities, net	2,207	(2,247)
Net cash provided by (used in) operating activities	7,532	(7,193)
Cash flows from investing activities:		
Purchases of investments	(12,224)	(7,910)
Proceeds from the sales of investments	1,700	-
Maturities of investments	11,750	5,760
Purchases of property and equipment	(62)	(153)
Changes in restricted cash	-	(9,561)
Net cash provided by (used in) investing activities	1,164	(11,864)
Cash flows from financing activities:		
Proceeds from notes payable	-	10,600
Repayment of notes payable	(3,905)	(3,725)
Proceeds from exercise of stock options	2,167	1,543
Proceeds from employee stock purchase plan	23	17
Proceeds from "at-the-market" stock issuance	5,327	-
Purchase of treasury stock	-	(336)
Windfall benefit from stock-based compensation	(97)	304
Net cash provided by financing activities	3,515	8,403
Effect of exchange rates on cash and cash equivalents	(226)	(1,457)
Net increase (decrease) in cash and cash equivalents	11,985	(12,111)
Cash and cash equivalents at beginning of period	44,102	52,022
Cash and cash equivalents at end of period	$ 56,087	$ 39,911

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

1. Business Organization and Basis of Presentation

Description of the Business

Sucampo Pharmaceuticals, Inc. (the Company) is a global biopharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs to treat gastrointestinal, ophthalmic, neurologic, and oncology-based inflammatory disorders. Over the next five years, we intend 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.

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 non-prostone clinical candidates.

In the United States (U.S.) 8 mcg and 24 mcg AMITIZA® (lubiprostone) capsules are marketed for three gastrointestinal indications under the October 2004 collaboration and license agreement (the Takeda Agreement) with Takeda Pharmaceutical Company Limited (Takeda). These three indications are: 1.) 24 mcg capsules for the treatment of chronic idiopathic constipation (CIC) in adults, 2.) 8 mcg capsules for the treatment of irritable bowel syndrome with constipation (IBS-C) in adult women, and 3.) 24 mcg capsules for the treatment of opioid-induced constipation (OIC) in adults suffering from chronic non-cancer pain. Under the Takeda Agreement the Company is primarily responsible for clinical development activities, while Takeda is primarily responsible for the commercialization of AMITIZA in the U.S. and Canada. Takeda also holds marketing rights to AMITIZA in Canada and the Company filed for regulatory approval in Canada at the end of October 2014. The Company and Takeda initiated commercial sales of AMITIZA in the U.S. for the treatment of CIC, IBS-C, and OIC in April 2006, May 2008 and May 2013, respectively. In September 2014, the Company and Takeda launched a pilot direct-to-consumer advertising campaign for AMITIZA in select U.S. markets for adults with CIC.

In Japan, 24 mcg AMITIZA capsules are marketed under a license, commercialization and supply agreement (the Abbott Agreement) with Abbott Japan Co. Ltd. (Abbott Japan) for the gastrointestinal indication of chronic constipation (CC), excluding constipation caused by organic diseases. Abbott Japan initiated commercial sales of AMITIZA in Japan for the treatment of CC in November 2012. AMITIZA is Japan's only prescription medicine for CC. The Company has been informed that Abbott Laboratories, Inc. has entered into an asset purchase agreement with Mylan, Inc. (Mylan), pursuant to which the Abbott Agreement will be sold to Mylan. The Company expects the transfer of the Abbott Agreement to Mylan will be completed in the first half of 2015, and 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 Abbott Agreement, Abbott Japan agreed to pay the Company a commercial milestone payment of $2.5 million within forty-five (45) days after the end of the month during which the first occurrence of annual net sales of lubiprostone in Japan exceeded ¥5.0 billion. On October 6, 2014, after confirming the October 2014 notification by Abbott Japan that annual net sales had exceeded ¥5.0 billion by the end of September 2014, the Company invoiced Abbott Japan $2.5 million for the commercial milestone payment. This revenue was recorded in the third quarter of 2014.

The Company holds license agreements for RESCULA® (unoprostone isopropyl ophthalmic solution) 0.15% 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. RESCULA is approved in the U.S. for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. The Company has ceased marketing RESCULA, and in the third quarter of 2014 incurred a $5.6 million intangible assets impairment related to RESCULA (see Note 5.)

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

Pediatric Functional Constipation

As previously disclosed, 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 24 mcg soft gelatin capsule formulation of lubiprostone in patients 6 to 17 years of age: a 12-week, randomized, placebo-controlled trial that initiated in December 2013 and a follow-on, long-term safety extension study that initiated in March 2014.

Alternate Formulation Lubiprostone

As previously disclosed, the Company has been developing a new dosage form of lubiprostone for patients who will not swallow the soft gelatin capsule. Takeda has agreed to fund 100% of the costs for the alternate formulation work for lubiprostone. Feasibility testing for this alternate formulation work is ongoing and is expected to be completed in the first quarter of 2015. If successful, the alternate formulation will enable future studies of lubiprostone in adults and younger children who will not swallow the current soft gelatin capsule formulation.

Intravenous and Oral Ion Channel Activators for Lumbar Spinal Stenosis

Two ion channel activators, in both the intravenous, or IV, and oral, or PO, forms, are in clinical development for the treatment of lumbar spinal stenosis (LSS). Positive top-line results from a phase 1b trial evaluating the safety and pharmacokinetics of the orally administered ion channel activator demonstrated the compound to be generally well-tolerated. The Company plans to initiate a phase 2a study with the orally administered compound in the second half of 2015 to evaluate the clinical effectiveness of the PO ion channel activator in patients with LSS. The Company has decided not to proceed with the IV version at this time.

Cobiprostone as an Oral Spray for Oral Mucositis

The Company has completed a phase 1b clinical trial for the target indication of prevention and/or treatment of oral mucositis. The results of this phase 1b trial showed that cobiprostone was well-tolerated and revealed low systemic exposure. The next phase of clinical development, a phase 2 trial, is expected to begin in 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 non-erosive reflux disease (NERD) for patients who have a non-satisfactory response to proton pump inhibitors. The Company plans to initiate a phase 2 program in NERD by the end of 2014.

Unoprostone isopropyl for Retinitis Pigmentosa (RP)

The Company has received orphan drug designation for unoprostone isopropyl from the FDA for the treatment of retinitis pigmentosa (RP) and from European Medicines Agency. In the first quarter 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 the Company's partner R-Tech Ueno. 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. Taken together, these will provide the Company with the information needed to decide on next steps in RP by mid-2015, with the aim to expand to a global program. Additionally, the Company is evaluating opportunities in other retinal diseases, such as geographic atrophy, the advanced stage of age-related macular degeneration.

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP, and the rules and regulations of the U.S. Securities and Exchange Commission, or SEC, for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company’s Consolidated Financial Statements as of and for the year ended December 31, 2013 included in the Company’s Annual Report on Form 10-K, which was filed with the SEC on March 12, 2014. The financial information as of September 30, 2014 and for the three and nine months ended September 30, 2014 and September 30, 2013 is unaudited. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. In the opinion of the Company’s management, all adjustments, consisting only of normal recurring adjustments or accruals, considered necessary for a fair statement of the results of these interim periods have been included. The results of the Company’s operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

The Condensed Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiaries: Sucampo AG (SAG) based in Zug, Switzerland, through which the Company conducts certain of its worldwide and European operations; Sucampo Pharma, Ltd. (SPL) based in Tokyo and Osaka, Japan, through which the Company conducts its Asian operations; Sucampo Pharma Americas LLC, (SPA) based in Bethesda, Maryland, through which the Company conducts its North and South American operations; and Sucampo Pharma Europe, Ltd., (SPE) based in Oxford, United Kingdom. The Company liquidated Ambrent Investments S.à.r.l., based in Luxembourg, at the end of 2013. 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.

Recent Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board (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.

Revision to Previously Issued Financial Statements

While preparing historical financial statements for the year ended December 31, 2013 and periods ended March 31, 2014 and June 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 has revised certain comparative periods to correct for these errors; however, certain account balances have not yet been revised. As a result, 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 Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2013 to correct errors in the presentation of gross profit. As a result of this revision, gross profit was removed as a sub-total and costs of goods sold was disclosed as an operating cost under the heading “Costs and expenses”. Gross profit was presented on the Condensed Consolidated Statements of Operations and Comprehensive Income beginning in the year ended December 31, 2012 and for periods ended March 31, June 30 and September 30, 2013.

In addition, the Company has revised the Consolidated Statements of Operations and Comprehensive Income for the year ended December 31, 2013 and 2012, the three months ended March 31, 2013 and March 31, 2014, the three and nine months ended September 30, 2013 and the Consolidated Balance Sheet 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 and the nine months ended September 30, 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			
(In thousands)	**Presentation as of December 31, 2012**		
Other liabilities	$ 1,253	$ (225)	$ 1,028
Total liabilities	84,766	(225)	84,541
Accumulated deficit	(34,100)	225	(33,875)
Total stockholders' equity	43,030	225	43,255
Consolidated Statements of Operations and Comprehensive Income			
(In thousands)	**Presentation as of the year ended December 31, 2012**		
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 the year ended December 31, 2013**		
Other income (expense), net	$ 2,921	$ 596	$ 3,517
Total non-operating income (expense), net	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 the year ended December 31, 2013**		
Net cash provided by (used in) operating activities	$ (5,418)	$ 1,209	$ (4,209)
Net cash provided by (used in) investing activities	(13,881)	1,265	(12,616)
Effect of exchange rates on cash and cash equivalents	798	(2,474)	(1,676)

Selected Items - Quarterly	As Previously Reported	Revision Adjustment	As 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			
(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
Consolidated Balance Sheet			
(In thousands)	**Presentation as of March 31, 2013**		
Other liabilities	$ 1,210	$ (293)	$ 917
Total liabilities	93,348	(293)	93,055
Accumulated deficit	(37,245)	293	(36,952)
Total stockholders' equity	40,003	293	40,296
Consolidated Statements of Operations and Comprehensive Income			
(In thousands, except per share data)	**Presentation as of the three months ended March 31, 2013**		
Other income (expense), net	$ 1,081	$ 69	$ 1,150
Total non-operating income (expense), net	605	69	674
Income (loss) before income taxes	(2,003)	69	(1,934)
Net income	(3,145)	69	(3,076)
Net income per share: Basic	(0.08)	0.01	(0.07)
Net income per share: Diluted	(0.08)	0.01	(0.07)
Comprehensive income	(3,108)	69	(3,039)

Selected Items - Quarterly	As Previously Reported	Revision Adjustment	As Revised
Consolidated Balance Sheet			
(In thousands)	**Presentation as of September 30, 2013**		
Other liabilities	$ 1,296	$ (651)	$ 645
Total liabilities	79,923	(651)	79,272
Accumulated deficit	(29,834)	651	(29,183)
Total stockholders' equity	49,797	651	50,448

	As Previously Reported		Revision Adjustment		As Revised	
Condensed Consolidated Statements of Operations and Comprehensive Income	Three Months Ended	Nine Months Ended	Three Months Ended	Nine Months Ended	Three Months Ended	Nine Months Ended
(In thousands, except per share data)	**September 30, 2013**					
Gross profit	$ 14,896	$ 55,647	$ (14,896)	$ (55,647)	$ 0	$ 0
Total costs and expenses	(15,940)	(49,130)	(6,267)	(9,457)	(22,207)	(58,587)
Other income (expense), net	(49)	1,776	232	427	183	2,203
Total non-operating income (expense), net	(490)	390	232	427	(258)	817
Income (loss) before income taxes	(1,534)	6,907	232	427	(1,302)	7,334
Net income	1,291	4,266	232	427	1,523	4,693
Net income per share: Basic	0.03	0.10	0.01	0.01	0.04	0.11
Net income per share: Diluted	0.03	0.10	0.01	0.01	0.04	0.11
Comprehensive income	1,056	3,863	232	427	1,288	4,290

Condensed Consolidated Statements of Cash Flows			
(In thousands)	**Presentation as of the nine months ended September 30, 2013**		
Net cash provided by (used in) operating activities	$ (8,178)	$ 985	$ (7,193)
Net cash provided by (used in) investing activities	(12,334)	470	(11,864)
Effect of exchange rates on cash and cash equivalents	(2)	(1,455)	(1,457)

Condensed Consolidated Statements of Operations and Comprehensive Income			
(In thousands, except per share data)	**Presentation as of the three months ended December 31, 2013**		
Net Income (loss)	$ 2,153	$ 170	$ 2,323
Net income per share: Basic	0.05	0.01	0.06

Condensed Consolidated Statements of Operations and Comprehensive Income			
(In thousands, except per share data)	**Presentation as of the three months ended December 31, 2012**		
Net Income (loss)	$ 13,532	$ 225	$ 13,757
Net income per share: Diluted	0.32	0.01	0.33

2. Summary of Significant Accounting Policies

Restricted Cash

Restricted cash primarily represents collateral pledged to support a loan agreement with The Bank of Tokyo-Mitsubishi UFJ, Ltd., or the Tokyo-Mitsubishi Bank; a loan agreement with The Mizuho Bank, Ltd., or the Mizuho Bank; a loan agreement between Numab AG, or Numab, and Zurcher Kantonalbank, or the Numab Loan, under which the Company serves as guarantor; and operating leases with certain financial institutions. Restricted cash totaled approximately $28.4 million at September 30, 2014 and $28.6 million at December 31, 2013.

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 September 30, 2014 and December 31, 2013, approximately $21.2 million, or 19.9%, 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 United States government or United States government agencies. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

Revenues from Takeda, an unrelated party, accounted for 62.4% and 73.9% of the Company's total revenues for the three months ended September 30, 2014 and 2013, respectively, and 66.7% and 82.9% for the nine months ended September 30, 2014 and 2013, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 72.4% and 88.2% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at September 30, 2014 and December 31, 2013, respectively.

Revenues from another unrelated party, Abbott, accounted for 36.2% and 24.5% of the Company's total revenues for the three months ended September 30, 2014 and 2013, respectively, and 31.8% and 16.4% for the nine months ended September 30, 2014 and 2013, respectively.

The Company depends significantly upon its collaborations with Takeda and Abbott, and its revenues may be adversely impacted if these relationships are disrupted.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments approximate their fair values based on their short maturities, independent valuations or internal assessments. The Company's financial instruments include cash and cash equivalents, restricted cash, current and non-current investments, receivables, accounts payable and accrued expenses. The carrying amounts of the notes payable at September 30, 2014 and December 31, 2013 were less than the estimated fair values (see Note 9 below).

Accounts Receivable and Unbilled Accounts Receivable

The Company's allowance for doubtful accounts related to certain disputed Takeda invoices totaled approximately $796,000 and $440,000 as of September 30, 2014 and December 31, 2013, respectively.

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 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 three and nine months ended September 30, 2014 and 2013 is shown below:

(In thousands, except per share data)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Basic net income per share:				
Net income	$ 1,480	$ 1,523	$ 3,846	$ 4,693
Weighted average class A common shares outstanding	43,796	41,863	43,613	41,644
Basic net income per share	$ 0.03	$ 0.04	$ 0.09	$ 0.11
Diluted net income per share:				
Net income	$ 1,480	$ 1,523	$ 3,846	$ 4,693
Weighted average class A common shares outstanding	43,796	41,863	43,613	41,644
Assumed exercise of stock options under the treasury stock method	-	924	-	1,018
	43,796	42,787	43,613	42,662
Diluted net income per share	$ 0.03	$ 0.04	$ 0.09	$ 0.11

The following securities were excluded from the computation of diluted net income per share for the three and nine months ended September 30, 2014 and 2013 as their effect would be anti-dilutive:

(In thousands)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Employee stock options	1,759	576	438	576

4. Current and Non-Current Investments

At September 30, 2014 and December 31, 2013, current and non-current available-for-sale investments consisted of the following securities:

	September 30, 2014			
(In thousands)	**Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Current:				
Commercial paper	$ 400	$ -	$ -	$ 400
U.S. government agencies	4,205	2	-	4,207
Certificates of deposits	4,250	-	-	4,250
Total	$ 8,855	$ 2	$ -	$ 8,857
Non-current:				
U.S. government agencies	$ 8,055	$ -	$ (24)	$ 8,031
Certificates of deposit	4,000	-	-	4,000
Corporate bonds	1,018	-	(3)	1,015
Total	$ 13,073	$ -	$ (27)	$ 13,046

	December 31, 2013			
(In thousands)	**Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair 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 deposits	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 Financial Accounting Standards Board's guidance for fair value measurements and disclosures, which defines fair value as the exchange price that would be received for selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy is established which requires the Company to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company classifies its investments into the following categories based on the three levels of inputs used to measure fair value:

Level 1: quoted prices in active markets for identical assets or liabilities;
Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or
Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's assets measured at fair value on a recurring basis, including cash equivalents, which are subject to the fair value disclosure requirements, at September 30, 2014 and December 31, 2013, were as follows:

	Fair Value Measurements at Reporting Date Using			
(In thousands)	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
Commercial paper	$ -	$ 8,499	$ -	$ 8,499
U.S. government agencies	-	12,239	-	12,239
Certificates of deposit	-	8,250	-	8,250
Corporate bonds	-	3,622	-	3,622
Money market funds	7,573	-	-	7,573
Total assets measured at fair value	$ 7,573	$ 32,610	$ -	$ 40,183

	Fair Value Measurements at Reporting Date Using			
(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. government agencies	-	13,260	-	13,260
U.S. commercial paper	-	6,449	-	6,449
Municipal securities	-	1,700	-	1,700
Certificates of deposit	-	6,000	-	6,000
Corporate bonds	-	5,533	-	5,533
Money market funds	5,955	-	-	5,955
Total assets measured at fair value	$ 5,955	$ 33,942	$ -	$ 39,897

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

5. 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 made the decision to cease RESCULA direct commercialization activities and will no longer market RESCULA for its approved U.S. Food and Drug Administration (FDA) indication. During the three months ended September 30, 2014 the company recorded an impairment charge of $5.6 million which represented the full amount of the remaining balances of the unamortized intangibles related to its two RESCULA license agreements described below. Fair value was determined based on an income approach. 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. There were no impairment charges recorded during the three months ended September 30, 2013.

In April 2009, the Company entered into an agreement with R-Tech (the 2009 R-Tech Agreement) to license all patents and other intellectual property rights related to RESCULA for its FDA approved indication and any new indications for unoprostone isopropyl in the United States and Canada. A supplemental new drug application 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. The $3.4 million is included in intangible assets, net in the accompanying Condensed Consolidated Balance Sheet as of December 31, 2013. During the three months ended September 30, 2014 the Company ceased direct commercialization activities of 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 $57,000 and $85,000 for the three months ended September 30, 2014 and 2013, respectively, and approximately $227,000 and $256,000 for the nine months ended September 30, 2014 and 2013, respectively. The unamortized amount included in intangible assets was nil at September 30, 2014 and $1.8 million at December 31, 2013, respectively.

In March 2011, the Company entered into a license agreement with R-Tech for unoprostone isopropyl, or the 2011 R-Tech Agreement, expanding the Company's development and commercialization rights as well as its territories beyond their previously agreed territory of the United States and Canada to the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China. 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 Condensed Consolidated Balance Sheet as of December 31, 2013. The Company has fully impaired the unamortized value of this intangible asset during the three months ended September 30, 2014 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 $102,000 and $153,000 for the three months ended September 30, 2014 and 2013, respectively, and approximately $409,000 and $460,000 for the nine months ended September 30, 2014 and 2013, respectively. The unamortized amount included in intangible assets was nil at September 30, 2014 and $4.4 million at December 31, 2013, respectively.

6. Accrued Expenses

Accrued expenses consist of the following as of September 30, 2014 and December 31, 2013:

(In thousands)	September 30, 2014	December 31, 2013
Research and development costs	$ 2,826	$ 1,775
Employee compensation	2,488	2,531
Selling and marketing costs	305	584
Legal service fees	983	14
Other accrued expenses	558	778
Total	$ 7,160	$ 5,682

7. Commitments

Operating Leases

The Company leases office space in the United States, Switzerland and Japan under operating leases through 2018. Total future minimum, non-cancelable lease payments under the Company's operating leases are as follows as of September 30, 2014:

(In thousands of U.S. dollars)	September 30, 2014
2014	$ 354
2015	1,258
2016	1,290
2017	345
2018	204
Total minimum lease payments	$ 3,451

Rent expense for all operating leases was approximately $343,000 and $323,000 for the three months ended September 30, 2014 and 2013, respectively, and $1.0 million for both the nine months ended September 30, 2014 and 2013, respectively.

Research and Development Costs

The Company routinely enters into agreements with third-party contract research organizations to oversee clinical research and development studies provided on an outsourced basis, and to 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 under these agreements as of September 30, 2014 were approximately $6.9 million.

Numab Commitment

In the event that Numab defaults under the Numab Loan, the Company's maximum contingent liability under the Numab Agreement (see Note 8) is $2.3 million. As of September 30, 2014, the potential amount of payments in the event of Numab's default under the Numab Loan was $2.1 million. At September 30, 2014 and December 31, 2013, the Company had a recorded liability of $1.0 million and $663,000, respectively, to meet a potential loan default by Numab.

8. Related Party Transactions

R-Tech Ueno, Ltd.

The Company recorded the following expenses for the three and nine months ended September 30, 2014 and 2013 under all of its agreements with R-Tech, including the 2009 R-Tech Agreement, the 2011 R-Tech Agreement and various exclusive supply agreements with R-Tech:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2014**	**2013**	**2014**	**2013**
Clinical supplies	$ 88	$ 35	$ 254	$ 255
Other research and development services	139	75	170	181
Commercial supplies	4,507	3,173	12,133	7,906
	$ 4,734	$ 3,283	$ 12,557	$ 8,342

The following table summarizes the amounts included in deferred revenue resulting from the deferral of upfront payments relating to the exclusive supply agreements with R-Tech as of September 30, 2014 and December 31, 2013:

(In thousands)	**September 30, 2014**	**December 31, 2013**
Deferred revenue, current	$ 369	$ 477
Deferred revenue, non-current	4,473	4,925
	$ 4,842	$ 5,402

The Company recognized approximately $160,000 and $105,000 of revenue relating to its agreements with R-Tech for the three months ended September 30, 2014 and 2013, respectively, and approximately $369,000 and $373,000 for the nine months ended September 30, 2014 and 2013, respectively. Such revenue was recorded as contract and collaboration revenue in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Income.

Numab AG

In September 2011, the Company entered into a Loan Guarantee and Development Agreement, or the Numab Agreement, with Numab. Numab is a related party of the Company as a result of the Company hiring as an executive officer an individual who holds an ownership interest in Numab. Under the terms of the Numab Agreement, the Company provided Numab with CHF 5.0 million as collateral and serves as guarantor for Numab on a loan from a third party, Zurcher Kantonalbank. During the first quarter of 2013, the collateral amount was reduced to CHF 2.2 million, or approximately $2.3 million as of September 30, 2014. As of September 30, 2014, Numab has utilized CHF 2.0 million of its loan facility, or approximately $2.1 million.

9. Notes Payable

In November 2010, the Company entered into a secured term loan agreement with the Tokyo-Mitsubishi Bank for ¥1.0 billion, approximating $11.6 million as of the closing date. The loan renews every November. The interest rate at September 30, 2014 was 1.21%. The outstanding loan balances included in the accompanying Condensed Consolidated Balance Sheets were $9.1 million and $9.5 million as of September 30, 2014 and December 31, 2013, respectively. A deposit of $14.9 million with the Tokyo-Mitsubishi Bank collateralizing the loan bears annual interest of 0.25%.

In March 2013, the Company entered into a secured term loan agreement with the Mizuho Bank for ¥1.0 billion, approximating $10.6 million as of the closing date. The interest rate at September 30, 2014 was 0.46%. The loan renews every March. The outstanding loan balances included in the accompanying Condensed Consolidated Balance Sheets were $9.1 million and $9.5 million as of September 30, 2014 and December 31, 2013, respectively. A deposit of $11.0 million with the Mizuho Bank collateralizing the loan bears annual interest of 0.30%.

In connection with the Company's acquisition of SAG in 2010, the Company issued a subordinated unsecured promissory note to each of the Ueno and Kuno Trusts. The interest rate beginning June 1, 2014 is 4.32%.

Due to changes in LIBOR rates, the Company has estimated the fair value of the notes payable as shown in the table below.

Notes payable at their fair value and carrying value consist of the following as of September 30, 2014 and December 31, 2013:

	Fair Value		Carrying Value	
(In thousands)	**September 30, 2014**	**December 31, 2013**	**September 30, 2014**	**December 31, 2013**
Loan agreements	$ 18,276	$ 19,008	$ 18,276	$ 19,008
Promissory notes, Sellers of SAG	30,984	34,889	29,807	33,712
	$ 49,260	$ 53,897	$ 48,083	$ 52,720
Notes payable, current			$ 26,342	$ 26,892
Notes payable, non-current			21,741	25,828
			$ 48,083	$ 52,720

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

10. Collaboration and License Agreements

Abbott Agreement

Under the Abbott Agreement, the Company has received a total of $37.5 million in upfront, development and commercial milestone payments through September 30, 2014. Additionally, on October 6, 2014, the Company invoiced Abbott $2.5 million pursuant to the Abbott Agreement for a commercial milestone payment as a result of the first occurrence of annual net sales of lubiprostone in Japan exceeding ¥5.0 billion. This milestone payment was recognized in the third quarter of 2014 and is expected to be received in the fourth quarter of 2014.

