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 March 31, 2009

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)

Delaware	**30-0520478**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. employer identification no.)*
4520 East-West Highway, Suite 300 Bethesda, MD 20814	
(Address of principal executive offices, including 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 ☑ No o

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

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). Yes o No ☑

As of May 1, 2009, there were 15,652,759 shares of the registrant's class A common stock outstanding and 26,191,050 shares of the registrant's class B common stock outstanding.

Sucampo Pharmaceuticals, Inc.

Form 10-Q Index

PART I — FINANCIAL INFORMATION

Item 1. ***Condensed Consolidated Financial Statements (Unaudited)***

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

	March 31, 2009	December 31, 2008
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 17,797	$ 11,536
Investments, current	103,257	93,776
Product royalties receivable	8,945	9,725
Unbilled accounts receivable	3,826	4,373
Accounts receivable	249	878
Prepaid and income taxes receivable	1,539	133
Deferred tax assets, net	413	963
Prepaid expenses and other current assets	3,209	3,641
Total current assets	139,235	125,025
Investments, non-current	9,494	16,222
Property and equipment, net	2,272	2,275
Deferred tax assets — noncurrent, net	4,225	4,026
Other assets	873	3,246
Total assets	$ 156,099	$ 150,794
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 2,763	$ 1,433
Accrued expenses	8,910	9,764
Deferred revenue — current	19,053	15,599
Total current liabilities	30,726	26,796
Deferred revenue, net of current portion	11,463	8,061
Other liabilities	2,047	2,147
Total liabilities	44,236	37,004
Commitments (Note 7)		
Stockholders' equity:		
Preferred stock, $0.01 par value; $5,000,000 shares authorized at March 31, 2009 and December 31, 2008; no shares issued and outstanding at March 31, 2009 and December 31, 2008	—	—
Class A common stock, $0.01 par value; 270,000,000 shares authorized at March 31, 2009 and December 31, 2008; 15,652,759 and 15,651,849 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	156	156
Class B common stock, $0.01 par value; 75,000,000 shares authorized at March 31, 2009 and December 31, 2008; 26,191,050 shares issued and outstanding at March 31, 2009 and December 31, 2008	262	262
Additional paid-in capital	98,359	98,243
Accumulated other comprehensive income	86	354
Retained earnings	13,000	14,775
Total stockholders' equity	111,863	113,790
Total liabilities and stockholders' equity	$ 156,099	$ 150,794

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2009	2008
Revenues:		
Research and development revenue	$ 5,526	$ 6,110
Product royalty revenue	8,946	6,080
Co-promotion revenue	896	1,222
Contract and collaboration revenue	146	142
Total revenues	15,514	13,554
Operating expenses:		
Research and development	9,965	11,216
General and administrative	3,455	3,167
Selling and marketing	2,512	2,848
Milestone royalties — related parties	500	1,031
Product royalties — related parties	1,590	1,081
Total operating expenses	18,022	19,343
Loss from operations	(2,508)	(5,789)
Non-operating income:		
Interest income	312	642
Other income, net	822	12
Total non-operating income, net	1,134	654
Loss before income taxes	(1,374)	(5,135)
Income tax (provision) benefit	(401)	5,640
Net (loss) income	$ (1,775)	$ 505
Net (loss) income per share:		
Basic net (loss) income per share	$ (0.04)	$ 0.01
Diluted net (loss) income per share	$ (0.04)	$ 0.01
Weighted average common shares outstanding — basic	41,844	41,733
Weighted average common shares outstanding — diluted	41,844	42,061
Comprehensive (loss) income:		
Net (loss) income	$ (1,775)	$ 505
Other comprehensive loss:		
Unrealized loss on investments, net of tax effect	(65)	(840)
Foreign currency translation	(203)	330
Comprehensive loss	$ (2,043)	$ (5)

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, except share data)

	Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2008	15,651,849	$ 156	26,191,050	$ 262	$ 98,243	$ 354	$ 14,775	$ 113,790
Employee stock option expense	—	—	—	—	111	—	—	111
Stock issued under employee stock purchase plan	910	—	—	—	5	—	—	5
Foreign currency translation	—	—	—	—	—	(203)	—	(203)
Unrealized loss on investments, net of tax effect	—	—	—	—	—	(65)	—	(65)
Net loss	—	—	—	—	—	—	(1,775)	(1,775)
Balance at March 31, 2009	15,652,759	$ 156	26,191,050	$ 262	$ 98,359	$ 86	$ 13,000	$ 111,863

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)

	Three Months Ended March 31,	
	2009	2008
Cash flows from operating activities:		
Net (loss) income	$ (1,775)	$ 505
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	122	102
Deferred tax provision (benefit)	394	(5,640)
Stock-based compensation	111	259
Unrealized gain on trading securities	(2,672)	—
Unrealized loss on settlement rights on auction rate securities	2,423	—
Changes in operating assets and liabilities:		
Accounts receivable	617	(309)
Unbilled accounts receivable	547	896
Product royalties receivable	780	2,587
Prepaid and income taxes receivable and payable, net	(1,406)	1,803
Accounts payable	1,382	1,413
Accrued expenses	(811)	(1,592)
Deferred revenue	7,245	(318)
Other assets and liabilities, net	348	(86)
Net cash provided by (used in) operating activities	7,305	(380)
Cash flows from investing activities:		
Purchases of investments	(77,289)	(45,909)
Proceeds from the sales of investments	47,452	38,325
Maturities of investments	29,504	15,000
Purchases of property and equipment	(127)	(171)
Net cash (used in) provided by investing activities	(460)	7,245
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	42
Proceeds from employee stock purchase plan	5	—
Net cash provided by financing activities	5	42
Effect of exchange rates on cash and cash equivalents	(589)	267
Net increase in cash and cash equivalents	6,261	7,174
Cash and cash equivalents at beginning of period	11,536	25,559
Cash and cash equivalents at end of period	$ 17,797	$ 32,733

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. (Sucampo or the Company) is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. Sucampo is focused on developing prostones for the treatment of gastrointestinal, respiratory, vascular and central nervous system diseases and disorders for which there are unmet or underserved medical needs and significant commercial potential. Sucampo was established in December 1996.

In January 2006, the Company received marketing approval from the U.S. Food and Drug Administration(FDA), for its first product, Amitiza ® (lubiprostone), to treat chronic idiopathic constipation in adults. In April 2008, the Company received a second marketing approval from the FDA for Amitiza to treat irritable bowel syndrome with constipation in adult women. Amitiza is being marketed and developed in the United States and Canada for gastrointestinal indications under a collaboration and license agreement with Takeda Pharmaceutical Company Limited (Takeda). Sucampo is primarily responsible for development activities under the agreement. Sucampo and Takeda initiated commercial sales of Amitiza in the United States for the treatment of chronic idiopathic constipation (CIC) in April 2006 and for the treatment of irritable bowel syndrome with constipation in May 2008 and they are currently developing Amitiza for the treatment of opioid-induced bowel dysfunction (OBD).

In February 2009, Sucampo entered into a license, commercialization and supply agreement with Abbott Japan Co. Ltd.(Abbott) for Amitiza in Japan. Under the terms of the agreement, Abbott received exclusive rights to commercialize lubiprostone in Japan for the treatment of CIC and received the right of first refusal to any additional indications for which lubiprostone is developed in Japan. Sucampo is primarily responsible for development activities under the agreement. Abbott is responsible for all commercialization expenses and efforts. The Company has retained the right to co-promote lubiprostone in Japan.

On April 23, 2009, Sucampo entered into two agreements with R-Tech Ueno Ltd. (R-Tech), a Japanese manufacturing and research and development company that is majority owned by the Company's founders, to acquire all patents and other intellectual property rights related to Rescula® (unoprostone isopropyl) in the United States and Canada. Although Rescula eye drops were approved by the FDA for the treatment of open-angle glaucoma and ocular hypertension in 2000, Rescula is not currently being marketed in the United States or Canada. Under the terms of the agreements, the Company made an upfront payment of $3.0 million and is required to make up to $5.5 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals.

The Company's founders own directly or indirectly the majority holdings in Sucampo as well as in other companies that have significant contractual relationships with Sucampo as described more fully in Note 7. One of the Company's founders serves as the chairman of the board of directors, chief executive officer and chief scientific officer of the Company and the second founder serves as a director and as executive advisor of international business development.

The Company's operations are conducted through its subsidiaries based in the United States, United Kingdom and Japan.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) and the rules and regulations of the Securities and Exchange Commission (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, 2008 included in the Company's Annual Report on Form 10-K. The financial information as of March 31, 2009 and for the three months ended March 31, 2009 and 2008 is unaudited. In the opinion of 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 Sucampo and its wholly owned subsidiaries. All significant inter-company balances and transactions have been eliminated in the consolidated accounts.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For the purpose of the condensed consolidated balance sheets and condensed consolidated statements of cash flows, cash equivalents include all highly liquid investments with an original maturity of 90 days or less at the time of purchase.

Current and Non-current Investments

Current and non-current investments consist primarily of U.S. Treasury bills and notes, municipal bonds and auction rate securities (ARS). The Company classifies its investments into current and non-current based on their maturities and management's reasonable expectation to realize these investments in cash. These investments are accounted for under the guidance of Statements of Financial Accounting Standards (SFAS) No.115*, Accounting for Certain Investments in Debt and Equity Securities*. Investments in U.S. Treasury bills, notes and municipal bonds are classified as available for sale securities and unrealized gains or losses, net of related tax effects, are reported in other comprehensive income. Pursuant to the Company's acceptance of settlement rights for its investments in ARS in October 2008, the Company classifies its investments in ARS as trading securities and records gains or losses resulting from the changes in fair values of its ARS and related settlement rights in other income, net. The fair value of the settlement rights related to ARS is recorded as non-current other assets. The fair value of the settlement rights has been derived from the par value of the Company's investment in ARS and the fair value of ARS as of the recognition date, since the settlement rights obligate the broker to redeem the ARS at par value.

Fair Value

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, restricted cash, current and non-current investments, receivables, accounts payable and accrued liabilities, approximate their fair values based on their short maturities, independent valuations or internal assessments. As of March 31, 2009 there was no material impact on condensed consolidated financial statements upon adoption of SFAS No.157, *Fair Value Measurements* (SFAS 157) for non-financial assets and liabilities.

Revenue Recognition

The Company's primary sources of revenue are derived from collaboration and license agreements and include up-front payments, development milestone payments, reimbursements of development and co-promotion costs and product royalties. The Company recognizes revenue from these sources in accordance with Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* (SAB 104), Emerging Issues Task Force (EITF) No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), and EITF No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21).

The Company evaluated the multiple deliverables within the collaboration and license agreements in accordance with the provisions of EITF 00-21 to determine whether the delivered elements that are the obligation of the Company have value to other parties to the agreement on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate recognition of revenue is then applied to each separate unit of accounting. The Company's deliverables under the Abbott and Takeda agreements are more fully described in Note 8.

The Company applies a time-based model of revenue recognition for cash flows associated with research and development deliverables under the Takeda collaboration and license agreement. Under this model, cash flow streams related to each unit of accounting are recognized as revenue over the estimated performance period. Upon receipt of cash payments, revenue is recognized to the extent the accumulated service time, if any, has occurred. The remainder is deferred and recognized as revenue ratably over the remaining estimated performance period. A change in the period of time expected to complete the deliverable is accounted for as a change in estimate on a prospective basis. Revenue is limited to amounts that are nonrefundable and that the other party to the agreement is contractually obligated to pay to the Company.

The Company applies a proportional-performance model using the percentage-of-completion method of revenue recognition for cash flows associated with research and development deliverables under the Abbott license, commercialization and supply agreement. Since the Company has previous research and development experience and the expected cost to complete the development can be reasonably estimated, the Company believes a proportional-performance methodology of revenue recognition is appropriate. Under this method, revenue in any period is recognized as a percentage of the actual cost expended in that period relative to the total

estimated costs required to satisfy the performance obligations under the arrangement related to the development. Revenue recognized is limited to the amounts that are non-refundable and that the other party to the agreement is contractually obligated to pay to the Company.

The Company recognizes reimbursable research and development costs under the Takeda agreement as research and development revenue using a time-based model over the estimated performance period. The research and development revenue for these obligations is limited to the lesser of the actual reimbursable costs incurred or the straight-line amount of revenue recognized over the estimated performance period. Revenues are recognized for reimbursable costs only if those costs are supported by an invoice or final contract with a vendor. Research and development costs are not reimbursable under the Abbott agreement.

Under the Takeda agreement, royalties from licensees are based on third-party sales of licensed products and are recorded on the accrual basis when earned in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met. Under the Abbott agreement, should Amitiza be commercialized in Japan, the Company will purchase and assume title to inventories of Amitiza and recognize revenues from the sales of such product when earned.

Contract revenue related to development and consulting activities with related parties is also accounted for under the time-based model.

The Company considers its participation in the joint committees under the collaboration agreements as separate deliverables under the contracts and recognizes the fair value of the such participation as revenue over the period of the participation obligated as per the terms of the contract.

Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal under both the Takeda and Abbott agreements and, as such, records revenue on a gross basis in the condensed consolidated statements of operations and comprehensive (loss) income.

Certain Risks, Concentrations and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents, restricted cash, investments and receivables. The Company places its cash and cash equivalents, restricted cash and investments with highly rated financial institutions. At March 31, 2009 and December 31, 2008, the Company had approximately $130.2 million and $118.6 million, respectively, of cash and cash equivalents, restricted cash and investments in excess of government insured limits. The Company's uninsured cash, cash equivalents and investments as of March 31, 2009 consisted primarily of $33.1 million of U.S. Treasury notes, $18.9 million of money market funds guaranteed under the U.S. Treasury's Temporary Guarantee Program, $27.1 million of municipal securities, $18.9 million of investments in auction rate securities, $14.8 million of other money market funds and $14.4 million of ordinary deposit accounts in foreign subsidiaries. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

As of March 31, 2009, all of the Company's ARS consisted of two non-mortgage related auction rate securities. On April 29, 2009, the issuer of one of the Company's ARS redeemed the security at par value of $9.4 million. The condensed consolidated financial statements as of March 31, 2009 included valuation adjustments and related gains relating to this redemption and classified this investment as current investments.

The settlement rights between the Company and UBS AG (ARS broker) obligate the ARS broker to purchase the remaining auction rate security at par during a two-year period beginning June 30, 2010 if the Company exercises its related settlement rights. The Company does not anticipate having to sell the remaining security in order to operate its business before the expected redemption date.

The Company's products and product candidates under development require approval from the FDA or other international regulatory agencies prior to commercial sales. For those product candidates or indications that have not yet been approved by the FDA or international regulatory agencies, there can be no assurance the products will receive the necessary approval. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company.

The Company's products, Amitiza and Rescula, compete in a rapidly changing, highly competitive market, which is characterized by advances in scientific discovery, changes in customer requirements, evolving regulatory requirements and developing industry standards. Any failure by the Company to anticipate or to respond adequately to scientific developments in its industry, changes in

customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products could have a material adverse effect on the Company's business, operating results and future cash flows.

The Company's expected activities may necessitate significant uses of working capital. The Company's working capital requirements will depend on many factors, including the successful sales of Amitiza and Rescula, research and development efforts to develop new products or indications, payments received under contractual agreements with other parties, the status of competitive products and market acceptance of the Company's new products by physicians and patients. The Company plans to continue financing operations with product royalty revenue as well as with cash received from milestones and other revenue related to its joint collaboration, license and supply agreements entered into with Takeda, Abbott and R-Tech.

Revenues from one unrelated party, Takeda, accounted for 97% and 99% of the Company's total revenues for the three months ended March 31, 2009 and March 31, 2008, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 99% and 97% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at March 31, 2009 and December 31, 2008, respectively. The Company depends significantly upon the collaboration with Takeda and its activities may be impacted if this relationship is disrupted (Note 8).

The Company has an exclusive supply arrangement with R-Tech, to provide it with commercial and clinical supplies of its product and product candidates. R-Tech also provides certain preclinical and other research and development services. Any difficulties or delays in performing the services under these arrangements may cause the Company to lose revenues, delay research and development activities or otherwise disrupt the Company's operations (Note 7).

The Company has previously entered into a restated license agreement with Sucampo AG (SAG) to grant the Company a royalty-bearing, exclusive, worldwide license to develop prostone compounds, including Amitiza and cobiprostone. SAG is a Swiss-patent holding company and an entity wholly owned by the Company's founders. The Company's success depends, in part, on SAG's ability to obtain and maintain proprietary protection for the intellectual property rights relating to the prostone technology and products (Note 7).

Reclassifications

Certain amounts in the previously issued financial statements have been reclassified to conform with the current presentation. The Company reclassified expenses that have been previously included within general and administrative expenses to research and development expenses. Such expenses primarily include salaries and other employee benefits of personnel who oversee the research and development process, and allocated depreciation and rent expenses and insurance costs. The Company also reclassified allocated depreciation and rent expenses and insurance costs from general and administrative expenses to selling and marketing expenses. For the three months ended March 31, 2008, the Company reclassified $1.1 million and $80,000 of general and administrative expenses to research and development expenses and selling and marketing expenses, respectively.

Recent Accounting Pronouncements

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements (*EITF 07-1). The consensus prohibits the equity method of accounting for collaborative arrangements under APB 18, *The Equity Method of Accounting for Investments in Common Stock*, unless a legal entity exists. Payments between the collaborative partners will be evaluated and reported in the income statement based on applicable GAAP. Absent specific GAAP, the participants to the arrangement will apply other existing GAAP by analogy or apply a reasonable and rational accounting policy consistently. The guidance in EITF 07-1 is effective for periods that begin after December 15, 2008 and applies to arrangements in existence as of the effective date. The effect of the new consensus shall be accounted for as a change in accounting principle through retrospective application. The Company adopted the provisions of EITF 07-1 effective January 1, 2009 and such adoption did not have a material impact on the condensed consolidated financial statements.

In February 2008, the FASB issued Financial Staff Positions (FSP), SFAS No.157-2, *Effective Date of FASB Statement No. 157,* (FSP 157-2), which delays the effective date of SFAS 157, for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. FSP 157-2 partially defers the effective date of SFAS 157 to fiscal years beginning after November 15, 2008. The Company adopted the provisions of FSP 157-2 effective January 1, 2009 and such adoption did not have a material impact on the condensed consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, (SFAS 162). SFAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States of America. SFAS 162 is effective for fiscal years beginning after November 15, 2008. The Company adopted the provisions of SFAS 162 effective January 1, 2009 and such adoption did not have a material impact on the condensed consolidated financial statements.