The following table summarizes the cash streams and related revenue recognized or deferred under the Abbott Agreements for the nine months ended September 30, 2014:

(In thousands)	**Amount Deferred at December 31, 2013**	**Cash Received for the Nine Months Ended September 30, 2014**	**Revenue Recognized for the Nine Months Ended September 30, 2014**	**Change in Accounts Receivable for the Nine Months Ended September 30, 2014**	**Foreign Currency Effects for the Nine Months Ended September 30, 2014**	**Amount Deferred at September 30, 2014**
Collaboration revenue:						
Up-front payment associated with the Company's obligation to participate in joint committees	$ 555	$ -	$ 30	$ -	$ (20)	$ 505
Product sales revenue	$ -	$ 20,775	$ 22,206	$ 1,824	$ (393)	$ -
Product sales milestone	$ -	$ -	$ 2,500	$ 2,500	$ -	$ -

Takeda Agreements

Under the Takeda Agreements, the Company has received a total of $160.0 million in upfront, development and commercial milestone payments through September 30, 2014.

The following table summarizes the cash streams and related revenue recognized or deferred under the Takeda Agreements for the nine months ended September 30, 2014:

(In thousands)	Amount Deferred at December 31, 2013	Cash Received for the Nine Months Ended September 30, 2014	Revenue Recognized for the Nine Months Ended September 30, 2014	Change in Accounts Receivable for the Nine Months Ended September 30, 2014*	Amount Deferred at September 30, 2014
Collaboration revenue:					
Up-front payment associated with participate in joint committees	$ 1,029	$ -	$ 73	$ -	$ 956
Research and development revenue:					
Reimbursement of research and development expenses	$ 419	$ 7,200	$ 5,281	$ 112	$ 2,450
Product royalty revenue	$ -	$ 42,218	$ 44,200	$ 1,982	$ -
Co-promotion revenue	$ -	$ 1,381	$ 2,021	$ 640	$ -

* Includes billed and unbilled accounts receivable.

11. Stock Option Plans

A summary of employee stock option activity for the nine months ended September 30, 2014 under the Company's Amended and Restated 2001 Stock Incentive Plan, or the 2001 Stock Incentive Plan, is presented below:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2013	146,200	$ 10.00		
Options expired	(25,500)	10.00		
Options outstanding, September 30, 2014	120,700	10.00	1.59	$ -
Options exercisable, September 30, 2014	120,700	10.00	1.59	$ -

A summary of employee stock option activity for the nine months ended September 30, 2014 under the Company's Amended and Restated 2006 Stock Incentive Plan is presented below:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2013	2,513,063	$ 5.03		
Options granted	1,861,745	7.29		
Options exercised	(405,140)	4.36		
Options forfeited	(209,493)	4.59		
Options expired	(193,275)	4.81		
Options outstanding, September 30, 2014	3,566,900	6.33	8.42	$ 3,085,216
Options exercisable, September 30, 2014	958,582	5.93	6.35	$ 1,402,961

Performance-based stock options granted to the CEO 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 the quarter ended September 30, 2014, the Company 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 341,745 and vest in equal annual installments over four years from date of grant and expire ten years from date of grant. The Company used a Black-Scholes option-pricing model to estimate the fair value of these options.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2014 and the year ended December 31, 2013 was $7.29 and $7.36, respectively. As of September 30, 2014, approximately $5.3 million of total unrecognized compensation costs, net of estimated forfeitures related to non-vested awards, are expected to be recognized over a weighted average period of 3.32 years.

A summary of non-employee stock option activity for the nine months ended September 30, 2014 under the Company's 2001 Stock Incentive Plan is presented below:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2013	410,000	$ 5.85		
Options exercised	(67,500)	5.85		
Options outstanding, September 30, 2014	342,500	5.85	0.58	$ 222,625
Options exercisable, September 30, 2014	342,500	5.85	0.58	$ 222,625

Employee Stock Purchase Plan

Under the Company's 2006 Employee Stock Purchase Plan, the Company received $9,670 and $6,416 upon employees' purchase of 1,566 and 1,082 shares of class A common stock during the three months ended September 30, 2014 and 2013, respectively, and $22,896 and $17,411 upon employees' purchase of 3,555 and 2,846 shares of class A common stock during the nine months ended September 30, 2014 and 2013, respectively.

12. Income Taxes

For the three months ended September 30, 2014 and 2013, the Company recorded a tax provision of $2.3 million and a tax benefit of $2.8 million, respectively. For the nine months ended September 30, 2014 and 2013, the Company recorded tax provisions of $5.4 million and $2.6 million, respectively. The tax provision for the three and nine months ended September 30, 2014 primarily pertained to the pre-tax income and losses generated by the Company's U.S., Japanese and Swiss subsidiaries. The tax benefit for the three months ended September 30, 2013 primarily pertained to the pre-tax losses generated by the Company's U.S. subsidiary. The tax provision for the nine months ended September 30, 2013 primarily pertained to pre-tax income generated by the Company's U.S. and Japanese subsidiaries.

The Company evaluated the need for a valuation allowance in foreign jurisdictions and concluded based on the most recent forecast of future income that it is more likely than not that it will not realize the benefit of a portion of its deferred tax assets in Japan; therefore, a discrete tax expense of approximately $517,000 was recorded for the three months ended September 30, 2014 to increase the valuation allowance. The Company will continue to evaluate the need for a valuation allowance in all foreign jurisdictions. Any release of valuation allowance would have a positive impact on the effective tax rate for the period.

Uncertain Tax Positions

The Company had an outstanding non-current income tax liability of approximately $969,000, including interest, for uncertain tax positions as of September 30, 2014. The amount represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in the Company's Condensed Consolidated Financial Statements. As of September 30, 2014, $969,000 is reflected as other liabilities in the accompanying Condensed Consolidated Balance Sheets. The liability for uncertain tax positions as of September 30, 2014 mainly pertained to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes. During the three and nine months ended September 30, 2014, the liability for income taxes has decreased approximately $2,000 and increased approximately $290,000, respectively. These changes in the liability are primarily related to the filing positions taken in various jurisdictions related to income tax nexus.

13. Segment Reporting

The following is a summary of financial information for the Company's reportable geographic segments:

(In thousands)	Americas	Europe	Asia	Consolidated
Three Months Ended September 30, 2014				
Research and development revenue	$ 1,797	$ -	$ -	$ 1,797
Product royalty revenue	16,811	-	-	16,811
Product sales revenue	170	142	11,405	11,717
Co-promotion revenue	936	-	-	936
Contract and collaboration revenue	141	51	10	202
Total revenues	19,855	193	11,415	31,463
Costs of goods sold	79	318	4,577	4,974
Intangible assets impairment	1,502	4,129	-	5,631
Research and development expenses	2,733	1,893	671	5,297
Depreciation and amortization	140	116	7	263
Other operating expenses	8,626	2,630	399	11,655
Income (loss) from operations	6,775	(8,893)	5,761	3,643
Interest income	24	2	-	26
Interest expense	(343)	-	(41)	(384)
Other non-operating income (expense), net	29	(443)	933	519
Income (loss) before income taxes	$ 6,485	$ (9,334)	$ 6,653	$ 3,804
Capital expenditures	$ 13	$ -	$ -	$ 13
Three Months Ended September 30, 2013				
Research and development revenue	$ 2,027	$ -	$ -	$ 2,027
Product royalty revenue	13,595	-	-	13,595
Product sales revenue	170	17	5,191	5,378
Co-promotion revenue	-	-	-	-
Contract and collaboration revenue	141	12	10	163
Total revenues	15,933	29	5,201	21,163
Costs of goods sold	3,389	4	2,874	6,267
Research and development expenses	3,860	(305)	919	4,474
Depreciation and amortization	309	47	8	364
Other operating expenses	8,893	1,646	563	11,102
Income (loss) from operations	(518)	(1,363)	837	(1,044)
Interest income	18	2	-	20
Interest expense	-	(417)	(44)	(461)
Other non-operating income, net	6	95	82	183
Income (loss) before income taxes	$ (494)	$ (1,683)	$ 875	$ (1,302)
Capital expenditures	$ 9	$ 4	$ -	$ 13

(In thousands)	Americas	Europe	Asia	Consolidated
Nine Months Ended September 30, 2014				
Research and development revenue	$ 5,281	$ -	$ -	$ 5,281
Product royalty revenue	44,200	-	-	44,200
Product sales revenue	551	297	24,724	25,572
Co-promotion revenue	2,021	-	-	2,021
Contract and collaboration revenue	424	165	30	619
Total revenues	52,477	462	24,754	77,693
Cost of goods sold	375	357	11,431	12,163
Intangible assets impairment	1,502	4,129	-	5,631
Research and development expenses	7,565	4,528	2,591	14,684
Depreciation and amortization	514	448	22	984
Other operating expenses	25,306	7,364	1,378	34,048
Income (loss) from operations	17,215	(16,364)	9,332	10,183
Interest income	67	6	33	106
Interest expense	(1,054)	-	(122)	(1,176)
Other non-operating income (expense), net	31	547	(435)	143
Income (loss) before income taxes	$ 16,259	$ (15,811)	$ 8,808	$ 9,256
Capital expenditures	$ 58	$ 2	$ 2	$ 62
Nine Months Ended September 30, 2013				
Research and development revenue	$ 16,288	$ -	$ -	$ 16,288
Product royalty revenue	37,271	-	-	37,271
Product sales revenue	277	37	10,680	10,994
Co-promotion revenue	61	-	-	61
Contract and collaboration revenue	424	34	32	490
Total revenues	54,321	71	10,712	65,104
Cost of goods sold	3,465	12	5,980	9,457
Research and development expenses	6,446	4,307	3,775	14,528
Depreciation and amortization	543	548	26	1,117
Other operating expenses	27,368	3,374	2,743	33,485
Income (loss) from operations	16,499	(8,170)	(1,812)	6,517
Interest income	54	8	1	63
Interest expense	-	(1,326)	(123)	(1,449)
Other non-operating income (expense), net	(9)	(169)	2,381	2,203
Income (loss) before income taxes	$ 16,544	$ (9,657)	$ 447	$ 7,334
Capital expenditures	$ 40	$ 110	$ 3	$ 153

14. Subsequent Events

On October 9, 2014, the Company and Takeda executed amendments to the Takeda Agreement as well as to the ancillary agreements which, in part, extended the term of the Takeda Agreement beyond December 2020. During the extended term, Takeda and the Company will share the profits of the branded AMITIZA products. Also, 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.

Also on October 9, 2014, the Company and its affiliate, Sucampo AG, or SAG, (collectively, the Company), along with 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. (collectively, Par) that resolves patent litigation in the United States 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 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, the 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, Par will share with the Company 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, 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.

On October 17, 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 United States, Japan and the People's Republic of China. Canada and the U.S. are covered by the Takeda Agreement, and Japan is covered by the Abbott Agreement. The Global License Agreement is effective until it expires on a country-by-country basis on the fourteenth (14^{th}) 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, with SAG assuming 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.

On October 21, 2014, the Compensation Committee of the Board of Directors approved a revision to the employment agreements applicable to certain executive officers. The revision to the employment agreements changes the amount of the lump sum payment to such executive officers in the event the Company terminates the executive officer's employment by not renewing the employment agreement or without cause from six (6) months to twelve (12) months of then current base salary and in the event that the executive officer is terminated other than for cause or terminates for good reason within twelve (12) months following the occurrence of a change in control of the Company as the result of a change in control from twelve (12) months to eighteen (18) months of then current annual base salary. On November 4, 2014, the Company and Mr. Andrew Smith entered into a revision to the employment agreement of Mr. Andrew Smith, the principal accounting officer, which changed the amount of the lump sum payment to Mr. Smith in the event the Company terminates Mr. Smith's employment by not renewing the employment agreement or without cause from thirty (30) days to six (6) months of then current base salary and in the event that the executive officer is terminated other than for cause or terminates for good reason within twelve (12) months following the occurrence of a change in control of the Company as the result of a change in control to twelve (12) months of then current annual base salary. This revision had been previously approved by the Compensation Committee of the Board of Directors but had not been finalized or executed by the Company and Mr. Smith.

Item 2. ***Management's Discussion and Analysis of Financial Condition and Results of Operations.***

This Quarterly Report on Form 10-Q contains forward-looking statements regarding Sucampo Pharmaceuticals, Inc., or the Company, we, us or our, and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Quarterly Report Form 10-Q and in our other filings with the Securities and Exchange Commission, or the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, which we filed with the SEC on March 12, 2014. You should also read the following discussion and analysis of our financial condition and results of operations in conjunction with our Consolidated Financial Statements as of and for the year ended December 31, 2013 included in our Annual Report on Form 10-K.

Overview

We are a global biopharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs to treat gastrointestinal, ophthalmic, neurologic, and oncology-based inflammatory disorders. Over the next five years, we intend 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.

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 approved products and other compounds, and seek partnering opportunities for our approved products and compounds on a global basis.

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

Drs. Ryuji Ueno and Sachiko Kuno have direct or indirect interests in our controlling stockholder, S&R Technology Holding, LLC, and are married to each other. 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.

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 Pharmaceutical Company Limited (Takeda) and Abbott Japan Co. Ltd. (Abbott), and other than for RESCULA in Japan, Korea, Taiwan and the People's Republic of China, or the R-Tech Territory. 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. Initiated mutual recognition process (MRP) for approval in other E.U. countries.	Consider seeking approval for AMITIZA in other E.U. countries following the MRP
	Irritable bowel syndrome with constipation (adult women) (IBS-C)	Marketed in the U.S.	Initiate phase 4 study on higher dosage and with additional male subjects
	Opioid-induced constipation (OIC) in patients with chronic non-cancer pain	Marketed in the U.S. and Switzerland	Discuss with MHRA regulatory options for obtaining OIC approval in the U.K.
	Chronic constipation	Marketed in Japan	——
	Alternate 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)	Alternate formulation in development	Initiate phase 3 program
Unoprostone Isopropyl (RESCULA ®)	Primary open angle glaucoma and ocular hypertension	Marketed in the U.S.	——
Unoprostone Isopropyl	Retinitis pigmentosa	In phase 3 by development partner R-Tech Ueno. Orphan drug status obtained in the U.S. and E.U.	Meet with the U.S. and European regulators
PO Ion Channel Activator	Lumbar spinal stenosis	Phase 1b completed	Initiate phase 2 trial
Cobiprostone	Oral mucositis	Phase 1b completed	Initiate phase 2 trial
	Non-erosive reflux disease (NERD)	Phase 1b completed	Initiate phase 2 trial

AMITIZA (lubiprostone)

United States (U.S.)

In the United States, we will cease co-promoting AMITIZA for OIC in adults with chronic, non-cancer pain after the end of 2014. 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. In October 2014, we signed an amendment to the Takeda Agreement which, in part, extended the term beyond December 2020. During the extended term, we will share the annual profits with Takeda on branded AMITIZA sales. Also, 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.

Japan

In Japan, upon the first occurrence of annual net sales of AMITIZA for CIC exceeding ¥5.0 billion, we recognized a $2.5 million milestone payment from Abbott in the third quarter of 2014, and will receive the milestone payment in the fourth quarter of 2014.

On July 14, 2014, Abbott announced that it had entered into a definitive agreement with Mylan Inc. (Mylan) whereby Mylan will acquire Abbott's non-U.S. developed markets specialty and branded generics business. We understand that under the license, commercialization and supply agreement, (the Abbott Agreement) with Abbott, pursuant to which AMITIZA is marketed, is one of the assets Abbott has agreed to sell to Mylan as part of this transaction. We expect to have discussions with Mylan about its performance of the Abbott Agreement and do not anticipate any adverse impact to sales of AMITIZA in Japan in 2014.

Global Markets

In February 2014 we announced that in Switzerland the Bundesamt fur Gesundheit (BAG) had 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, we announced that Swissmedic, the Swiss Agency for Therapeutic Products, approved AMIITZA for the treatment of OIC in chronic, non-cancer adult patients. In September 2014, Swissmedic indicated that it would not permit reimbursement for OIC prescriptions. We are currently evaluating the appropriate next steps with the BAG.

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.

On October 17, 2014, we 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 United States, Japan and the People's Republic of China. Canada and the U.S. are covered by the Takeda Agreement, and Japan is covered by the Abbott Agreement. The Global License Agreement is effective until it expires on a country-by-country basis on the fourteenth (14^{th}) anniversary of the date of first commercial sale in that country. Under the terms of the Global License Agreement, we 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, we 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, with us assuming responsibility for the first $6 million in development expenses incurred by Takeda. We 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. There will be a transition period while the marketing authorization is transferred from us to Takeda in the United Kingdom and Switzerland, during which we will be progressing the Mutual Recognition Procedure for certain European Union (EU) countries selected by Takeda. We will also be responsible for the conduct of the European Pediatric Investigation Plan at our cost but will not be required to conduct any additional studies.

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

RESCULA (unoprostone isopropyl)

Under the 2009 R-Tech Agreement and the 2011 R-Tech Agreement, we hold the exclusive rights to commercialize and develop unoprostone isopropyl worldwide, excluding the R-Tech Territory, for its approved indication and all new ophthalmic indications developed by us. However, we have ceased marketing RESCULA and in the third quarter of 2014 incurred a $5.6 million intangible assets impairment related to RESCULA (see Note 5.)

Our Other Clinical Development Programs

Lubiprostone

Pediatric Functional Constipation

As previously disclosed, two of the four planned phase 3 studies for our pediatric functional constipation development program are ongoing, both of which are testing the 24 mcg soft gelatin capsule formulation of lubiprostone in patients 6 to 17 years of age: a 12-week, randomized, placebo-controlled trial that initiated in December 2013 and a follow-on, long-term safety extension study that initiated in March 2014.

Alternate Formulation Lubiprostone

As previously disclosed, we have been developing a new dosage form of lubiprostone for patients who will not swallow the soft gelatin capsule. Takeda has agreed to fund 100% of the costs for the alternate formulation work for lubiprostone. Feasibility testing for this alternate formulation work is ongoing and is expected to be completed in the first quarter of 2015. If successful, the alternate formulation will enable future studies of lubiprostone in adults and younger children who will not swallow the current soft gelatin capsule formulation.

Intravenous and Oral Ion Channel Activators

Lumbar Spinal Stenosis

Two ion channel activators, in both the intravenous (IV) and oral (PO) forms, are in clinical development for the treatment of lumbar spinal stenosis, or LSS. Positive top-line results from a phase 1b trial evaluating the safety and pharmacokinetics (PK) of the orally administered ion channel activator demonstrated the compound to be generally well-tolerated. We plan to conduct an additional phase 2 study in the second half of 2015 to evaluate the clinical effectiveness of the PO ion channel activator in LSS. We have decided not to proceed with the IV version at this time.

Cobiprostone

Oral Spray for Oral Mucositis

Cobiprostone is in development for the target indication of prevention and/or treatment of oral mucositis. In the first quarter of 2014, we completed our phase 1b trial that evaluated the safety and PK 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 2 trial, is expected to begin in the first half of 2015.

Cobiprostone for Non-Erosive Reflux Disease (NERD)

We announced we will begin a development program for cobiprostone to treat non-erosive reflux disease (NERD) for patients who have a non-satisfactory response to proton pump inhibitors. We plan to initiate a phase 2 program in NERD by the end of 2014.

Unoprostone isopropyl for Retinitis Pigmentosa (RP)

We have received orphan drug designation for unoprostone isopropyl from the FDA for the treatment of retinitis pigmentosa (RP) and from European Medicines Agency. In the first quarter 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 our partner R-Tech Ueno. We continue 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. Taken together, these 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. Additionally, we are currently evaluating opportunities in other retinal diseases, such as geographic atrophy, the advanced stage of age-related macular degeneration.

Results of Operations

Comparison of three months ended September 30, 2014 and September 30, 2013

Revenues

The following table summarizes our revenues:

	Three Months Ended September 30,	
(In thousands)	**2014**	**2013**
Research and development revenue	$ 1,797	$ 2,027
Product royalty revenue	16,811	13,595
Product sales revenue	11,717	5,378
Co-promotion revenue	936	-
Contract and collaboration revenue	202	163
Total	$ 31,463	$ 21,163

Total revenues were $31.5 million for the three months ended September 30, 2014 compared to $21.2 million for the three months ended September 30, 2013, an increase of $10.3 million, or 48.7%.

Research and development revenue

Research and development revenue was $1.8 million for the three months ended September 30, 2014 compared to $2.0 million for the three months ended September 30, 2013, a decrease of $230,000.

Product royalty revenue

Product royalty revenue was $16.8 million for the three months ended September 30, 2014 compared to $13.6 million for the three months ended September 30, 2013, an increase of $3.2 million, or 23.7%. The increase was primarily due to higher net sales of AMITIZA as reported by Takeda for royalty calculation purposes.

Product sales revenue

Product sales revenue represents drug product net sales of AMITIZA in Japan and Switzerland, and drug product net sales of RESCULA in the United States. Product sales revenue was $11.8 million for the three months ended September 30, 2014 compared to $5.4 million for the three months ended September 30, 2013, an increase of $6.3 million, or 117.9%. The increase was primarily due to the increased volume of 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 was $936,000 for the three months ended September 30, 2014 compared to nil for the three months ended September 30, 2013, an increase of $936,000. The increase resulted from our specialty sales force shifting back to co-promoting AMITIZA in 2014 after having shifted away from co-promoting AMITIZA in 2013.

Contract and collaboration revenue

Contract and collaboration revenue was $202,000 for the three months ended September 30, 2014 compared to $163,000 for the three months ended September 30, 2013, an increase of $39,000.

Costs of Goods Sold

The following table summarizes our costs of goods sold expenses:

	Three Months Ended September 30,	
(In thousands)	**2014**	**2013**
Product purchases	$ 4,886	$ 3,180
Inventory write-off	-	3,041
Distribution	88	46
Total	$ 4,974	$ 6,267

Total costs of goods sold for the three months ended September 30, 2014 were $5.0 million compared to $6.3 million for the three months ended September 30, 2013, a decrease of $1.3 million, or 20.6%. The decrease was primarily due to a $3.0 million non-cash write-off of RESCULA inventory in the prior year period which did not reoccur, partially offset by higher product purchases expenses as a result of increased volume of AMITIZA sales in Japan.

Research and Development Expenses

The following table summarizes our research and development expenses:

	Three Months Ended September 30,	
(In thousands)	**2014**	**2013**
Direct costs:		
Lubiprostone	$ 3,238	$ 2,712
Cobiprostone	241	83
Ion channel activators	333	795
Unoprostone isopropyl	346	(396)
Other	392	239
Total	4,550	3,433
Indirect costs	747	1,041
Total	$ 5,297	$ 4,474

Total research and development expenses for the three months ended September 30, 2014 were $5.3 million compared to $4.5 million for the three months ended September 30, 2013, an increase of $823,000, or 18.4%. The increase was primarily due to increased costs of our lubiprostone pediatric trial.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Months Ended September 30,	
(In thousands)	**2014**	**2013**
Salaries, benefits and related costs	$ 2,551	$ 2,032
Legal, consulting and other professional expenses	3,727	1,527
Stock option expense	438	268
Pharmacovigilance	153	337
Other expenses	1,248	1,276
Total	$ 8,117	$ 5,440

General and administrative expenses were $8.1 million for the three months ended September 30, 2014, compared to $5.4 million for the three months ended September 30, 2013, an increase of $2.7 million, or 49.2%. The increase was primarily due to a significant increase in legal fees incurred prosecuting a patent infringement lawsuit filed by us in February 2013.

Selling and Marketing Expenses

The following table summarizes our selling and marketing expenses:

(In thousands)	Three Months Ended September 30, 2014	2013
Salaries, benefits and related costs	$ 677	$ 1,652
Consulting and other professional expenses	1,409	1,245
Samples expense	87	1,632
Contract fees	515	71
Data purchases	209	194
Promotional materials & programs	302	471
Other expenses	602	761
Total	$ 3,801	$ 6,026

Selling and marketing expenses were $3.8 million for the three months ended September 30, 2014, compared to $6.0 million for the three months ended September 30, 2013, a decrease of $2.2 million, or 36.9%. The decrease was primarily the result of a non-cash write-off of RESCULA samples in the prior year period of $1.5 million that did not reoccur this year, and the replacement in 2014 of our in-house sales force with a lower-cost contract sales force.

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense:

(In thousands)	Three Months Ended September 30, 2014	2013
Interest income	$ 26	$ 20
Interest expense	(384)	(461)
Other income, net	519	183
Total	$ 161	$ (258)

Interest income was $26,000 for the three months ended September 30, 2014, compared to $20,000 for the three months ended September 30, 2013, an increase of $6,000.

Interest expense was $384,000 for the three months ended September 30, 2014, compared to $461,000 for the three months ended September 30, 2013, a decrease of $77,000, or 16.7%, primarily due to lower principal balances.

Other income, net was $519,000 for the three months ended September 30, 2014, compared to $183,000 for the three months ended September 30, 2013, an increase of $336,000, or 183.6%. The majority of the increase is due to increases in unrealized and non-cash foreign exchange gains.

Income Taxes

We recorded an income tax provision of $2.3 million for the three months ended September 30, 2014, and an income tax benefit of $2.8 million for the three months ended September 30, 2013. The income tax provision for the three months ended September 30, 2014 primarily pertains to the pre-tax income and losses generated by our U.S., Japanese and Swiss subsidiaries. The income tax benefit for the three months ended September 30, 2013 primarily pertained to the pre-tax losses generated by our U.S. subsidiary.

Comparison of nine months ended September 30, 2014 and September 30, 2013

Revenues

The following table summarizes our revenues:

(In thousands)	Nine Months Ended September 30, 2014	2013
Research and development revenue	$ 5,281	$ 16,288
Product royalty revenue	44,200	37,271
Product sales revenue	25,572	10,994
Co-promotion revenue	2,021	61
Contract and collaboration revenue	619	490
Total	$ 77,693	$ 65,104

Total revenues were $77.7 million for the nine months ended September 30, 2014 compared to $65.1 million for the nine months ended September 30, 2013, an increase of $12.6 million, or 19.3%.

Research and development revenue

Research and development revenue was $5.3 million for the nine months ended September 30, 2014 compared to $16.3 million for the nine months ended September 30, 2013, a decrease of $11.0 million, or 67.6%. 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 was $44.2 million for the nine months ended September 30, 2014 compared to $37.3 million for the nine months ended September 30, 2013, an increase of $6.9 million, or 18.6%. The increase was primarily due to higher net sales of AMITIZA as reported by Takeda for royalty calculation purposes.

Product sales revenue

Product sales revenue represents drug product net sales of AMITIZA in Japan and Switzerland, and drug product net sales of RESCULA in the United States. Product sales revenue was $25.6 million for the nine months ended September 30, 2014 compared to $11.0 million for the nine months ended September 30, 2013, an increase of $14.6 million, or 133.0%. The increase was primarily due to the increased volume of 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 was $2.0 million for the nine months ended September 30, 2014 compared to $61,000 for the nine months ended September 30, 2013, an increase of $2.0 million. The increase resulted from our specialty sales force shifting back to co-promoting AMITIZA in 2014 after having shifted away from co-promoting AMITIZA in 2013.

Contract and collaboration revenue

Contract and collaboration revenue was $619,000 for the nine months ended September 30, 2014 compared to $490,000 for the nine months ended September 30, 2013, an increase of $129,000.

Costs of Goods Sold

The following table summarizes our costs of goods sold expenses:

(In thousands)	Nine Months Ended September 30, 2014	2013
Product purchases	$ 11,963	$ 6,302
Inventory write-off	-	3,041
Distribution	200	114
Total	$ 12,163	$ 9,457

Costs of goods sold for the nine months ended September 30, 2014 were $12.2 million compared to $9.5 million for the nine months ended September 30, 2013, an increase of $2.7 million, or 28.6%. The increase 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 the prior year period which did not reoccur.

Research and Development Expenses

The following table summarizes our research and development expenses:

(In thousands)	Nine Months Ended September 30, 2014	2013
Direct costs:		
Lubiprostone	$ 7,981	$ 6,487
Cobiprostone	919	435
Ion channel activators	1,293	2,490
Unoprostone isopropyl	781	298
Other	1,250	1,997
Total	12,224	11,707
Indirect costs	2,460	2,821
Total	$ 14,684	$ 14,528

Research and development expenses for the nine months ended September 30, 2014 were $14.7 million compared to $14.5 million for the nine months ended September 30, 2013, an increase of $156,000, or 1.1%.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

(In thousands)	Nine Months Ended September 30, 2014	2013
Salaries, benefits and related costs	$ 6,584	$ 6,196
Legal, consulting and other professional expenses	10,603	4,779
Stock option expense	1,135	945
Pharmacovigilance	942	2,103
Other expenses	4,307	4,612
Total	$ 23,571	$ 18,635

General and administrative expenses were $23.6 million for the nine months ended September 30, 2014, compared to $18.6 million for the nine months ended September 30, 2013, an increase of $4.9 million, or 26.5%. The increase is primarily due to a significant increase in legal fees incurred 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 table summarizes our selling and marketing expenses:

(In thousands)	Nine Months Ended September 30, 2014	2013
Salaries, benefits and related costs	$ 2,052	$ 5,333
Consulting and other professional expenses	4,653	3,223
Samples expense	228	2,587
Contract fees	1,313	71
Data purchases	658	630
Promotional materials & programs	784	1,562
Other expenses	1,773	2,561
Total	$ 11,461	$ 15,967

Selling and marketing expenses were $11.5 million for the nine months ended September 30, 2014, compared to $16.0 million for the nine months ended September 30, 2013, a decrease of $4.5 million, or 28.2%. 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 the prior year that did not reoccur this year, partially offset by increased commercialization costs for AMITIZA in Europe.

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense:

	Nine Months Ended September 30,	
(In thousands)	**2014**	**2013**
Interest income	$ 106	$ 63
Interest expense	(1,176)	$ (1,449)
Other income, net	143	$ 2,203
Total	$ (927)	$ 817

Interest income was $106,000 for the nine months ended September 30, 2014, compared to $63,000 for the nine months ended September 30, 2013, an increase of $43,000.

Interest expense was $1.2 million for the nine months ended September 30, 2014, compared to $1.4 million for the nine months ended September 30, 2013, a decrease of $273,000, or 18.8% primarily due to lower principal balances.

Other income, net was $143,000 for the nine months ended September 30, 2014, compared to $2.2 million for the nine months ended September 30, 2013, a decrease of $2.1 million, or 93.5%. The majority of the decrease related to the change from unrealized and non-cash foreign exchange gains in the prior year period, to unrealized and non-cash foreign exchange losses in the current year period.

Income Taxes

We recorded income tax provisions of $5.4 million and $2.6 million for the nine months ended September 30, 2014 and 2013, respectively. The tax provision for the nine months ended September 30, 2014 primarily pertains to the pre-tax income and losses generated by our U.S., Japanese and Swiss subsidiaries. The tax provision for the nine months ended September 30, 2013 primarily pertained to the pre-tax income generated by our U.S. and Japanese subsidiaries.

Reportable Geographic Segments

We have determined that we have three reportable segments based on our method of internal reporting, which disaggregates business by geographic location. These segments are the Americas, Europe and Asia. We evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors that depend on the growth of these geographies. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other factors. The financial results of our segments reflect their varying stages of development. The following table summarizes the financial results and the identifiable assets of our reportable geographic segments:

(in thousands)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Americas				
Total revenues	$ 19,855	$ 15,933	$ 52,477	$ 54,321
Income (loss) before income taxes	6,485	(494)	16,259	16,544
Europe				
Total revenues	193	29	462	71
Loss before income taxes	(9,334)	(1,683)	(15,811)	(9,657)
Asia				
Total revenues	11,415	5,201	24,754	10,712
Income before income taxes	6,653	875	8,808	447
Consolidated				
Total revenues	31,463	21,163	77,693	65,104
Income (loss) before income taxes	3,804	(1,302)	9,256	7,334

(in thousands)	September 30, 2014	December 31, 2013
Identifiable assets		
Americas	$ 110,229	$ 95,350
Europe	12,679	23,843
Asia	21,710	17,684
Consolidated	144,618	136,877

Our Americas segment recorded income before income taxes of $6.5 million and loss before income taxes of $494,000 for the three months ended September 30, 2014 and 2013, respectively, an increase of $7.0 million. The increase was primarily due to a $3.2 million increase in Product Royalty Revenue as a result of higher net sales of AMITIZA as reported by Takeda for royalty calculation purposes, as well as a $3.3 million decrease in Costs of Goods Sold due to a $3.0 million non-cash write-off of RESCULA inventory in the prior year period which did not reoccur. For the nine months ended September 30, 2014 and 2013, our Americas segment recorded income before income taxes of $16.3 and $16.5 million, respectively, a decrease of $285,000.

Our Europe segment recorded a loss before income taxes of $9.3 million and $1.7 million for the three months ended September 30, 2014 and 2013, a decrease of $7.7 million. For the nine months ended September 30, 2014 and 2013, our Europe segment recorded a loss before income taxes of $15.8 and $9.7 million, respectively, a decrease of $6.2 million, or 63.7%.

Our Asia segment recorded income before income taxes of $6.7 million and $875,000 for the three months ended September 30, 2014 and 2013, respectively, an increase of $5.8 million. For the nine months ended September 30, 2014 and 2013, our Asia segment recorded income before income taxes of $8.8 million and $447,000, respectively, an increase of $8.4 million. The increases in each period were primarily due to increased product sales of AMITIZA.

Financial Condition, Liquidity and Capital Resources

Financial Condition

Sources of Liquidity

We finance our operations principally with cash generated from revenues, cash and cash equivalents on hand, and to a lesser extent, cash generated from the issuance and sale of our class A common stock through "at-the-market" equity offerings or through the exercise of employee stock options. Revenues generated from operations principally consist of a combination of upfront payments, milestone and royalty payments, product sales, and research and development expense reimbursements received from Takeda, Abbott and other parties.

Our cash, cash equivalents, restricted cash and investments consisted of the following as of September 30, 2014 and December 31, 2013:

(In thousands)	September 30, 2014	December 31, 2013
Cash and cash equivalents	$ 56,087	$ 44,102
Restricted cash, current	26,114	26,115
Restricted cash, non-current	2,313	2,471
Investments, current	8,857	16,003
Investments, non-current	13,046	7,219
Total	$ 106,417	$ 95,910

Our 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 September 30, 2014 and December 31, 2013, our restricted cash consisted primarily of the collateral pledged to support a loan agreement with Tokyo-Mitsubishi Bank, a loan agreement with the Mizuho Bank, Numab's loan with Zurcher Kantonalbank and operating leases with certain financial institutions.

As of September 30, 2014, our current investments consisted of U.S. government securities, certificates of deposit, and corporate bonds that mature in one year or less.

Cash Flows

The following table summarizes our cash flows:

(In thousands)	Nine Months Ended September 30, 2014	2013
Cash provided by (used in):		
Operating activities	$ 7,532	$ (7,193)
Investing activities	1,164	(11,864)
Financing activities	3,515	8,403
Effect of exchange rates	(226)	(1,457)
Net increase (decrease) in cash and cash equivalents	$ 11,985	$ (12,111)

Nine months ended September 30, 2014

Net cash provided by operating activities of $7.5 million for the nine months ended September 30, 2014 was primarily due to a net income of $3.8 million plus non-cash expenses totaling $10.4 million (including an intangible assets impairment of $5.6 million), plus cash provided by net changes in other assets and liabilities of $2.2 million, offset by increases in receivables of $9.1 million.

Net cash provided by investing activities of $1.2 million for the nine months ended September 30, 2014 was primarily due to proceeds from the sales of investments.

Net cash provided by financing activities of $3.5 million for the nine months ended September 30, 2014 was realized through the issuance of class A common stock through the "at-the-market" program totaling $5.3 million, exercised options totaling $2.2 million, offset by repayments of notes payable totaling $3.9 million.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for nine months ended September 30, 2014 was a decrease of $226,000.

Nine months ended September 30, 2013

Net cash used in operating activities was $7.2 million for the nine months ended September 30, 2013. This reflected a net income of $4.7 million, a decrease in accounts payable and accrued expenses of $6.7 million, a decrease in deferred revenue of $3.0 million as well as changes in other operating assets and liabilities.

Net cash used in investing activities was $11.9 million for the nine months ended September 30, 2013. This primarily reflected an increase in restricted cash associated with collateral pledged to support loan agreements and purchase of investments, partially offset by our proceeds from the sales and maturities of investments.

Net cash provided by financing activities was $8.4 million for the nine months ended September 30, 2013. This primarily reflected proceeds from a loan agreement with the Mizuho Bank, partially offset by a payment of $3.7 million on our notes payable and purchases under our stock repurchase program.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for the nine months ended September 30, 2013 was a decrease of $1.5 million.

Off-Balance Sheet Arrangements

As of September 30, 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 1933, as amended.

Funding Requirements

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

- our share of the on-going development program of AMITIZA in the United States;
- development, regulatory and marketing efforts in Europe and Asia for lubiprostone;
- development and regulatory activities for unoprostone isopropyl in the United States and Canada and other countries excluding the R-Tech Territory;
- 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, and the integration of such acquisitions;
- the continuing purchase of shares of our class A common stock up to $5.0 million pursuant to the repurchase program, which may be increased up to $10.0 million as previously approved by our Board of Directors; and
- the payment of principal and interest under our loan note obligations.

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

- the cost and time involved to pursue our research and development programs;
- our ability to establish collaborative arrangements and to enter into licensing agreements and contractual arrangements with others; and

- any future change in our business strategy.

To the extent that our capital resources may be insufficient to meet our future capital requirements, we may need to finance our future cash needs through at-the-market offerings, public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. In addition, any future equity funding would dilute the ownership of our stockholders.

At September 30, 2014, based upon our current business plan, we believe we have sufficient liquidity for the next 12 months.

Effects of Foreign Currency

We currently incur a portion of our operating expenses in Switzerland, Japan and the United Kingdom. The reporting currency for our Condensed Consolidated Financial Statements is United States dollars. As such, the results of our operations could be adversely affected by changes in exchange rates either due to transaction losses, which are recognized in the statement of operations, or translation losses, which are recognized in comprehensive income. We currently do not hedge foreign exchange rate exposure via derivative instruments.

Recent Accounting Pronouncements

Refer to Note 1 of the Notes to Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk.***

Our market risks during the three months ended September 30, 2014 have not materially changed from those discussed in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2013, which was filed with the SEC on March 12, 2014.

Foreign Currency Exchange Rate Risk

We are subject to foreign exchange rate risk for revenues and expenses denominated in foreign currencies. Foreign exchange rate risk arises from the fluctuation of foreign exchange rates and the degree of volatility of these rates relative to the United States dollar. We do not currently hedge our foreign currency transactions.

Interest Rate Risk

Our exposure to market risks associated with changes in interest rates relates primarily to the increase or decrease in the amount of interest income earned on our investment portfolio. We ensure the safety and preservation of invested funds by attempting to limit default risk, market risk and reinvestment risk. We attempt to mitigate default risk by investing in investment grade securities. A hypothetical one percentage point decline in interest rates would not have materially affected the fair value of our interest-sensitive financial instruments as of September 30, 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 September 30, 2014 and December 31, 2013, approximately 19.9% and 17.1%, respectively, of our cash, cash equivalents, restricted cash and investments are 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 4. ***Controls and Procedures.***

a) Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), as of September 30, 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 September 30, 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.

b) Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. ***Legal Proceedings.***

On October 9, 2014, we and our affiliate, SAG (collectively, Sucampo), along with 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. (collectively, Par) that resolves patent litigation in the United States related to Sucampo's AMITIZA (lubiprostone) 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule product. Under the terms of the Settlement and License Agreement, Sucampo 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 January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par will share with Sucampo the gross profits of the licensed products or an authorized generic sold during the term of the Settlement and License Agreement, which continues until each of the Sucampo patents has expired. In the event Par elects to launch an authorized generic product, Sucampo will supply Par under the terms of a manufacturing and supply agreement at a negotiated price. Additionally, Sucampo, R-T-tech, Takeda, and Par have agreed to dismiss with prejudice the patent litigation filed in the U.S. District Court for the District of Delaware. While we are awaiting approval of the settlement by the District Court, we also lodged with the Federal Trade Commission and Department of Justice the settlement documents and the company has not received any objections as of the filing date of third quarter Form 10-Q.

On October 3, 2014, or the Notice Date, Sucampo received a Paragraph IV certification notice letter, or the Notice Letter, regarding an abbreviated new drug application, or ANDA, submitted to the FDA by Dr. Reddy's Laboratories, Inc., or Dr. Reddy's, requesting approval to market, sell, and use a generic version of the 8 mcg and 24 mcg AMITIZA soft gelatin capsule, or the lubiprostone capsule, products. In the 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 (collectively, the Patents), 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 the Patents expire in 2027. We are currently reviewing the Notice Letter. By statute, if we initiate a patent infringement lawsuit against Dr. Reddy's within 45 days of the Notice Date, the FDA would automatically stay approval of Dr. Reddy's ANDA until the earlier of 30 months from the Notice Date or entry of a district court decision finding the Patents invalid or not infringed. The Company intends to vigorously enforce its intellectual property.

Item 1A. ***Risk Factors.***

Our business is subject to certain risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our common stock. For a discussion of these risks, please refer to the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed by us with the SEC on March 12, 2014. There have not been any material changes from the risk factors as previously disclosed in our Form 10-K for the fiscal year ended December 31, 2013.

Item 2. ***Unregistered Sales of Equity Securities and Use of Proceeds.***

(a) None.
(b) Not applicable.
(c) None.

Item 3. ***Defaults Upon Senior Securities.***

(a) None.
(b) None.

Item 4. ***Mine Safety Disclosures.***

None.

Item 5. ***Other Information.***

(a) None.
(b) None.

Item 6. ***Exhibits***

Exhibit Number	Description	Reference
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 to Certificate of Incorporation	Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2008)
3.3	Amended and Restated Bylaws	Exhibit 3.1 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*	Lubiprostone Exclusive Manufacturing and Supply Agreement, dated as of January 1, 2014, by and between Sucampo AG and R-Tech Ueno, Ltd.	Included herewith
10.2*	Settlement and License Agreement, dated September 30, 2014, by and among Applicant, 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.	Included herewith
10.3*	Manufacturing and Supply Agreement, dated as of September 30, 2014, by and between Sucampo AG and Par Pharmaceutical, Inc.	Included herewith
10.4*	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	Included herewith
10.5	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	Included herewith
10.6*	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.	Included herewith
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended	Included herewith
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended	Included herewith
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.	Included herewith
32.1	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. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.	Included herewith
101.[INS]†	XBRL Instance Document	Included herewith
101.[SCH]†	XBRL Taxonomy Extension Schema Document	Included herewith
101.[CAL]†	XBRL Taxonomy Extension Calculation Linkbase Document	Included herewith
101.[LAB]†	XBRL Taxonomy Extension Label Linkbase Document	Included herewith

101.[PRE]†	XBRL Taxonomy Extension Presentation Linkbase Document	Included herewith

* Confidential treatment has been requested for certain portions of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.

† 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 the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Sucampo Pharmaceuticals, Inc.

November 7, 2014 By: /s/ PETER GREENLEAF
Peter Greenleaf
Chief Executive Officer
(Principal Executive Officer)

November 7, 2014 By: /s/ CARY J. CLAIBORNE
Cary J. Claiborne
Chief Financial Officer
(Principal Financial Officer)

Sucampo Pharmaceuticals, Inc.
Exhibit Index

Exhibit Number	Description	Reference
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 to Certificate of Incorporation	Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2008)
3.3	Amended and Restated Bylaws	Exhibit 3.1 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*	Lubiprostone Exclusive Manufacturing and Supply Agreement, dated as of January 1, 2014, by and between Sucampo AG and R-Tech Ueno, Ltd.	Included herewith
10.2*	Settlement and License Agreement, dated September 30, 2014, by and among Applicant, 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.	Included herewith
10.3*	Manufacturing and Supply Agreement, dated as of September 30, 2014, by and between Sucampo AG and Par Pharmaceutical, Inc.	Included herewith
10.4*	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	Included herewith
10.5	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	Included herewith
10.6*	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.	Included herewith
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended	Included herewith
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended	Included herewith
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.	Included herewith
32.1	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. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.	Included herewith
101.[INS]†	XBRL Instance Document	Included herewith
101.[SCH]†	XBRL Taxonomy Extension Schema Document	Included herewith
101.[CAL]†	XBRL Taxonomy Extension Calculation Linkbase Document	Included herewith

101.[LAB]†	XBRL Taxonomy Extension Label Linkbase Document	Included herewith
101.[PRE]†	XBRL Taxonomy Extension Presentation Linkbase Document	Included herewith

* Confidential treatment has been requested for certain portions of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.

† 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.

EXHIBIT 10.1

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

LUBIPROSTONE EXCLUSIVE MANUFACTURING AND SUPPLY AGREEMENT

THIS LUBIPROSTONE EXCLUSIVE MANUFACTURING AND SUPPLY AGREEMENT ("Agreement") is made this 1st day of January 2014 (the "Effective Date"), by and between Sucampo AG, a corporation organized and existing under the laws of Switzerland, and having its principal office at Baarerstrasse 22, 6300 Zug, Switzerland ("SAG"), and R-Tech Ueno, Ltd., a corporation organized and existing under the laws of Japan and having its registered office at NBF Hibiya Bldg., 10F, 1-1-7 Uchisaiwaicho, Chiyoda-ku, Tokyo 100-0011, Japan ("RTU") (each referred to herein as a "Party" and collectively as the "Parties").

WHEREAS, the affiliates of SAG have entered into the following manufacturing and supply agreements with RTU for Lubiprostone (also known as RU-0211, SPI-0211, and AMITIZA®): 1) RU--0211 Exclusive Manufacturing And Supply Agreement ("SPE Agreement") dated 24th day of June 2005 between Sucampo Pharma Europe, Ltd. ("SPE") and RTU, 2) Lubiprostone Exclusive Manufacturing And Supply Agreement ("SPL Agreement") dated 23th day of February 2009 between Sucampo Pharma, Ltd. ("SPL") and RTU, 3)

RU-0211 Exclusive Manufacturing And Supply Agreement ("SPA Agreement") dated 23rd day of June 2004 between Sucampo Pharmaceuticals, Inc., now known as Sucampo Pharma Americas, LLC, (hereinafter, "SPA") and RTU, 4) Supply Agreement ("Supply Agreement") dated October 29, 2004 among Takeda Pharmaceutical Company Limited ("Takeda"), SPA and RTU, and 5) Supply and Purchase Agreement dated January 25, 2006, by and among SPA, Takeda and RTU ("Takeda RTU SPA Agreement");

WHEREAS, SAG is the Switzerland based subsidiary of Sucampo Pharmaceuticals, Inc. and has obtained and licensed rights to certain patents, patent applications and know-how, and certain data related to Lubiprostone, and has developed the Product and seeks a supply source for Drug Substance and Drug Product (defined below) for SAG clinical evaluation and commercial sale in the SAG Territory (defined below);

WHEREAS, the SPA Agreement, SPE Agreement and SPL Agreement have been assigned to SAG on September 22, 2011;

WHEREAS, the Parties intend that the SPA Agreement, SPE Agreement and SPL Agreement (except that the SPL Agreement will not be superseded as it applies to Japan) will be superseded by this Agreement and do not intend to affect any of the provisions of the SPL Agreement (as it applies to Japan), the Supply Agreement and Takeda RTU SPA Agreement;

WHEREAS, RTU has continued to demonstrate expertise in the manufacture of drug substances and drugs for preclinical, clinical and commercial use and has in the past supplied to SAG and its affiliates Lubiprostone for preclinical and clinical development as well as commercial sale, and as such RTU has developed a substantial level of expertise in the manufacture of Drug Substance and Drug Product;

WHEREAS, RTU desires to be the exclusive global clinical and commercial supplier of Drug Substance and Drug Product to SAG and its affiliates; and

WHEREAS, SAG seeks to have RTU supply Drug Substance and Drug Product as further defined herein for use in SAG clinical development and for commercial sale in the SAG Territory and desires to have RTU be SAG's exclusive supplier of Drug Substance and Drug Product.

NOW, THEREFORE, in consideration of the mutual promises herein, the Parties agree as follows:

ARTICLE 1. DEFINITIONS

Article 1.1. "**Additional Formulation**" means any and all formulations other than the Initial Formulation.

Article 1.2. "**Additional Materials**" means all raw materials, resins, chemical intermediates, components, excipients, and other ingredients and packaging materials and supplies, needed to manufacture the Drug Substance and Drug Product for use in SAG Territory, including costs for relevant in-bound freight.

Article 1.3. "**API**" means Lubiprostone.

Article 1.4. "**Applicable Law**" means all federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations, or requirements 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 hereunder.

Article 1.5. "**Authorized Generic**" means a drug product, which includes a drug substance identical to the Drug Substance, approved by a Regulatory Authority for SAG to manufacture but for the third company to market, sell, or distribute such drug product with either labeling, packaging, product code, labeler code, trade name, or trade mark that differs from SAG's Drug Product.

Article 1.6. "**Bulk Capsule**" means capsules in a bulk bottle that can be transferred to a commercial supply bottle or blister format.

Article 1.7. "**Certificate of Analysis**" means a certificate provided by RTU to SAG with each shipment of the Drug Substance and the Drug Product, which sets forth: (a) the results of any quality assurance testing; and (b) the manufacturing date.

Article 1.8. "**Clinical Supply**" means cGMP compliant Drug Product specifically produced and packaged for clinical studies for indications that are the subject of Regulatory Filings within the SAG Territory.

Article 1.9. "**Commercial Product**" means Drug Product specifically produced and packaged for commercial use and sale for indications with Regulatory Approval within the SAG Territory in final labeling and packaging as approved incident to the NDA.

Article 1.10. "**Confidential Information**" means all information, whether in tangible form or not, provided by either Party to the other, including but not limited to: financial information, including but not limited to current and projected financials and funding needs; information on research and development compounds, products, and processes; trade secrets; technical know-how; formulas; studies; regulatory submissions and records; research data and information; sales and marketing information (including, without limitation, customer lists); inventions; patent information and all other information pertaining to a Party's intellectual property in any form (including but not limited to information provided orally, electronically, or in writing). It shall further include the existence and nature and terms of this Agreement, and any and all attachments or exhibits thereto.