In October 2008, the FASB issued FSP FAS No. 157-3, *Determining the Fair Value of a Financial Asset in a Market That is Not Active (*FSP FAS 157-3). FSP FAS 157-3 clarifies the application of SFAS 157 in a market that is not active. FSP FAS 157-3 addresses how management should consider measuring fair value when relevant observable data does not exist. FSP FAS 157-3 also provides guidance on how observable market information in a market that is not active should be considered when measuring fair value, as well as how the use of market quotes should be considered when assessing the relevance of observable and unobservable data available to measure fair value. FSP FAS 157-3 is effective upon issuance, for companies that have adopted SFAS 157. Revisions resulting from a change in the valuation technique or its application shall be accounted for as a change in accounting estimate in accordance with SFAS 154, *Accounting Changes and Error Corrections*. The application of the provisions of FSP FAS 157-3 did not have a material impact on the condensed consolidated financial statements.

3. Earnings per Share

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

The computation of net (loss) income per share for the three months ended March 31, 2009 and 2008 is shown below:

	Three Months Ended March 31,	
(In thousands, except per share data)	**2009**	**2008**
Basic net (loss) income per share:		
Net (loss) income	$ (1,775)	$ 505
Weighted average class A and B common shares outstanding	41,844	41,733
Basic net (loss) income per share	$ (0.04)	$ 0.01
Diluted net (loss) income per share:		
Net (loss) income	$ (1,775)	$ 505
Weighted average class A and B common shares outstanding for diluted net (loss) income per share	41,844	41,733
Assumed exercise of dilutive stock options under the treasury stock method	—	328
	41,844	42,061
Diluted net (loss) income per share	$ (0.04)	$ 0.01

For the periods listed above, the potentially dilutive securities used in the calculations of diluted net (loss) income per share as of March 31, 2009 and 2008 are as follows:

	Three Months Ended March 31,	
(In thousands)	**2009**	**2008**
Employee stock options	—	608
Non-employee stock options	—	510

For the periods listed above, the following securities were excluded from the computation of diluted net (loss) income per share as their effect would be anti-dilutive as of March 31, 2009 and 2008:

	Three Months Ended March 31,	
(In thousands)	**2009**	**2008**
Employee stock options	694	268
Non-employee stock options	450	—

4. Current and Non-Current Investments

The Company adopted the provisions of SFAS 157, *Fair Value Measurement*s, as of January 1, 2008 for its financial assets and liabilities. The Company's financial assets and liabilities subject to the disclosure requirements of SFAS 157 include investments and ARS related settlement rights assets.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

At March 31, 2009 and December 31, 2008, investments consisted of the following securities:

	March 31, 2009			
(In thousands)	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
U.S. Treasury bills and notes	$ 33,061	$ 27	$ —	$ 33,088
Money market funds	33,662	—	—	33,662
Municipal securities	27,111	—	(4)	27,107
Auction rate securities	9,400	—	—	9,400
Total	$ 103,234	$ 27	$ (4)	$ 103,257
Non-current:				
Auction rate securities	$ 10,000	$ —	$ (506)	$ 9,494

	December 31, 2008			
(In thousands)	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
U.S. Treasury bills and notes	$ 42,620	$ 130	$ —	$ 42,750
Money market funds	51,026	—	—	51,026
Total	$ 93,646	$ 130	$ —	$ 93,776
Non-current:				
Auction rate securities	$ 19,400	$ —	$ (3,178)	$ 16,222

The Company records unrealized gains and losses resulting from changes in the fair value of the auction rate securities and related settlement rights within other income, net, in the condensed consolidated statements of operations and comprehensive (loss) income.

The Company's assets measured at fair value on a recurring basis, which are subject to the disclosure requirements of SFAS 157, at March 31, 2009 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 as of March 31, 2009
U.S. Treasury bills and notes	$ 33,088	$ —	$ —	$ 33,088
Municipal securities	27,107	—	—	27,107
Auction rate securities	—	—	18,894	18,894
Settlement rights for auction rate securities*	—	—	395	395
Other available-for-sale securities	33,662	—	—	33,662
Total assets measured at fair value	$ 93,857	$ —	$ 19,289	$ 113,146

* *included in non-current other assets in the accompanying condensed consolidated balance sheets*

The following table presents the Company's assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in SFAS 157 during the three months ended March 31, 2009:

(In thousands)	Auction Rate Securities and Related Settlement Rights
Balance at December 31, 2008	$ 19,040
Total net unrealized gains included in earnings	249
Balance at March 31, 2009	$ 19,289

5. Accrued Expenses

Accrued expenses consisted of the following as of:

(In thousands)	March 31, 2009	December 31, 2008
Research and development costs	$ 5,620	$ 7,086
Employee compensation	788	1,748
Selling and marketing costs	39	346
Product royalty liability — related party	1,582	—
Other accrued expenses	881	584
Total	$ 8,910	$ 9,764

6. Commitments

Operating Leases

The Company leases office space in the United States, the United Kingdom and Japan under operating leases through 2017. Total future minimum, non-cancelable lease payments under operating leases, which do not include future sub-lease receipts of $199,000, were as follows as of March 31, 2009:

(In thousands)	
2009 (April-December)	$ 1,145
2010	1,140
2011	1,001
2012	963
2013	992
2014 and thereafter	3,297
Total minimum lease payments	$ 8,538

Rent expense for all operating leases was $301,000 and $285,000 for the three months ended March 31, 2009 and 2008, respectively.

Research and Development Costs

The Company routinely enters into agreements with third-party clinical research organizations (CROs) to oversee clinical research and development studies provided on an outsourced basis. The Company is not generally contractually obligated to pay the CRO if the service or reports are not provided. Total future estimated costs under these agreements as of March 31, 2009 were approximately $14.7 million.

7. Related Party Transactions

R-Tech Ueno, Ltd.

The Company is a party to multiple exclusive license and supply agreements with R-Tech.

On February 23, 2009, Sucampo entered into an Exclusive Manufacturing and Supply Agreement, under which it granted R-Tech the exclusive right to manufacture and supply lubiprostone to meet its commercial and clinical requirements in Asia, Australia and

New Zealand. In consideration, R-Tech made an up-front payment of $250,000 to the Company and is obligated to make milestone payments of $500,000 upon regulatory approval of lubiprostone in Japan and $250,000 upon the commercial launch of lubiprostone in Japan.

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

(In thousands)	Three Months Ended March 31, 2009	2008
Clinical supplies	$ 1,044	$ 388
Other research and development services	5	10
	$ 1,049	$ 398

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:

(In thousands)	March 31, 2009	December 31, 2008
Deferred revenue — current	$ 430	$ 419
Deferred revenue, net of current portion	6,552	6,444
	$ 6,982	$ 6,863

The Company recognized approximately $105,000 of deferred revenue relating to its agreements with R-Tech for each of the three months ended March 31, 2009 and 2008, which was recorded as contract and collaboration revenue in the accompanying condensed consolidated statements of operations and comprehensive (loss) income.

On April 23, 2009, the Company entered into two agreements with R-Tech to acquire rights to Rescula in the United States and Canada. Under the terms of the agreements, the Company holds the exclusive rights to commercialize Rescula, in the United States and Canada for the treatment of glaucoma and ocular hypertension and any new indication developed by the Company and has the right of first refusal to commercialize in the United States and Canada, any additional indications for which unoprostone isopropyl is developed by R-Tech. Under the terms of the agreements, the Company made an upfront payment of $3.0 million and is required to make up to $5.5 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The Company is solely responsible for the development, as well as regulatory and commercialization activities and expenses, for Rescula in the United States and Canada and R-Tech is exclusively responsible for the supply of Rescula to the Company within the United States and Canada.

Sucampo AG License Agreements

In February 2009, the Company entered into an addendum to the Amended and Restated Patent Access Agreement originally entered between the Company and Sucampo AG (SAG) on June 30, 2006. Under the addendum, the patent and know-how royalties Sucampo Japan is obligated to pay to SAG were reduced with respect to sales of lubiprostone in Asia, Australia and New Zealand as follows:

- the patent royalty on net sales, due until the expiration of the last patent covering lubiprostone that existed at the time of the Company's initial public offering, was reduced from 4.5% to 2.2%;
- the patent royalty on net sales, due thereafter until all other patents covering lubiprostone have expired in the relevant country, was reduced from 2.25% to 1.1%; and
- the know-how royalty on net sales, due until the fifteenth anniversary of the first commercial sale of lubiprostone, was reduced from 2.0% to 1.0%.

In February 2009, the Company entered into a Technology Assignment and License Agreement with R-Tech and SAG, under which the parties agreed that R-Tech and SAG would share joint ownership of eight U.S. patents and patent applications, and several related international patents and patent applications, which had previously been filed by R-Tech. These patents relate to specific prostone compounds and formulations and to methods for producing prostone compounds. The parties also agreed that R-Tech and SAG would share joint ownership of know-how and other inventions previously created by R-Tech relating to prostones. R-Tech and SAG cross-licensed to each other, on a worldwide, royalty-free, perpetual, exclusive basis, their respective rights in these patents, patent applications, know-how and other inventions. R-Tech's right to utilize the licensed intellectual property is limited to uses in connection with research, development and commercialization of Rescula, and three other prostone compounds it is currently

developing. SAG's right to utilize the licensed intellectual property is limited to uses in connection with research, development and commercialization of all other prostone compounds. SAG's rights under this agreement are in turn licensed to the Company under the existing patent license arrangements. None of the parties made any monetary payments to the other parties under this agreement.

During the first quarter of 2009, pursuant to the license and commercialization agreement with Abbott for the development of lubiprostrone in Japan, the Company received a $10.0 million upfront payment from Abbott. The receipt of the upfront payment triggered the obligation on the part of the Company under the license agreement with SAG to make a $500,000 payment to SAG. The Company recorded the expense as milestone royalties — related parties during the three months ended March 31, 2009.

The Company expensed approximately $1.6 million and $1.1 million in product royalties — related parties under the license agreement with SAG for the three months ended March 31, 2009 and 2008, respectively, reflecting 3.2% of Amitiza net sales during each of these periods.

8. Collaboration and License Agreements

Abbott license and commercialization and supply agreement

In February 2009, the Company entered into a 15-year license, commercialization and supply agreement with Abbott to develop and commercialize lubiprostone for the treatment of chronic idiopathic constipation (CIC) in Japan. The agreement grants Abbott exclusive rights to commercialize lubiprostone in Japan for the treatment of CIC and also the right of first refusal to any additional indications for which lubiprostone is developed in Japan under all relevant patents, know-how and trademarks.

The collaboration efforts under the agreement are governed by two committees consisting of an equal number of representatives from both parties. The joint commercialization and steering committee oversees commercialization-related activities and resolves any conflicts arising from a joint development committee, which oversees the development-related activities in Japan.

The Company is required to fund and complete all the development work including additional clinical studies required to obtain regulatory approval for the treatment of CIC in Japan. The Company owns all the rights covered under the regulatory filings.

Abbott is responsible to fund and undertake all commercialization efforts including pre-launch and post-launch marketing, promotion and distribution. Abbott is required to maintain the number of sales staff and the estimated level of annual net sales based on the commercialization plan to be developed and approved by the joint commercialization and steering committee described above. The Company has retained the right to co-promote the product in Japan and is responsible for such cost of co-promotion. Abbott shall procure finished product ready for commercial sale from the Company at agreed-upon prices.

Under the terms of the agreement, payments to the Company include a non-refundable upfront payment and non-refundable development and commercial milestone payments based on achieving specified development, regulatory and sales goals. Following marketing authorization and pricing approval, Abbott will purchase the finished product from the Company for distribution in Japan. Based on the terms of the agreement, the Company received an upfront payment of $10.0 million upon execution of the agreement in February 2009.

The following table summarizes the cash streams and related revenue recognized under the license, commercialization and supply agreement with Abbott for the three months ended March 31, 2009:

(In thousands)	Amount Deferred at December 31, 2008	Cash Received for the Three Months Ended March 31, 2009	Revenue Recognized for the Three Months Ended March 31, 2009	Foreign Currency Effects for the Three Months Ended March 31, 2009	Amount Deferred at March 31, 2009
Collaboration revenue:					
Up-front payment associated with the Company's obligation to participate in joint commercialization and steering committee with Abbott	$ —	$ 677	$ 5	$ 34	$ 638
Research and development revenue:					
Up-front payment	$ —	$ 9,323	$ 374	$ 475	$ 8,474

Takeda commercialization and license agreement

In October 2004, the Company entered into a 16-year collaboration and license agreement with Takeda to exclusively co-develop, commercialize and sell products that contain lubiprostone for gastroenterology indications in the United States and Canada. On February 1, 2006, the Company entered into a supplemental agreement with Takeda, which amended the responsibilities of both the Company and Takeda for the co-promotion of Amitiza and clarified the responsibilities and funding arrangements for other marketing services to be performed by both parties. Payments to the Company under these agreements include a non-refundable up-front payment, non-refundable development and commercial milestone payments, reimbursement of certain development and co-promotion costs and product royalties.

The Company has received a total of $150.0 million in up-front and development milestone payments through March 31, 2009 under these agreements. Subject to future development and commercial milestones, the Company is potentially entitled to receive up to $10.0 million in additional development milestone payments and up to $50.0 million in commercial milestone payments, under the collaboration and license agreements with Takeda, although there can be no assurance that the Company will receive any such payments.

The following table summarizes the cash streams and related revenue recognized under the collaboration and license agreements with Takeda for the three months ended March 31, 2009:

(In thousands)	Amount Deferred at December 31, 2008	Cash Received for the Three Months Ended March 31, 2009	Revenue Recognized for the Three Months Ended March 31, 2009	Change in Accounts Receivable for the Three Months Ended March 31, 2009	Amount Deferred at March 31, 2009
Collaboration revenue:					
Up-front payment associated with the Company's obligation to participate in joint committees with Takeda	$ 1,764	$ —	$ 37	$ —	$ 1,727
Research and development revenue:					
Reimbursement of research and development expenses	$ —	$ 18,126	$ 5,152	$ (540)	$ 12,434
Product royalty revenue	$ —	$ 9,891	$ 8,946	$ (945)	$ —

(In thousands)	Accounts Receivable at December 31, 2008*	Cash Received for the Three Months Ended March 31, 2009	Revenue Recognized for the Three Months Ended March 31, 2009	Accounts Receivable at March 31, 2009*	Amount Deferred at March 31, 2009
Research and development revenue:					
Reimbursement of research and development expenses	$ 4,407	$ 18,126	$ 5,152	$ 3,867	$ 12,434
Product royalty revenue	$ 9,890	$ 9,891	$ 8,946	$ 8,945	$ —
Co-promotion revenue	$ 395	$ 1,165	$ 896	$ 126	$ —

* Includes billed and unbilled accounts receivable.

9. Stock Option Plans

The following table summarizes the employee stock option activity for the three months ended March 31, 2009 under the Company's 2001 Incentive Plan:

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2008	455,600	$ 10.34		
Options forfeited	(850)	10.00		
Options expired	(7,650)	10.00		
Options outstanding, March 31, 2009	447,100	10.34	3.99	$ —
Options exercisable, March 31, 2009	438,600	10.35	3.93	$ —

The following table summarizes the employee stock option activity for the three months ended March 31, 2009 under the Company's 2006 Incentive Plan:

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2008	275,000	$ 13.86		
Options forfeited	(46,750)	13.38		
Options expired	(2,000)	14.12		
Options outstanding, March 31, 2009	226,250	13.96	6.27	$ —
Options exercisable, March 31, 2009	118,250	14.34	5.23	$ —

The Company did not grant any stock options during the three months ended March 31, 2009. As of March 31, 2009, approximately $658,000 of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards are expected to be recognized over a weighted average period of 1.93 years.

The following table summarizes the non-employee stock option activity for the three months ended March 31, 2009 under the Company's 2001 Incentive Plan:

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2008	450,000	$ 5.85		
Options outstanding, March 31, 2009	450,000	5.85	6.09	$ 126
Options exercisable, March 31, 2009	450,000	5.85	6.09	$ 126

There were no non-employee stock options that were exercised, forfeited or expired for the three months ended March 31, 2009.

Employee Stock Purchase Plan

Under the 2006 Employee Stock Purchase Plan (ESPP), a total of 910 shares of class A common stock were purchased during the three months ended March 31, 2009. The ESPP is intended to qualify as an Employee Stock Purchase Plan as defined in Section 423 of the Internal Revenue Code of 1986 and in accordance with SFAS No. 123(R), this plan is non-compensatory. The Company received $5,299 upon purchase of shares under the ESPP for the three months ended March 31, 2009.

10. Income Taxes

For the three months ended March 31, 2009 and 2008, the Company recorded a tax provision of $401,000 and a tax benefit of $5.6 million, respectively. The tax provision for the three months ended March 31, 2009 primarily pertained to taxable income generated by the Company's U.S. subsidiary. The Company's other subsidiaries based in Japan and Europe incurred pre-tax losses for the three months ended March 31, 2009, for which no tax benefit was recognized. The tax benefit recorded for the three months ended March 31, 2008 was primarily due to a discrete release of U.S. deferred tax asset valuation allowances and a reduction in the projected effective tax rate for 2008 based on an increase in projected milestone and product royalty income.

As required under Accounting Principles Board Opinion (APB) No. 28, *Interim Financial Reporting*, the Company has estimated its annual effective tax rate for the full fiscal year 2009 and 2008 and applied that rate to its income before income taxes in determining its income tax provision for the interim periods. There is no tax benefit provided on the net operating losses incurred in the foreign jurisdictions due to the lack of evidence supporting the Company's ability to use these losses in the future.

Uncertain Tax Positions

The Company applies the provisions of FASB Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 requires the application of a more likely than not threshold to the recognition and derecognition of uncertain tax positions.

The Company had an outstanding non-current income tax liability of $525,240 for uncertain tax positions as of March 31, 2009. 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, and is reflected in other liabilities in the accompanying condensed consolidated balance sheets. The liability for uncertain tax positions as of March 31, 2009 mainly pertained to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes.

The Company recognizes accrued interest and penalties related to uncertain tax positions as a component of the income tax provision. The Company has identified no uncertain tax position for which it is reasonably possible that the total amount of liability for unrecognized tax benefits will significantly increase or decrease within 12 months, except for recurring accruals on existing uncertain tax positions.