Article 1.11. "**Drug Substance**" means the Lubiprostone active ingredient, prior to formulation as a final drug product.

Article 1.12. "**Drug Product**" means a finally formulated Lubiprostone drug product ready as Clinical Supply or Commercial Product, as appropriate.

Article 1.13. "**Good Manufacturing Practices**" or "**GMP**" means quality systems and the current good manufacturing practices applicable to the manufacture, labeling, packaging, handling, storage, and transport of active pharmaceutical ingredients, bulk dosage forms and packaged dosage forms, as set forth in 21 USC 351(a)(2)(B) and 21 CFR Parts 210 and 211 or any successor provisions, Pharmaceutical Affairs Law and its related Ordinances including the Ministry of Health, Labour and Welfare of Japan ("MHLW") Ordinance No. 179, December 24, 2004, any update thereto, and any other laws, regulations, policies, or guidelines applicable to the manufacture, labeling, packaging, handling, storage, and transport of pharmaceutical products in the Territory, and/or any applicable foreign equivalents thereof, and any updates of any of the foregoing .

Article 1.14. "**Initial Formulation**" shall mean the oral formulation of Drug Product in soft gelatin capsules as of the Effective Date.

Article 1.15. "**Latent Defect**" means Drug Substance or Drug Product not conforming to RTU's obligation for Drug Product pursuant to Article 2.1 and pursuant to batch testing and release such that the related non-conformance of Drug Substance or Drug Product is not readily discoverable based on SAG's or SAG designee's normal incoming-goods inspections, as the case may be.

Article 1.16. "**Lubiprostone**" means the compound known as RU-0211, SPL-0211, or SPI-0211 or Lubiprostone as described in more detail in Appendix A.

Article 1.17. "**NDA**" refers to a New Drug Application, as defined under Applicable Law and applicable regulations promulgated thereunder, or other appropriate marketing authorization, or any counterpart application or marketing authorization in any country of the SAG Territory.

Article 1.18. "**Order**" means, with respect to clinical or commercial supply of Drug Product, a written communication from SAG to RTU of SAG's need for a particular supply period, issued in accordance with Articles 2.4, 2.5, 2.6 and 3.

Article 1.19. "**Person**" means any individual, trust (or any of its beneficiaries), estate, partnership, limited partnership, association, limited liability company, corporation, any other enterprise engaged in the conduct of business or operating as a non-profit entity, however formed or wherever organized, or any governmental body, agency or unit.

Article 1.20. "**Pre-mix**" means […***…].

Article 1.21. "**Product Defect**" means Drug Product not conforming to RTU's obligations for Drug Product pursuant to Article 2.1 and pursuant to batch testing and release and includes a Latent Defect.

Article 1.22. "**Regulatory Approval**" means any and all approvals, licenses (including product and establishment licenses), registrations, or authorizations of any Regulatory Authority necessary to develop, manufacture, commercialize, promote, distribute, transport, store, use, sell or market the Drug Substance or Drug Product for use in the SAG Territory.

Article 1.23. "**Regulatory Authority**" means any national, supra-national, regional, federal, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity regulating or otherwise exercising authority over the distribution, importation, exportation, manufacture, use, storage, transport, clinical testing or sale of the Drug Substance or Drug Product.

Article 1.24. "**Regulatory Filings**" means, with respect to the Product in the Territory, all applications, registrations, 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 data contained in any of the foregoing.

Article 1.25. "**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 Drug Product.

Article 1.26. "**Specifications**" mean the manufacturing, formulation, quality control, packaging, labeling, shipping and storage specifications as separately set out for Drug Substance and Drug Product in Appendix B and as updated from time to time on mutual agreement in writing by the Parties.

Article 1.27. "**SAG Territory**" means all of the countries that are located in North, Central and South America, including the Caribbean, and their territories and possessions; all of the countries located in Japan, Asia and Oceania, and their territories and possessions; and all of the countries located in EU, Middle East, Africa, and their territories and possessions; except Japan, United States and Canada so long as the SPL Agreement and the Supply Agreement respectively, have not been terminated.

Article 1.28. "**Term**" means the definition set forth in Article 11.1.

Article 1.29. "**Third Parties**" means any Person other than SAG and RTU and their respective affiliates and subsidiaries.

***Confidential Treatment Requested**

ARTICLE 2. GENERAL TERMS OF MANUFACTURING AND SUPPLY

Article 2.1. Supply Agreements. The Parties intend that the SPA Agreement, SPE Agreement and SPL Agreement, except that the SPL Agreement shall not be superseded as it applies to Japan, have no further effect and shall be superseded by this Agreement.

Article 2.2. Supply. Subject to the terms of this Agreement, and to the terms and conditions of agreements related to development and commercialization of Drug Substance and Drug Product with Third Parties, RTU agrees to manufacture and supply the Drug Substance and the Drug Product to SAG in accordance with the Specifications and in the Initial Formulation and SAG agrees to purchase said Drug Substance and Drug Product in the Initial Formulation in all such quantities as required by SAG for SAG's clinical and commercial purposes. All such Drug Substance and Drug Product manufactured or supplied by RTU in accordance with this Agreement shall:

(a) be manufactured in accordance and in compliance with Applicable Law, including GMP;
(b) be manufactured in accordance with the applicable Regulatory Filings and Regulatory Approvals;
(c) upon delivery, not be adulterated or misbranded as defined by Applicable Law;
(d) upon delivery, have a minimal shelf life of the longer of […***…] ([…***…]) months or […***…] percent ([…***…]%) of the shelf life registered in the underlying Regulatory Approval;
(e) be free from defects in materials and workmanship; and
(f) be in compliance with all Specifications for the Drug Substance and Drug Product.

Article 2.3. Cost to Produce. RTU, at its sole expense, will provide all labor, utilities, equipment, personnel, facilities, raw materials and components necessary for manufacturing, development and implementation of all appropriate quality control measures, shipping, and storage of the Drug Substance and the Drug Product in compliance with the Specifications and the warranties contained in Article 9 and the Regulatory and Legal requirements of Article 7. RTU shall also be responsible for all process development and scale-up. SAG, at its sole expense, will provide all resources necessary to ship, store, and otherwise handle such Drug Substance and Drug Product in a manner necessary to meet applicable Regulatory and Applicable Law requirements, after delivery of the Drug Substance and the Drug Product to SAG as described in Article 2.9. RTU shall purchase all Additional Materials (as referred to in the relevant Regulatory Approvals) which are needed for the manufacture of the Drug Substance and Drug Products as per the current regulatory files, under its own liability and costs. If RTU wishes to change suppliers, such change shall be subject to SAG's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed and RTU shall bear the costs of such change including any regulatory fees required for any Regulatory Filings by RTU or SAG

***Confidential Treatment Requested**

Article 2.4. Quality Assurance. RTU, at its sole expense, will perform all testing for compliance with the Specifications and the applicable GMPs and will supply a chemical Certificate of Analysis with each batch of Drug Substance and Drug Product and any other documentation required by Applicable Law requirements. Complete copies of all test results and/or assays will be submitted to SAG promptly following any reasonable request therefor during the Term. RTU shall make available their facilities and relevant records for inspection by the appropriate government authorities, SAG or SAG's agents for regulatory or quality assurance purposes upon reasonable notice and at reasonable times during normal business hours; provided, however, that the inspection by SAG or its agents hereunder shall be within the scope of inspection that is allowed under the relevant statutes and regulations.

Article 2.5. Clinical Supply; Order. During the Term of this Agreement, SAG shall grant RTU the exclusive right to manufacture and supply Drug Substance and Drug Product to SAG for Clinical Supply. During the Term of this Agreement, RTU and SAG shall from time to time confer and agree on SAG's Clinical Supply needs for SAG's ongoing clinical development program. SAG shall inform RTU of its final requirements in advance of needing Clinical Supply in such timing as RTU shall reasonably need to duly perform its obligations hereunder, which shall constitute SAG's Order to RTU and which, subject to the terms and conditions of this Agreement, RTU agrees to supply.

Article 2.6. Commercial Supply; Exclusivity; Forecasting; Order. During the Term of this Agreement, SAG shall grant RTU the exclusive right to manufacture and supply Drug Substance and Drug Product to SAG for commercial purposes subject to appropriate marketing authorization in any country of the SAG Territory in respect of the Drug Substance and Drug Product and subject to Article 2.14. Commencing from the date of filing of the first NDA for a particular Drug Product after the Effective Date, SAG shall provide RTU in writing a 12 month forecast of its requirements for Drug Product which forecast will be updated quarterly until SAG's first commercial sale. Thereafter, SAG shall provide RTU a forecast in accordance with the following:

(a) No later than the last business day of each calendar quarter during the Term, SAG will provide RTU with an updated twenty-four (24) month rolling forecast of the Commercial Product to be manufactured and supplied by RTU (each a "Rolling Forecast") for the twenty-four (24) month period commencing at the beginning of the following month with the first six (6) months considered an Order. Each Rolling Forecast will be broken down for each month of such period into the quantity (by SKU, packaging and size of Commercial Product) and shipping dates. The five (5) months of each Rolling Forecast will restate the balance of the purchase order period of the prior Rolling Forecast, and the fifth month of the Rolling Forecast will constitute the new Order for which SAG will be obligated to purchase and take delivery of the Commercial Product.

(b) Except as set forth herein, all months of the Rolling Forecast other than the first six (6) months will set forth SAG's best estimate of its requirements for the supply of Commercial Product, and the Rolling Forecast for the months seven (7) through twenty-four (24) of each Rolling Forecast will not be binding.

(c) The Rolling Forecast for the months seven (7) through twenty-four (24) of each Rolling Forecast shall not increase or decrease, in aggregate by more than […***…] percent ([…***…]%) on a month-to-month basis.

(d) Increases or decreases in the Rolling Forecast beyond those set out in Article 2.6(c) may be accepted by RTU at its discretion.

***Confidential Treatment Requested**

With regard to supply for validation required for Regulatory Filings, the batch size and cost will be separately negotiated by SAG and RTU.

Article 2.7. Promotional Sample Supply. During the Term of this Agreement, RTU and SAG shall from time to time confer and agree on SAG's Commercial Product supply needs for promotional purpose. SAG shall inform RTU of its final requirements in advance of needing promotional sample in such timing as RTU shall reasonably need to duly perform its obligations hereunder, which shall constitute SAG's Order to RTU and which, subject to the terms and conditions of this Agreement, RTU agrees to supply.

Article 2.8. Placement and Acceptance of an Order.

(a) Placement. All purchases of Clinical Supply or Commercial Products shall be pursuant to written Orders consistent with Article 2.6(a), which shall be placed by SAG and/or its distributors at least sixty (60) days prior to the date of which Clinical Supply or Commercial Products shall be delivered to SAG or the applicable distributor. Each such purchase order will be in agreement with the purchase order period of the most recent Rolling Forecast. If an Order for any month is not submitted by the above deadline, SAG will be deemed to have submitted an Order in that month for the amount of Clinical Supply or Commercial Product set forth in the most recent Rolling Forecast for such month. Each Order hereunder shall specify the desired quantities of each of the Clinical Supply or Commercial Products, in finished forms and samples, and the delivery dates therefore.

(b) Rejection. RTU shall have ten (10) Business Days from receipt of an Order from SAG to reject or propose to modify an Order. RTU may only reject an Order that (a) lists products that are not covered by this Agreement, or (b) that is in excess of the amount permitted by Article 2.6 and Article 2.8(a).

Article 2.9. Delivery; Risk of Loss. The Drug Substance and Drug Products hereunder shall be delivered per SAG specifications for the relevant Drug Product on or up to three (3) days before the delivery date specified in the order accepted by RTU, subject to the release of the relevant Drug Substance or Drug Products as per Article 2.4. Any Drug Substance and Drug Product supplied hereunder to SAG shall be shipped from RTU's manufacturing facility or its contract manufacturer and delivered to a common carrier to be transported for importation into the SAG Territory. The identity of the common carrier and the port of entry shall be mutually determined by the Parties in writing. SAG or a designated Third Party shall bear the costs for transport of the Drug Substance or Drug Product from the port of entry and will be invoiced directly by the carrier. The quantity of each Drug Substance or Drug Product actually delivered by RTU with respect to each accepted Order shall not exceed a range of […***…] percent ([…***…]%) up to […***…] percent ([…***…]%) of the quantity of the relevant Drug Substance or Drug Product specified in the Order, unless agreed differently by SAG or its designated Third Party. Delivery documents shall include Order, quantity, copy of the Certificate of Analysis, items codes and description, lot number, expiry date of Drug Substance or Drug Products, number of shippers, weight, and number of pallets. Title and risk of loss shall pass to SAG at the time the goods are delivered to SAG or its designee, and SAG shall assume all responsibility for and costs associated with the goods upon such delivery.

***Confidential Treatment Requested**

Article 2.10. Inventory; Reports. On a monthly basis, RTU shall provide SAG with a report detailing present inventory of Drug Substance and Drug Product, along with RTU's schedule for production for the succeeding three months. In the event that Drug Substance or Drug Product available to SAG is in short supply, RTU shall notify SAG of such shortage as soon as possible. In the event there is a short supply of Drug Substance or Drug Product and RTU cannot supply Drug Substance or Drug Product to SAG in an amount equal to SAG's firm order, then RTU (i) shall indemnify SAG for any loss, including but not limited to loss of profit, arising from such shortage of Drug Substance or Drug Product and (ii) shall allocate available Drug Substance or Drug Product to SAG in each month that such a shortfall exists (and in each month thereafter until the shortfall to SAG is remedied) in an amount equal to the Drug Substance or Drug Product of (a) the amount of available Drug Substance or Drug Product for that month, and (b) a fraction the numerator of which is (i) the aggregate of firm orders made by SAG over the subsequent twenty-four (24) 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 SAG over the subsequent twenty-four (24) month period including the shortfall months and (y) the aggregate quantity of Drug Substance or Drug Product over the same twenty-four (24) month period required by other licensees outside the SAG Territory by reference to firm orders placed with RTU for such licensees' requirements outside the SAG Territory.

Article 2.11. Non-Exclusivity. Nothing in this Agreement shall prohibit RTU, either clinically or commercially, from manufacturing or supplying, either on its behalf or for any third party, drug products containing the Drug Substance, or drug products containing different active ingredients which require the same reagents as the production of Lubiprostone, either in the SAG Territory or in other parts of the world; provided, however, that RTU shall be prohibited from supplying the Drug Substance or the Drug Products in the SAG Territory or to those that induce or facilitate sale in the SAG Territory of the Drug Substance or the Drug Products by any party other than SAG.

Article 2.12. Performance Issue. If either Party becomes aware of any issue that may materially impact RTU's ability to fulfill its obligations under this Agreement, it shall immediately notify the other Party and both Parties shall confer in good faith in order to address such issue.

Article 2.13. Manufacturing Changes. Upon consultation with SAG, RTU assumes any and all responsibility to make changes to the manufacturing processes, test methods, etc. for the manufacture of Additional Materials, Drug Substance and Drug Products at the manufacturing location, not specific to the Drug Substance and Drug Product, and will solely bear all expenses related thereto. For changes that are not required by a Regulatory Authority, including but not limited to reformulations of the Drug Substance or Drug Product, addition of new strengths to the Drug Product, new presentations and formats of the Product that negatively impacts SAG's commercialization of the Product, then RTU shall indemnify SAG or its designee for any loss, including but not limited to loss of profit, arising from such change.

Article 2.14. Back-up Supplier. Notwithstanding Article 2.2, SAG may elect to qualify a back-up supplier ("Back-Up Supplier") reasonably acceptable to RTU for any Authorized Generic, Additional Formulation or the supply of Drug Substance and Drug Product which acceptance shall not be unreasonably withheld, conditioned or delayed in the event that RTU is unable, or determines that it will be unable, to produce Drug Substance or Drug Product in accordance with SAG's Orders or Specifications, Authorized Generic or Additional Formulation. For such purpose, RTU shall grant to such Back-Up Supplier a non-exclusive, royalty-free, license under the patent rights and know-how owned by RTU to manufacture Drug Substance and Drug Product, Authorized Generic or Additional Formulation solely as the Back-Up Supplier pursuant to the terms of this Agreement. Further, RTU shall promptly provide, at such times and locations as may reasonably be requested by SAG, and at SAG's expense at reasonable consulting rates, cooperation to enable the Back-Up Supplier to establish such manufacturing capability. Notwithstanding anything to the contrary in this Agreement, if RTU recovers the ability to produce Drug Substance and Drug Product in accordance with SAG's Orders or Specifications, Authorized Generic or Additional Formulation and at the same terms as the Back-Up Supplier, RTU shall promptly notify SAG and SAG shall cause the Back-Up Supplier to cease manufacturing and supplying Drug Substance and Drug Product, Authorized Generic or Additional Formulation within thirty (30) business days, and SAG shall not purchase from the Back-Up Supplier after such thirtieth business day any Drug Substance or Drug Product, Authorized Generic or Additional Formulation. RTU shall indemnify SAG or its designee for any loss, including but not limited to loss of profit, arising from SAG's cancellation of the supply from the Back-Up Supplier.

Article 2.15. Maintenance of Inventory. In furtherance of Article 2.10, RTU agrees to maintain at least a six (6) month inventory of Drug Substance and at least a six (6) month inventory of Bulk Capsule. RTU shall ensure the inventory of Drug Product has an expiration date of at least twenty-four (24) months at all times; provided however, that if the shelf life approved by the FDA is less than thirty-six (36) months, the shelf life shall be such period minus ten (10) months, but in no event less than fourteen (14) months.

ARTICLE 3. ADDITIONAL SERVICES

Article 3.1. Laboratory and Regulatory Consulting. From time-to-time, under this Agreement, SAG may request performance of "Additional Services" by RTU, which may include without limitation (i) the formulation and/or process development of Drug Substance and/or Drug Product, or (ii) regulatory consulting in connection with RTU's supply of such Drug Substance and/or Drug Product. The resulting work products of Additional Services shall be defined as "Deliverables".

Article 3.2. Placement and Acceptance of an Order for Additional Services.

(a) Placement. SAG shall place an Order for Additional Services at least thirty (30) days prior to the date of which Deliverable shall be due to SAG.

(b) Acceptance. RTU shall have ten (10) Business Days from receipt of an Order for Additional Services from SAG to reject or propose to modify such Order. If such Order is not rejected it shall be deemed accepted and RTU shall, subject to the terms and conditions of this Agreement, be obligated to supply it by its terms.

Article 3.3. Performance of Additional Services. RTU shall perform Additional Services in accordance with the terms of this Agreement, the Order, and all Applicable Laws. RTU shall provide, at its own expense, a place of work and all equipment, tools, and other materials necessary to complete the Order. In performing the Additional Services, RTU shall not utilize the intellectual property of a third party or incorporate know-how owned by any third party without first obtaining SAG's prior written approval. RTU shall not initiate any Additional Services prior to execution of the applicable Order by the Parties.

Article 3.4. Change Proposals. Upon receipt of proposal from SAG to change the terms of an Order for Additional Services (a "Change Proposal"), RTU shall promptly provide (i) any information requested in such proposal, and (ii) its written acceptance or rejection of the proposal. RTU may not reject any Change Proposal that does not materially shorten the delivery or performance schedule or materially alter the Additional Services or Deliverables, and may not unreasonably reject any other Change Proposal. The Order shall be revised accordingly and authorized by the Parties involved, including any change in fees and costs caused by or resulting from such Change Proposal.

Article 3.5. Acceptance of Additional Services and/or Deliverables. SAG shall have the right to inspect RTU's progress of the Additional Services or preparation of Deliverables in accordance with a schedule set forth in the applicable Order. SAG shall have the right to accept or reject the Service and/or Deliverable, or any portion thereof, in writing, within five (5) Business Days from the date of such inspection or the receipt of the Services and/or Deliverables at the conclusion of the Additional Services, as the case may be. Such acceptance or rejection shall be consistent with the criteria set forth in the Order. If SAG does not reject in writing within five (5) Business Days, the Additional Service and /or Deliverable shall be considered accepted by SAG. Within five (5) Business Days, SAG shall clearly state in writing the reasons for any rejection, and within five (5) Business Days of receipt of rejection, RTU shall present a corrective plan of action to SAG. Upon approval by SAG, RTU, at no additional cost to SAG, shall make corrections, and where applicable RTU shall resubmit the corrected Additional Service or Deliverable to SAG.

ARTICLE 4. PRICING AND PAYMENT

Article 4.1. Clinical Supply Price. In consideration for RTU's supply of Drug Product for Clinical Supply, SAG shall pay such amount as set forth in Article 4.3 if there is Commercial Product available and can be produced and packaged for Clinical Supply; otherwise, the price for Clinical Supply shall be separately agreed upon between the Parties taking into account that production cost for Clinical Supply will inevitably be higher than otherwise. Notwithstanding the foregoing, purchase price for placebo shall be […***…].

Article 4.2. Promotional Supply Price. The Promotional samples described in Article 2.6 shall be supplied at prices set forth in Article 4.1.

Article 4.3. Commercial Cost of Goods. In consideration for RTU's supply of Commercial Product hereunder,

(a) SAG shall pay […***…] JPY/capsule including […***…] for […***…] count bottles.

(b) In the event, reimbursement price in any country in the SAG Territory is less than or equal to $[…***…]/day, the following prices shall apply to an Order for supply to that country:

***Confidential Treatment Requested**

Production Stage	Price
[…***…]	¥[…***…]
[…***…]	¥[…***…]
[…***…]	¥[…***…]

In the event the Commercial Cost of Goods falls under the price set forth in Article 4.3(b), SAG agrees to the following terms and conditions: 1) the minimum batch shall be the equivalent of […***…] capsules, 2) shipping terms for delivery shall be FOB shipping point or FCA shipping point, and 3) in the event the container that contained the […***…] is not returned to RTU, SAG shall pay RTU the replacement cost of such container. Notwithstanding the terms above, in the event of significant economic changes, including those with regards to the price of Lubiprostone, the Parties shall meet and discuss in good faith about modifications to the Commercial Cost of Goods in accordance with Article 13.1 below.

Article 4.4. Formulation Other Than Initial Formulation. Notwithstanding anything to the contrary contained in this Article 4, the Parties shall meet and discuss in good faith the Clinical Supply Price and the Commercial Supply Price for any and all formulations other than the Initial Formulation and matching placebo in accordance with Article 13.1 below. In the event the Parties cannot agree upon the Clinical Supply Price and the Commercial Supply Price for the Additional Formulation, SAG may use a qualified Back-Up Supplier for the manufacture of the Additional Formulation in accordance with Article 2.14.

Article 4.5. Terms of Payment. Any payments due hereunder shall be made within […***…] ([…***…]) days of receipt of an invoice. Payment may be made by wire transfer or other suitable means agreed upon by the Parties.

Article 4.6. Shipping Terms. All payments for Drug Substance and Drug Product supplied hereunder are inclusive of all cost, insurance and freight (CIF) necessary for delivery to SAG as described in Article 2.8 and title and risk of loss shall pass to SAG upon delivery to SAG or its designee .

Article 4.7. Non-conforming Shipments. SAG or its designee will have a period of thirty (30) business days from the date of its receipt of a shipment of Drug Product to inspect and reject such shipment for non-conformance with the obligations under this Article 4.7 and the obligations of RTU pursuant to Article 2.2 including the Specifications based on SAG's normal incoming-goods inspections procedures, by providing RTU with written notice of rejection for any Product Defect within such period of thirty (30) business days together with samples of the non-conforming Drug Products in the relevant shipment for testing. In the case of Product with Latent Defects, SAG or its designee will promptly, and in no event more than thirty (30) business days of SAG knowing of any such Latent Defect, notify RTU of such Latent Defect; provided however, that any Latent Defect must be notified no later than one (1) month following the expiry date of the applicable Drug Product, together with samples of the non-conforming Drug Products in the relevant shipment for testing. If RTU determines that such shipment did conform to the warranties of RTU for Drug Product pursuant to Article 2.2 including the Specifications and did conform to documented batch testing and release, the Parties will submit samples of such shipment to a mutually acceptable independent laboratory

for testing. If such independent laboratory determines that the shipment conformed to the obligations of RTU for Drug Product pursuant to Article 2.2 including the Specifications and conformed to batch testing and release and was not affected by a Product or Latent Defect, SAG or its designee will bear all expenses of shipping and testing by such independent laboratory of such shipment samples. If RTU or such independent laboratory confirms that such shipment did not meet the obligations of RTU for Drug Product pursuant to Article 2.2 including the Specifications and did not conform to documented batch testing and release, RTU will, as soon as practicable, give SAG or its designee a credit for any amount paid with respect to that portion of the Drug Product which does not conform and will bear all of SAG's expenses of returning such Drug Product to RTU or its nominee. RTU or SAG, as directed by RTU, will dispose of any non-conforming portion of any shipment, at RTU's expense. The costs of the activities of any such independent laboratory will be borne by the Party in error.

ARTICLE 5. CONFIDENTIALITY

Article 5.1. General Obligation. In order that each Party may provide appropriate products and services, each has, and will continue to provide the other with, certain Confidential Information prepared by or on behalf of and belonging to the "Disclosing Party." The "Receiving Party" shall maintain Confidential Information in confidence and shall not, without Disclosing Party's written authorization, disclose to any Person any Confidential Information. Receiving Party shall not use Confidential Information for any purpose except for the purposes delineated in this Agreement and for the Disclosing Party's benefit.

Article 5.2. Exceptions. Article 5.1 shall not apply to any information (1) that was in Receiving Party's possession prior to receipt from Disclosing Party, (2) that was in the public domain at the time of receipt from Disclosing Party, (3) that becomes part of the public domain without breach of any obligation of confidentiality to Disclosing Party, (4) that is lawfully received by Receiving Party from a third party independent of Disclosing Party that has no obligation of confidentiality to Disclosing Party, or (5) that is required by law to be disclosed.

Article 5.3. Notice; Return of Confidential Information. Receiving Party shall provide immediate notice to Disclosing Party of any request or demand for Disclosing Party's Confidential Information, or any request or demand for information pertaining to the subject matter of this Agreement. Upon written request, Receiving Party shall promptly provide to Disclosing Party all Confidential Information provided to Receiving Party or prepared by Receiving Party on Disclosing Party's behalf in connection with this agreement.

Article 5.4. Irreparable Harm. The Parties mutually acknowledge and agree that Confidential Information disclosed under this Agreement is valuable principally because of its confidential nature, and so any improper disclosure of Confidential Information will represent irreparable harm that cannot be adequately compensated monetarily.

Article 5.5. Term. This Article 5 confidentiality provision in all events shall remain in effect for ten (10) years following any disclosure made hereunder. Notwithstanding the foregoing, however, any trade secret disclosed to either Party, shall be held in strict confidence in perpetuity or until said trade secret is publicly disclosed through no fault of the receiving Party.

ARTICLE 6. INTELLECTUAL PROPERTY

Article 6.1. Ownership.

(a) Prior to each Order placed hereunder, and in compliance with any existing agreements between the Parties as of the date of each Order, each Party shall retain all right, title and interest in its intellectual property, including without limitation information, improvements, developments, inventions, patents, trade secrets and know-how, and Confidential Information ("Intellectual Property").

(b) RTU shall retain sole rights to any data processes, software (including codes), technology, means and know-how developed by RTU which relate solely to manufacture and supply processes and its refinement/improvement and which do not utilize SAG's Intellectual Property.

(c) SAG shall retain sole rights to any know-how developed for SAG in (i) the production of Drug Substance and Drug Product and/or (ii) Additional Services and/or Deliverables, which are prepared or submitted to SAG by RTU under this Agreement.

(d) RTU will disclose to SAG (in accordance with Article 13.7 (Notices) hereunder) within ten (10) business days of occurrence, any and all inventions, discoveries and/or improvements utilizing SAG Intellectual Property ("Inventions"). Ownership of such Inventions shall be negotiated by the Parties in good faith in compliance with each Party's Intellectual Property obligations to any third party at the time of Invention.

Article 6.2. Grant of Limited License. Subject to the terms and conditions of this Agreement, each Party hereby grants to the other Party a non-exclusive, non-transferable license to the extent, and only to the extent, necessary to perform this Agreement. All rights and licenses not granted herein are reserved to each Party, and no other rights or licenses are granted or will be deemed to be granted to the other Party (whether by implication, estoppel or otherwise). Without limiting the generality of the foregoing, RTU retains the right to manufacture the Drug Substance and the Drug Product, and to permit third parties to manufacture the Drug Substance and the Drug Product, both in and out of the SAG Territory, subject, however, to the provisions of Article 2.14.

ARTICLE 7. REGULATORY & LEGAL

Article 7.1. Compliance. RTU shall at all times remain in substantial compliance, with all applicable laws, regulations and guidelines that apply to the manufacturing and supply contemplated hereunder.

Article 7.2. Records. RTU shall keep accurate written records in substantial compliance with all Applicable Law that apply to the manufacturing and supply contemplated hereunder. Such records will be made available to SAG on reasonable request for inspection, to the same extent that they would be available to an appropriate governmental inspector, during normal business hours. Records shall be maintained for the period of time required by applicable laws or regulations, or if there is no period of time specified by such laws or regulations, for three (3) years following the respective dates of records.

Article 7.3. Authorization of the Manufacturing Facility by Regulatory Authority. RTU shall be responsible for providing information that may be used in, or referenced by, an application filed by SAG with the applicable Regulatory Authority for purposes of ensuring that the RTU manufacturing facility is authorized to manufacture the Drug Substance and Drug Product to be supplied under this Agreement. SAG shall have no obligation to purchase any Drug Product from RTU if they are produced in a manufacturing facility that is not, in any material respect, in compliance with all Applicable Law.

Article 7.4. Regulatory Audits; Notice of Audit. RTU shall make its facilities, records and personnel available to the Regulatory Authority as may be needed for compliance with the applicable laws, rules and regulations enforced by such authority. RTU shall advise SAG in writing immediately if:

(a) an agent of any regulatory body having jurisdiction over the manufacture or distribution of the Drug Product makes an inquiry about the Drug Product or visits RTU's manufacturing facility for the Drug Product, and shall specify what, if any, inquiry was made; or

(b) any Regulatory Authority takes action against RTU on any issue related directly or indirectly to the manufacturing or distribution of the Drug Product.

Article 7.5. Drug Master File. RTU shall produce and maintain a drug master file for Drug Substance made under this Agreement, which shall contain all information necessary to comply with the applicable Regulatory Authority, and all U.S. Pharmacopoeia standards with respect to the applicable manufacturing processes and Drug Product.

Article 7.6. Import/Export Issues. RTU shall be responsible for (i) obtaining all governmental permits, consents and approvals which are required in order to export Drug Substance and Drug Product from the country of origin, and (ii) making any required notifications or other filings (whether before or after shipment) which are required in connection with the exportation of Drug Substance and Drug Product from the country of origin.

Article 7.7. Quality Agreements. The Parties shall negotiate an appropriate quality agreement within three months from the Effective Date to replace the existing quality agreements supporting the SPA Agreement, SPE Agreement and SPL Agreement except that the SPL Agreement will not be superseded as it applies to Japan so long as the SPL Agreement has not been terminated..

ARTICLE 8. REPRESENTATIONS & WARRANTIES OF SAG

Article 8.1. Organization. SAG represents and warrants to RTU that it is a corporation duly organized, validly existing, and, where applicable, in good standing under the laws of the jurisdiction of its incorporation.

Article 8.2. Authority. SAG represents and warrants that it: (a) has the right to enter into this Agreement; (b) has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and (c) has by all necessary corporate action duly and validly authorized the execution and delivery of this Agreement and the performance of its obligations hereunder.

Article 8.3. No Conflicts. SAG represents and warrants to RTU that it has not and will not during the Term of this Agreement enter into any agreement which conflicts with or which will result in any breach of, or constitute a default under, any note, security agreement, commitment, contract or other agreement, instrument or undertaking to which it is a party.

Article 8.4. Insurance. SAG represents that it will at all times maintain commercially reasonable levels of insurance, including general liability insurance, in light of their responsibilities hereunder. SAG shall provide RTU with certificates of insurance upon RTU's written request for the same.

Article 8.5. Obligations of Confidentiality. SAG represents and warrants that any and all employees and other affiliated persons, including subcontractors, who will be involved in performing this Agreement are bound, or will be bound prior to performing any work, by a proprietary information and technology agreement in favor of RTU, consistent with the obligations of Article 5, pursuant to which such employee or other person is obligated to confidentiality.

ARTICLE 9. REPRESENTATIONS AND WARRANTEES OF RTU

Article 9.1. Organization. RTU represents and warrants to SAG that it is a corporation duly organized, validly existing, and, where applicable, in good standing under the laws of the jurisdiction of its incorporation.

Article 9.2. Authority. RTU represents and warrants that it: (a) has the right to enter into this Agreement; (b) has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and (c) has by all necessary corporate action duly and validly authorized the execution and delivery of this Agreement and the performance of its obligations hereunder.

Article 9.3. No Conflicts. RTU represents and warrants to SAG that it has not and will not during the Term of this Agreement enter into any agreement which conflicts with or which will result in any breach of, or constitute a default under, any note, security agreement, commitment, contract or other agreement, instrument or undertaking to which it is a party.

Article 9.4. Insurance. RTU represents that it will at all times maintain commercially reasonable levels of insurance, including general liability insurance, in light of their responsibilities hereunder. RTU shall provide SAG with certificates of insurance upon SAG's written request for the same.

Article 9.5. Qualified Personnel. RTU warrants that it will at all times use appropriately qualified personnel, having the appropriate levels of training and skill, to fulfill its obligations arising under this Agreement.

Article 9.6. Regulatory and Legal Compliance. RTU hereby warrants that its facilities and processes supplied hereunder substantially comply with, or will substantially comply with at all relevant times, all applicable legal and regulatory requirements necessary to fulfill its obligations under this Agreement, including without limitation, securing and maintaining any necessary certificates or permits.

Article 9.7. Obligations of Confidentiality. RTU represents and warrants that any and all employees and other affiliated persons, including subcontractors, who will be involved in performing this Agreement is bound, or will be bound prior to performing any work, by a proprietary information and technology agreement in favor of SAG, consistent with the obligations of Article 5, pursuant to which such employee or other person is obligated to confidentiality.

Article 9.8. Process and Product Warranties. RTU warrants and represents that:

(a) Drug Product sold by RTU to SAG hereunder shall (i) materially comply with the Specifications for Drug Product, and (ii) materially conform with the information shown on the Certificate of Analysis provided for the particular shipment;
(b) no Drug Product sold by RTU to SAG hereunder shall be adulterated or misbranded within the meaning of the Applicable Law, as amended and in effect at the time of shipment; provided, however, that this paragraph shall not apply to, and RTU shall have no responsibility for, misbranding caused directly by SAG as a result of labels or package texts specified or provided by SAG for the Drug Product; and RTU shall have no responsibility for issues of regulatory and legal compliance that are the responsibility of SAG, including but not limited to (1) maintaining a complete and valid NDA for the product, (2) ensuring that the product specifications are consistent with the NDA, and (3) ensuring that the product is stored and distributed in the SAG Territory in a manner that does not result in its becoming adulterated, misbranded, or otherwise in violation of law.

Article 9.9. Continuity of Supply. The Parties acknowledge that continuous supply of Drug Substance and Drug Product are of critical importance to the commercial interests of both Parties, and accordingly, RTU shall use commercially reasonable efforts to maintain the continuity of supply, and SAG shall reasonably cooperate with RTU (including but not limited to providing forecasts pursuant to Article 2.5 of this Agreement), so that Drug Substance and Drug Product be supplied continuously during the Term of this Agreement. RTU shall maintain a safety stock of active Drug Substance equal to six (6) months of forecast demand based on SAG's most recent Rolling Forecast RTU shall maintain a safety stock of Additional Materials to support the Drug Product manufacture and packaging equal to three (3) months of forecast demand based on SAG's most recent Rolling Forecast.

ARTICLE 10. INDEMNIFICATION

Article 10.1. RTU's Obligation. RTU shall defend, indemnify and hold SAG, and the respective officers, directors and employees of each, harmless from and against any and all claims, demands, losses, damages, liabilities (including without limitation product liability), settlement amounts, cost or expenses whatsoever (including reasonable legal fees and costs and court costs) arising from or relating to any claim, action or proceeding made or brought against such person by a third party as a result of RTU's negligence, willful misconduct or breach of this Agreement (including, without limitation, RTU's failure to comply with the Specifications, any breach by RTU of the warranties contained in Article 9, or otherwise any breach of the provisions of this Agreement by RTU). RTU shall have no obligation under this clause to indemnify SAG for claims described in Article 10.2. For the avoidance of doubt with regard to product liability claims relating to Drug Substance and Drug Product, RTU's indemnification of SAG hereunder shall extend only to matters of drug quality.

Article 10.2. SAG's Obligation. SAG shall defend, indemnify and hold RTU and the respective officers, directors and employees of each harmless from and against any and all claims, demands, losses, damages, liabilities (including without limitation product liability), settlement amounts, cost or expenses whatsoever (including reasonable legal fees and costs and court costs) arising from or relating to any claim, action or proceeding made or brought against such person by a third party as a result of (1) SAG's negligence, willful misconduct or any breach of the terms of this Agreement (including any of its representations and warranties set forth therein), (2) the manufacture and delivery to SAG of Drug Substance and Drug Product done in accordance with the Specifications, warranties and provisions of this Agreement, and/or (3) the investigation, administration, use, sale, marketing, promotion, advertising, storage, distribution, and any other activity with respect to the Drug Substance and the Drug Product that is the responsibility of SAG under this Agreement. SAG shall have no obligation under this clause to indemnify RTU for claims described in Article 10.1. For the avoidance of doubt with regard to product liability claims relating to Drug Product, SAG's indemnification of RTU hereunder shall extend only to matters inherent to the Drug Substance.

Article 10.3. Notice; Defense of Claims. In the event of any claim, action or proceeding for which a person is entitled to indemnity hereunder, the Person seeking indemnity ("Claimant") shall promptly notify the relevant party ("Indemnitor") in reasonable detail in writing the factual basis for such claim, action or proceeding and the amount of the claim; provided, however, that any delay by the Claimant in giving such notice shall not relieve the Indemnitor of its obligations under this Agreement except and only to the extent that the Indemnitor is materially damaged by such delay. The Indemnitor shall be entitled to assume the defense thereof at its own expense, with counsel satisfactory to such Claimant in its reasonable judgment; provided, however, that any Claimant may, at its own expense, retain separate counsel to participate in such defense. The Claimant shall not settle, compromise, discharge or otherwise admit to any liability for any claim or demand for which it is indemnified without the prior written consent of the Indemnitor (which consent shall not be unreasonably withheld or delayed). The Indemnitor shall not settle, compromise, discharge or otherwise admit to any liability for any claim or demand on a basis that would adversely affect the future activity or conduct of the Claimant without the prior written consent of the Claimant.

ARTICLE 11. TERM AND TERMINATION

Article 11.1. Term. This Agreement shall become effective as of the date hereof and remain in full force and effect for ten (10) years from the Effective Date with an automatic renewal for ten (10) years, unless otherwise earlier terminated by mutual written agreementor by the provisions set forth below.

Article 11.2. Termination for Cause. In addition to any other rights or remedies a Party may have, either Party may terminate this Agreement upon the occurrence of any of the following events of default which is not cured within sixty (60) days after written notice thereof is received by the other Party:

(a) breach by the other Party of any of its material obligations hereunder; or
(b) should the other Party become subject of proceedings involving bankruptcy, receivership, administration, insolvency, moratorium of payment reorganization or liquidation, or make any assignment for the benefit of the creditors or any equivalent measures in any relevant jurisdiction.

Article 11.3. Survival of Certain Rights and Obligations. The obligations under Article 5, Article 6, Article 8, Article 9, Article 10, this Article 11.3 and Article 12 shall survive any expiration or other termination of this Agreement in accordance with their terms.

ARTICLE 12. DISPUTE RESOLUTION

Article 12.1. Negotiation. The Parties agree to consult and negotiate in good faith to try to resolve any dispute, controversy or claim, of any nature or kind, whether in contract, tort or otherwise, that arises out of or relates to this Agreement. No formal dispute resolution shall be used by either Party unless and until the chief executive officers of each Party shall have attempted to meet in person to achieve such an amicable resolution.

Article 12.2. Arbitration. Any dispute, controversy or claim that arises out of or relates to this Agreement that is not resolved under Article 12.1 shall be settled by final and binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC") in effect on the Effective Date, as modified by Article 12.3 below. Judgment upon the award rendered by the arbitrators may be entered in any court of competent jurisdiction. The place of arbitration shall be Paris, France unless another location is agreed upon between the parties and arbitrators. The arbitration shall be conducted in the English language by three (3) neutral arbitrators selected by mutual agreement of the Parties or, if that is not possible within thirty (30) days of the initial demand for such arbitration, by the ICC. At least one (1) arbitrator shall have knowledge of and experience in the ethical pharmaceutical industry.

Article 12.3. Special Rules. Notwithstanding any provision to the contrary in the ICC's Rules of Arbitration, the Parties hereby stipulate that any arbitration hereunder shall be subject to the following special rules:
(a) The arbitrators may not award or assess punitive damages against either Party; and
(b) Each Party shall bear its own costs and expenses of the arbitration and shall share equally the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing Party.

ARTICLE 13. MISCELLANEOUS

Article 13.1. Changed Circumstances. The Parties recognize that the obligations of this Agreement may run for many years in the future. In the event of any material change in circumstances, the Parties shall meet and confer in good faith in order to try and find a solution that accommodates the interests of both Parties. RTU acknowledges that SAG will enter into one or more agreements with third parties for the purpose of commercial sale of Lubiprostone in the SAG Territory, and in the event that such third parties raise concerns or place demands on SAG concerning matters pertaining to this Agreement, RTU shall work with SAG to resolve such concerns or demands, including amending this Agreement, as may be commercially appropriate or necessary. SAG acknowledges that RTU will enter into agreements with third parties for the purpose of procuring various materials necessary for RTU to manufacture and supply Lubiprostone hereunder, and in the event that such third parties raise concerns or place demands on RTU that will result in increase of manufacturing costs, SAG shall work with RTU to resolve such concerns or demands, including amending this Agreement, as may be commercially appropriate or necessary.

Article 13.2. Subcontracting. RTU may subcontract its obligations hereunder with the consent of SAG, which shall not be unreasonably withheld, conditioned or delayed; provided, however, that RTU shall assume complete responsibility for the acts of its subcontractor and agrees to make SAG whole for any act or omission not in compliance with the provisions of this Agreement of RTU's subcontractor that damages SAG as if the act or omission were RTU's.

Article 13.3. Entire Agreement. This Agreement, together with the Appendices attached hereto, constitutes the entire agreement of the Parties with respect to the subject matter hereof and supersedes the Term Sheet and any and all other previous proposals or agreements, oral or written, and all negotiations, conversations or discussions heretofore between the Parties related to the subject matter of this Agreement.

Article 13.4. Independent Contractor; No Agency. This Agreement shall not be construed to create an employment or agency relationship between the Parties. This Agreement is not intended to create any agency relationship of any kind; the Parties agree not to contract any obligations in the name of the other or to use each other's credit in conducting any activities under this Agreement. Each Party is solely responsible for the payroll taxes, workman's compensation insurance, and any other benefits owed to their own employees.

Article 13.5. Assignment. Upon written approval of the other Party, which approval shall not unreasonably be withheld or delayed, a Party may assign or otherwise transfer its rights and obligations under this Agreement to any successor in interest (by merger, share exchange, combination or consolidation of any type, operation of law, purchase or otherwise), provided that such assignee or successor agrees to be bound by the terms hereof. Notwithstanding anything contained in this Article, this Agreement shall be assigned from SAG to any entity which acquired, or otherwise succeeded in interest in, all or substantially all of the assets in relation to Lubiprostone, and such entity shall be bound by this Agreement. For the avoidance of doubt, the Parties acknowledge that SAG is entering into this Agreement on the basis of RTU's special expertise in manufacturing the Drug Substance and Drug Product, and so SAG may withhold their approval of a proposed assignment if the proposed successor does not have reasonably comparable expertise.

Article 13.6. Governing Law. This Agreement shall be construed in accordance with New York law, excluding its choice of law provisions.

Article 13.7. Notices. All notices or other communications to a Party required or permitted hereunder shall be in writing and shall be delivered personally or by telecopy (receipt confirmed) to such Party (or, in the case of an entity, to an executive officer of such Party) or shall be given by certified mail, postage prepaid with return receipt requested, addressed as follows:

if to SAG:

Sucampo AG
Baarerstrasse 22
6300 Zug
Switzerland
Attention: VP, Operations and Finance
Email: asmith@sucampo.com

and if to RTU:

R-Tech Ueno, Ltd.
Hibiya Bldg., 10F, 1-1-7 Uchisaiwaicho
Chiyoda-ku, Tokyo 100-0011,
Japan
Attention: Director, Office of the President
Facsimile number: 81-3-3596-8023

Article 13.8. Severability. If a court of competent jurisdiction holds any provision of this Agreement invalid, the remaining provisions shall nonetheless be enforceable according to their terms. Further, if any provision is held to be overbroad as written, such provision shall be deemed amended to narrow its application to the extent necessary to make the provision enforceable according to applicable law and shall be enforced as amended.

Article 13.9. Waiver, Discharge, etc. This Agreement may not be released, discharged, abandoned, changed or modified in any manner, except by an instrument in writing signed on behalf of each of the Parties by their duly authorized representatives. The failure of either Party to enforce at any time any of the provisions of this Agreement shall in no way be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part of it or the right of either Party after any such failure to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach. No inspection or acceptance, approval, acquiescence, or payment by SAG with respect to non-conforming Drug Product shall relieve RTU from any portion of its warranty obligations hereunder unless expressly agreed by SAG in writing.

Article 13.10. Titles and Headings; Construction. The titles and headings to Articles herein are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the party causing this Agreement to be drafted.

Article 13.11. Benefit. Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the Parties or their respective permitted successors or assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

Article 13.12. Execution in Counterparts. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement, and shall become a binding agreement when one or more counterparts have been signed by each Party and delivered to the other Party.

IN WITNESS WHEREOF, each of the Parties has caused this Exclusive Supply Agreement to be executed in the manner appropriate to each, effective as of the date first above written.

R-TECH UENO, LTD.

By: _____
Yukihiko Mashima, M.D., PhD.
President

SUCAMPO AG

By: _____
Peter Greenleaf
President

Appendix A
Description of Lubiprostone

Generic name:	lubiprostone
Chemical names:	[…***…]
Code name:	Lubiprostone
CAS No.:	333963-40-9 (bicyclic type) or 136790-76-6 (monocyclic type
Structural Formula:	[…***…]

***Confidential Treatment Requested**

Appendix B
Specifications for Lubiprostone
Drug Product

[…***…]

***Confidential Treatment Requested**

EXHIBIT 10.2

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

SETTLEMENT AND LICENSE AGREEMENT

This SETTLEMENT AND LICENSE AGREEMENT (this "Agreement") is made and effective as of September ___, 2014 (the "Effective Date"), by and between, on the one hand, Sucampo AG and Sucampo Pharmaceuticals, Inc. (collectively, "Sucampo"), R-Tech Ueno, Ltd. ("RTU"), Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals USA, Inc. and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda"), and on the other hand, Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. (collectively, "Par"). Sucampo, RTU, Takeda, and Par are collectively referred to as the "Parties," and each separately as a "Party."

RECITALS

WHEREAS, Sucampo, RTU, Takeda, and Par are parties to a good faith patent infringement litigation captioned, *Sucampo AG, et al. v. Anchen Pharmaceuticals, Inc., et al.*, Civil Action No. 13-CV-00202-GMS, pending in the United States District Court for the District of Delaware (the "Court") before the Honorable Chief Judge Gregory M. Sleet (the "Patent Litigation");

WHEREAS, RTU currently manufactures and Sucampo and Takeda currently market AMITIZA® brand lubiprostone capsules (8 mcg and 24 mcg dosages) under New Drug Application ("NDA") No. 021908 (the "AMITIZA® Products" or "AMITIZA® Oral Capsule Products");

WHEREAS, Sucampo and/or RTU believe in good faith that they have lawfully obtained valid and enforceable patents issued by the U.S. Patent and Trademark Office containing claims covering the AMITIZA® Products, which products Takeda sells under an exclusive license from Sucampo and RTU in the United States;

WHEREAS, the U.S. Patent and Trademark Office has issued the following seven patents which are listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") for AMITIZA® and are owned by Sucampo alone and/or jointly with RTU: U.S. Patent Nos. 6,414,016; 7,795,312; 8,071,613; 8,026,393; 8,097,653; 8,338,639; and 8,389,542 (collectively, the "Sucampo Patents");

WHEREAS, Par filed an Abbreviated New Drug Application No. 201442 (the "Par ANDA") with the United States Food and Drug Administration (the "FDA") which contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Par's PIV certifications") regarding the Sucampo Patents and seeking approval to market generic versions of capsules containing 8 mcg and/or 24 mcg of lubiprostone ("Par's ANDA Products") before the expiration of the Sucampo Patents;

WHEREAS, the expiration dates for the seven Sucampo patents which are in suit for this Patent Litigation are:

- U.S. Patent No. 6,414,016 expires on September 5, 2020;
- U.S. Patent No. 8,071,613 expires on September 5, 2020;

- U.S. Patent No. 8,097,653 expires on November 14, 2022;
- U.S. Patent No. 8,389,542 expires on November 14, 2022;
- U.S. Patent No. 7,795,312 expires on September 17, 2024;
- U.S. Patent No. 8,338,639 expires on January 23, 2027; and
- U.S. Patent No. 8,026,393 expires on October 25, 2027;

WHEREAS, Sucampo has requested the FDA issue a Written Request under 21 U.S.C. § 505(A)(d)(2)(A)(i) for pediatric exclusivity, which request is pending with the FDA and if granted, could have further barred Par's launch of Par's ANDA Products, in the absence of this Agreement;

WHEREAS, in response to Par's PIV certifications and attendant notice letters, Sucampo, RTU, and Takeda lawfully commenced the objectively-based Patent Litigation and asserted infringement of the Sucampo Patents in good faith;

WHEREAS, the Parties acknowledge the significant future legal expenses and inherent legal risks involved in continuing protracted patent litigation with an uncertain end;

WHEREAS, the Parties wish to fully and finally settle the Patent Litigation upon the terms and subject to the conditions set forth below;

WHEREAS, the Plaintiffs are making no payment to Par in connection with this Agreement;

WHEREAS, this Agreement's generic entry date for Par's ANDA Products and other terms of this Agreement are unequivocally understood to be and are intended to be strictly within the scope of the Sucampo Patents at issue in this Patent Litigation and any other intellectual property held by Sucampo or Takeda, as the case may be, that could be asserted against Par at any time in view of acts related to Par's ANDA and Par's ANDA Products;

WHEREAS, settlement of the Patent Litigation will permit the Parties to avoid the substantial costs, uncertainty and risk involved with prolonged patent-infringement litigation, trial and appeal;

WHEREAS, settlement of the Patent Litigation will permit the management of the Parties to refocus on running their respective companies rather than devoting substantial time and resources to the Patent Litigation;

WHEREAS, the public will benefit significantly from this procompetitive final settlement of this Patent Litigation as it saves judicial resources and creates certainty for the Parties that will encourage the development, investment, and marketing of lubiprostone products and other pharmaceutical products;

WHEREAS, by reducing litigation expenses, this Agreement allows saved money to be spent on procompetitive activities, including marketing and further drug development, allowing the products to reach a larger group of patients and thus improving lives; and

WHEREAS, money saved by settling the Patent Litigation and avoiding potential future litigation against Par can now be invested by the Parties into research and development, thereby benefiting consumers by identifying new uses for current drugs, as well as furthering the creation of new proprietary medications;

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Section 1.1 Certain Defined Terms. The following terms, when used with initial capital letters, shall have the meanings set forth below:

"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, Takeda, and RTU are not Affiliates of each other.