11. Segment Reporting

The Company has determined that it has three reportable geographic segments based on the Company's method of internal reporting of its three operating entities. These segments are the United States, Europe and Japan. The Company evaluates the performance of these segments based primarily on income (loss) from operations, as well as other factors that depend on the development status of the operating entities. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other measures. The reportable segments have historically derived their revenue from collaboration and license agreements. Transactions between the segments consist primarily of loans and the provision of research and development services by the European and Japanese entities to the United States entity.

Following is a summary of financial information by reportable geographic segment.

(In thousands)	United States	Europe	Japan	Intercompany Eliminations	Consolidated
Three Months Ended March 31, 2009					
Research and development revenue	$ 5,152	$ —	$ 374	$ —	$ 5,526
Product royalty revenue	8,946	—	—	—	8,946
Co-promotion revenue	896	—	—	—	896
Contract and collaboration revenue	141	—	215	(210)	146
Total revenues	15,135	—	589	(210)	15,514
Depreciation and amortization	117	3	2	—	122
Other operating expenses	14,458	480	3,172	(210)	17,900
Income (loss) from operations	560	(483)	(2,585)	—	(2,508)
Interest income	359	—	3	(50)	312
Other non-operating income (expense), net	244	(36)	564	50	822
Income (loss) before income taxes	$ 1,163	$ (519)	$ (2,018)	$ —	$ (1,374)
Capital expenditures	$ 127	$ —	$ —	$ —	$ 127
Three Months Ended March 31, 2008					
Research and development revenue	$ 6,110	$ —	$ —	$ —	$ 6,110
Product royalty revenue	6,080	—	—	—	6,080
Co-promotion revenue	1,222	—	—	—	1,222
Contract and collaboration revenue	142	—	207	(207)	142
Total revenues	13,554	—	207	(207)	13,554
Depreciation and amortization	100	—	2	—	102
Other operating expenses	16,944	1,838	669	(210)	19,241
Loss from operations	(3,490)	(1,838)	(464)	3	(5,789)
Interest income	656	4	3	(21)	642
Other non-operating (expense) income, net	(27)	19	2	18	12
Loss before income taxes	$ (2,861)	$ (1,815)	$ (459)	$ —	$ (5,135)
Capital expenditures	$ 171	$ —	$ —	$ —	$ 171
As of March 31, 2009					
Property and equipment, net	$ 2,143	$ 36	$ 93	$ —	$ 2,272
Identifiable assets, net of intercompany loans and investments	$ 140,984	$ 2,564	$ 13,044	$ (493)	$ 156,099
As of December 31, 2008					
Property and equipment, net	$ 2,134	$ 39	$ 102	$ —	$ 2,275
Identifiable assets, net of intercompany loans and investments	$ 146,074	$ 568	$ 4,469	$ (317)	$ 150,794

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. ("Sucampo," 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. You should 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, 2008 included in our Annual Report on Form 10-K.

Overview

We are an international biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. In January 2006, we received marketing approval from the U.S. Food and Drug Administration, or FDA, for our first product, Amitiza® (lubiprostone), for the treatment of chronic idiopathic constipation, or CIC, in adults. In April 2008, the FDA approved Amitiza for its second indication for the treatment of irritable bowel syndrome with constipation in adult women. We are currently developing Amitiza for the treatment of opioid-induced bowel dysfunction, or OBD.

In the United States and Canada, Amitiza is being marketed and developed under a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, for gastrointestinal indications. Under the agreement with Takeda, we are primarily responsible for the research and development of Amitiza, while Takeda is primarily responsible for the commercialization and marketing activities. Additionally, Takeda funds the majority of our research and development activities in the United States and part of the co-promotion activities of our own sales force, per the terms of the agreement. Takeda records all product revenue and we receive a royalty on such product sales.

In February 2009, we entered into a license, commercialization and supply agreement with Abbott Japan Co. Ltd., or Abbott, for Amitiza in Japan. Under the terms of the agreement, Abbott received exclusive rights to commercialize lubiprostone in Japan for the treatment of CIC and received the right of first refusal to any additional indications for which lubiprostone is developed in Japan under all relevant patents, know-how and trademarks. Abbott is responsible for all commercialization expenses and efforts. We are responsible for development activities under the agreement. We have retained the right to co-promote lubiprostone in Japan and we are responsible for such costs of co-promotion. Based on the terms of the agreement, we received an upfront payment of $10.0 million upon execution of the agreement in February 2009. We will recognize revenue from the upfront payment over the term of the CIC development program in Japan on a percentage of completion basis.

On April 23, 2009, we entered into two agreements with R-Tech Ueno Ltd., or R-Tech, a Japanese manufacturing and research and development company that is majority owned by our founders, to acquire all patents and other intellectual property rights related to Rescula® (unoprostone isopropyl) in the United States and Canada. Although Rescula eye drops have been approved by the FDA for the treatment of open-angle glaucoma and ocular hypertension since 2000, Rescula is not currently being marketed in the United States or Canada. Under the terms of the agreements, we made an upfront payment of $3.0 million and are required to make up to $5.5 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. We plan to re-launch Rescula in the United States for the treatment of glaucoma and ocular hypertension and to initiate clinical trials of Rescula for the treatment of dry aged-related macular degeneration, or dry AMD, in 2010. We plan to capitalize and amortize the upfront payment over the estimated life of the license agreement, which approximates the useful life of the underlying rights and data.

We generate revenue mainly from product royalties, development milestone payments, and research and development activities. We expect to continue to incur significant expenses for the next several years as we continue to expand our research and development activities, seek regulatory approvals for additional indications for Amitiza and for other compounds in the United States and abroad and expand our international operations. Although we reported net income for the years ended December 31, 2008, 2007 and 2006, whether we are able to sustain profitability will depend upon our ability to generate sufficient revenues and receive payments under our contracts with Takeda, Abbott and similar future arrangements. In the near term, our ability to generate product revenues will depend primarily on the growth of Amitiza sales in the United States, continued development of additional indications for Amitiza, successful development and approval of our pipeline of prostone product candidates and additional future licensing agreements.

We hold an exclusive worldwide royalty-bearing license from Sucampo AG, or SAG, a Swiss patent-holding company and an entity wholly owned by our founders, to develop and commercialize Amitiza and all other prostone compounds covered by patents and patent applications held by SAG. We are obligated to assign to SAG all patentable improvements that we make in the field of prostones, which in turn SAG is obligated to license back to us on an exclusive basis.

Drs. Ryuji Ueno and Sachiko Kuno, our founders, own directly or indirectly the majority of our common stock, a majority of the stock of R-Tech and all of the stock of SAG. Dr. Ueno serves as the chairman of our board of directors and is our chief executive officer and chief scientific officer. Dr. Kuno is a member of our board of directors and executive advisor of international business development.

We conduct our business through our subsidiaries based in the United States, the United Kingdom and Japan. These subsidiaries represent our reportable geographic segments and we evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors that depend on the development status of these subsidiaries. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other measures.

Our Clinical Development Programs

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

- *Amitiza (lubiprostone) in the United States and Canada.* We currently are developing Amitiza to treat opioid-induced bowel dysfunction. We recently have completed enrollment into two identically designed Phase III placebo-controlled pivotal clinical trials of Amitiza for the treatment of OBD and we expect to complete these trials in mid-2009. We are also conducting a follow-on open label safety extension trial that we plan to complete by the end of 2009. If these trials are successful, we plan to file a supplemental new drug application for Amitiza in OBD with the FDA in 2010.

  In connection with our marketing approval for Amitiza for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in pediatric patients, in patients with renal impairment and in patients with hepatic impairment, which were initiated in January 2007. We anticipate filing results from these post-marketing studies with the FDA in the second quarter of 2009. In connection with our marketing approval for Amitiza for the treatment of irritable bowel syndrome with constipation in adult women, we committed to the FDA to conduct a post-marketing study to evaluate the safety and efficacy for the treatment of irritable bowel syndrome in pediatric patients ages 6 to 17. In addition, we committed to conduct a post-marketing study in male and female patients with irritable bowel syndrome with constipation utilizing a higher dose than currently recommended for this indication. In accordance with the collaboration and co-promotion arrangement, Takeda funds the majority of Amitiza's development program in the United States.

- *Amitiza (lubiprostone) in other countries.* We currently are awaiting responses to our marketing authorization applications for lubiprostone, 24 mcg, for the treatment of chronic idiopathic constipation in adults filed in ten European countries in early 2008.

  In September 2008, we announced positive results from our multi-center Phase 2b dose-ranging study in Japan to evaluate the safety and efficacy of lubiprostone for treating chronic idiopathic constipation in adults. The results enabled us to enter into the license agreement with Abbott in Japan. We plan to initiate Phase III clinical trials in Japan during the second quarter of 2009.

- *Rescula.* In April 2009, we licensed from R-Tech the development and commercialization rights to Rescula (unoprostone isopropyl) in the United States and Canada, including all associated patents and other intellectual property. Although Rescula has been approved for marketing in the United States for the treatment of open-angle glaucoma and ocular hypertension since 2000, it was marketed only to a limited extent by a previous licensee shortly after the approval and is not currently commercialized in these countries. We plan to relaunch Rescula in the United States for the treatment of glaucoma and ocular hypertension in 2010. We also intend to initiate a phase 2 clinical trial of unoprostone isopropyl to treat dry age-related macular degeneration in 2010.

- *Cobiprostone.* We are developing orally administered cobiprostone to treat various gastrointestinal and liver disorders, including the prevention of non-steroidal anti-inflammatory drug-induced ulcers and the treatment of non-alcoholic fatty

liver disease. We also plan to develop an inhaled formulation of cobiprostone for the treatment of respiratory symptoms of cystic fibrosis and chronic obstructive pulmonary disease and a topical formulation for the treatment of ulcers and wounds.

Our near-term focus is on the development of cobiprostone for the prevention of non-steroidal anti-inflammatory drug-induced ulcers. We commenced a Phase II clinical trial of cobiprostone for the prevention of non-steroidal anti-inflammatory drug-induced ulcers in the third quarter of 2007. The trial was fully enrolled in December 2008 and we anticipate completion of the study in mid-2009. In December 2008, we discontinued enrollment into a Phase II proof-of-concept study of cobiprostone for the treatment of portal hypertension in patients with liver cirrhosis due to lower than anticipated enrollment resulting from lack of patient eligibility, interest and study compliance. We are reviewing the trial design to determine if future studies for this indication are warranted.

- *SPI-017.* We are conducting pre-clinical development of SPI-017 to treat vascular disease and central nervous system disorders. We are initially focused on developing an intravenous formulation of this product candidate for the treatment of peripheral arterial disease. We commenced a phase 1 clinical trial of the intravenous formulation of SPI-017 in December 2008 in Japan.

Reclassifications

We have reclassified certain amounts in the previously issued financial statements to conform with the current presentation. We reclassified expenses that have been previously included within general and administrative expenses to research and development expenses. Such expenses primarily include salaries and other employee benefits of personnel who oversee the research and development process, and allocated depreciation and rent expenses and insurance costs. We also reclassified allocated depreciation and rent expenses and insurance costs from general and administrative expenses to selling and marketing expenses. During the three months ended March 31, 2008, we reclassified $1.1 million and $80,000 of general and administrative expenses to research and development expenses and to selling and marketing expenses, respectively.

Results of Operations

Comparison of three months ended March 31, 2009 and March 31, 2008

Revenues

The following table summarizes our revenues for the three months ended March 31, 2009 and 2008:

	Three Months Ended March 31,	
(In thousands)	**2009**	**2008**
Research and development revenue	$ 5,526	$ 6,110
Product royalty revenue	8,946	6,080
Co-promotion revenue	896	1,222
Contract and collaboration revenue	146	142
Total	$ 15,514	$ 13,554

Total revenues were $15.5 million for the three months ended March 31, 2009 compared to $13.6 million for the three months ended March 31, 2008, an increase of $1.9 million or 14.5%.

Research and development revenue was $5.5 million for the three months ended March 31, 2009 compared to $6.1 million for the three months ended March 31, 2008, a decrease of $584,000 or 9.6%. This decrease was primarily due to reduced revenue recognized in respect to the pediatric, renal, hepatic and OBD trials for Amitiza funded by Takeda, offset in part by $374,000 in revenue recognized from the initial $10.0 million upfront payment received under the agreement with Abbott in Japan. The revenue from the upfront and development milestone payments from Abbott in Japan are being recognized using a percentage of completion model through the estimated date of approval of CIC by the regulatory authorities of Japan.

Product royalty revenue represents royalty revenue earned on net sales of Amitiza in the United States. For the three months ended March 31, 2009 and 2008, we recognized $8.9 million and $6.1 million, respectively, of product royalty revenue, an increase of $2.8 million or 47.1%. The increase reflects the continued acceptance by patients and physicians of Amitiza, 8 mcg, for the treatment of irritable bowel syndrome with constipation in adult women, following its approval by the FDA in April 2008.

Co-promotion revenue represents partial reimbursement by Takeda of Amitiza co-promotion costs for our 38 member specialty sales force targeting long-term care facilities. For the three months ended March 31, 2009 and 2008, we recognized $900,000 and $1.2 million, respectively, of co-promotion revenue for reimbursement of our sales force costs. The co-promotion reimbursement is capped at $4.5 million annually and is calculated for twelve month periods ending March 31. The reduced revenue during the three months ended March 31, 2009 reflects this annual limit.

Research and Development Expenses

The following summarizes our research and development expenses for the three months ended March 31, 2009 and 2008:

	Three Months Ended March 31,	
(In thousands)	**2009**	**2008**
Direct costs:		
Amitiza	$ 6,771	$ 8,986
Cobiprostone	890	994
SPI - 017	1,637	679
Other	144	135
Total	9,442	10,794
Indirect costs	523	422
Total	$ 9,965	$ 11,216

Total research and development expenses for the three months ended March 31, 2009 were $10.0 million compared to $11.2 million for the three months ended March 31, 2008, a decrease of $1.2 million or 11.2%. During the three months ended March 31, 2008, we incurred filing and data purchase costs of approximately $2.5 million, which were necessary to submit our European regulatory filings. No such expenditure was recorded during the three months ended March 31, 2009. The increase in the SPI-017 costs reflect the costs associated with the ongoing phase 1 trial for SPI-017 for peripheral arterial disease in Japan as well as non-clinical expenses for the exploration of other indications.

General and Administrative Expenses

The following summarizes our general and administrative expenses for the three months ended March 31, 2009 and 2008:

	Three Months Ended March 31,	
(In thousands)	**2009**	**2008**
Salaries, benefits and related costs	$ 1,159	$ 915
Legal, consulting and other professional expenses	1,077	958
Other operating expenses	1,219	1,294
Total	$ 3,455	$ 3,167

General and administrative expenses were $3.5 million for the three months ended March 31, 2009 compared to $3.2 million for the three months ended March 31, 2008, an increase of $288,000 or 9.1%. The increase in salaries, benefits and related costs was primarily attributable to severance payments made during the three months ended March 31, 2009 as a result of a reduction in force in January 2009. The increase in legal, consulting and other professional expenses was associated with our license agreement with Abbott partially offset by the reduction in compliance and regulatory consulting expenses.

Selling and Marketing Expenses

Selling and marketing expenses represent costs we incur to co-promote Amitiza, including salaries, benefits and related costs of our sales force and other sales and marketing personnel, costs of market research and analysis and other selling and marketing expenses. Selling and marketing expenses were $2.5 million for the three months ended March 31, 2009 compared to $2.8 million for the three months ended March 31, 2008, a decrease of $336,000 or 11.8%. The decrease was primarily due to streamlined operations of promotional programs and a reduction in market research expenses.

Milestone Royalties — Related Parties

Milestone royalties — related parties expense was $500,000 for the three months ended March 31, 2009, reflecting the 5% royalty payment we owed to SAG as a result of the $10.0 million upfront payment we received from Abbott. We expensed $1.0 million for the three months ended March 31, 2008, reflecting a payment to SAG in connection with our European regulatory filings. We are required to pay $1.0 million for the first foreign regulatory filing, in each of the three following territories covered by the license agreement with SAG: North, Central and South America (including the Caribbean); Asia; and the rest of the world. Our European filings represented the first such filing for the rest-of-the-world territory.

Product Royalties — Related Parties

Product royalties — related parties expense, representing 3.2% of Amitiza net sales for the respective periods payable to SAG, increased to $1.6 million for the three months ended March 31, 2009 from $1.1 million for the three months ended March 31, 2008, proportionally with the increase of product royalty revenue.

Non-Operating Income

The following table summarizes our non-operating income and expense for the three months ended March 31, 2009 and 2008:

	Three Months Ended March 31,	
(In thousands)	**2009**	**2008**
Interest income	$ 312	$ 642
Other income, net	822	12
Total non-operating income, net	$ 1,134	$ 654

Interest income was $312,000 for the three months ended March 31, 2009 compared to $642,000 for the three months ended March 31, 2008, a decrease of $330,000, or 51.4%. The decrease was primarily due to lower prevailing interest rates earned by our investments in U.S. Treasury funds, notes and money market securities during the three months ended March 31, 2009 as compared to three months ended March 31, 2008. The increase in other income was primarily attributable to foreign exchange gains and fair value changes in auction rate securities, or ARS, and related settlement rights.

Income Taxes

We recorded a tax provision of $401,000 and a tax benefit of $5.6 million for the three months ended March 31, 2009 and 2008, respectively. The tax provision for the three months ended March 31, 2009 mainly pertained to taxable income generated by our U.S. subsidiary. Our other subsidiaries based in Japan and Europe incurred pre-tax losses for the three months ended March 31, 2009, for which no tax benefit was recognized. The tax benefit recorded for the three months ended March 31, 2008 was primarily due to a reversal of U.S. deferred tax asset valuation allowances of $4.8 million based on a $50.0 million milestone payment from Takeda and expected increase of product royalty income. As of March 31, 2009, we had an outstanding non-current income tax liability of $525,240 for uncertain tax positions which represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in the our condensed consolidated financial statements. The liability for uncertain tax positions as of March 31, 2009 was mainly a result of our interpretation of nexus in certain states related to revenue sourcing for state income tax purposes.