"Authorized Generic" means 8 mcg and 24 mcg lubiprostone products sold in the Territory pursuant to NDA No. 021908 but not under the AMITIZA® trademark.

"Authorized Generic Supply Cost" has the meaning set forth in Section 3.12 of this Agreement.

"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.

"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.

"Fully Loaded Manufacturing Cost" means the Party's direct out-of-pocket costs actually incurred for the manufacturing, labeling, and packaging of an Authorized Generic or a Licensed Product, including API, excipients, packaging components, labeling components, internal direct labor, and quality control and assurance testing that are a necessary part of manufacturing. […***…].

"Generic Equivalent" means a pharmaceutical product that has received FDA approval for marketing in the Territory pursuant to an ANDA (or equivalent regulatory mechanism) as a generic equivalent to the AMITIZA® Products.

"Gross Profits" means […***…].

"Licensed Products" means Par's ANDA Products, consisting of an 8 mcg soft gelatin capsule for irritable bowel syndrome with constipation and a 24 mcg soft gelatin capsule ANDA Products for chronic idiopathic constipation and opioid-induced constipation as existing on the Effective Date, as described in the Par ANDA that may be amended or supplemented by Par from time to time in the ordinary course of business, provided that any such amendment or supplement does not change the […***…] Par's ANDA Products; provided, however, that any such amendment or supplement for a […***…] may be sought by Par only if any such amendment or supplement of […***…] that is approved after the Effective Date of this Agreement […***…] is stated for such […***…].

"License Effective Date" means the earliest to occur of the following dates:

(a) January 1, 2021; or

(b) 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

(c) in the event that Sucampo or any of its Affiliates enters into an agreement with any Third Party that would permit such Third Party to market or sell in the Territory a Generic Equivalent, the date provided for by Section 3.6 of this Agreement; or

(d) in the event that Sucampo or any of its Affiliates, or a Third Party, Commercially Markets or sells an Authorized Generic, the date provided for by Section 3.7 of this Agreement; or

(e) the date on which a Market Decline Event occurs

*Confidential Treatment Requested

"Losses" means all pending and potential claims, demands, all manner of actions, causes of action, suits, debts, liabilities, losses, damages, reasonable attorneys' fees, costs, expenses (including expert fees), judgments, settlements, interest, punitive damages and other damages or costs of whatever nature, whether known or unknown, pending or future, certain or contingent.

"Market Decline Event" means the first day of the month after which (x) Sucampo or an Affiliate of Sucampo, Commercially Markets in the Territory […***…] under a marketing approval that is obtained for the first time after the Effective Date of this Agreement and (y) […***…] of the AMITIZA® Oral Capsule Products decline […***…] from the average quarterly IMS NPA total prescriptions for such AMITIZA® Oral Capsule Products, as determined on a rolling basis by dividing […***…].

"Net Sales" means the gross sales of the Par ANDA Products 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 the Par ANDA Products, 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 the Par ANDA Products;

(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.

*Confidential Treatment Requested

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 Licensed Products between Par and its Affiliates or sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Licensed Products to a Third Party shall be included within the computation of Net Sales. If any of the Licensed Products are 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 Licensed Products.

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 such Licensed 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 such Licensed 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 the Licensed 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 the Licensed Product and such other product).

"Non-Litigated Patents" refers to each patent listed and that may in the future be listed in the Orange Book for the AMITIZA® Products that has not been asserted against Par in the Patent Litigation.

"Person" means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, governmental authority, or other entity or organization.

"Proceeding" means any administrative, judicial or legislative action, audit, litigation, investigation, suit or other proceeding in any tribunal.

"Product Liability Claims" means any claim, demand, or lawsuit involving allegations that a manufacturing, design or warning defect, regardless of whether the claim, demand, or lawsuit sounds in negligence or strict liability, injured a patient.

"Territory" means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico and the District of Columbia.

"Third Party" means any Person other than Sucampo, RTU, Takeda, Par, their Affiliates, and their subsidiaries.

ARTICLE 2
SETTLEMENT AND RELEASE

Section 2.1 Mutual Release. Upon the terms and subject to the conditions of this Agreement and the Consent Judgment and Order of Permanent Injunction, each Party, on behalf of itself and its Affiliates and subsidiaries hereby releases, acquits and forever discharges the other Parties and their Affiliates and subsidiaries, and their respective directors, officers, employees,

agents, representatives, heirs, assigns, predecessors and successors ("Related Parties") from any and all Losses arising out of, derived from, predicated upon or relating to infringement of the Sucampo Patents and Non-Litigated Patents, that Sucampo, RTU, and/or Takeda owns or will own, in whole or in part, that is, or could be alleged to be infringed by the Licensed Products, and the actions underlying the Patent Litigation, or otherwise related to the Par ANDA. Notwithstanding the foregoing, nothing in this Agreement shall prevent or impair the right of any Party to bring a Proceeding in court or any other forum for breach of this Agreement (including, without limitation, any claim for infringement of any intellectual property based upon activities that are not the subject of the license and rights granted hereunder) or any representation, warranty or covenant herein. […***…].

Section 2.2 Submission of Consent Judgment and Order of Permanent Injunction and Final Dismissal of Patent Litigation. The Parties agree to the entry of a Consent Judgment and Order of Permanent Injunction attached hereto as Exhibit A. To effectuate this final settlement and dismissal of the Patent Litigation, within three (3) business days following the execution of this Agreement, the Parties shall notify the District Court for the District of Delaware of the fact of this settlement and submit the executed settlement Agreement under seal with the District Court for the District of Delaware. Within five (5) business days following the expiration of the 30-day review period in Section 6.8 (the "Regulatory Review Period"), the Parties shall cause the Consent Judgment and Order of Permanent Injunction attached hereto as Exhibit A (each Party acknowledging that the approval of the Court is required in order to make such Consent Judgment and Order of Permanent Injunction effective) to be filed with the District Court for the District of Delaware and shall take all other necessary actions to obtain the settlement and dismissal of the Patent Litigation and entry of the Consent Judgment and Order of Permanent Injunction, provided that no Party shall be required to agree to any modification of the Consent Judgment and Order of Permanent Injunction or this Agreement that materially affects the economic value of the transactions contemplated hereby. Each Party shall bear its own costs and expenses in connection with the foregoing.

Section 2.3 Mutual Agreements. Each Party acknowledges and agrees that:

(a) It may have sustained Losses that are presently unknown and unsuspected, and that such Losses might give rise to Losses in the future. Nevertheless, each Party acknowledges and agrees that this Agreement has been negotiated and agreed upon, notwithstanding the existence of such possible Losses, all of which have been hereby released under Section 2.1 hereof.

(b) If any fact relating to this Agreement or the Patent Litigation and now believed to be true is found hereafter to be other than, or different from, that which is now believed, each Party expressly assumes the risk of such difference in fact and agrees that this Agreement shall be, and will remain, effective notwithstanding any such difference in fact, subject to each Party's right to bring a Proceeding for a breach of any representation, warranty or covenant herein.

*Confidential Treatment Requested

(c) This Agreement may be pleaded as a full and complete defense to, and used as a basis for injunction against, any Proceeding that may be instituted, prosecuted or attempted in breach hereof.

(d) If Par acquires the right, title, or interest to another ANDA for 8 mcg and/or 24 mcg capsules of lubiprostone products that references NDA No. 021908 and that ANDA contains a PIV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the Sucampo Patents and seeks approval to market generic versions of 8 mcg and/or 24 mcg capsules of lubiprostone products before the expiration of the Sucampo Patents, the terms of this Agreement shall apply equally to that ANDA and its products as they do to the Par ANDA and its products.

ARTICLE 3
LICENSE

Section 3.1 License Grant. Effective upon the License Effective Date, 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 Licensed Products in the Territory, and (ii) to make and have made the Licensed Products outside the Territory only for use, sale and importation in the Territory.

Section 3.2 Covenant Not to Sue Licensed Products. With respect only to the Licensed Products, and effective upon the License Effective Date, each of Sucampo, RTU, and Takeda (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 (a) any Sucampo Patents and/or any other patents (issued or that may issue in the future) owned by or licensed to Sucampo, RTU, Takeda, or any of their Affiliates purporting to cover the Licensed Products, the AMITIZA® Products, and/or the use or administration thereof, including, but not limited to, any continuations, continuations-in-part, divisionals, reissues or reexaminations of the foregoing patents (collectively referred to herein as the "Covenant Not To Sue Patents"), 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, the Licensed Products.

Section 3.3 Restrictions Prior to License Effective Date. Subject to Section 3.4, Par and its Affiliates and Related Parties shall not make, have made, import into, distribute, offer to sell or sell in the Territory any Licensed Products prior to the License Effective Date. Par agrees that any breach by it, or its Affiliates and/or Related Parties, of this Section 3.3 shall cause irreparable harm to Sucampo, RTU, and Takeda, 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 3.3. 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 3.4, prior to the License Effective Date.

Notwithstanding the foregoing, the contractual restrictions and remedies stated in this

Section 3.3 shall not apply if a court enters a Final Court Decision holding that each of the unexpired patent claims included in the Sucampo Patents that were asserted against Par in the Patent Litigation is invalid or unenforceable. Par agrees that any relief from the restrictions and remedies of this Section 3.3 pursuant to the preceding sentence shall not be construed as a license under the Sucampo Patents and shall have no effect on the License Effective Date.

Section 3.4 Pre-Marketing Activities. Par and its Affiliates and Related Parties may, but not earlier than […***…] ([…***…]) calendar days prior to the License Effective Date, […***…] and otherwise take such steps necessary to develop inventory of the Par ANDA Products solely for the purpose of preparing for commercial launch as of the License Effective Date. Par and its Affiliates and Related Parties shall not be allowed to engage in taking orders before the applicable License Effective Date; however, 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 […***…] ([…***…]) calendar days before the License Effective Date. For the avoidance of doubt, in no event shall Par and its Affiliates and Related Parties offer for sale, sell, launch, Commercially Market, distribute, or ship the Par ANDA Products prior to the License Effective Date.

Section 3.5 Covenant Not to Challenge and Assist Challenges to the Sucampo Patents. 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 shall not (1) challenge the validity or enforceability of, or assert the noninfringement of, any of the Sucampo Patents and the Non-Litigated Patents; 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 Patent Litigation, 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 Patents or Non-Litigated Patents; 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. 021908.

Section 3.6 Impact of Granting Certain Licenses to Third Parties. In the event that Sucampo, RTU, and/or Takeda is a party to or enters into an agreement with any Third Party (i) granting such Third Party a license and/or sublicense, as applicable, to Commercially Market in the Territory a Generic Equivalent on a date effective earlier than the License Effective Date in this Agreement, or (ii) providing […***…] set forth in Section 3.13, then (x) the License Effective Date shall automatically be amended to be the earliest date such Third Party is permitted to Commercially Market such Generic Equivalent in the Territory and/or (y) […***…] and to be effective only for the remaining term of this Agreement.

(a) In the event that Sucampo, RTU, and/or Takeda is a party to or enter into any agreement with a Third Party granting such Third Party a license and/or sublicense to Commercially Market in the Territory a Generic Equivalent, Sucampo, RTU, and/or Takeda shall

*Confidential Treatment Requested

provide written notice thereof to Par no fewer than ten (10) business days after the entry into such agreement.

(b) Par may elect, within five (5) business days after Par's receipt of such notice, to have Sucampo submit […***…], mutually acceptable to Par and Sucampo, by providing written notice of such election to Sucampo.

(c) In the event that […***…] hereunder shall be automatically amended to become such […***…] to be effective only for the remaining term of this Agreement.

Section 3.7 Impact of Authorized Generic. In the event that Sucampo, RTU, and/or Takeda enter into an agreement with any Third Party to Commercially Market an Authorized Generic, or if Sucampo, RTU, and/or Takeda elect to Commercially Market an Authorized Generic, earlier than the License Effective Date in this Agreement, then the License Effective Date in this Agreement shall automatically be amended to be the earliest date such Third Party is permitted to Commercially Market an Authorized Generic in the Territory under the license and/or sublicense from Sucampo, RTU, and/or Takeda or the date Sucampo, RTU, and/or Takeda Commercially Markets an Authorized Generic in the Territory. In either case, Sucampo, RTU, and/or Takeda shall provide notice to Par no fewer than […***…] ([…***…]) calendar days after the entry into any agreement with any Third Party to Commercially Market an Authorized Generic and in either case, no later than […***…] ([…***…]) calendar days prior the date on which either the Third Party or Sucampo/RTU/Takeda Commercially Markets the Authorized Generic.

Section 3.8 Regulatory Delay. No provision of this Agreement shall be affected by any delay in the approval of the Par ANDA by the FDA, […***…], except to the extent that such provision is affected by the delay of Par's Commercial Marketing**.**

Section 3.9 Limited Use of Agreement Outside Territory. The Parties agree that they will not use this Agreement or the Consent Judgment and Order of Permanent Injunction outside of the Territory for any purpose except to enforce the Agreement.

Section 3.10 Effect of Third Party Launch. If any Third Party Commercially Markets any Generic Equivalent (i) without authorization, permission, license, or the like from Sucampo, Takeda, and RTU and (ii) without a Final Court Decision (a "Third-Party At-Risk Launch"), Par has the option of Commercially Marketing Par's ANDA Products without a license at that time ("Par At-Risk Launch") only under the following conditions:

(a) Par may commence a Par At-Risk Launch no earlier than […***…] ([…***…]) calendar days after the first Third-Party At-Risk Launch, and only after providing Sucampo written notice […***…] ([…***…]) calendar days before any intended Par At-Risk Launch.

(b) Par agrees that during such Par At-Risk Launch, if (i) Sucampo, RTU, and/or Takeda obtains a court order from any court requiring the cessation of sales of the Generic Equivalent that is the subject of the Third Party At-Risk Launch or (ii) the Third Party ceases sales

*Confidential Treatment Requested

of the Generic Equivalent that is the subject of the Third Party At-Risk Launch, by agreement or otherwise, Par will cease any shipping, Commercial Marketing, and At-Risk sales of Par's ANDA Products within its own custody and control and any other infringing activities until the occurrence of the License Effective Date (including any advancement of the License Effective Date under the terms of this Agreement).

(c) Notwithstanding Section 2.1 above, in the event of a Final Court Decision that any claim of the Sucampo Patents asserted against Par is not invalid and is not unenforceable, Par agrees to pay Sucampo liquidated damages equal to […***…] percent ([…***…]%) of […***…] sold during Par's At-Risk Launch before the License Effective Date (including any advancement of the License Effective Date under the terms of this Agreement).

Section 3.11 Effect of Non-Infringement Judgment. If any Third Party obtains a decision or judgment from a trial court that its Generic Equivalent does not infringe each of the unexpired claims of the Sucampo Patents that were asserted against that Third Party and that decision or judgment does not also contain a final judgment that each such claim is also invalid or unenforceable, and that Third Party subsequently Commercially Markets its Generic Equivalent, that Commercial Marketing will not qualify as a Third Party At-Risk Launch under Section 3.10.

Section 3.12 Par's Option to Sell Authorized Generic Products. Par shall have the option to Commercially Market an Authorized Generic, but not earlier than January 1, 2021. 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 Authorized Generic products to resell, which Authorized Generic products shall be supplied to Par at […***…] (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 B hereto. Except as stated above in this Section 3.12, all terms in this Agreement that apply to Licensed Products shall apply equally to the Authorized Generic products manufactured for, and supplied to Par, including the payment of royalties pursuant to Section 3.13, as though Par were Commercially Marketing Licensed Products.

Section 3.13 Royalty Payments and Reporting.

(a) Beginning on the License Effective Date, Par shall pay Sucampo a royalty of […***…] of the Licensed Products sold during the term of this Agreement, 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 3.13. If within two years prior to the License Effective Date, (x) Sucampo or an Affiliate of Sucampo, Commercially Markets in the Territory for the first time, either alone or in partnership with another Person, a new lubiprostone-containing drug product indicated for the treatment of constipation or irritable bowel syndrome under a marketing approval that is obtained for the first time after the Effective Date of this Agreement and (y) the total prescriptions for the AMITIZA® Oral Capsule Products (in the aggregate) for any quarter during the two year window decline by at least […***…] ([…***…]%) from the average quarterly IMS NPA total prescriptions for the AMITIZA® Oral Capsule Products (in the aggregate), as determined on a

*Confidential Treatment Requested

rolling basis by dividing such total prescriptions for the immediately preceding twelve (12) month period by four (4), Par shall as of the License Effective Date pay Sucampo a royalty of […***…] of the Licensed Products sold during the term of this Agreement, 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 3.13.

(b) During any period after the License Effective Date 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 Takeda or an Affiliate is Commercially Marketing an Authorized Generic in the Territory) the royalty rate provided for in Section 3.13(a) shall be […***…] and Sucampo or its Affiliates have the option to supply Par with Authorized Generic products at a negotiated costs plus price.

(c) During any period after the License Effective Date 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 Takeda or an Affiliate is Commercially Marketing Authorized Generics in the Territory), the royalty rate provided for in Section 3.13(a) shall be […***…] and Sucampo or its Affiliates have the option to supply Par with Authorized Generic products at a negotiated costs plus price.

(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.

*Confidential Treatment Requested

(g) Sucampo 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 shall be paid on the next date payment is due hereunder. To the extent that the difference between such accruals or estimates and the actual results has led to an overpayment 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 3.13(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.

Section 3.14 Reservation of Rights. All rights not expressly granted to Par hereunder are expressly reserved to Sucampo, RTU, and/or Takeda including Sucampo, RTU, and Takeda's right to continue to manufacture and/or Commercially Market AMITIZA® Products to the extent permitted by contract and law, and Sucampo, RTU, and Takeda have no obligation to make available any intellectual property rights or to take any other actions other than as expressly set forth herein. Except as expressly provided in this Article 3, nothing in this Agreement shall be construed as granting Par or its Affiliates, subsidiaries or Related Parties any rights: (a) with respect to any Licensed Products outside the Territory; (b) with respect to any product other than Licensed Products; or (c) to make, have made, use, offer to sell, sell, import, or otherwise dispose of any generic version of any AMITIZA® Products covered by the Sucampo Patents at any time prior to the License Effective Date. Nothing in this Agreement shall restrict the ability of Sucampo, from launching, Commercially Marketing and/or selling an Authorized Generic or from licensing a Third Party to launch, Commercially Market and/or sell an Authorized Generic, or from launching, Commercially Marketing, and selling any product for indications or dosages not set forth in Par's ANDA.

Section 3.15 Sucampo, RTU, and Takeda, on behalf of themselves and their Affiliates, will impose the license grants, covenants, waivers and other obligations contained in this Article 3 and elsewhere in this Agreement on any Person to whom Sucampo, RTU, and Takeda or their Affiliates may assign or otherwise transfer title or interest in or to NDA No. 021908 and the Covenant Not To Sue Patents.

ARTICLE 4
REPRESENTATIONS, AND WARRANTIES, AND COVENANTS

Section 4.1 Mutual Representations. Each Party hereby represents and warrants to the other Parties as of the Effective Date as follows:

(a) Due Authorization. Such Party is an entity duly organized and in good standing as of the Effective Date, and the execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary action on the part of such Party.

(b) Due Execution. This Agreement has been duly executed and delivered by such Party and, with due authorization, execution and delivery by the other Parties, constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.

(c) No Conflict. Such Party's execution, delivery and performance of this Agreement do not: (i) violate, conflict with or result in the breach of any provision of the charter or by-laws (or similar organizational documents) of the Party; (ii) conflict with or violate any law or governmental order applicable to the Party or any of its assets, properties or businesses; or (iii) conflict with, result in any breach of, constitute a default (or event which with the giving of notice or lapse of time, or both, would become a default) under, require any consent under, or give to others any rights of termination, amendment, acceleration, suspension, revocation or cancellation of any note, bond, mortgage or indenture, contract, agreement, lease, sublease, license, permit, franchise or other instrument or arrangement to which it is a party.

Section 4.2 Sucampo's Representations, Warranties and Additional Covenants. Sucampo represents and warrants to Par that, as of the Effective Date, Sucampo (i) is the owner of the full right, title and interest in, to and under the Sucampo Patents alone and/or jointly with RTU, and has the right to grant to Par the licenses granted hereunder with respect to the Sucampo Patents, (ii) has the right to settle the Patent Litigation, and (iii) does not license from a Third Party any patents or pending patent applications that would preclude Par and its Affiliates from making, using, selling, offering for sale, importing or otherwise disposing of the Licensed Products in the Territory. Sucampo further represents and warrants that, as of the Effective Date, no Third Party has any right (as owner, licensee or otherwise) to enforce or sue for infringement of the Sucampo Patents.

Section 4.3 Par Representations and Warranties. Par represents and warrants to Par that, as of the Effective Date, (i) Par or its Affiliates own all right, title and interest in, to and under the Par ANDA, and Par and its Affiliates have not granted or assigned to any Third Party, directly or indirectly, any rights under or to the Par ANDA or Par's ANDA Products, (ii) Par and its Affiliates will not transfer ownership, in whole or in part, of said Par ANDA, except to an Affiliate of Par or to a successor to all or substantially all of the business to which this Agreement pertains, until the expiration of the license granted herein, and (iii) Par has the right to settle the Patent Litigation.

Section 4.4 Par's Covenant Not to Sue Sucampo Products. With respect to the AMITIZA® Products or an Authorized Generic, and effective upon the License Effective Date, Par, its Affiliates, and its Related Parties covenants not to sue Sucampo, RTU, Takeda and its/or their 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 patents (issued or that may issue in the future) owned, licensed, or controlled by Par or any of its Affiliates or Related Parties purporting to cover the AMITIZA® Products or an Authorized Generic, and/or the use or administration thereof, including any continuations, continuations-in-part, divisionals, reissues or reexaminations of the foregoing patents, 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, the AMITIZA® Products or an Authorized Generic.

Section 4.5 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF APPLICABLE LAW, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS SUCH WARRANTIES.

ARTICLE 5
INDEMNIFICATION

Section 5.1 Sucampo, RTU, and Takeda Indemnification. Sucampo, RTU, and Takeda shall indemnify and hold harmless Par, their Affiliates, and their Related Parties ("Par Indemnitees") from and against any liabilities, damages, costs, or expenses, including reasonable attorneys' fees and expert fees, incurred by any Par Indemnitee that arise from any claims, actions, demands, suits, or other cause of action by a Third Party arising out of or related to any breach of their respective representations, warranties and covenants set forth in this Agreement.

Section 5.2 Par Indemnification. Par shall indemnify and hold harmless Sucampo, RTU, Takeda and their Affiliates, and their Related Parties ("Sucampo, RTU, and Takeda Indemnitees") from and against any liabilities, damages, costs, or expenses, including reasonable attorneys' fees and expert fees, incurred by any Sucampo, RTU, and Takeda Indemnitee that arise from any claims, actions, demands, suits or other cause of action by a Third Party arising out of or related to: (i) any breach of Par's, as applicable, representations, warranties and covenants set forth in this Agreement, (ii) the design, manufacture, marketing, sale or use of any Licensed Products, including any Product Liability Claims, (iii) the failure by Par as applicable, to comply with any FDA or other governmental requirement with respect to any Licensed Products, and/or (iv) the infringement or misappropriation of any Third Party patent, copyright, trademark, service mark, trade secret or other intellectual property based on any Licensed Products, except to the extent Sucampo, RTU, and Takeda are required to indemnify Par Indemnitees pursuant to Section 5.1.

Section 5.3 Indemnification Procedures. The obligations to indemnify, defend, and hold harmless set forth in Section 5.1 and Section 5.2 shall be contingent upon the Party seeking indemnification (the "Indemnitee"): (i) notifying the indemnifying Party of a claim, demand or suit within fifteen (15) days of receipt thereof; provided, however, that the Indemnitee's failure or delay in providing such notice shall not relieve the indemnifying Party of its indemnification obligation except to the extent the indemnifying Party is prejudiced thereby; (ii) allowing the indemnifying Party and/or its insurers the right to assume direction and control of the defense of any such claim, demand or suit; (iii) cooperating with the indemnifying Party and/or its insurers in the defense of such claim, demand or suit at the indemnifying Party's expense; and (iv) agreeing not to settle or compromise any claim, demand or suit without prior written authorization of the indemnifying Party. The Indemnitee shall have the right to participate in the defense of any such claim, demand or suit referred to in this Section utilizing attorneys of its choice, at its own expense, provided, however, that the indemnifying Party shall have full authority and control to handle any such claim, demand or suit.

ARTICLE 6
MISCELLANEOUS

Section 6.1 Assignment. No Party hereto may assign any of its rights or obligations under this Agreement, except to an Affiliate or successor to all or substantially all of the business of the Party to which this Agreement pertains, without the prior written consent of the other Parties. Any Party may assign this Agreement without the prior written consent of the other Parties to an Affiliate or in connection with a merger, reorganization, change of control or sale of all or substantially all of the applicable business of such Party, in each case, on written notice to the other Parties, provided that the successor Person agrees in writing to adhere to all of the terms and conditions of this Agreement. Any purported assignment in violation of the foregoing shall be null and void and of no force or effect. No assignment of this Agreement will relieve the assigning Party from any of its obligations hereunder. In the event of a permitted assignment, this Agreement shall be binding upon and inure solely to the benefit of the Parties and their respective successors and permitted assigns.

Section 6.2 Dispute Resolution. Any dispute, controversy or claim arising out of or relating to this Agreement (a "Dispute") shall be attempted to be settled by the Parties, in good faith, by submitting each such Dispute to the Chief Executive Officers of each Party by written notice from any Party to the other Parties specifying the terms of such Dispute in reasonable detail. Within fourteen (14) calendar days of receipt of such notice, the Chief Executive Officers of each Party involved in the Dispute or a member of management designated by the respective Chief Executive Officer, shall meet in person (at a mutually agreed upon time and location) or by telephone for the purpose of resolving such Dispute. They will discuss the problems and/or negotiate for a period of up to twenty (20) calendar days in an effort to resolve the Dispute or negotiate an acceptable interpretation or revision of the applicable portion of this Agreement mutually agreeable to the Parties, without the necessity of formal procedures relating thereto. If the problem is not resolved within the period set forth above, the Parties shall be free to pursue all available remedies, at law or in equity, consistent with the terms of this Agreement. Notwithstanding the foregoing, any Party may apply to a court of competent jurisdiction for a temporary restraining order, preliminary injunction, or other equitable relief, where such relief is necessary to protect its interests. For avoidance of doubt, this Section 6.2 does not apply to any breach as set forth in Section 3.3 of this Agreement.

Section 6.3 Governing Law and Venue. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to its conflict of laws principles. The Parties hereby consent to the exclusive jurisdiction of the federal courts located in Delaware, and expressly waive any objections or defenses based on lack of personal jurisdiction or venue in connection with any dispute arising out of or relating to this Agreement.

Section 6.4 Bankruptcy. All rights and licenses granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code (the "Bankruptcy Code"), licenses of "intellectual property" as defined under the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code.

Section 6.5 Confidentiality. The Parties and their respective Affiliates and Related Parties shall not use or disclose to Third Parties (other than the Parties' respective financial advisors, legal advisors, and Affiliates, or by Par in connection with securing FDA approval to market Par's ANDA Products, or by any Party in connection with a potential or actual assignment pursuant to Section 6.1) either (a) the terms of this Agreement or (b) any information received from the other Parties or otherwise developed or obtained (including prior to the date hereof) by any Party in the performance of activities under this Agreement without first obtaining the written consent of the disclosing Party, except as may be otherwise provided in, or required in order for a Party to exercise its rights or fulfill its obligations under, this Agreement. This confidentiality obligation shall not apply to information that (i) is or becomes a matter of public knowledge (other than by breach of this Agreement by the receiving Party), (ii) is required by law, regulation or order of a court or administrative agency of competent jurisdiction, to be disclosed, and then only to the extent required by law provided that the disclosing Party shall (a) give the other Parties reasonable prior notice of such required disclosure and (b) provide such other Parties a reasonable opportunity to seek a protective order or other injunctive relief to limit or protect the confidentiality of such disclosures, (iii) the receiving Party can establish was already known to it or was in its possession at the time of disclosure, (iv) the receiving Party can establish was independently developed by Persons in its employ who had no contact with and were not aware of the content of the confidential information, or (v) is disclosed to the receiving Party by a Third Party having no obligation of confidentiality to the disclosing Party with respect to such information. The Parties shall take reasonable measures to assure that no unauthorized use or disclosure is made by others to whom access to such information is granted. Notwithstanding the foregoing, Sucampo, RTU, and Takeda have the right to disclose to Third Parties the License Effective Date defined in this Agreement if required in order to comply with the provisions of agreements with those Third Parties analogous to Section 3.6 above. Nothing in this provision bars the Parties from disclosing this Agreement to the Court, and the Parties have agreed to submit this settlement to the Court. Disclosure of this Agreement to the FTC and to the DOJ Antitrust Division on a confidential basis is contemplated by this Agreement, as provided in Section 6.8.

Section 6.6 Publicity. Except as consistent with a press release mutually agreed by Sucampo and Par, or other publicly disclosed information, no public announcement or other disclosure to Third Parties concerning the existence of or terms of this Agreement shall be made, except as permitted under Article 3 of the Agreement, either directly or indirectly, by any Party, without first obtaining the written approval of the other Parties and agreement upon the nature, text and timing of such announcement or disclosure, which approval shall not be unreasonably withheld, conditioned, or delayed; provided, however, each Party shall have the right to make any such public announcement or other disclosure required by law after such Party has provided to the other Parties a copy of such announcement or disclosure and an opportunity to comment thereon. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission, the Federal Trade Commission, and the Food and Drug Administration, and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of any Party included in any such disclosure. No Party shall be required to provide the other Parties with any advance notice of any public announcements or other disclosures related to periodic, routine financial reporting unless such announcement or other disclosure will include non-routine information relating to the Licensed Products or this Agreement.

Section 6.7 Cooperation and Compliance with Laws. Subject to confidentiality restrictions that may be reasonably requested, the Parties shall use their respective commercially reasonable efforts to:

(a) Make all required filings with all governmental authorities (*e.g.*, the FTC and DOJ filings described in Section 6.8) and obtain all necessary approvals in connection with this Agreement to the extent required under applicable laws. Subject to confidentiality restrictions that may be reasonably requested and to the extent permissible by law, the Parties shall coordinate and exchange all filings and documents submitted to all government authorities regarding this Agreement;

(b) Cooperate with each other in any review, investigation, inquiry or proceeding regarding the Agreement by any government authority. Subject to such confidentiality restrictions as may be reasonably requested and to the extent permissible by law, the Parties, will render reasonable assistance as the other may request in connection with this Agreement and coordinate and cooperate with one another in exchanging information, permitting reasonable access to the Parties' and their respective Affiliates' documents, officials, and data in connection with any such review, investigation, inquiry or proceeding by any governmental authority;

(c) Promptly inform each other of any material communication made to, or received by such Party from any governmental authority regarding this Agreement, including any amendments or supplements of the Par ANDA;

(d) Defend, contest and resist any administrative, judicial or legislative action or proceeding that is instituted (or threatened to be instituted) challenging the transactions contemplated by this Agreement as violative of any applicable law, and have vacated, lifted, reversed or overturned any decree, judgment, injunction or other order (whether temporary, preliminary or permanent) that is in effect and that challenges this Agreement, including, without limitation, by pursuing all reasonable avenues of administrative and judicial appeal;

(e) Without limiting any other provision of this Agreement, take all actions and do all things reasonably necessary or proper (at its own cost and expense), including under applicable law to make effective and further the intent and purposes of the transactions contemplated by this Agreement, including executing any further instruments reasonably requested by the other Parties, and to resist and to contest any proposals or efforts to materially alter the terms of the Agreement so as to permit the Parties to fulfill their obligations under and to obtain the full benefits contemplated by the Agreement; and

(f) The Parties agree that the entering into of this Agreement and the performance of their respective obligations hereunder shall be in compliance with all applicable federal, state and local laws, rules, guidelines and regulations.

Section 6.8 Government Notifications and Government Proceedings. 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. 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.

Section 6.9 Notices. All notices required or permitted under this Agreement must be in writing and must be given by addressing the notice to the address for the recipient set forth below or at such other address as the recipient may specify in writing under this procedure. Notice shall be delivered by using a recognized express delivery service such as Federal Express/Airborne/United Parcel Service/DHL Worldwide, or United States Express Mail, charges prepaid or charged to the sender's account, in which case notice is effective on delivery, if delivery is confirmed by the delivery service. In addition to delivery by express delivery service, notice shall also be sent by e-mail.

If to Sucampo:

Sucampo Pharmaceuticals, Inc.
4520 East West Highway, 3rd Flr.
Bethesda, MD 20814
Attn: Chief Legal Officer
Fax: 301-961-3440
Email: tknapp@sucampo.com

With a copy to:
Paul Hastings LLP
75 East 55th Street
New York, NY 10022
Phone (212) 318-6000
Attn: Joseph M. O'Malley, Jr.
josephomalley@paulhastings.com
Preston K. Ratliff II
prestonratliff@paulhastings.com

If to Par:

Par Pharmaceutical, Inc.
300 Tice Boulevard
Woodcliff Lake, New Jersey 07677
Attn: General Counsel
Fax: (201) 802-4600

With a copy to:
Daniel G. Brown
Terrence J. Connolly
Latham & Watkins LLP
885 Third Avenue
New York, NY 10022
Telephone: (212) 906-1200
Facsimile: (212) 751-4864
Email: Daniel.Brown@lw.com
Email: Terrence.Connolly@lw.com

If to Takeda:

Takeda Pharmaceutical Company Limited
1-1 Doshomachi 4-chome, Chuo-ku
Osaka 540-8645, Japan,
Attention: General Manager, Intellectual Property Department
Fax No.: +81-6-6300-6601
Email: yoichi.okumura@takeda.com

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
Email: naoko.okabe@rtueno.co.jp

copy to:

Takeda Pharmaceuticals U.S.A., Inc.
One Takeda Parkway
Deerfield, IL 60015
Attention: General Counsel
Fax No.: 224-554-7831
Email: ken.greisman@takeda.com
copy to:

Takeda Pharmaceuticals America, Inc.
One Takeda Parkway
Deerfield, IL 60015
Attention: General Counsel
Fax No.: 224-554-7831
Email: ken.greisman@takeda.com

copy to:

Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Phone (212) 336-2000
Attn: Chad Peterman
cjpeterman@pbwt.com

Section 6.10 Amendment. This Agreement may not be amended or modified except by an instrument in writing signed by authorized representatives of the Parties.

Section 6.11 No Waiver. The failure of any Party to enforce at any time for any period the provisions of or any rights deriving from this Agreement shall not be construed to be a waiver of such provisions or rights or the right of such Party thereafter to enforce such provisions.

Section 6.12 Severability. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any law or public policy, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any Party.

Section 6.13 Headings. The descriptive headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of the Agreement.

Section 6.14 Counterparts. This Agreement may be executed in one or more counterparts, and by the respective Parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same Agreement.

Section 6.15 Entire Agreement. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and no oral or written statement that is not expressly set forth in this Agreement may be used to interpret or vary the meaning of the terms and conditions hereof. This Agreement supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof.

Section 6.16 Third Party Beneficiaries. Except as expressly provided herein, nothing in this Agreement, either express or implied, is intended to or shall confer upon any Third Party any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

Section 6.17 Scope of Agreement. The mutual releases, licenses, and other provisions set forth in this Agreement shall be limited to the Par ANDA and the AMITIZA® Products, and shall be without prejudice to, shall have no preclusive effect as to, and shall not be admissible in any proceedings pertaining to any future or different product(s) or ANDA(s).

[Remainder of Page Intentionally Left Blank; Signature Page(s) Follow]

IN WITNESS WHEREOF, this Agreement has been executed by the Parties as of the date first written above.

SUCAMPO AG

By: _____
Name: _____
Title: _____

ANCHEN PHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

SUCAMPO PHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

PAR PHARMACEUTICAL, INC.

By: _____
Name: _____
Title: _____

R-TECH UENO, LTD.

By: _____
Name: Yukihiko Mashima
Title: President

PAR PHARMACEUTICAL COMPANIES, INC.

By: _____
Name: _____
Title: _____

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: _____
Name: _____
Title: _____

TAKEDA PHARMACEUTICALS USA, INC.

By: _____
Name: _____
Title: _____

TAKEDA PHARMACEUTICALS AMERICA, INC.

By: _____
Name: _____
Title: _____

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SUCAMPO AG, SUCAMPO PHARMACEUTICALS, INC., R-TECH UENO, LTD., TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS USA, INC. AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	Civil Action No. 13-202 (GMS)

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement (the "Patent Litigation") has been brought by Plaintiffs Sucampo AG, Sucampo Pharmaceuticals, Inc., R-Tech Ueno, Ltd., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs") against Defendants Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. (collectively, "Par") for infringement of United States Patent Nos. 6,414,016 ("the '016 patent"); U.S. Patent No. 7,795,312 ("the '312 patent"); 8,206,393 ("the '393 patent"); U.S. Patent No. 8,071,613 ("the '613 patent"); 8,097,653 ("the '653 patent"); 8,338,639 ("the '639 patent"); and 8,389,542 ("the '542 patent") (collectively the "Sucampo Patents"). Plaintiffs' commencement of the Patent Litigation was based on its receipt of notice from Par that Par filed ANDA No. 201442 with the United States Food and Drug Administration containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the Sucampo Patents and seeking approval to market generic versions of 8 mcg and 24 mcg lubiprostone capsules.

Plaintiffs and Par have agreed to enter into a good-faith final settlement agreement regarding this Patent Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Plaintiffs and Par during the Patent Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. The final settlement between the Plaintiffs and Par has been submitted to this Court under seal, and the Court has reviewed this settlement agreement. This reasonable final settlement will afford Plaintiffs and Par the procompetitive opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Patent Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

Each of Plaintiffs and Par acknowledge there is significant risk to each of them associated with the continued prosecution of this Patent Litigation and have consented to judgment through a final settlement as reflected in the consent judgment set forth herein. The Court, upon the consent and request of Plaintiffs and Par, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Order.

Plaintiffs and Par now consent to this Consent Judgment and Order of Permanent Injunction and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

This Court has subject matter jurisdiction, over this patent infringement action, and personal jurisdiction over Plaintiffs and Par for purposes of this action. Venue is proper in this Court as to Plaintiffs and Par as to this action.

In this Patent Litigation, which was filed on February 7, 2013, Plaintiffs have charged Par with infringement of the Sucampo Patents in connection with Par's submission of Abbreviated New Drug Application ("ANDA") No. 201442 directed to generic tablets containing 8 mcg and 24 mcg of lubiprostone per capsule ("Par's ANDA No. 201442 Products") to the U.S. Food and Drug Administration ("FDA").

In response to Plaintiffs' charges of patent infringement, Par has alleged certain defenses, including that Sucampo Patents are invalid and/or not infringed. No decision has been obtained by the parties from this Court regarding these charges of infringement or these defenses.

Par has not obtained a decision from the Court finding that it has rebutted the statutory presumption that the Sucampo Patents are valid and enforceable in the Patent Litigation.

Par admits that the submission of ANDA No. 201442 containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of Par's ANDA No. 201442 Products within the United States before the expiration of the Sucampo Patents was a technical act of infringement of the Sucampo Patents under 35 U.S.C. § 271(e)(2)(A). This admission is further without prejudice to any claim, defense or counterclaim in any future action between Par and Plaintiffs, or any successor-in-interest to Sucampo, regarding the Sucampo Patents and/or a generic lubiprostone product other than Par's ANDA No. 201442 Products.

Both parties have agreed that each of the defenses set forth in Par's Answer, including the allegations and averments contained therein, should be dismissed, without prejudice.

Par, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, 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 the Settlement and License Agreement that the Parties have entered into.

Plaintiffs and Par each expressly waives any right to appeal or otherwise move for relief from this final Consent Judgment And Order of Permanent Injunction.

This court retains jurisdiction over Plaintiffs and Par for purposes of enforcing this final Consent Judgment And Order of Permanent Injunction.

This Consent Judgment and Order of Permanent Injunction is without prejudice to, and shall have no preclusive effect as to, any claim, defense or counterclaim in any future action between Par or any successor-in-interest to Par, and Plaintiffs, or any successor-in-interest to Plaintiffs, regarding the Sucampo Patents and/or a generic lubiprostone product other than Par's ANDA No. 201442 Products. Further, this Consent Judgment and Order of Permanent Injunction shall not be admissible in evidence, as an admission of Par or otherwise, in any such future action.

The Clerk of the Court is directed to enter this final Consent Judgment and Order of Permanent Injunction forthwith.

IT IS HEREBY STIPULATED:

Dated: _____, 2014

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

_____
Jack B. Blumenfeld (# 1014)
Karen Jacobs (# 2881)

Dated: _____, 2014

RICHARDS LAYTON & FINGER, P.A.

_____
Steven J. Fineman (# 4025)
Katherine C. Lester (# 5629)

Regina S.E. Murphy (# 5648)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com
rmurphy@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Joseph M. O'Malley, Jr.
Preston K. Ratliff II
Evan D. Diamond
PAUL HASTINGS LLP
75 E. 55th Street
New York, NY 10022
(212) 318-6000

Attorneys for Plaintiffs Sucampo AG, Sucampo Pharmaceuticals, Inc. and R-Tech Ueno, Ltd.

William F. Cavanaugh
Chad J. Peterman
Aileen M. McGill
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorneys for Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc. and Takeda Pharmaceuticals America, Inc.

One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 888-6960
fineman@rlf.com
lester@rlf.com

Attorneys for Defendants

OF COUNSEL:

Daniel G. Brown
Terrence J. Connolly
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022
(212) 906-1200

Roger J. Chin
LATHAM & WATKINS LLP
505 Montgomery Street
Suite 2000
San Francisco, CA 94111
(415) 391-0600

Marc N. Zubick
Lauren Sharkey
Matthew C. Darch
LATHAM & WATKINS LLP
233 South Wacker Drive, Suite 5800
Chicago, IL 60606
(312) 876-7700

SO ORDERED:

This _____ day of _____, 2014.

_____

THE HONORABLE GREGORY M. SLEET
Chief United States District Judge

EXHIBIT B

MANUFACTURING AND SUPPLY AGREEMENT

[ATTACHED]

EXHIBIT 10.3

*** 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 SEPTEMBER 30, 2014

MANUFACTURING AND SUPPLY AGREEMENT

Manufacturing and Supply Agreement (this **"Agreement"**) is hereby entered into and effective as of September [ ], 2014 (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, Par and Sucampo, among other parties, have entered into that certain Settlement and License Agreement dated September 30, 2014 (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, 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 Lubiprostone.

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, (d) to have been otherwise rightfully known by the Receiving Party prior to disclosure of such information by the Disclosing Party to the Receiving 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 Technology that is related to or associated with the Product. Each Party agrees to keep the terms and conditions of this Agreement confidential.

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 "Force Majeure Event" has the meaning set forth in Section 13.13.

1.17 "**Forecast Period**" has the meaning set forth in Section 3.2.

1.18 "GAAP" means generally accepted accounting principles as in effect in the United States from time to time, consistently applied.

1.19 "GDEA" has the meaning set forth in Section 9.1.5.

1.20 "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.

1.21 "Indemnitee" has the meaning set forth in Section 10.3.

1.22 "Indemnitor" has the meaning set forth in Section 10.3.

1.23 "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 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.

1.24 "Label," "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.

1.25 "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.

1.26 "**License Agreement**" has the meaning set forth in the fourth recital hereof.

1.27 "Losses" has the meaning set forth in Section 10.1.

1.28 "Lubiprostone" means the compound described in more detail in Exhibit A.

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 "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.

1.35 "Product" means a generically labeled (and not under the AMITIZA® trademark) version of Lubiprostone capsules, 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.

1.36 "Product Liability Litigation" has the meaning set forth in Section 10.4.

1.37 "**Product NDA**" means New Drug Application No. 021908, as may be amended or supplemented.

1.38 "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.

1.39 "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 pursuant to Section 3.13 of the License Agreement.

1.40 "Quality Agreement" has the meaning set forth in Section 5.3.

1.41 "Recall" has the meaning set forth in Section 5.2.

1.42 "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.

1.43 "**Rejection Notice**" has the meaning set forth in Section 3.6.2.

1.44 "Responsible Party" has the meaning set forth in Section 5.2.

1.45 "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.

1.46 "Sucampo Parties" has the meaning set forth in Section 10.1.

***Confidential Treatment Requested**

1.47 "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.

1.48 "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.

1.49 "Third Party" or "Third Parties" means any Person other than a Party or its Affiliates.

ARTICLE 2. COMMERCIAL MANUFACTURING & SUPPLY

2.1 Supply. 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, Amitiza® (Lubiprostone capsules) or other Lubiprostone products under the Amitiza® 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

***Confidential Treatment Requested**

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 the 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, 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 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 the 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 of the Product 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 three 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

***Confidential Treatment Requested**

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 […***…]%, 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 requirements 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 the 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 FCA (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 contractor's facility, and Par shall assume all responsibility for all costs associated with the goods upon such delivery.

***Confidential Treatment Requested**

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 that are readily apparent upon Par's or Par's designee's incoming-goods inspections promptly and in any event 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 and (y) any such analysis or review and (ii) promptly reimburse Sucampo for any out-of-pocket amounts previously paid for shipping or to 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, the numerator of which is (i) the aggregate of firm Orders made by Par over the subsequent twelve (12) month period (or such shorter period if Par has purchased Product for less than twelve (12) months) and the denominator of which is (ii)

the sum of (x) the aggregate quantity of firm Orders made by Par over the subsequent 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) over the same twelve (12) month period (or such shorter period) required 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

***Confidential Treatment Requested**

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 its original shelf life at the time of delivery to Par.

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 us Commercially Reasonable Efforts to 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 Third Party's Intellectual Property rights 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 and licensees of "AMITIZA® Products" 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, provided 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; provided, however, 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 debarment, 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 licensees of "AMITIZA® Products" as defined in the License Agreement 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 the 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 the 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. Indemnitor shall not settle any claim without the prior written approval of the Indemnitee. No Persons other than Par or Sucampo may claim indemnity hereunder.

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 10.3.2 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 seven (7) 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 theeffect 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.

***Confidential Treatment Requested**

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.

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:

EXHIBIT A
Description of Compound

Generic Name:	lubiprostone
Chemical names:	[…***…]
Code Name:	SPI-0211
CASNo:	136790-76-6

***Confidential Treatment Requested**

EXHIBIT 10.4

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

AMENDMENT NO. 1
TO
COLLABORATION AND LICENSE AGREEMENT
AND
SUPPLEMENTAL AGREEMENT

This Amendment No. 1 is made and entered into as of September 30, 2014 (the "Effective Date"), by and between Sucampo Pharma Americas, LLC (formerly known as Sucampo Pharma Americas, Inc., which was further formerly known as Sucampo Pharmaceuticals, Inc.) ("Sucampo") and Takeda Pharmaceutical Company Limited ("Takeda"). Sucampo and Takeda are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Sucampo and Takeda are parties to a Collaboration and License Agreement dated October 29, 2004 (the "CLA") and a Supplemental Agreement dated February 1, 2006 (the "Supplemental Agreement"); and

WHEREAS, the Parties now desire to amend certain terms of the CLA and the Supplemental Agreement (collectively, "the Agreements").

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, the Parties agree as follows:

1. Reference to SPI in the Agreements. It is understood by the Parties that references to "SPI" in the changes set forth in this Amendment No. 1 are made for consistency with the other terms and conditions of the Agreements which contain references to "SPI," and that references to "SPI" in the Agreements (including those effectuated by the changes herein) will refer to Sucampo.

2. Amendments to the CLA.

2.1 Definition of Best Efforts. All instances of the term "Best Efforts" in the CLA are hereby amended to read "Commercially Reasonable Efforts", which is defined as follows:

'"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, manufacture, seeking and obtaining regulatory approval, or commercialization of the Compound or Product, such efforts and resources shall be consistent with those efforts and resources commonly used by a Party under similar circumstances for similar compounds or products owned by it or to which it has similar rights, which compound or product, as applicable, is at a similar stage in its development or product life and is of similar market potential taking into

account: (a) issues of efficacy, safety, and expected and actual approved labeling, (b) the expected and actual competitiveness of alternative products sold by third parties in the marketplace, (c) the expected and actual product profile of the Compound or Product, (d) the expected and actual patent and other proprietary position of the Compound or Product, (e) the likelihood of regulatory approval given the regulatory structure involved, including regulatory or data exclusivity, (f) the expected and actual profitability and return on investment of the Compound or Product, or other compounds or products in a Party's portfolio of compounds or products, taking into consideration, among other factors, expected and actual (1) third party costs and expenses, (2) royalty, milestone and other payments to third parties and SPI, and (3) the pricing and reimbursement relating to the Product(s). Commercially Reasonable Efforts shall be determined on an indication/dosage-by-indication/dosage basis for the Compound or Product, as applicable, and it is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" with respect to a particular indication will change over time, reflecting changes in the status of the Compound or Product, as applicable. Notwithstanding the foregoing, neither Party shall be obligated to Develop, seek Regulatory Approval for, or Commercialize a Compound or Product: (i) which, in its reasonable opinion after discussion with the other Party, caused or is likely to cause a fatal, life-threatening or other serious adverse safety event that is reasonably expected, based upon then available data, to preclude obtaining Regulatory Approval for such Product or Compound, or, if Regulatory Approval of such Product has already been obtained, to preclude continued marketing of such Product; or (ii) in a manner inconsistent with applicable laws.'