Cost Reduction Initiatives

To conserve cash and more closely align our spending towards our strategic objectives, we implemented cost reduction initiatives in January 2009, including a workforce reduction and a refocusing of our research and development plans. We expect that these initiatives will result in reduced costs of approximately $3.0 million during 2009. However, there is no assurance that we will be successful in achieving these cost savings if actual spending varies from our estimates.

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 United States, Europe and Japan. We evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors, including the results of operations, the progress of research and development activities and other measures.

The financial results of our segments reflect their varying stages of development. Our United States segment recorded income before taxes of $1.1 million for the three months ended March 31, 2009 compared to a loss before taxes of $2.9 million for the three months ended March 31, 2008, primarily due to an increase in product royalty revenues offset in part by a decrease in research and development expenses.

Our segment in Europe recorded a loss before taxes of $519,000 for the three months ended March 31, 2009 compared to a loss before taxes of $1.8 million for the three months ended March 31, 2008, primarily related to the expenses incurred in connection with our European regulatory filings during the three months ended March 31, 2008.

Our segment in Japan recorded a loss before taxes of $2.0 million for the three months ended March 31, 2009 as compared to a loss before taxes of $460,000 during the three months ended March 31, 2008. These losses reflect the ongoing investment to plan and implement a phase 3 clinical program for Amitiza, the ongoing phase 1 trial of SPI-017 for peripheral arterial disease and the ongoing preclinical programs for other prostone-based compounds.

The following is a summary of financial information by reportable segment.

(In thousands)	United States	Europe	Japan	Intercompany Eliminations	Consolidated
Three Months Ended March 31, 2009					
Total revenues	$ 15,135	$ —	$ 589	$(210)	$ 15,514
Income (loss) before taxes	1,163	(519)	(2,018)	—	(1,374)
Three Months Ended March 31, 2008					
Total revenues	$ 13,554	$ —	$ 207	$(207)	$ 13,554
Loss from before taxes	(2,861)	(1,815)	(459)	—	(5,135)
Identifiable Assets, net of intercompany loans and investments					
At March 31, 2009	$140,984	$ 2,564	$13,044	$(493)	$156,099
At December 31, 2008	146,074	568	4,469	(317)	150,794

Liquidity and Capital Resources

Sources of Liquidity

We require cash principally to meet our operating expenses. Historically, we have financed our operations with a combination of up-front payments, milestone and royalty payments and research and development expense reimbursements, private placements of equity securities and our initial public offering.

Our cash, cash equivalents and investments consisted of the following:

(In thousands)	March 31, 2009	December 31, 2008
Cash and cash equivalents	$ 17,797	$ 11,536
Investments, current	103,257	93,776
Investments, non-current	9,494	16,222
	$ 130,548	$ 121,534

Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity at time of purchase of 90 days or less.

As of March 31, 2009, our short-term investments consisted of money market funds, U.S. Treasury notes and bills which have short-term maturities. Our non-current investments primarily consist of investments in ARS. Pursuant to a settlement rights agreement from our ARS broker, we can require the broker to purchase our ARS at par value between June 30, 2010 and July 2, 2012. We do not anticipate having to sell these securities in order to operate our business before the expected redemption dates.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2009 and 2008:

(In thousands)	Three Months Ended March 31, 2009	2008
Cash provided by (used in):		
Operating activities	$ 7,305	$ (380)
Investing activities	(460)	7,245
Financing activities	5	42
Effect of exchange rates	(589)	267
Net increase in cash and cash equivalents	$ 6,261	$ 7,174

Three Months ended March 31, 2009

Net cash provided by operating activities was $7.3 million for the three months ended March 31, 2009. This reflected a net loss of $1.8 million, which included a non-cash unrealized loss on settlement rights of $2.4 million, offset in part by a $2.7 million unrealized gain on trading securities, an increase in deferred revenue of $7.2 million, and an increase in accounts payable of $1.4 million and a $1.4 million increase in prepaid and income taxes receivable and payable, net. The increase in deferred revenue primarily related to a $10.0 million upfront payment from Abbott upon execution of the license and commercialization agreement by Sucampo Japan in February 2009.

Net cash used in investing activities of $460,000 for the three months ended March 31, 2009 primarily reflected our purchases of investments, offset in part by proceeds from the sales and maturities of investments.

Net cash provided by financing activities of $5,000 for the three months ended March 31, 2009 resulted from proceeds we received under our employee stock purchase plan.

Three Months ended March 31, 2008

Net cash used in operating activities was $380,000 for the three months ended March 31, 2008. The net income of $505,000 was offset primarily by a non-cash reversal of deferred tax asset valuation allowances of $5.6 million, an increase in product royalties receivable of $2.6 million related to product royalty revenue for Amitiza, an increase in prepaid and income taxes receivable and payable of $1.8 million, an increase in accounts payable of $1.4 million and a decrease in accrued liabilities of $1.6 million.

Net cash provided by investing activities of $7.2 million for the three months ended March 31, 2008 primarily reflected our purchases of investments, offset in part by proceeds from the sales and maturities of investments.

Net cash provided by financing activities of $42,000 for the three months ended March 31, 2008 was attributable to net proceeds we received from the exercise of stock options.

Off-Balance Sheet Arrangements

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

- fund our share of the development program of Amitiza in the United States;
- fund development and regulatory efforts in Europe and Japan for Amitiza;
- fund development and regulatory activities for Rescula in the United States and Canada;
- fund research and development activities for other prostone compounds including cobiprostone and SPI-017;

- fund the expansion of our commercialization activities in the United States and the initiation of commercialization efforts in non-U.S. markets;
- fund costs for capital expenditures to support the growth of our business; and
- fund the purchase of shares of our class A common stock up to $10.0 million, if we elect to do so, pursuant to our board-approved stock repurchase program.

The timing of these funding requirements is difficult to predict due to many factors, including the outcomes of our 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 revenue from Amitiza;
- the future expenditures we may incur to increase revenue from Amitiza;
- the cost and time involved to pursue our research and development programs;
- our ability to establish collaborative arrangements and to enter into licensing agreements and contractual arrangements with others; and
- any future change in our business strategy.

To the extent that our capital resources may be insufficient to meet our future capital requirements, we may need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements.

Fair Value Estimates

We adopted the provisions of Statement of Financial Accounting Standards, or SFAS 157, *Fair Value Measurement*s, effective January 1, 2008 for our financial assets and liabilities and adopted SFAS 157 for non-financial assets and liabilities effective January 1, 2009. The carrying amounts of our financial instruments, which include cash and cash equivalents, restricted cash, current and non-current investments, receivables, accounts payable and accrued liabilities, approximate their fair values based on their short maturities, independent valuations or internal assessments. The adoption of SFAS 157 for non-financial assets and liabilities did not have a material impact on the accompanying condensed consolidated financial statements.

For the three months ended March 31, 2009, we recorded a net $249,000 gain within other income, net in the accompanying condensed consolidated statements of operations and comprehensive (loss) income as a change in the fair value of our investments in ARS and related settlement rights.

Recent Accounting Pronouncements

Recent accounting pronouncements applicable to our financial statements are described in Note 2 to the accompanying condensed consolidated financial statements.

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

Foreign Exchange Risk

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

Interest Rate Risk

Our exposure to market risks associated with changes in interest rates relates primarily to the increase or decrease in the amount of interest income earned on our investment portfolio. We ensure the safety and preservation of invested funds by attempting to limit default risk, market risk and reinvestment risk. We attempt to mitigate default risk by investing in investment grade securities. A hypothetical one percentage point decline in interest rates would not have materially affected the fair value of our interest-sensitive financial instruments as of March 31, 2009.

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 and cash equivalents, restricted cash and investments with what we believe to be highly rated financial institutions. Our uninsured cash, cash equivalents and investments as of March 31, 2009 consisted primarily of $33.1 million of U.S. Treasury notes, $18.9 million of money market funds guaranteed under the U.S. Treasury's Temporary Guarantee Program, $27.1 million of municipal securities, $18.9 million of investments in ARS, $14.8 million of other money market funds and $14.4 million of ordinary deposit accounts in foreign subsidiaries. We have not experienced any losses on these accounts related to amounts in excess of insured limits.

(In thousands)	March 31, 2009
Cash and cash equivalents	$ 17,797
Investments	112,751
Restricted cash	213
Less: amounts subject to federally insured limits	(578)
Total amounts in excess of federally insured limits	$ 130,183

As of March 31, 2009, we had $18.9 million invested in two non-mortgage related ARS. On April 29, 2009, one ARS was redeemed by the issuer at par and we received $9.4 million. Pursuant to the settlement rights offered by our ARS broker, we have the right to require the broker to purchase the remaining ARS at par value at any time during the two-year period beginning June 30, 2010. In addition, given the complexity of ARS and their valuations, our estimates of their fair value may differ from the actual amount we would be able to collect at the time of redemption under the settlement rights offer or ultimate sale.

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 Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of March 31, 2009. 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 this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2009, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified under applicable rules of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

b) Changes in Internal Controls

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2009 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***

We and our subsidiaries are not currently a party to any legal proceedings of which the ultimate outcome, in our judgment, would have a material adverse effect on our business, financial condition or results of operations.

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

Except for the risk factors listed below, we do not believe that there have been material changes to the risk factors affecting our business that we included in our Annual Report on Form 10-K for the year ended December 31, 2008.

Risks Related to Our Recently Licensed Product, Rescula®

In April 2009, we acquired from R-Tech the development and commercialization rights to Rescula (unoprostone isopropyl) in the United States and Canada, including all associated patents and other intellectual property. Although Rescula has been approved for marketing in the United States for the treatment of open-angle glaucoma and ocular hypertension since 2000, it was marketed only to a limited extent by a previous licensee shortly after the approval and is not currently commercialized in these countries.

Our existing sales force may not be sufficient to effectively market Rescula, which could limit our ability to generate Rescula sales, require us to invest significant additional resources in our sales force and hurt our sales of Amitiza.

We plan to re-launch Rescula in the United States for the treatment of glaucoma and ocular hypertension in 2010. This will be a new product and a new market for us. We intend to market Rescula using our existing specialty sales force, which currently consists of 38 sales representatives who focus in the institutional segment of the gastrointestinal market, including specialist physicians based in academic medical centers and long-term care facilities. This sales force, which currently markets Amitiza, may not be sufficiently large and their focus may not be broad enough to effectively market Rescula in the ophthalmic field. We may need to invest significantly in enlarging our sales force to reach this new specialty market. We might also dilute their current focus on the institutional gastrointestinal market by adding a second product to their portfolio, which might compromise our sales of Amitiza.

The market for glaucoma and ocular hypertension treatments is highly competitive.

We will face significant competition for Rescula as a treatment for glaucoma and ocular hypertension in the United States. There are currently several approved therapies for these conditions, including Xalatan®, marketed by Pfizer; Travatan®, marketed by Alcon; Cosopt and Trusopt, marketed by Merck; Alphagan/-P and Lumigan, marketed by Allergan; and generic timolol. We may not be effective in differentiating Rescula from the established competing products, which would compromise our ability to generate significant sales. Many of these competitors have significantly greater financial resources and expertise in marketing pharmaceutical products than we do.

Our planned clinical trials for other indications for Rescula will be expensive and may not demonstrate safety and efficacy in humans.

A key element of our strategy with respect to Rescula is to pursue its development for other indications. We plan to initiate a phase 2 clinical trial of Rescula to treat dry age-related macular degeneration in 2010. This clinical trial will be expensive and we might need to divert financial resources from our existing development efforts to fund this trial. As with all clinical trials, there will be significant uncertainty about the potential efficacy and safety results. If Rescula does not demonstrate effectiveness at treating dry age-related macular degeneration or any other potential indication we may decide to pursue for it in the future, we may be limited to commercializing it only for the existing indication and we may not be able to recover our investments in Rescula. If safety issues develop in the trials, we would likely be required to abandon our development for this indication and we might even be forced to discontinue marketing Rescula for the currently approved indications.

Our dependence on a sole supplier to meet our commercial and clinical requirements for Rescula may significantly impair our ability to successfully commercialize and develop the drug.

We have granted R-Tech the exclusive right to manufacture and supply Rescula to meet our commercial and clinical requirements and we do not have an alternative source of supply for Rescula. We do not own or operate manufacturing facilities and we have no experience in manufacturing pharmaceutical products. We also do not have provisions for a backup supplier. If R-Tech is not able to supply Rescula on a timely basis, in sufficient quantities or at acceptable levels of quality, sales of Rescula would be significantly impaired and our Rescula development program could be jeopardized.

Risk Related to Regulatory Approval and Oversight

Even if we receive regulatory approval for a product, the product could be subject to regulatory restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with ongoing regulatory requirements.

Amitiza and any other product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. We have, for example, recently become aware of a petition filed with the FDA by a citizen's activist group requesting additional label warnings for Amitiza. The petition questions the original FDA approval process for the drug but does not present any new information arising since the FDA's approval. We believe the petition is without merit, but we cannot assure you that the FDA will not require an additional warning that would apply to some uses of Amitiza. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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

On December 11, 2008, we announced a stock repurchase program pursuant to which we are authorized to purchase up to $10.0 million of our class A common stock from time to time in open market transactions. During the quarter ended March 31, 2009, we did not purchase any shares under this program.

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

None.

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the quarter ended March 31, 2009.

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

None.

Item 6. Exhibits

(a) 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, 2009)
3.2	Certificate of Amendment	Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2009)
3.3	Restated Bylaws	Exhibit 3.3 to the Company's Current Report on Form 8-K (filed December 29, 2009)
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*	Unoprostone Exclusive Manufacturing and Supply Agreement between R-Tech Ueno, Ltd. and Sucampo Pharma Americas, Inc.	Included herewith
10.2*	Unoprostone NDA Transfer, Patent and Know-how Licensing, and Data Sharing Agreement between R-Tech Ueno, Ltd. and Sucampo Pharma Americas, Inc.	Included herewith
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith

* Confidential treatment has been requested for portions of this exhibit.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

May 11, 2009

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

May 11, 2009

By: /s/ JAN SMILEK
Jan Smilek
Chief Financial Officer
(Principal Financial and Accounting Officer)

Sucampo Pharmaceuticals, Inc.
Exhibit Index

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[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Unoprostone

Exclusive Manufacturing and Supply Agreement

(also, Exhibit B to *Unoprostone NDA Transfer, Data-Sharing and License Agreement*)

Effective Date:

April 23, 2009

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of The Securities Exchange Act of 1934, as amended.

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Unoprostone Exclusive Manufacturing & Supply Agreement

THIS UNOPROSTONE EXCLUSIVE MANUFACTURING AND SUPPY AGREEMENT ("Agreement") is made this 23 day of April, 2009 (the "Effective Date"), by and among Sucampo Pharma Americas, Inc., ("SPA") a corporation organized and existing under the laws of the State of Delaware, U.S.A., (and a wholly-owned subsidiary of Sucampo Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware, U.S.A.), and having its principal office at 4520 East West Highway, Third Floor, Bethesda, Maryland 20814, and R Tech Ueno, Ltd., ("RTU") a corporation organized and existing under the laws of Japan and having its registered office at Uchisaiwai-cho 1-1-7, Chiyoda-ku, Tokyo, Japan, 100-0011 (each referred to herein as a "Party" and collectively as the "Parties").

WHEREAS, SPA is a United States based pharmaceutical company that seeks a supply source for Drug Substance and Drug Product (defined below) for SPA clinical evaluation and commercial sale in the SPA Territory (defined below);

WHEREAS, RTU is a Japan based pharmaceutical company and RTU holds an NDA with respect to the manufacture, promotion, use and sale of UNOPROSTONE (also known as Rescula®) in Japan as a pharmaceutical product, and Unoprostone has been manufactured for preclinical and clinical development and commercial use as a human pharmaceutical by RTU;

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

NOW, THEREFORE, in consideration of the mutual promises exchanged herein, and in consideration of the conclusion of the Unoprostone NDA Transfer, Patent and Know-How Licensing and Data-Sharing Agreement (**"Unoprostone License Agreement"**) to be executed between the Parties contemporaneously with this Agreement, the Parties agree as follows:

Article 1. Definitions

1.1 "Additional Materials" means all raw materials, resins, chemical intermediates, consumables, components, excipients, packaging, labeling and other ingredients needed to manufacture the Drug Substance and/or Drug Product, including costs for relevant in-bound freight for the foregoing items.

1.2 "Adverse Event" means any untoward medical occurrence in any patient use of a Licensed Product or clinical investigation subject administered a Licensed Product and which does not necessarily have to have a causal relationship with this pharmaceutical treatment. An adverse event (AE) can

therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product, including but not limited to those events that must or may be reported in accordance with the pre-clinical testing, clinical trial testing or in market pharmaco-vigilance or other reporting requirements as may be required by any Regulatory Agency incident to the prosecution or maintenance of an IND or an NDA or similar regulatory filing with respect to the testing, registration, manufacture use or sale of a product as a pharmaceutical for human use **"Affiliate"** means, with the respect to either Party, any Person that, directly or through one or more Affiliates, controls, or is controlled by, or is under common control with, such Party. For purposes of this definition, "control" means (i) ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than fifty percent (50%) of the equity or management voting interests in the case of any other type of legal entity, (ii) status as a general partner in any partnership, or (iii) any other arrangement whereby a Person controls or has the right to control, directly or indirectly, the commercial operations, the Board of Directors or the equivalent governing body of a corporation or other entity. Notwithstanding the foregoing, in no event at any time during the Term of this Agreement shall SPA be considered Affiliate of RTU nor RTU be considered Affiliate of SPA for the purpose of this Agreement.

1.3 "Annual Maintenance" means annual stability testing, sample storage, annual audit and annual updating of the e Drug Master File/ Chemistry, Manufacturing and Controls ("DMF/CMC") elements of the NDA as required in accordance with Applicable Law shall remain with and be maintained by RTU.

1.4 "Applicable Law" means all federal, state, local, national and supra-national treaties, conventions laws or statutes statutes, and any implementing orders, rules and/or regulations, including any rules, regulations, orders, judgments, determinations, guidance, or requirements of Regulatory Authorities, courts of competent jurisdiction and any non-governmental agencies that control any aspect of the pharmaceutical, medical, commercial or financial activities contemplated by the parties in utilizing the rights granted or received incident to this Agreement, including but not limited to development of pharmaceutical products in accordance with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") standards, listing of securities on stock exchanges governed by major national securities exchanges or major securities listing organizations or compliance with financial and accounting standards as promulgated by the Financial Accounting Standards Board or its foreign equivalent for IFRF reporting standards, that may be in effect from time to time during the Term and applicable to a particular activity hereunder.

1.5 "Business Day" means a day, other than a Saturday or Sunday, on which banking institutions in Washington, DC, USA, or Tokyo, Japan, are open for business, such that a bank holiday in the United States which is not a banking holiday in Japan is nevertheless a Business Day under the terms of this Agreement.

1.6 "Certificate of Analysis" means a certificate provided by RTU to SPA with each shipment of the Drug Substance and Drug Product, which sets forth: (i) the results of any quality assurance testing; and (ii) the manufacturing date and the compliance of the report with relevant cGLP, cGMP and Applicable Law as may apply to the issuance and intended use of such certificate of analysis.

1.7 "cGLP" means quality systems, testing and current good laboratory practices applicable to the manufacture, labeling, packaging, handling, storage, and transport of active pharmaceutical ingredient, bulk dosage forms and packaged dosage forms, as set forth in the Food, Drug and Cosmetic Act (FDCA), including any regulations found in Title 21 of the U.S. Code of Federal Regulations (including Parts 11, 210 and 211), any update thereto and any other laws, regulations, policies, or guidelines applicable to the testing, manufacture, labeling, packaging, handling, storage, and transport of testing or pre-clinical pharmaceutical products, and/or any foreign equivalents thereof and any updates thereto.

1.8 "cGMP" means quality systems and current good manufacturing practices applicable to the manufacture, labeling, packaging, handling, storage, and transport of active pharmaceutical ingredient, bulk dosage forms and packaged dosage forms, as set forth in the Food, Drug and Cosmetic Act (FDCA), including any regulations found in Title 21 of the U.S. Code of Federal Regulations (including Parts 11, 210 and 211), any update thereto and any other laws, regulations, policies, or guidelines applicable to the manufacture, labeling, packaging, handling, storage, and transport of pharmaceutical products, and/or any foreign equivalents thereof and any updates thereto.

1.9 "Clinical Study(ies)" means a human clinical study, or other test or study in humans, with respect to a Drug Substance or a Drug Product performed incident to an open IND , including, but not limited to Phase I study, Phase II study, Phase III Study, Phase IV study, early access programs, compassionate use and single patient INDs, epidemiological studies, modeling and pharmacoeconomic studies, post-marketing studies, investigator sponsored studies, and health economics studies.

1.10 "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 SPA Territory.

1.11 "Commercial" or **"Commercialize"** means any and all activities (whether before or after Regulatory Approval) directed to the commercialization of the Drug Product, including pre-launch and post-launch marketing, Promoting, distributing, offering to sell and selling the Drug Product, and importing or exporting the Drug Product for sale. When used as a verb, "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

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

1.13 "Confidential Information" means all information that is not in the public domain and is protectable by a Disclosing Party as a trade secret under Applicable Law (including, without limitation, Regulatory Data and Information, as defined below) provided to a Party by another Party, whether oral,

in writing or otherwise, including, without limitation, any information on the research, development, markets, customers, suppliers, patent applications, inventions, products, procedures, designs, formulas, business plans, financial projections, organizations, employees, consultants or any other similar aspects of a Party's present or future business.

1.14 "Data Exclusivity" means any data or market exclusivity granted to a Drug Substance or Drug Product in the SPA Territory by any Regulatory Authority as of the Effective Date or at any time during the Term.

1.15 "Drug Approval Application" means, on a Drug Product-by-Drug Product basis in SPA Territory, an application submitted to a Regulatory Authority for Regulatory Approval for the Drug Product, and all supplements and amendments that may be filed with respect to the foregoing.

1.16 "DMF/CMC Package" means a collection of all necessary data and information relating to a Drug Substance documenting Drug Substance's and RTU's compliance with the Regulatory Authority standards in SPA Territory (including but not limited to the US Food & Drug Administration, the US Environmental Protection Agency, and US Pharmacopoeia and corresponding regulations promulgated by Applicable Law in other countries in SPA Territory).

1.17 "Drug Product" means a final galenic formulation of UNOPROSTONE Drug Substance supported as a cGMP formulation under an IND for the purposes of Clinical Trials or under as an approved and support formulation under an issued NDA in the SPA Territory for the purposes of commercial manufacture and sale of such specific formulations of Drug Substance as SPA may elect to register as a Drug Product in the SPA Territory from time to time. Drug Product shall be complete PRIOR to packaging for clinical use or commercial sale, as appropriate. Drug Product shall also mean Commercial Product and/or Promotional Sample, where applicable.

1.18 "Drug Substance" means bulk NDA and cGMP compliant UNOPROSTONE active pharmaceutical ingredient, prior to formulation as a final Drug Product. Drug Substance shall also mean non-formulated Clinical Supply and/or Commercial Product, where applicable.

1.19 "IND" means an application filed with a Regulatory Authority for authorization to commence human clinical trials of Unoprostone or prosecute a Drug Approval Application for Unoprostone, including, but not limited to (i) an Investigational New Drug Application as defined in the Food, Drug and Cosmetic Act (FDCA) or any update thereto or any successor application or procedure filed with the Food and Drug Administration (FDA), (ii) any foreign equivalent of a United States IND, and (iii) all supplements and amendments that may be filed with respect to the foregoing.

1.20 "Latent Defect" means Drug Substance or Drug Product not conforming to RTU's warranty for pursuant to Section 9.7 such that the related non-conformance of Drug Substance or Drug Product is not readily discoverable based on SPA's (or SPA designee's) normal incoming-goods inspections.

1.21 Need to insert the definition of "Licensed Product" (from the IP agreement)

1.22 "Licensed Patents" means all patent and patent applications related to Unoprostone that are hereunder licensed to SPA and/or enable SPA activities in SPA Territory (i) that are owned by or licensed (with the right of sublicense) to RTU on before the Effective Date of this Agreement or (ii) which derive from inventions that are acquired, made, created, developed, conceived or reduced to practice by RTU during the Term of this Agreement, to the extent that such patents or patent applications relate to Unoprostone (including, without limitation, its composition of matter, its method of use, its formulation(s) (either alone or in combination with other agents), its dosing regimens, its manufacture, its synthesis, its metabolism, its safety and/or its utility) or necessary, used, or useful for the development, manufacture or commercialization of Unoprostone, or (iii) which derive from an invention that is made, created, developed, conceived or reduced to practice by SPA after the Effective Date of this Agreement the practice of which would in the absence of a license, infringe on a claim of any unexpired patent described in (i) or (ii). Licensed Patents include all reissues, continuations, continuations-in-part, extensions, reexaminations, and foreign counterparts of any of the foregoing. Licensed Patents include listing set forth in Exhibit C (*Licensed Patents*), which may be amended from time-to-time to add additional patents and patent applications.

1.23 NDA" means a New Drug Application, as defined by laws for such application within the SPA Territories (as defined below) and applicable regulations promulgated in the countries or territories there under, or other appropriate marketing authorization in Japan, or any counterpart application or marketing authorization in any country of the SPA Territory. For the avoidance of doubt, maintenance of the NDA with respect to compliance of the Drug Substance or the Drug Product with the Drug Master File/Chemistry, Manufacturing and Controls ("DMF/CMC") elements of the NDA shall remain with and be maintained by RTU .

1.24 "Order" means, with respect to Clinical Supply, Drug Substance, Drug Product Commercial Product, and/or Promotional Sample, a written communication from SPA to RTU of SPA's order for purchase of a specified amount of need for Unoprostone or Licensed Product at a delivery date, delivery price and delivery location set forth in such written purchase order communication.

1.25 "Order Year" means each twelve-month period commencing from the date of the first Order placed by SPA for the Drug Product.

1.26 "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 or formal non-governmental organization.

1.27 "Product Valid Claims" means, with respect to the Drug Substance or Drug Product, a claim of any issued and unexpired patent included within the Licensed Patents, the enforceability of which has not been subject to one or more of any of the following: (i) irretrievable lapse, revocation or abandonment; (ii) holding of unenforceability or invalidity by a decision of a court or other appropriate body of competent jurisdiction, that is unappealable or unappealed within the time allowed for appeal;

and/or (iii) disclaimer or admission of invalidity or unenforceability through reissue or re-examination or opposition, nullity action or invalidation suit response, terminal disclaimer or otherwise. The foregoing notwithstanding, in the event a claim of a patent within the Licensed Patent(s) has been held to be invalid or unenforceable, and an appeal is pending, such claim shall not be considered a Product Valid Claim until reinstated by a final decision of a court or governmental agency of competent jurisdiction.

1.28 "Promote" or **"Promotion"** means those activities normally undertaken by a pharmaceutical company's sales force and marketing team to implement marketing plans and strategies aimed at encouraging the appropriate use of a particular prescription or other pharmaceutical product, including detailing. When used as a verb, "Promote" means to engage in such activities.

1.29 "Promotional Sample" means Drug Product specifically produced and packaged to Promote the Drug Product for indications with Regulatory Approval within the SPA Territory.

1.30 "Product Defect" means Drug Substance or Drug Product not conforming to RTU's warranty for pursuant to Section 9.7 such that the related non-conformance of Drug Substance or Drug Product may be readily discovered based on SPA's (or SPA designee's) normal incoming-goods inspections procedures.

1.31 "Regulatory Approval" means, in the SPA Territory, any and all approvals, licenses (including product and establishment licenses), registrations, or authorizations of any Regulatory Authority necessary to Develop (as defined in the Unoprostone Licensing Agreement), manufacture, Commercialize (as defined in the Unoprostone Licensing Agreement), promote, distribute, transport, store, use, sell or market the Drug Product, including, where applicable, pricing or reimbursement approval, or pre- and post-approval marketing authorizations, labeling approvals, import and export licenses, technical, medical and scientific licenses.

1.32 "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, Commercialization, or sale of the Drug Substance, unpackaged Drug Product and/or Drug Product in final NDA approved labeling and packaging.

1.33 "Regulatory Data and Information" consists of data and information relating to a Drug Product that is derived from any or several of the following business activities undertaken by any of the Parties at any time: (i) market and business research and intelligence; (ii) research and development of pharmaceutical and medicinal products; (iii) obtaining marketing approval for pharmaceutical and medicinal products; and (iv) consultation with respect to any or several of the above activities.

1.34 "Regulatory Filings" means, collectively: all INDs, Drug Approval Applications, diagnostic product device approval applications, establishment license applications, Drug Master Files, and any product approvals under Section 505 (a) and (b) of the Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. § 355(b)(4)(B)) or any update thereto or all other similar filings (including, without limitation, any

counterparts of any of the foregoing in SPA Territory) as may be required by any Regulatory Authority for the development, manufacture or commercialization of the Drug Substance or the Drug Product; and (b) all supplements and amendments to any of the foregoing.

1.35 "Specifications" mean the manufacturing, formulation, quality control, packaging, labeling, shipping and storage specifications as separately set out for Drug Substance or Drug Product in Exhibit B and as updated from time to time on mutual agreement in writing by the Parties as reflected in the relevant formulae edition and Regulatory Approvals.

1.36 "SPA Territory" means the United States of America and Canada, and their territories and possessions.

1.37 "Term" means the definition provided in Section 11.1.

1.38 "Third Party" means any Person other than RTU and SPA and their respective Affiliates.

1.39 "UNOPROSTONE" (also known by the USAN name of Unoprostone isopropyl) is the composition of matter defined chemically as [*] as described in more detail in Exhibit A and its salts, metabolites, as well as any active pro-drugs, isomers, tautomers, hydrates, chelates, complexes and polymorphs and all other pharmaceutically acceptable modifications as may be projected in the public domain as motivation to an medicinal chemistry expert in the drug development field.

Article 2. General Terms of Manufacturing and Supply

2.1 Supply. Subject to the terms and conditions of this Agreement, (i) SPA shall exclusively engage RTU to manufacture (or have manufactured), in compliance with the Specifications, cGMP standards and the NDA, test and deliver the Drug Substance and/or Drug Product for SPA and/or its Affiliates, sublicensees or distributors for the SPA Territory, in the specific formulations, quantities and at times as provided herein, and (ii) RTU shall exclusively provide the same in the SPA Territory to SPA in accordance with orders issued by SPA and received by RTU. All such Drug Substance and Drug Products manufactured and supplied by RTU shall:

a) be manufactured in accordance and in compliance with Applicable Law, including cGMP;

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 [*] months shelf life;

e) be free from defects in materials and workmanship; and

f) be in compliance with all Specifications for the Drug Product ordered.

2.2 Cost to Produce.

2.2.1 General. RTU, at its sole liability and cost, will provide all labor, utilities, equipment, personnel, facilities, raw materials, utilities, consumables, disposables 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. SPA, at its sole expense, will provide all resources necessary to ship, store, and otherwise handle the Drug Substance and Drug Product in a manner necessary to meet applicable Regulatory and Legal requirements, after delivery of the Drug Substance and Drug Product to SPA as described in Article 2.8.

2.2.2 Supply of Additional Materials. At RTU's own expense, RTU shall purchase all Additional Materials (as referred to in the relevant Regulatory Approvals) which are needed for the manufacture of Drug Substance and/or Drug Products as per the current regulatory files, under its own liability and costs, from suppliers approved by SPA. If RTU wishes to change suppliers, this must be approved in advance in writing by SPA, such approval not to be unreasonably withheld. RTU is responsible for the testing and approval of the Additional Materials.

2.2.3 Novel Drug Product Formulations. The Parties acknowledge that SPA may from time to time elect to register Unoprotone for additional indications in the SPA Territory that may require development of a novel formulation as a new form of Drug Product form pursuant to pre-clinical testing, novel CMC manufacturing and formulation process development, new product specifications, IND enabled clinical testing and NDA approval and labeling. In the course of the selection, research and development of new Drug Product formulations, the parties will collaborate on the development of costs, processes, specifications and facilities that will optimize the safety, efficacy, cost and utility of any anticipated novel formulation. The parties shall also agree upon a process and cost improvements to that process consistent with compliance obligations with Applicable Laws that enable the most inexpensive, flexible, simplest, shortest and most reliable production process practicable. In the course of such efforts, the Parties shall reasonably agree upon the cost estimates for the production of such novel Drug Product dosage forms. Such novel Drug Product formulation shall become a new supply obligation between the Parties with such costs, timing and compliance obligations as will fairly compensate both of the Parties for their respective rights, contributions and efforts and optimize the launch and promotion of the novel Drug Product.

2.2.4 Sufficient Inventories. For the Term, at its own expense, RTU shall maintain sufficient inventories of Additional Materials required to manufacture the Drug Substance and such different Drug Product(s) as SPA may register and order from RTU in order to ensure timely

delivery of such amounts of a particular Drug Product in accordance with any issued order or reasonably anticipated order.

2.3 Quality Assurance.

2.3.1 General. RTU, at its sole expense, will perform all testing for compliance with the Specifications and the applicable cGMPs and will supply a chemical Certificate of Analysis prepared in accordance with cGLP with each batch of Drug Substance and Drug Product and any other documentation required by Applicable Law. Complete copies of all test results and/or assays will be submitted to SPA promptly following any reasonable request therefore during the Term of this Agreement. Should SPA further require a separate Quality Assurance Agreement at any time during the Term of this Agreement, and give reasonable written notice of such requirement to RTU, the Parties will negotiate such agreement in good time and in good faith.

2.3.2 Non-Conforming Product. SPA will have a period of ten (10) Business Days from the date of its receipt of a shipment of Drug Substance and Drug Product to inspect and reject such shipment for non-conformance with the obligations under this Section 2.3.2 and the warranties of RTU pursuant to Section 9.7 including the Specifications based on SPA's (or SPA designee's) normal incoming-goods inspections procedures, by providing RTU with written notice of rejection for any Product Defect within such period of ten (10) Business Days together with samples of the non-conforming or Drug Substance and Drug Products in the relevant shipment for testing. In the case of Product with Latent Defects, SPA will promptly, and in no event more than ten (10) Business Days of SPA 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 Substance and Drug Product, together with samples of the non-conforming Drug Substance and Drug Products in the relevant shipment for testing. If RTU determines that such shipment did conform to the warranties of RTU for product pursuant to Section 9.7, 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 warranties of RTU for Drug Substance and Drug Product pursuant to Section 9.7 including the Specifications and was not affected by a Product or Latent Defect, SPA 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 warranties of RTU for product pursuant to Section 9.7 including the Specifications, RTU will, as soon as practicable, give SPA a credit for any amount paid with respect to that portion of the Drug Substance or Drug Product which does not conform and will bear all of SPA's expenses of returning such Drug Substance or Drug Product to RTU or its nominee. RTU or SPA, 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.

2.4 Clinical Order; Supply. During the Term of this Agreement, RTU shall have the exclusive right to manufacture and supply Clinical Supply upon Order for SPA for clinical development purposes. During the Term of this Agreement, RTU and SPA shall from time to time confer and agree on SPA's drug supply needs for SPA's ongoing clinical development program and the projected costs of such supply. SPA 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 SPA's Order to RTU and which, subject to the terms and conditions of this Agreement, RTU agrees to supply. The minimum of Clinical Product units per Order is [*] bottles.

2.5 Promotional Sample Supply. In the year prior to SPA's first commercial sale of Commercial Product, RTU shall provide [*] Promotional Samples at no cost to SPA. Thereafter, SPA shall be entitled to purchase a commercially reasonable number of units of Promotional Samples at US$[*] per unit being a sample including 5 mL of 0.15% formulation of the Drug Product (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid), provided that (excepting the first re-launch year) the total number of Promotional Samples purchased does not exceed [*] percent [*] of the Commercial Product.

2.6 Commercial Supply; Exclusivity; Forecasting; Order. During the Term of this Agreement, RTU shall have the exclusive right to manufacture and supply Commercial Product upon Order for SPA for commercial purposes subject to appropriate Regulatory Approval in any country of the SPA Territory in respect of the Commercial Product. SPA shall provide to RTU in writing a twenty-four (24) month forecast of its requirements for Commercial Product which forecast will be updated quarterly and the first 90 days shall constitute SPA's supply Order to RTU, which, subject to the terms and conditions of this Agreement, RTU agrees to supply. The minimum number of Commercial Product units per Order is [*] bottles.