2.2 Definition of Negative Event. Subsection (c) of the definition of "Negative Event" in the CLA is hereby amended in its entirety to read as follows:

'(c) the entry into the market of a significant competing product which was unexpected based on information known as of the Effective Date of Amendment No. 1 of the Collaboration Agreement and Supplemental Agreement.'

2.3 Definition of Takeda Affiliates. The definition of "Takeda Affiliates" in the CLA is hereby amended in its entirety to read as follows:

'"Takeda Affiliates" shall mean those Affiliates of Takeda listed on Exhibit D; provided that Exhibit D shall be modified by Takeda from time to time during the term of this Agreement upon written notice to SPI.'

2.4 Amendment to Section 2.3. Section 2.3 of the CLA is hereby amended in its entirety to read as follows:

'2.3 Sub-license by Takeda. The right to sub-license to a third party granted to Takeda under Section 2.1 and 2.2 shall be on the condition that the terms of any such sub-license shall be in accordance with the terms of the license granted to Takeda hereunder and shall be subject to the prior approval of SPI, such approval not to be unreasonably withheld or

delayed. The right to sub-license to Takeda Affiliates under Section 2.1 and 2.2 shall be without the prior written consent from SPI.'

2.5 Amendment to Section 5.1. The last sentence in Section 5.1(a) of the CLA is hereby amended in its entirety to read as follows:

'(a) All decisions of the JCC shall be unanimous, except that after consultation with the JCC, Takeda will have sole discretion with respect to decisions related to pricing, market access and, subject to Takeda's MACI obligation (as defined in Section 5.3(f)), number of sales representatives, product positioning and promotional mix as long as […***…]. The foregoing condition to Takeda's continued exercise of such sole discretion will not apply in the event of […***…] where such decrease is due to market events such as (i) a competitive recall, launch or withdrawal of a competitive product(s), (ii) aggressive pricing, rebating and/or discounting by a competitor, or (iii) other market events that may affect the growth potential of the Product. In the event of such a market event, Takeda agrees to use Commercially Reasonable Efforts in the exercise its discretion to increase or decrease annual commercial investment.'

2.6 Amendment to Section 5.1(c). The last sentence in Section 5.1(c) of the CLA is hereby deleted in its entirety.

2.7 Amendment to Section 5.2(a). The first sentence of Section 5.2(a) of the CLA is hereby amended in its entirety to read as follows:

'(a) Takeda (or, if applicable, Takeda Affiliates or its sub-licensee(s)) shall Commercialize the Product for the Initial Indications and, if applicable, Additional Indications and/or New Formulations in the Initial Territory at its own expense in accordance with the terms and conditions contained herein and in accordance with the Commercialization Plan approved by the JCC.'

2.8 Amendment to Section 5.2. Section 5.2(b) of the CLA is hereby deleted in its entirety.

2.9 Amendment to Section 5.3. Section 5.3(f) of the CLA is hereby amended in its entirety to read as follows:

'(f) Beginning on January 1, 2015, Takeda (or, as applicable, Takeda Affiliates or its sub-licensee(s)) shall be obligated to fund per calendar year a minimum annual commercial investment ("MACI") set at the lesser of: (a) […***…] United States Dollars (US$[…***…]) or (b) […***…] percent ([…***…]%) of annual Net Sales Revenue. MACI shall include Takeda's fully-burdened commercialization expenses, including those expenses incurred with respect to field promotion, marketing and medical education. Notwithstanding the foregoing, Takeda's MACI obligation (including any remaining amounts thereof budgeted for the then-current calendar year but not yet expended) will expire on the earlier of: (a) […***…] or (b) […***…]. Upon expiration of Takeda's MACI obligation, Takeda may reduce its annual commercial investment at its sole discretion. For the avoidance of doubt, the first commercial sale by or on behalf of Par Pharmaceutical, Inc. ("Par") or any Affiliate of Par of a pharmaceutical product that has received FDA approval for marketing in the Initial Territory pursuant to an Abbreviated New Drug Application (or equivalent regulatory mechanism) as a generic equivalent to the Product shall constitute the first commercial sale of a Generic Equivalent in the Initial Territory pursuant to subpart (b) in the preceding sentence.

***Confidential Treatment Requested**

2.10 Amendment to Section 5.4. Section 5.4 of the CLA is hereby amended as follows:

(i) by replacing Section 5.4(b) in its entirety with the following:

'Subject to Takeda's final decision-making rights under Section 5.1(a), the JCC shall determine the annual number of PDEs that shall be made in each calendar year by Takeda (or, if applicable, Takeda Affiliates or its sub-licensee(s)).'

(ii) by adding the following new Section 5.4(d):

'(d) Takeda's obligation to pay SPI a fee per PDE under Section 5.4(a) will terminate on […***…]. In addition, after […***…], and notwithstanding the provisions of Section 5.4(c), SPI shall pay for its own samples and promotional materials required for SPI's co-promotion activities, if any, in the Initial Territory. Takeda shall provide SPI with samples and promotional materials at SPI's cost.'

2.11 Amendment to Section 5.7. Section 5.7 of the CLA is hereby amended in its entirety to read as follows:

'5.7 During the Initial Term, Takeda (or, if applicable, Takeda Affiliates or its sub-licensee(s)) shall not directly or indirectly promote, market or sell in the Initial Territory […**…].'

2.12 Amendment to Section 7.3. Section 7.3 of the CLA is hereby amended as follows:

(i) by amending the first paragraph in its entirety to read as follows:

'7.3 Running Royalties. In addition to all other amounts payable hereunder, Takeda shall, for the Product sold during the Initial Term of this Agreement, pay
to SPI within […***…] ([…***…]) days after the end of each calendar quarter the following royalties, in consideration for the license grant to the Licensed Patents, Licensed Know-How and Licensed Trademarks hereunder, on Net Sales Revenue in the Initial Territory, as set forth below.'

***Confidential Treatment Requested**

(ii) by adding the following new subsection (d):

‘(d) During the Extended Term, and only with respect to the Net Sales Revenue of Product Covered by the Valid Claims of the Licensed Patents, Takeda shall pay to SPI within […***…] ([…***…]) days after the end of each calendar quarter a running royalty of […***…] percent ([…***…]%) of Net Sales Revenue less Takeda’s cost of goods.’

2.13 Amendment to Article 11. Section 11.3 of the CLA is hereby amended by replacing the last sentence of that section with the following:

‘In addition, the receiving Party may disclose Confidential Information to its Affiliates and its and their officers, directors, employees, contractors, consultants, agents and advisors on a “need-to-know” basis in order for the receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in Article 11.’

2.14 Amendment to Section 13. Section 13.1 of the CLA is hereby amended in its entirety to read as follows:

‘“13.1 Term of Agreement. The initial term of this Agreement shall commence on the Effective Date and unless earlier terminated in accordance with the provisions of this Article 13 or Section 12.3, shall continue in full force an effect until December 31, 2020 (“Initial Term”). Upon expiration of the Initial Term, the Agreement shall automatically continue in full force and effect until terminated by Takeda upon ninety (90) days prior written notice to SPI or terminated earlier in accordance with the provisions of this Article 13. The period of time following the expiration of the Initial Term and continuing until the termination of this Agreement as provided in the immediately preceding sentence is referred to as the “Extended Term.” For the avoidance of doubt, references in this Agreement to “the term of this Agreement” shall mean the period beginning on the Effective Date and ending on the last day of the Extended Term.’

3. Amendments to the Supplemental Agreement.

3.1 Amendment to Article 6. Section 6.1 of the Supplemental Agreement is hereby deleted in its entirety.

***Confidential Treatment Requested**

3.2 Amendment to Article 8. Section 8.1(a) of the Supplemental Agreement is hereby amended in its entirety to read as follows:

'8.1 Affiliates.

(a) The Parties agree that Takeda may contract with its Affiliates for the performance of any of its obligations under, or the activities contemplated in, the Original Agreement or this Supplemental Agreement, including the Annexes hereto, or any activities related thereto provided (1) that Takeda shall ensure that its Affiliates comply with the provisions of the Original Agreement and this Supplemental Agreement, including the Annexes hereto, and including the confidentiality obligations and provisions of Section 11.3 of the Original Agreement; (2) that any such contracting by Takeda shall not relieve Takeda's duty to perform, either directly or through Affiliates, the obligations and the activities contemplated in the Original Agreement and this Supplemental Agreement, including the Annexes hereto, and any activities related thereto; and (3) that each such Affiliate shall comply with the provisions of Article 7.6 of the Original Agreement. Sucampo shall be entitled to a financial audit, to be conducted by an independent certified public accountant pursuant to Section 7.6 of the Original Agreement *mutatis mutandis*, of any Affiliate of Takeda with whom Takeda contracts for the performance of any of its obligations under, or the activities contemplated in, the Original Agreement or this Supplemental Agreement, including the Annexes hereto, or any activities related thereto, which audit shall be limited in scope to (a) establishing the good standing of Takeda's Affiliates and (b) establishing and understanding the entity structure and revenue flow among Takeda and its Affiliates as such structure and revenue flow pertains to the computation of Net Sales Revenue. The financial audit authorized by this Section 8.1 shall be in addition to any audit authorized by Section 7.6 of the Original Agreement.'

4. Cost of Pediatric Studies.

4.1 Pediatric Studies. Future out-of-pocket costs for pediatric studies that exceed the total budgeted costs for such studies approved by the JDC and JCC as of the Effective Date of this Amendment No. 1 shall be […***…] between the Parties.

5. Miscellaneous.

5.1 Full Force and Effect. The provisions of the Agreements, as amended by this Amendment No. 1 as of its Effective Date, remain in full force and effect during the Initial Term and the Extended Term; provided that the rights and obligations of the Parties as accrued under the Agreements prior to this Amendment No.1 will remain unchanged and continue to be binding on the Parties.

5.2 Entire Agreement. The Agreements and this Amendment No. 1 constitute the entire agreement, both written and oral, between the Parties with respect to the subject matter hereof, and any and all prior agreements with respect to the subject matter hereof, either written or oral, expressed or implied, are superseded hereby, merged and canceled, and are null and void and of no effect.

***Confidential Treatment Requested**

5.3 Counterparts. This Amendment No. 1 may be executed in one or more counterparts, each of which will be an original and all of which together will constitute one instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 1 as of the date first written above.

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: _____
Name: Christophe Weber
Title: President & COO

SUCAMPO PHARMA AMERICAS, LLC

By: _____
Name: Peter S. Greenleaf
Title: President

EXHIBIT 10.5

AMENDMENT NO. 1 TO AGREEMENT

This Amendment No. 1 is made and entered into as of September 30, 2014 (the "Effective Date"), by and between Sucampo Pharma Americas, LLC (formerly known as Sucampo Pharma Americas, Inc., which was further formerly known as Sucampo Pharmaceuticals, Inc.) ("SPA"), Takeda Pharmaceutical Company Limited ("Takeda") and Sucampo AG ("SAG"). SPA, Takeda and SAG are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, SPA and Takeda are parties to a Collaboration and License Agreement dated October 29, 2004 (the "CLA");

WHEREAS, SPA, Takeda and SAG are parties to an Agreement dated October 29, 2004 which is attached to the CLA as Appendix B (the "Agreement"); and

WHEREAS, the Parties now desire to amend certain terms of the Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, the Parties agree as follows:

1. Reference to SPI in the Agreement. It is understood by the Parties that references to "SPI" in the changes set forth in this Amendment No. 1 are made for consistency with the other terms and conditions of the Agreement which contain references to "SPI," and that references to "SPI" in the Agreement (including those effectuated by the changes herein) will refer to SPA.

2. Amendments to the Agreement.

2.1 Definition of Best Efforts. All instances of the term "Best Efforts" in the Agreement are hereby amended to read "Commercially Reasonable Efforts", which is defined as follows:

'"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, manufacture, seeking and obtaining regulatory approval, or commercialization of the Compound or Product, such efforts and resources shall be consistent with those efforts and resources commonly used by a Party under similar circumstances for similar compounds or products owned by it or to which it has similar rights, which compound or product, as applicable, is at a similar stage in its development or product life and is of similar market potential taking into account: (a) issues of efficacy, safety, and expected and actual approved labeling, (b) the expected and actual competitiveness of alternative products sold by third parties in the

marketplace, (c) the expected and actual product profile of the Compound or Product, (d) the expected and actual patent and other proprietary position of the Compound or Product, (e) the likelihood of regulatory approval given the regulatory structure involved, including regulatory or data exclusivity, (f) the expected and actual profitability and return on investment of the Compound or Product, or other compounds or products in a Party's portfolio of compounds or products, taking into consideration, among other factors, expected and actual (1) third party costs and expenses, (2) royalty, milestone and other payments to third parties and SPI, and (3) the pricing and reimbursement relating to the Product(s). Commercially Reasonable Efforts shall be determined on an indication/dosage-by-indication/dosage basis for the Compound or Product, as applicable, and it is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" with respect to a particular indication will change over time, reflecting changes in the status of the Compound or Product, as applicable. Notwithstanding the foregoing, neither Party shall be obligated to Develop, seek Regulatory Approval for, or Commercialize a Compound or Product: (i) which, in its reasonable opinion after discussion with the other Party, caused or is likely to cause a fatal, life-threatening or other serious adverse safety event that is reasonably expected, based upon then available data, to preclude obtaining Regulatory Approval for such Product or Compound, or, if Regulatory Approval of such Product has already been obtained, to preclude continued marketing of such Product; or (ii) in a manner inconsistent with applicable laws.'

2.2 Definition of Takeda Affiliates. The definition of "Takeda Affiliates" in the Agreement is hereby amended in its entirety to read as follows:

'"Takeda Affiliates" shall mean those Affiliates of Takeda listed on Exhibit D to the Collaboration and License Agreement.'

2.3 Deletion of Exhibit B. Exhibit B to the Agreement is hereby deleted in its entirety.

2.4 Amendment to Article 10. Section 10.3 of the Agreement is hereby amended by replacing the last sentence of that section with the following:

'In addition, the receiving Party may disclose Confidential Information to its Affiliates and its and their officers, directors, employees, contractors, consultants, agents and advisors on a "need-to-know" basis in order for the receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in Article 10.'

2.5 Amendment to Article 12. Paragraph (a) of Article 12 is hereby amended in its entirety to read as follows:

'(a) The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until termination of the Collaboration and License Agreement. SPI shall notify SAG of the termination of the Collaboration and License Agreement when such termination occurs.'

3. Miscellaneous.

3.1 Full Force and Effect. The provisions of the Agreement, as amended by this Amendment No. 1 effective as of its Effective Date, remain in full force and effect; provided that the rights and obligations of the Parties as accrued under the Agreement prior to this Amendment No. 1 will remain unchanged and continue to be binding on the Parties.

3.2 Entire Agreement. The Agreement and this Amendment No. 1 constitute the entire agreement, both written and oral, between the Parties with respect to the subject matter hereof, and any and all prior agreements with respect to the subject matter hereof, either written or oral, expressed or implied, are superseded hereby, merged and canceled, and are null and void and of no effect.

3.3 Counterparts. This Amendment No. 1 may be executed in one or more counterparts, each of which will be an original and all of which together will constitute one instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 1 as of the date first written above.

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: _____
Name: Christophe Weber
Title: President & COO

SUCAMPO PHARMA AMERICAS, LLC

By: _____
Name: Peter S. Greenleaf
Title: President

SUCAMPO AG

By: _____
Name: Peter S. Greenleaf
Title: President

[Signature page to Amendment No. 1 to Agreement Dated October 29, 2004]

EXHIBIT 10.6

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

AMENDMENT NO. 1
TO
SUPPLY AGREEMENT
AND
SUPPLY AND PURCHASE AGREEMENT
AND
ADDENDUM TO SUPPLY & PURCHASE AGREEMENT

This Amendment No. 1 is made and entered into as of September 30, 2014 (the "Effective Date"), by and between Sucampo Pharma Americas, LLC (formerly known as Sucampo Pharma Americas, Inc., which was further formerly known as Sucampo Pharmaceuticals, Inc.) ("SPA"), Takeda Pharmaceutical Company Limited ("Takeda") and R-Tech Ueno, Ltd. ("RTU"). SPA, Takeda and RTU are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, SPA, RTU and Takeda are parties to the Supply Agreement dated October 29, 2004 (the "Supply Agreement"), the Supply and Purchase Agreement dated January 25, 2006 (the "Supply and Purchase Agreement"), and the Addendum to Supply and Purchase Agreement dated November 6, 2013; (collectively the "Supply Agreements"); and

WHEREAS, the Parties now desire to amend certain terms of the Supply Agreements.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, the Parties agree as follows:

1. Reference to SPI in the Agreement. It is understood by the Parties that references to "SPI" in the changes set forth in this Amendment No. 1 are made for consistency with the other terms and conditions of the Supply Agreements which contain references to "SPI," and that references to "SPI" in the Supply Agreements (including those effectuated by the changes herein) will refer to SPA.

2. Amendments to the Supply Agreements.

2.1 Definition of Best Efforts. All instances of the term "Best Efforts" in the Supply Agreements are hereby amended to read "Commercially Reasonable Efforts", which is defined as follows:

'"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, manufacture, seeking and obtaining regulatory approval, or commercialization of the Compound or Product, such efforts and resources shall be consistent with those efforts and resources commonly used

by a Party under similar circumstances for similar compounds or products owned by it or to which it has similar rights, which compound or product, as applicable, is at a similar stage in its development or product life and is of similar market potential taking into account: (a) issues of efficacy, safety, and expected and actual approved labeling, (b) the expected and actual competitiveness of alternative products sold by third parties in the marketplace, (c) the expected and actual product profile of the Compound or Product, (d) the expected and actual patent and other proprietary position of the Compound or Product, (e) the likelihood of regulatory approval given the regulatory structure involved, including regulatory or data exclusivity, (f) the expected and actual profitability and return on investment of the Compound or Product, or other compounds or products in a Party's portfolio of compounds or products, taking into consideration, among other factors, expected and actual (1) third party costs and expenses, (2) royalty, milestone and other payments to third parties and SPI, and (3) the pricing and reimbursement relating to the Product(s). Commercially Reasonable Efforts shall be determined on an indication/dosage-by-indication/dosage basis for the Compound or Product, as applicable, and it is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" with respect to a particular indication will change over time, reflecting changes in the status of the Compound or Product, as applicable. Notwithstanding the foregoing, neither Party shall be obligated to Develop, seek Regulatory Approval for, or Commercialize a Compound or Product: (i) which, in its reasonable opinion after discussion with the other Party, caused or is likely to cause a fatal, life-threatening or other serious adverse safety event that is reasonably expected, based upon then available data, to preclude obtaining Regulatory Approval for such Product or Compound, or, if Regulatory Approval of such Product has already been obtained, to preclude continued marketing of such Product; or (ii) in a manner inconsistent with applicable laws.'

2.2 Definition of Takeda Affiliates. The definition of "Takeda Affiliates" in the Supply Agreements is hereby amended in its entirety to read as follows:

'"Takeda Affiliates" shall mean those Affiliates of Takeda listed on Exhibit D to the Collaboration and License Agreement.'

2.3 Amendment to Article 6. The following new Section 6.8 is hereby added to Article 6 the Supply and Purchase Agreement:

'6.8 Separate Lots. RTU shall supply Product and Samples to Takeda from lots used exclusively to supply Takeda and no other RTU customers.'

2.4 Amendment to Article 8. Article 8 of the Supply and Purchase Agreement among Takeda, SPA and RTU is hereby amended adding the following paragraphs after the existing paragraph in Article 8 with the following:

'Not later than April 1, 2016, SPI shall identify one or more third party contract manufacturers ("Backup Supplier") reasonably acceptable to RTU and Takeda to act as a secondary source for the Manufacture and supply of the Product. Within ninety (90) days

after October 1, 2014, SPI shall use Commercially Reasonable Efforts to provide Takeda with a written list of potential Backup Suppliers identified by SPI. Not later than twelve (12) months after April 1, 2016 ("Qualification Period"), with assistance of RTU, SPI shall use Commercially Reasonable Efforts to obtain all Regulatory Approvals required for the Backup Supplier to Manufacture and supply the Product for use in Development and Commercialization of the Product in the United States ("Required Approvals"). If SPI does not obtain the Required Approvals prior to the expiration of the Qualification Period, then beginning on the first day after the expiration of the Qualification Period, the provisional price paid by Takeda to RTU for the Product and Samples as determined under Section 3.3 will be […***…] until the date on which SPI notifies Takeda in writing that the Required Approvals have been obtained. Beginning on the first day of the second full calendar month after Takeda receives such notice from SPI, […***…].

Not later than twelve (12) months after April 1, 2016 or the date on which the Product is approved for commercial sale in Canada, whichever is later, SPI , with assistance of RTU shall use Commercially Reasonable Efforts to obtain all Regulatory Approvals necessary for the Backup Suppliers to manufacture and supply the Product for Development and Commercialization of the Product in Canada.

SPI and RTU will be responsible for all costs associated with qualifying the Backup Supplier, including costs for materials, start up, validation and test batches, stability testing and equipment. Upon written request by SPI or Takeda from time to time, RTU shall provide a reasonably detailed written report of RTU's efforts and progress to qualify the Backup Suppliers as required hereunder.

SPI and RTU shall ensure that the Backup Supplier has the capacity to Manufacture and supply the 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. SPI and RTU, at their cost, shall prepare and submit to the applicable Regulatory Authorities in the Initial Territory 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 Product for clinical and commercial use in the Initial Territory during the term of this Agreement.

For the avoidance of doubt, Takeda shall continue to purchase the Product and the Samples directly from RTU in the event that it is necessary for RTU to use the Backup Supplier to Manufacture, and supply to Takeda, the Product. Under no circumstances shall RTU willfully withhold supply of the Compound, the Product or the Samples from Takeda during the term of this Agreement, including, but not limited to, during a dispute with Takeda or a dispute between Takeda and SPI.'

***Confidential Treatment Requested**

2.5 Amendment to Article 8. Section 8.3 of the Supply Agreement among Takeda, SPA and RTU is hereby amended by replacing the last sentence of that section with the following:

'In addition, the receiving Party may disclose Confidential Information to its Affiliates and its and their officers, directors, employees, contractors, consultants, agents and advisors on a "need-to-know" basis in order for the receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in Article 8.'

2.6 Amendment to Article 9. Article 9 of the Supply and Purchase Agreement among Takeda, SPA and RTU is hereby amended in their entirety to read as follows:

'The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until termination of the Collaboration and License Agreement in accordance with Article 13 of the Collaboration and License Agreement. SPI shall notify RTU of the termination of the Collaboration and License Agreement when such termination occurs.'

2.7 Amendment to Article 10. Paragraph (a) of Article 10 of the Supply Agreement among Takeda, SPA and RTU is hereby amended in their entirety to read as follows:

'(a) The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until termination of the Collaboration and License Agreement in accordance with Article 13 of the Collaboration and License Agreement. SPI shall notify RTU of the termination of the Collaboration and License Agreement when such termination occurs.'

3. Miscellaneous.

3.1 Full Force and Effect. The provisions of the Supply Agreements, as amended by this Amendment No. 1 effective as of its Effective Date, remain in full force and effect; provided that the rights and obligations of the Parties as accrued under the Supply Agreements prior to this Amendment No. 1 will remain unchanged and continue to be binding on the Parties.

3.2 Entire Agreement. The Supply Agreements and this Amendment No. 1 constitute the entire agreement, both written and oral, between the Parties with respect to the subject matter hereof, and any and all prior agreements with respect to the subject matter hereof, either written or oral, expressed or implied, are superseded hereby, merged and canceled, and are null and void and of no effect.

3.3 Counterparts. This Amendment No. 1 may be executed in one or more counterparts, each of which will be an original and all of which together will constitute one instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 1 as of the date first written above.

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: _____
Name: Christophe Weber
Title: President & COO

SUCAMPO PHARMA AMERICAS, LLC

By: _____
Name: _____
Title: _____

R-TECH UENO, LTD.

By: _____
Name: Yukihiko Mashima
Title: President

EXHIBIT 31.1

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 Quarterly Report on Form 10-Q 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: November 7, 2014

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

EXHIBIT 31.2

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

I, Cary J. Claiborne, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 7, 2014

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

EXHIBIT 32.1

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

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

(1) The Quarterly Report on Form 10-Q for the quarter ended September 30, 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: November 7, 2014

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

EXHIBIT 32.2

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

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

(1) The Quarterly Report on Form 10-Q for the quarter ended September 30, 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: November 7, 2014

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