2.7 Placement and Acceptance of an Order.

2.7.1 Placement. All purchases of Drug Product shall be pursuant to Order(s) placed by SPA and/or its Affiliates, sublicensees or distributors at least ninety (90) days prior to the date of which Drug Products shall be delivered to SPA or the applicable Affiliate, sublicensee or distributor. Each Order hereunder shall specify the desired quantities and formulation of each of the Drug Product ordered, and the delivery dates therefore.

2.7.2 Acceptance. RTU shall have ten (10) Business Days from receipt of an Order from SPA to reject or propose to modify an Order. If an Order is not rejected or modified it shall be deemed accepted and RTU shall, subject to the terms and conditions of this Agreement, be obligated to supply such order in accordance with its terms.

2.8 Delivery and Acceptance; Risk of Loss. Any and all Clinical Supply, Commercial Product, or Promotional Sample supplied hereunder to SPA shall be shipped from RTU's manufacturing facility in Sanda (Hyogo, Japan) or its contract manufacturer and delivered to a common carrier to be transported

for importation into the SPA Territory. The identity of the common carrier and the port of entry shall be mutually determined by the Parties in writing. Title and risk of loss shall pass to SPA at the time the goods are delivered to SPA or its designee, and SPA shall assume all responsibility for and costs associated with the goods upon such acceptance.

2.9 Inventory. RTU agrees to at all times maintain commercially reasonable inventory levels of Additional Materials required to manufacture the Drug Substance and Drug Products commensurate with orders received or reasonably anticipated.

2.10. 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 UNOPROSTONE, outside of SPA Territory, provide, however, that RTU shall be prohibited from supplying the Drug Substance or the Drug Products in the SPA Territory or to those doing business either in the SPA Territory or outside the SPA Territory resulting in inducing or facilitating sale in the SPA Territory of the Drug Substance or the Drug Products to or by any party other than SPA.

2.11. Performance Issue; Safety Reporting. 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. The parties shall be responsible for filing annual safety reports with the Regulatory Authority in accordance with a separate safety data exchange protocol to be mutually agreed by SPA and RTU.

2.12. Product Liability. Liability for defects to Drug Product determined to have been caused by or during the production process and the damage to Drug Product or packaging caused prior to acceptance of Drug Product by SPA will be assumed by RTU. All liability for non-defective Drug Product or damage to Drug Product after acceptance of Drug Product by SPA will be assumed by SPA.

Article 3. Additional Services

3.1 Laboratory and Regulatory Consulting Services. Laboratory services, including without limitation formulation services regarding Drug Substance and Drug Product, and regulatory consulting provided by RTU to SPA shall be transacted under a separate Laboratory and Consulting Services Agreement.

Article 4. Pricing and Payment

4.1 Clinical Supply Price. Clinical Supply shall be supplied pursuant to an Order issued in accordance with Section 2.4 (*Clinical Order; Supply)* at the cost of US$ [*] per bottle (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid). The bottle will be supplied in bulk packaged condition from R-Tech, and SPA assures clinical labeling and kitting.

4.2 Promotional Sample Price. Promotional Samples shall be supplied and priced pursuant to an Order issued in accordance with Section 2.5 (*Promotional Sample Supply).*

4.3 Commercial Product Price; Cost of Goods; Royalty; Annual Maintenance.

4.3.1 Commercial Product shall be supplied pursuant to an Order issued in accordance with Section 2.6 (*Commercial Supply; Exclusivity; Forecasting; Order)*, and shall be priced per Order Year as follows:

For Glaucoma and/or Ocular Hypertension Use:

For bottles [*] ordered by SPA in an Order Year	US$[*] per bottle of 5 mL of 0.15% formulation of Drug Product (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid)
For bottles [*] ordered by SPA in an Order Year	US$[*] per bottle of 5 mL of 0.15% formulation of Drug Product (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid)
For bottles [*] and over ordered by SPA in an Order Year	US$[*] per bottle of 5 mL of 0.15% formulation of Drug Product (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid)

For Other Indication Use:

For bottles [*] ordered by SPA in an Order Year	US$[*] per bottle of 5 mL of 0.15% formulation of Drug Product (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid)
For bottles [*] and over ordered by SPA in an Order Year	US$[*] per bottle of 5 mL of 0.15% formulation of Drug Product (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid)

Payment issued under this Section 4.3.1 shall be considered payment-in-full of all cost-of-goods plus royalties.

4.3.2 SPA shall pay to RTU an Annual Maintenance service fee based on Drug Product Specifications and Commercial Product Orders as follows:

For bottles [*] ordered by SPA in an Order Year	US$[*] (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid)
For bottles [*] ordered by SPA in an Order Year	US$[*] (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid)
For bottles [*] and over ordered by SPA in an Order Year	US$[*] (payable in Japanese Yen, converted at the spot rate at the close of Business Day in which Order invoice is paid)

4.3.3 Notwithstanding the prices in Section 2.5 and herein Section 4.3, in the event of significant economic changes, including those with regards to the price of Rescula®, the Parties shall meet and discuss in good faith modifications to the pricing detailed herein in accordance with Section 13.1 below.

4.4 Withholding Taxes. All payments made under this Agreement shall be free and clear of any and all taxes, duties, levies, fees or other charges, except for withholding taxes. Where any sum due to be paid to a Party hereunder is subject to any withholding tax, the Parties shall use commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the paying Party shall deduct any withholding taxes from payment and pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to the receiving Party and secure and send to the receiving Party the best available evidence of such payment.

4.5 Terms of Payment. All payments due under this Agreement shall be payable in Japanese Yen, converted at the spot rate at the close of the business day in which each such payment becomes payable. Unless specified otherwise herein, RTU will invoice SPA for Clinical Supply, Commercial Product and/or Promotional Sample upon RTU's delivery thereof to SPA's carrier and payments shall be due within thirty (30) days from the date of receipt of invoice. All payments under this Agreement shall be by appropriate electronic funds transfer in immediately available funds to such bank account as RTU shall designate. Each payment shall reference this Agreement and identify the obligation under this Agreement that the payment satisfies. If at any time legal restrictions prevent the remittance of part or all of payments owed by a Party hereunder, the Parties shall promptly negotiate in good faith the terms for repayment under lawful means or methods.

4.6 No Other Compensation. Unless otherwise agreed to by the Parties and set forth in writing, RTU and SPA hereby agree that the terms of this Agreement and all ancillary agreements hereto (including, without limitation, the Unoprostone License Agreement attached hereto) shall fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by

each Party to the other in connection with the transactions contemplated herein. Neither Party has previously paid or entered into any other commitment to pay, whether orally or in writing, any employee of the other Party, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transactions contemplated herein.

4.7 Shipping Terms. All payments under this Agreement are inclusive of all cost, insurance and freight (CIF by Airfreight) necessary for delivery to SPA as described in Section 2.8, except that title and risk of loss shall pass to SPA upon delivery to SPA or its designee not upon delivery of shipping documents.

Article 5. Confidentiality and Non-Disclosure

5.1 Confidentiality.

5.1.1 Nondisclosure Obligations. Except to the extent expressly permitted by this Agreement, at all times during the Term and for a period of ten (10) years following the expiration or termination hereof, the Receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than the purpose of this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party shall treat and protect the trade secret status of Confidential Information as it would its own proprietary information which in no event shall be with less than a reasonable standard of care, and take reasonable precautions to prevent the publication or unauthorized use or unauthorized disclosure of Confidential Information to a Third Party, except as explicitly set forth herein, without prior, explicit, written consent of the other Party.

5.1.2 Exceptions to Confidentiality. The Receiving Party's obligations set forth in this Agreement shall not extend to any l Information of the Disclosing Party or information developed in the performance of this Agreement that:

a) is or hereafter becomes part of the public domain in accordance with Article 4, by public use, publication, general knowledge or the like or is made generally available in the public domain by a Third Party, with right to make such publication, in each case, other than through a breach of this Agreement;

b) is received from a Third Party without restriction and with the right to disclose such iInformation or information developed in the performance of this Agreement;

c) the Receiving Party can demonstrate by competent pre-existing written evidence properly maintained as a formal business record was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party;

d) the Receiving Party can demonstrate by competent written evidence properly maintained as a formal business record was independently developed by or for the Receiving Party without reference to, use of or disclosure of the Disclosing Party's

Confidential Information or information developed in confidence in the performance of this Agreement; or

e) is released from the restrictions set forth in this Agreement by the express prior written consent of the Disclosing Party, or in the case of information developed in confidence in the performance of this Agreement, the other Party.

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

5.1.3 Authorized Disclosures. Each Party may disclose Confidential Information and/or Program Confidential Information to the extent that such disclosure is:

a) made in response to a valid relevant unappealed or unappealable order of a court of competent jurisdiction or other Regulatory Authority or any political subdivision or regulatory body thereof of competent jurisdiction; provided that the Receiving Party shall first have, if reasonably possible, given notice to the Disclosing Party and given the Disclosing Party, at such Disclosing Party's own expense, a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information and/or information developed in confidence in the performance of this Agreementor documents that are the subject of such order be held in confidence by such court or Regulatory Authority or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such order shall be limited to that information which is legally required, in the opinion of legal counsel to the Receiving Party, to be disclosed in such response to such court or governmental order;

b) otherwise required by Applicable Law or the pre-existing requirements of a major national securities exchange (e.g., U.S. Securities and Exchange Commission), in the opinion of legal counsel to the Receiving Party, provided that the Party disclosing such Confidential Information and/or information developed in confidence in the performance of this Agreement shall exercise its commercially reasonable efforts to obtain a protective order or other reliable assurance that confidential treatment will be accorded and if possible give the other Party a reasonable opportunity to review and

comment on any such disclosure in advance thereof (but not less than five (5) Business Days, if possible, prior to the date of such disclosure);

c) made to an applicable Regulatory Authority as useful or required in connection with any filing, application or request for Regulatory Approval; provided that reasonable measures shall be taken to assure confidential treatment and narrowest possible use and disclosure of such information;

d) to the extent necessary, and subject to subcontracting provisions set forth in this Agreement, to its Affiliates, directors, officers, employees, consultants, sublicensees of SPA or RTU (or bona fide potential sublicensees of SPA or RTU), vendors and clinicians, under written agreements of confidentiality substantially similar or at least as restrictive as those set forth in this Agreement, who have a need to know such information in connection with a Party performing its obligations or exercising its rights under this Agreement; provided, that either Party may enter into such written agreements that provide for shorter timeframes for maintaining confidentiality than those set forth in this Agreement with the written consent of the other Party.

5.2 Patient Information. The Parties shall abide (and cause their respective Affiliates to abide), and take (and cause their respective Affiliates to take) all reasonable and appropriate actions to ensure that all Third Parties conducting or assisting with any clinical development activities hereunder in accordance with, and subject to the terms of, this Agreement, shall abide, to the extent applicable, by all Applicable Law concerning the confidentiality or protection of patient identifiable information and other patient protected health information, the confidentiality of Confidential Information and the patentability of any concepts, ideas, or inventions developed incident to the performance of this Agreement.

5.3 Use of Name and Disclosure of Terms. Each Party shall keep the existence of, the terms of and the transactions and the subject matter covered by this Agreement confidential and shall not disclose such information to any Third Party through a press release, publication, promotional material, other form of publicity or otherwise, or, except as expressly permitted in this Agreement, mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates in any manner without the prior written consent of the other Party in each instance. The restrictions imposed by this Section shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law, rule or regulation or the requirements of a major national securities exchange or another similar regulatory body, provided that any such disclosure shall be governed by this Article and that the other Party is given a reasonable opportunity to review and comment on any such press release or public communication in advance thereof (but not less than five (5) Business Days prior to the date of disclosure). Further, the restrictions imposed on each Party under this Section are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to this Article. Each Party agrees that it shall obtain its own legal advice with regard to its compliance with

securities laws, rules and regulations, and will not rely on any statements made by the other Party relating to such securities laws, rules and regulations.

Article 6. Intellectual Property Rights

6.1 Ownership.

6.1.1 Prior to each transaction hereunder, each Party shall retain all right, title and interest in its intellectual property, including information, improvements, developments, inventions, patents, trade secrets and know-how, and Confidential Information.

6.1.2 RTU shall retain all rights to and ownership of any data processes, software (including codes) technology, means and know how developed by RTU.

6.1.2 SPA shall retain all rights to and ownership of any data processes, software (including codes) technology, means and know how developed by SPA

6.2 Grant of Limited License. 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 SPA Territory, subject, however, to the provisions of Section 2.10.

Article 7. Regulatory and Legal

7.1 Compliance.

7.1.1 RTU shall manufacture and package the Drug Substance and Drug Product in compliance with (i) the Specifications, (ii) cGMP, and (iii) any other requirements set forth in the Regulatory Approval for the relevant Drug Substance or Drug Product including but not limited to DMF/CMC package requirements.

7.1.2 RTU shall not make any modifications to the manufacturing process, Specifications, suppliers of Additional Materials specified in the relevant Drug Substance or Drug Product dossier, testing and control methods, or sampling procedures for the Drug Substance or Drug Products, without obtaining SPA's prior written consent, then, where relevant, the authorization of the **Regulatory Authority** and other competent government agencies, based on a dossier to be submitted by SPA and prepared with the assistance of RTU. SPA may make any modifications to the Specifications upon prior written notification and in accordance with the relevant Regulatory Approvals subject that RTU may request SPA to compensate in cash for any additional works and services to be done by RTU to accommodate such modifications.

7.1.3 RTU assumes any and all responsibility to make changes required by any Regulatory Authority following Effective Date to the manufacturing processes, test methods, etc. that would be

required for the manufacture of products at that location, not specific to the Drug Substance or Drug Product, and will solely bear all expenses related thereto ("**Required Manufacturing Changes**"). For changes to the Specifications that are not Required Manufacturing Changes, including but not limited to reformulations of the Drug Substance or Drug Product, addition of new strengths to the Drug Substance or Drug Product, new formulations, presentations and formats of the Product and changes to labeling and packaging (collectively "**Discretionary Manufacturing Changes**"), RTU and SPA must each agree to any Discretionary Manufacturing Change and will, to the extent commercially reasonable under the circumstances, cooperate in making such changes, and each agrees that it will not unreasonably withhold or delay its consent to such Discretionary Manufacturing Changes proposed by the other Party. SPA or RTU, as the case may be, shall be deemed to have reasonably withheld consent to a proposed change if such change will result in a material disruption of the supply of the Drug Substance or Drug Product or have a material adverse impact on pending, existing or reasonably anticipated Regulatory Filings or Regulatory Approvals of the Drug Substance or Drug Product. RTU, or SPA as the case may be, shall use commercially reasonable efforts to ensure that any regulatory or manufacturing change will not result in a material disruption of the supply of the Drug Substance or Drug Product. Notwithstanding the foregoing, RTU's standard change control procedures will be utilized in reviewing such changes. Notwithstanding the foregoing, all reasonable internal and external costs, associated with the Required Manufacturing Changes will be borne by RTU and all reasonable internal and external costs associated with Discretionary Manufacturing Changes will be borne by the Party requesting the change.

7.2 Records. At its own cost, RTU shall keep and maintain documentation and records with respect to manufacturing, testing and delivery of Drug Substance and/or Drug Product in accordance with any requirements of Applicable Law. Such records will be made available to SPA 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.

7.3 Authorization of the Manufacturing Facility by FDA. RTU shall be responsible for providing information that may be used in, or referenced by, an application filed by SPA with the US Food and Drug Administration and other Regulatory Authorities 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. SPA shall have no obligation to purchase any Drug Substance or Drug Product from RTU if they are produced in a manufacturing facility that is not, in any material respect, in compliance with all applicable legal and regulatory requirements for the importation, registration, use or sale of Drug Substance or Drug Product in the SPA Territory.

7.4 Testing and Release. During the Term, and as part of the Annual Maintenance fee, RTU will conduct the commercial stability program with respect to the Drug Substance and Drug Product pursuant to applicable regulatory requirements.

7.5 Audits.

7.5.1 Regulatory Audit. RTU shall make its facilities, records and personnel available to any other Regulatory Authority as may be needed for compliance with the Applicable Laws enforced by such authority. RTU shall advise SPA in writing immediately if:

a) an agent of any Regulatory Authority having jurisdiction over the manufacture or distribution of the Drug Substance or Drug Product in the SPA Territory (i) makes an inquiry about the Drug Substance or Drug Product or (ii) visits RTU's manufacturing facility for the manufacture, storage or distribution of Drug Substance or 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 Substance or Drug Product.

7.5.2 SPA Audit. At no additional charge by RTU to SPA or any other charges by RTU outside of the Annual Maintenance fee, SPA may conduct audits or inspections of the Drug Substance and Drug Product production, storage and distribution sites. SPA and its designated representatives shall have the right to inspect the Drug Substance and Drug Product, work in process, Additional Materials, inventories, premises, documentation, manufacturing methods, testing and packaging procedures associated with the manufacture of the Drug Substance and Drug Products at all reasonable intervals not more than once each calendar year during RTU's normal business hours, but provided that follow up inspections will be permitted to assure .

7.6 DMF/CMC Package. At no charge by RTU to SPA by RTU outside of the Annual Maintenance fee, RTU shall produce and maintain a Drug Master File/complete Chemistry, Manufacturing and Controls ("DMF/CMC") package as required in support of the NDA in accordance with Applicable Law and the requirements of the applicable Regulatory Authority for Drug Substance and/or Drug Product in the SPA Territory.

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

Article 8. Representations and Warranties of SPA

8.1 Organization. SPA 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.

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

8.3. No Conflicts. SPA 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.

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

8.5. Obligations of Confidentiality. SPA represents and warrants that any employee or other affiliated person, 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 the other party, consistent with the obligations of Article 5, pursuant to which such employee or other person is obligated to confidentiality.

Article 9. Representations and Warranties of RTU

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

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

9.3. No Conflicts. RTU represents and warrants to SPA 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.

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

9.5 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.

9.6 Obligations of Confidentiality. RTU represents and warrants that any employee or other affiliated person, 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 the other party, consistent with the obligations of Article 5, pursuant to which such employee or other person is obligated to confidentiality.

9.7 Process and Product Warranties. RTU warrants and represents that:

a) Drug Substance or Drug Product sold by RTU to SPA hereunder shall (i) materially comply with the Specifications for Drug Substance or Drug Product, and (ii) materially conform with the information shown on the Certificate of Analysis provided for the particular shipment;

b) no Drug Substance or Drug Product sold by RTU to SPA hereunder shall be adulterated or misbranded within the meaning of the United States Food, Drug, and Cosmetic Act and implementing regulations, as amended and in effect at the time of shipment and foreign equivalents of such law in the SPA Territory (the "**Act**"), or within the meaning of any state or municipal laws in the United States applicable to the Drug Product and containing terms with substantially similar meanings as the meaning of adulteration or misbranding under the Act and foreign equivalents of such law in the SPA Territory; provided, however, that this paragraph shall not apply to, and RTU shall have no responsibility for, misbranding caused directly by SPA as a result of labels or package texts specified or provided by SPA for the Drug Product; and RTU shall have no responsibility for issues of regulatory and legal compliance that are the responsibility of SPA, 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 SPA Territory in a manner that does not result in its becoming adulterated, misbranded, or otherwise in violation of Applicable Law.

9.8 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 SPA shall reasonably cooperate with RTU (including but not limited to providing forecasts pursuant to Section 2.6 of this Agreement), so that Drug Substance and Drug Product be supplied continuously during the Term of this Agreement.

Article 10. Indemnification; Insurance

10.1 Indemnification by SPA. SPA agrees to indemnify, defend and hold harmless RTU and its Affiliates and their respective employees, agents, officers, directors and permitted assigns ("**RTU Indemnitees**") from and against any Third Party claims, judgments, expenses (including reasonable attorneys' fees), damages and awards (collectively a "**Third Party Claim**") arising out of or resulting from the following occurrences:

10.1.1 improper storage or handling of the Unoprostone or the Drug Substance or Drug Product by SPA or its Affiliates or sublicensees;

10.1.2 any personal injury and/or product liability arising from SPA's failure to warn of aspects of the lack of inherent safety of the Licensed Products.

10.1.3 SPA's negligence or willful misconduct in regard to its performance, or non-performance, under this Agreement; or

10.1.4 a breach of any of SPA's representations or warranties hereunder;

except, in each case, to the extent that such Third Party Claim arises out of or results from the gross negligence or willful misconduct of any RTU Indemnitee.

10.2 Indemnification by RTU. RTU agrees to indemnify, defend and hold harmless SPA and its Affiliates and their respective employees, agents, officers, directors and permitted assigns ("**SPA Indemnitees"**) from and against any Third Party Claim arising out of or resulting from the following occurrences:

10.2.1 improper storage, handling, manufacturing, formulation or contamination of the Unoprostone or the Drug Substance or Drug Product by RTU or its Affiliates;

10.2.2 Infringement of Third Party intellectual property rights by the Drug Substance or Drug Products or any Licensed Patents;

10.2.3 failure by RTU or any Affiliate or subcontractor of RTU to supply Drug Substance or Drug Product in accordance with the Specifications and Applicable Law;

10.2.4 any product liability claims arising from quality defect of the Product or failure to warn of an inherent lack of safety of the Drug Substance or Drug Product;

10.2.5 non-conforming product per Section 2.3.2;

10.2.6 RTU's and/or its subcontractors' negligence or willful misconduct in regard to its performance, or non-performance, under this Agreement; or

10.2.7 a breach of any of RTU's representations or warranties hereunder;

except, in each case, to the extent that such Third Party Claim arises out of or results from the gross negligence or willful misconduct of any SPA Indemnitee.

10.3 Procedures for Indemnification. The obligations of an indemnifying Party under Section 14.1 and Section 14.2 shall be governed by and contingent upon the following:

10.3.1 Notice of Claim. Each Party shall give the other Party prompt written notice of any Third Party Claim (an "Indemnification Claim Notice"). Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of the loss claimed (to the extent that the nature and amount of such loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any such Third Party Claim. The indemnifying Party shall not be required to provide indemnification notice with respect to a Third Party Claim to the extent that the defense of such Third Party Claim is materially prejudiced by the failure to give timely notice by the indemnified Party or the intentional misconduct of the indemnified Party.

10.3.2 Assumption of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the indemnified Party within fourteen (14) days after the indemnifying Party's receipt of an Indemnification Claim Notice or sooner if necessary. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgement that the indemnifying Party is liable to indemnify any SPA Indemnitees or RTU Indemnitees (as applicable) in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any indemnified Party's claim for indemnification.

10.3.3 Control of the Defense. Upon the assumption of the defense of a Third Party Claim by the indemnifying Party:

a) the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party, which shall be reasonably acceptable to the indemnified Party;

b) the indemnified Party shall promptly deliver to the indemnifying Party all original notices and documents (including court papers) received by the indemnified Party in connection with the Third Party Claim; and

c) except as expressly provided in Section 14.3.4, the indemnifying Party shall not be liable to the indemnified Party for any legal expenses subsequently incurred by such indemnified Party or any SPA Indemnitee or RTU Indemnitee (as applicable) in connection with the analysis, defense or settlement of the Third Party Claim. To the extent that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless an Indemnitee from and against the Third Party Claim, the indemnified Party shall reimburse the indemnifying Party for any and all costs

and expenses (including reasonable attorneys' fees and costs of suit) and any loss incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such indemnified Party or Indemnitee.

10.3.4 Right to Participate in the Defense. Without limiting Section 14.3.2 or Section 14.3.3, any SPA Indemnitee or RTU Indemnitee (as applicable) shall be entitled to participate in, but not control, the defense of a Third Party Claim and to retain counsel of its choice for such purpose; provided that such retention shall be at its own expense unless, (i) the indemnifying Party has failed to assume the defense and retain counsel in accordance with Section 14.3.2 (in which case the indemnified Party shall control the defense), or (ii) the interests of the Indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under Applicable Law, ethical rules or equitable principles.

10.3.5 Settlement. The indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of any Third Party Claim, on such terms as the indemnifying Party, in its reasonable discretion, shall deem appropriate; provided that:

a) the sole relief provided is the payment of money damages;

b) the consent, settlement or other disposition does not, and will not, result in a finding or admission of any negligence, intentional malfeasance ,violation of any Applicable Law or any violation of the rights of any person and does not effect on any other claims that may be made against the indemnified Party;

c) the consent, settlement or other disposition does not, and will not, result in the indemnified Party's rights under this Agreement being adversely affected; and

d) the consent, settlement or other disposition does not, and will not, result in the indemnified Party becoming subject to injunctive or other relief or otherwise will adversely affect the business of the indemnified Party in any manner.

With respect to all other Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 10.3.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Third Party Claim with the prior written consent of the indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Third Party Claim by an indemnified Party that is reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no indemnified Party shall admit any liability with respect to, or settle, compromise or

discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

10.3.6 Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the indemnified Party shall, and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the indemnified Party for any out-of-pocket expenses in connection therewith.

10.4 Insurance. Each Party shall obtain and carry in full force and effect the minimum insurance requirements set forth herein, which shall protect Indemnitees with respect to events covered by Section 10.1 and Section 10.2. Such insurance (i) shall be primary insurance with respect to each Party's own participation under this Agreement, (ii) shall be issued by a recognized insurer rated by A.M. Best "A-VII" (or its equivalent) or better, or an insurer pre-approved in writing by the other Party, (iii) shall list the other Party as an additional named insured thereunder, and (iv) shall require thirty (30) days written notice to be given to the other Party prior to any cancellation, non-renewal or material change thereof. The types of insurance, and minimum limits shall be General liability insurance with a minimum limit of [*] per occurrence and [*] in aggregate. General liability insurance shall include, at a minimum, Professional Liability, Clinical Trial Insurance and, beginning at least thirty (30) days prior to First Commercial Sale of Drug Product, product liability insurance. Upon request by a Party, the other Party shall provide Certificates of Insurance evidencing compliance with this Section. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement during any period in which such Party continues to make, to have made, to use, to offer for sale, to sell or to import a product that was the Drug Substance or Drug Product under this Agreement, and thereafter for a period of five (5) years. Notwithstanding the foregoing, either Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies.

Article 11. Term and Termination

11.1 Term. The Term for this Agreement shall be as follows:

11.1.1 If no Order is submitted from SPA to RTU, or no Clinical Trials are initiated from two (2) years of the Effective Date, then this Agreement shall terminate without consideration; OR

11.1.2 With respect to each Drug Substance or Drug Product, the term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Agreement, shall expire upon the later of (i) a period of ten (10) years, or (ii) the expiry of all Product Valid Claims in SPA Territory with respect to such Drug Substance or Drug Product, or (iii) the loss of Data Exclusivity with respect to such Drug Substance or Drug Product. If this Agreement expires (*i.e.*, not terminated pursuant to Section 11.2.1, *Termination for Material Breach,* then, at RTU's request, the Parties shall negotiate in good faith the terms by which SPA could continue to promote or co-promote and distribute the Drug Product or SPA will sell back to RTU, and RTU will repurchase from SPA, at SPA's actual cost, remaining inventory with greater than twelve (12) months remaining shelf life.

11.2 Termination.

11.2.1 Termination for Material Breach. In the event of an alleged material breach of this Agreement by a Party, the other Party must give the Party that is allegedly in default notice thereof if such non-breaching party intends to terminate the Agreement pursuant to this Section 11.2.1. Any dispute regarding an alleged material breach of this Agreement shall be resolved in accordance with this Article. It is the Parties' express intent that consideration shall first and foremost be given to remedying any breach of this Agreement through the payment of monetary damages or such other legal or equitable remedies as shall be appropriate under the circumstances, as decided, in each case, according to the provisions of Article 12 (*Dispute Resolution)*, and that there shall only be a limited right to terminate this Agreement as a matter of last resort. If, however, a Party receives a notice of material breach that relates solely to the payment of amounts due hereunder, and (i) there is no dispute as to the amounts owed and (ii) such breach for non-payment is not cured within ninety (90) days after receipt of such notice, the notifying Party shall be entitled to immediately terminate this Agreement by giving written notice to the defaulting Party. In the event that the neutral (as defined in Article 12 (*Dispute Resolution*), in accordance with the procedures set forth in Article 12, has rendered a ruling that a Party has materially breached this Agreement, which ruling specified the remedies imposed on such breaching Party for such breach, and the breaching Party has failed to comply with the terms of such adverse ruling within the time period specified therein for compliance, or if such compliance cannot be fully achieved by such date, the breaching Party has failed to commence compliance and/or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible, or in the event the material breach cannot be remedied, then in each case the non-breaching Party shall then in each case the non-breaching Party shall have the following rights:

a) if SPA is the breaching Party that failed to cure such breach or, if applicable comply with an adverse ruling and if the basis for such breach is SPA's failure to abide by a material obligation under this Agreement, RTU may terminate this Agreement with respect only to such specific Drug Substance or Drug Product(s) to which such breach relates to by

delivering written notice to SPA after the expiration of the period during which SPA was to comply as set forth in the adverse ruling (if applicable) or may at its option continue this Agreement in effect and seek monetary or relief against SPA in an amount commensurate with the damages suffered;; and

b) if RTU is the breaching Party that failed to cure such breach or, if applicable, comply with an adverse ruling and if the basis for such breach is RTU's failure to abide by a material obligation under this Agreement, SPA may terminate this Agreement with respect only to such specific Drug Substance or Drug Product(s) to which such breach relates to by delivering written notice to RTU after the expiration of the period during which RTU was to comply as set forth in the adverse ruling (if applicable) or may at its option continue this Agreement in effect and seek monetary relief against SPA in an amount commensurate with the damages suffered;.

11.2.2 Termination for Insolvency. In the event a Party files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

11.2.3 Termination for Drug Substance or Drug Product Withdrawal or Material Adverse Event. In the event the Drug Substance or Drug Product is withdrawn from the market by a Regulatory Authority in any country in the world or a material Adverse Event occurs, then SPA may terminate this Agreement effective immediately upon written notice to RTU.

11.3 Consequences of Termination of Agreement in its Entirety. Upon any termination of this Agreement in its entirety by a Party pursuant to Sub-Sections 11.2.1 or 11.2.2:

11.3.1 the licenses granted by RTU to SPA under this Agreement shall terminate;

11.3.2 with respect to all Clinical Studies or post approval studies for any Drug Substance or Drug Product(s) being conducted as of the effective date of termination, the applicable Party shall end such Clinical Studies or post approval studies with respect to enrolled subjects in an orderly and prompt manner in accordance with Applicable Law, including any required follow up treatment with previously enrolled subjects, and all other activities under this Agreement shall promptly cease;

11.3.3 each Party shall return, or if allowed by the other Party destroy (and soon thereafter provide to the other Party written certification evidencing such destruction), all data, files, records and other materials in its possession or control relating to the other Party's Confidential Information.

11.4 Consequences of Termination of Agreement with respect to a Drug Substance or Drug Product.

Upon any termination of this Agreement with respect to a Drug Substance or Drug Product by a Party pursuant to Sub-Sections 12.2.1:

11.4.1 the licenses granted by RTU to SPA under this Agreement shall terminate with respect to such terminated Drug Substance or Drug Product(s);

11.4.2 with respect to all Clinical Studies or post approval studies for such terminated Drug Substance or Drug Product being conducted as of the effective date of termination, the applicable Party shall end such Clinical Studies or post approval studies with respect to enrolled subjects in an orderly and prompt manner in accordance with Applicable Law, including any required follow up treatment with previously enrolled subjects, and all other Development, Commercialization and Promotion activities under this Agreement shall promptly cease.

11.5 Surviving Provisions. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination of this Agreement only to the extent expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of Articles 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13 and all defined terms referenced in such Articles as will provide agreed meanings used in such Articles shall survive and govern any after termination claims, liabilities, disputes and rights and, to the extent applicable, all other Articles referenced in any such Article shall survive such termination. Without limiting the generality of the foregoing, the obligations of confidentiality non-disclosure and non use set forth in Article 5 of this Agreement and Intellectual Property set forth in Article 6 and Indemnification set forth in Article 10 shall survive for not less than ten (10) years past effective termination of this Agreement.

11.6 Continued Obligations. Upon expiration or termination of this Agreement, in whole or in part, for any reason, nothing herein shall be construed to release either Party from any accrued rights or obligations that matured prior to the effective date of such expiration or termination, nor preclude either Party from pursuing any right or remedy it may have hereunder or at law or in equity with respect to any breach of this Agreement.

Article 12. Dispute Resolution

12.1 Negotiation and Arbitration.

12.1.1 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.

12.1.2 Arbitration. Any dispute, controversy or claim that arises out of or relates to this Agreement that is not resolved under Section 12.1.1 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 Section 12.1.3 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 professional knowledge of and experience in the regulation of and terms of trade of the ethical pharmaceutical industry.

12.1.3 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

13.1 Changed Circumstances; Equitable Relief.

13.1.1 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 equitably accommodates the interests of both parties. RTU acknowledges that SPA will enter into one or more agreements with Third Parties for the purpose of commercial sale of UNOPROSTONE in the SPA Territory, and in the event that such Third Parties raise concerns or place demands on SPA concerning matters pertaining to this Agreement, RTU shall work with SPA to resolve such concerns or demands, including amending this Agreement, as may be commercially appropriate or necessary. SPA acknowledges that RTU will enter into agreements with Third Parties for the purpose of procuring various materials necessary for RTU to manufacture and supply UNOPROSTONE hereunder, and in the event that such Third Parties raise concerns or place demands on RTU that will result in increase of manufacturing costs, SPA shall work with RTU to resolve such concerns or demands, including amending this Agreement, as may be commercially appropriate or necessary.

13.1.2 The Parties acknowledge and agree that the restrictions set forth in Article 5 (*Confidentiality and Non-Disclosure*) are reasonable and necessary to protect the legitimate interests of the Parties and that neither Party would have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of Article 5 (*Confidentiality and Non-Disclosure*) may result in irreparable injury to the other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of Article 5 (*Confidentiality and Non-Disclosure*) by a Party, the other Party may be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. Nothing in this Section is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

13.2. Subcontracting. Subject to Articles 2 and 7 above, RTU may subcontract its obligations hereunder without the consent of SPA; PROVIDED, HOWEVER, that RTU shall assume complete responsibility for the acts of its subcontractor and agrees to make SPA whole for any act or omission of RTU's subcontractor that damages SPA as if the act or omission were RTU's.

13.3. Entire Agreement; Binding Effect.

13.3.1 This Agreement and the Unoprostone License Agreement, and all subsequent related agreements, constitute the entire agreement between the Parties with respect to the subject matter of the Agreement. This Agreement supersedes all prior agreements and understandings, whether written or oral, with respect to the subject matter of the Agreement, including all confidentiality agreements entered in to between the Parties with respect to the subject matters hereof. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement. All Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Exhibits and this Agreement, the terms of this Agreement shall govern.

13.3.2 All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party, provided that such Party, if it survives, shall remain jointly and severally liable for the performance of such delegated obligations under this Agreement.

13.4. Relationship of Parties. Nothing in this Agreement shall be construed (i) to create or imply a partnership, association, joint venture or fiduciary duty between the Parties, (ii) to make either Party the agent of the other for any purpose, (iii) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, or (d) to give either

Party the right to bind the other or to create any duties or obligations between the Parties, except as expressly set forth herein. All Persons employed by a Party shall be employees of such Party and not of the other Party and all costs/expenses and obligations incurred by reason of such employment shall be for the account and expense of such Party. The Parties agree that the rights and obligations under this Agreement are not intended to constitute a partnership or similar arrangement that will require separate reporting for tax purposes in SPA Territory.

13.5. Assignment and Successors. Unless otherwise stated herein this Supply Agreement, this Agreement is personal to both Parties and neither Party shall sell, transfer, assign, delegate, pledge or otherwise dispose of its rights or delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which shall not be unreasonably withheld,, excepting always that each Party may, on providing written notice to the other Party, assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, without the written consent of the other Party to any of its Affiliates, or to any purchaser of all or substantially all of its assets and/or all or substantially all of its assets to which this Agreement relates or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation. Any permitted assignee of all of a Party's rights under this Agreement shall be deemed to be a party to this Agreement as though named herein; provided with respect to an assignment to an Affiliate, such assigning Party shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. Any attempted assignment or delegation in violation of this Section shall be void.

13.6. Governing Law. This Agreement and all disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the substantive laws of New York, United States of America, without regard to conflict of laws principles, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. The Parties hereby exclude the United Nations Convention on Contracts for the International Sale of Goods from this Agreement.

13.7. Notices.

13.7.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing and in English, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand with written confirmation of receipt, by telefax with written confirmation of receipt issued by other means than by automated telefax response or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Sub-Section 15.2.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed by other means than automated telefax response)) or upon

receipt (at the place of delivery) if sent by an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered by internationally recognized overnight delivery service that maintains records of delivery as soon as practicable thereafter. This Section is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

13.7.2 Addresses for Notice.

For SPA:
Sucampo Pharma Americas Inc.
4520 East West Highway
3rd Floor
Bethesda, MD 20814
USA
Attention: Legal Department
Fax: 301 961 3440

For RTU:
R-Tech Ueno, Ltd.
4-1, Techno-Park
Sanda, Hyogo, 669-1339
Japan
Attention: Mr. Ryu Hirata
Facsimile Number: 81-795-60-7180

13.8. Severability. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions or parts thereof of this Agreement, or the application hereof to any circumstances, to be illegal, invalid or to be unenforceable in a final non-appealable order, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, in each case provided that the basic purpose and structure of this Agreement is not altered.

13.9. Amendment; Waiver. This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a written instrument signed by duly authorized representatives of each Party or, in the case of waiver, signed by duly authorized representatives of the Party or Parties waiving compliance. The delay or failure of any Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or

considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

13.10. Headings; References; Interpretation.

13.10.1 Article, Section and Subsection headings are inserted for convenience of reference only and do not form a part of this Agreement. Unless otherwise specified, (i) references in this Agreement to any Article, Section or Exhibit shall mean references to such Article, Section or Exhibit of this Agreement, (ii) references in any section to any clause are references to such clause of such section, and (iii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or as amended if expressly stated in this Agreement.

13.10.2 Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The term “including” as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties acknowledge and agree that: (i) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (ii) the terms and provisions of this Agreement shall be construed fairly as to all Parties and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

13.11 No Third Party Beneficiaries. Except as set forth in Section 10.1 (*Indemnification by SPA)* and Section 10.2.2, the provisions of this Agreement are for the sole benefit of the Parties and their permitted successors and permitted assigns and none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, without limitation, any employee or creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

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

13.13 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties under this Agreement which is not within the reasonable control of the Party affected, not due to malfeasance, and which, with the exercise of due diligence could not have been avoided (**“Force Majeure"**), including, without limitation, fire, explosion, flood,

earthquake, war, accident, strike, riot, terrorist attacks, civil commotion, acts of God, or the like, will not excuse such Party from the performance of its obligations or duties under this Agreement, but will suspend such performance during the continuation of Force Majeure. The Party prevented from performing its obligations or duties because of Force Majeure shall be required to, as soon as reasonably possible, notify the other Party hereto of the occurrence and particulars of such Force Majeure and shall be required to provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure and with notice of the termination thereof. The Party so affected shall use reasonable efforts to avoid or remove such causes of nonperformance. Upon termination of Force Majeure, the obligation to perform any previously suspended obligation or duty shall promptly recommence.

13.14 Expenses. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective attorneys and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

13.15 Further Assurances. Each Party shall perform all further acts and things and execute and deliver such further documents as may be reasonable and necessary or as the other Party may reasonably require to give effect to this Agreement.

IN WITNESS WHEREOF, each of the Parties to this Agreement has caused one of its duly authorized representatives to execute this Agreement where provided below effective this 23 day of April 2009, on its behalf and in evidence of its intention to be bound to the terms, obligations, representations and warranties of this Agreement as set forth above.

For and on behalf of Sucampo Pharma Americas, Inc.

By Its Duly Authorized Representative

Signature: /s/ Gayle Dolecek

Name: Gayle Dolecek, PD, MPH

Title: SVP Research and Development

Date: April 23, 2009

For and On Behalf of R Tech Ueno, Ltd.

By Its Duly Authorized Representative

Signature: /s/ Yukiko Hashitera

Name: Yukiko Hashitera

Title: President

Date: April 23, 2009

Exhibit A

Specifications

Specification of Unoprostone Isopropyl Drug Substance

Test Items	Acceptance Criteria
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit A

CONFIDENTIAL Unoprostone Manuf. & Supply Agreement

Specifications for Unoprostone isopropyl ophthalmic solution 0.15%

Test Items	Acceptance Criteria
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

Quantitative Composition of Unoprostone Isopropyl Ophthalmic Solution 0.15%

RAW MATERIAL	FORMULA (mg/mL)
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of The Securities Exchange Act of 1934, as amended.

Unoprostone

NDA Transfer,

Patent and Know-how Licensing,

and

Data Sharing

Agreement

Effective Date:

April 23, 2009

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Unoprostone NDA Transfer, Patent and Know-how Licensing and Data Sharing Agreement

THIS UNOPROSTONE NDA TRANSFER, PATENT AND KNOW-HOW LICENSING AND DATA SHARING AGREEMENT ("**Agreement**") is made this 23 day of April, 2009 (the "**Effective Date**"), by and among Sucampo Pharma Americas, Inc. ("**SPA**"), a corporation organized and existing under the laws of the State of Delaware, U.S.A., (a wholly-owned subsidiary of Sucampo Pharmaceuticals, Inc., ("SPI") a corporation organized and existing under the laws of the state of Delaware, U.S.A.), and having its principal office at 4520 East West Highway, Third Floor, Bethesda, Maryland 20814, and R Tech Ueno, Ltd. ("RTU"), a corporation organized and existing under the laws of Japan and having its registered office at 1-1-7 Uchisaiwai-cho, Chiyoda-ku, Tokyo, Japan ,100-0011 (SPA and RTU each referred to herein as a "**Party**" and collectively as the "**Parties**").

WHEREAS, SPA is a United States based pharmaceutical company that seeks the right to hold and maintain the NDA (as defined below) for Unoprostone (as defined below and further described in Exhibit A) within the SPA Territory (as defined below) in accordance with the requirements of the Regulatory Authority (as defined below);

WHEREAS, SPA also seeks exclusive rights to license the existing Licensed Product (as defined below) and Unoprostone patents and trademarks within the SPA Territory;

WHEREAS SPA also seeks the exclusive right to develop the Licensed Product and Unoprostone for further patents and trademarks worldwide; and

WHEREAS, SPA also seeks to share in the further Clinical Development (defined below) and commercial sale of Licensed Product and Unoprostone within the SPA Territory; and

WHEREAS, RTU has the right to transfer NDA control and maintenance responsibilities for Unoprostone within the SPA Territory to SPA; RTU has the right to license existing Licensed Product and Unoprostone patents and trademarks within the SPA Territory to SPA ; and RTU has the right to license the Licensed Product and Unoprostone for further patents and trademarks worldwide to SPA; and RTU has the right to license the further Clinical Development and commercial sale of Licensed Product and Unoprostone within the SPA Territory to SPA;

WHEREAS, for this Agreement, SPA and RTU agreed upon a Draft Term Sheet dated December 15, 2008 (the "**Term Sheet**"), which sets forth the basic terms and conditions under which RTU shall license and supply certain products to SPA consistent with the terms of this Agreement, and the parties now wish to enter into this definitive agreement in accordance with the Term Sheet.

NOW, THEREFORE, in consideration of the mutual promises exchanged herein, and in consideration of the execution of the Unoprostone Exclusive Manufacturing and Supply Agreement (the **"Unoprostone**

Supply Agreement") (Exhibit B) to be executed between the Parties contemporaneously with this Agreement the receipt and sufficiency of such consideration is hereby acknowledged, the Parties agree as follows:

Article 1. Definitions

1.1 "Adverse Event" means any untoward medical occurrence in any patient use of discontinuance of a Licensed Product or clinical investigation subject administered a Licensed Product and which does not necessarily have to have a causal relationship with this pharmaceutical treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product, including but not limited to those events that must or may be reported in accordance with the pre-clinical testing, clinical trial testing or in market pharmaco-vigilance or other reporting requirements as may be required by any Regulatory Agency incident to the prosecution or maintenance of an IND or an NDA or similar regulatory filing with respect to the testing, registration, manufacture use or sale of a product as a pharmaceutical for human use .

1.2 "Affiliate" means, with the respect to either Party, any Person that, directly or through one or more Affiliates, controls, or is controlled by, or is under common control with, such Party. For purposes of this definition, "control" means (i) ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than fifty percent (50%) of the equity or management voting interests in the case of any other type of legal entity, (ii) status as a general partner in any partnership, or (iii) any other arrangement whereby a Person controls or has the right to control, directly or indirectly, the commercial operations, the Board of Directors or the equivalent governing body of a corporation or other entity. Notwithstanding the foregoing, in no event at any time during the Term of this Agreement shall SPA be considered Affiliate of RTU nor RTU be considered Affiliate of SPA for the purpose of this Agreement.

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

1.4 "Applicable Law" means all federal, state, local, national and supra-national treaties, conventions laws or statutes, and any implementing orders, rules and/or regulations, including any rules, regulations, orders, judgments, determinations, guidance, or requirements of Regulatory Authorities, the tax authorities, courts of competent jurisdiction and any non-governmental agencies that control any aspect of the pharmaceutical, medical, commercial or financial activities contemplated by the parties in utilizing the rights granted or received incident to this Agreement, including but not limited to development of pharmaceutical products in accordance with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") standards, listing of securities on stock exchanges governed by major national securities exchanges or major securities listing organizations or compliance with financial and accounting standards as promulgated by the Financial Accounting Standards Board or its foreign equivalent for IFRF reporting

standards, that may be in effect from time to time during the Term and applicable to a particular activity hereunder.

1.5 "Business Day" means a day, other than a Saturday or Sunday, on which banking institutions in Washington, DC, USA, or Tokyo, Japan, are open for business, such that a bank holiday in the United States which is not a banking holiday in Japan is nevertheless a Business Day under the terms of this Agreement.

1.6 "Clinical Studies" means a human clinical study, or other test or study in humans, with respect to a Unoprostone or a Licensed Product performed incident to an open IND, including, but not limited to Phase I Study, Phase II Study, Phase III Study, Phase IV Study, early access programs, compassionate use and single patient INDs, epidemiological studies, modeling and pharmacoeconomic studies, post-marketing studies, investigator sponsored studies, and health economics studies.

1.7 "Commercialization" or **"Commercialize"** means any and all activities (whether before or after Regulatory Approval) directed to the commercialization of the Licensed Product, including pre-launch and post-launch marketing, Promoting, distributing, offering to sell and selling the Licensed Product, and importing or exporting the Licensed Product for sale. When used as a verb, "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

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

1.9 "Confidential Information" means all information that is not in the public domain and is protectable by a Disclosing Party as a trade secret under Applicable Law (including, without limitation, Regulatory Data and Information, as defined below) provided to a Party by another Party, whether oral, in writing or otherwise, including, without limitation, any information on the research, development, markets, customers, suppliers, patent applications, inventions, products, procedures, designs, formulas, business plans, financial projections, organizations, employees, consultants or any other similar aspects of a Party's present or future business.

1.10 "Corporate Names" means (i) in the case of SPA, the trademark SPA and the Sucampo corporate logo or such other names and logos used generally by SPA and its Affiliates in their business (and not relating to a specific product or technology) as SPA may designate in writing from time to time, and (ii) in the case of RTU, the trademark RTU and the RTU corporate logo or such other names and logos used generally by RTU in its business (and not relating to a specific product or technology) as RTU may designate in writing from time to time, in each case ((i) and (ii)), together with any variations and derivatives thereof.

1.11 "Data Exclusivity" means any data or market exclusivity granted to a Licensed Product in the SPA Territory by any Regulatory Authority as of the Effective Date or at any time during the Term.

1.12 "Development" or **"Develop"** means, with respect to the Licensed Product, all research, all pre-clinical and clinical activities conducted relating to the Licensed Product for any indication, including without limitation, test method development and stability testing, toxicology, animal studies, formulation, process development, manufacturing scale-up, quality assurance/quality control development for clinical studies, statistical analysis and report writing, and Clinical Studies, including without limitation clinical trial design, operations, data collection and analysis and report writing, publication planning and support, risk assessment mitigation strategies, health economics outcomes research planning and support, clinical laboratory work, disposal of drugs and regulatory activities in connection therewith, the transfer of information, materials, Licensed Product regulatory documentation and other technology with respect to the foregoing, the preparation of Regulatory Filings, and obtaining and/ or maintaining Regulatory Approvals (including regulatory affairs activities and preparation of meetings with Regulatory Authorities). When used as a verb, "Developing" means to engage in Development and "Developed" has a corresponding meaning.

1.13 "Disclosing Party" means the Party disclosing Confidential Information; provided a Party owning certain property as provided hereunder shall be considered the Disclosing Party and the other Party shall be considered the Receiving Party regardless of which Party discloses such information.

1.14 "Drug Approval Application" means, on a Licensed Product-by-Licensed Product basis in SPA Territory, an application submitted to a Regulatory Authority for Regulatory Approval for the Licensed Product, and all supplements and amendments that may be filed with respect to the foregoing.

1.15 "Glaucoma and Ocular Hypertension Indication" means the prophylactic or therapeutic use in the prevention and/or treatment of glaucoma and Ocular Hypertension.

1.16 "Improvement Patent" shall mean any patent relating to any invention made by a Party that improves the performance of the Licensed Product in terms of its safety, efficacy, patient acceptance, cost, manufacture, formulation, dosing, use or sale, but shall not include inventions that involve new compositions of matter used as active ingredients, or new formulation technology otherwise patentable and applicable to other compositions of matter than the Licensed Product.

1.17 "IND" means an application filed with a Regulatory Authority for authorization to commence human clinical trials or prosecute a Drug Approval Application of Unoprostone, including, but not limited to, (i) an Investigational New Drug Application as defined in the Food, Drug and Cosmetic Act (FDCA) or any update thereto or any successor application or procedure filed with the Food and Drug Administration (FDA), (ii) any foreign equivalent of a United States IND, and (c) all supplements and amendments that may be filed with respect to the foregoing.

1.18 "Licensed Know-How" means all Technology controlled by RTU or its Affiliates as of the Effective Date or at any time during the Term that is useful or necessary for developing, using, making, having made, offering for sale, registering, selling or importing the Licensed Product.

1.19 "Licensed Patents" means all patent and patent applications related to Unoprostone that are hereunder licensed to SPA and/or enable SPA activities in SPA Territory (i) that are owned by or licensed (with the right of sublicense) to RTU on before the Effective Date of this Agreement or (ii) which derive from inventions that are acquired, made, created, developed, conceived or reduced to practice by RTU during the Term of this Agreement, to the extent that such patents or patent applications relate to Unoprostone (including, without limitation, its composition of matter, its method of use, its formulation(s) (either alone or in combination with other active ingredients), its dosing regimens, its manufacture, its synthesis, its metabolism, its safety and/or its utility) or necessary, used, or useful for the development, manufacture or commercialization of Unoprostone, or (iii) which derive from an invention that is made, created, developed, conceived or reduced to practice jointly by RTU and SPA after the Effective Date of this Agreement the practice of which would in the absence of a license, infringe on a claim of any unexpired patent described in (i) or (ii). Licensed Patents include all reissues, continuations, continuations-in-part, extensions, reexaminations, and foreign counterparts of any of the foregoing. Licensed Patents include listing set forth in Exhibit C (*Licensed Patents*), which may be amended from time-to-time to add additional patents and patent applications.

1.20 "Licensed Product" means any human or veterinary pharmaceutical product (whether prescription or over-the-counter and in any form or dosage form of a pharmaceutical composition or preparation), comprising of Unoprostone (whether as a sole active ingredient or in combination with one or more other active ingredients) for which the rights to manufacture, to use and to sell such product in the SPA Territory as a pharmaceutical product are granted hereunder to SPA under the Licensed Patents and the Licensed Know-How.

1.21 "Market Withdrawal" means a "market withdrawal" as such term is defined in Title 21, United States Code of Federal Regulations, Part 7.3 (as amended from time to time, or such successor Applicable Law as may take effect in the United States) or in equivalent Applicable Law outside the United States, governing the possible withdrawal of the Licensed Product in the SPA Territory.

1.22 "NDA" means a New Drug Application, as defined by laws for such application within the SPA Territories (as defined below) and applicable regulations promulgated in the countries or territories there under, or other appropriate marketing authorization in Japan, or any counterpart application or marketing authorization in any country of the SPA Territory. For the avoidance of doubt, maintenance of the NDA with respect to compliance of the Drug Substance or the Drug Product with the Drug Master File/Chemistry, Manufacturing and Controls ("DMF/CMC") elements of the NDA shall remain with and be maintained by RTU .

1.23 "Net Sales" means the total amount billed or invoiced on sales of Licensed Product by SPA or its Affiliates in SPA Territory to independent, unrelated Third Parties such as wholesalers or distributors and actually received in payment from such unrelated Third Parties in bona fide arm's length transactions, less the following deductions (specifically excluding any royalty payments made by SPA or its Affiliates to RTU), in each case related specifically to Commercialization and sale of the Licensed Product and actually allowed and taken by such Third Parties and not otherwise recovered by or reimbursed to SPA or its Affiliates:

(i) trade, cash and quantity discounts;

(ii) price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to governmental authorities;

(iii) taxes on sales (such as sales or use taxes) to the extent added to the sale price and set forth separately as such in the total amount invoiced;

(iv) freight, insurance and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced, as well as any fees for services provided by wholesalers and warehousing chains related to the distribution of the Licensed Product;

(v) amounts repaid or credited by reason of rejections, defects, one percent (1%) return credits, recalls or returns or because of retroactive price reductions, including, but not limited to, rebates or wholesaler charge backs; and

(vi) the portion of management, commercialization costs or fees paid during the relevant time period to distributors, co-promotion partners, group purchasing organizations and/or pharmaceutical benefit managers relating specifically to the finished Licensed Product.

Net Sales will include the amount or fair market value of all other consideration received by SPA or its Affiliates in respect of the Licensed Product, whether such consideration is in cash, payment in kind, exchange or other form.

Subject to the above, Net Sales will be calculated in accordance with SPA's standard internal policies and procedures, which must be in accordance with GAAP (Generally Accepted Accounting Principles as regularly applied under the Financial Accounting Standards Board ("FASB") as may be promulgated from time to time).

Net sales will not include sales between or among SPA and its Affiliates. For purposes of calculating Net Sales, all Net Sales will be converted into United States dollars using SPA's standard conversion methodology consistent with GAAP. The standard conversion methodology is based on monthly averages (for example, the spot rate at the end of the month immediately prior to the reporting month plus the spot rate at the end of the reporting month, divided by two) using open market rates.

If SPA or its Affiliates appoint Third Party distributors for the Licensed Product or grant a license or sublicense to any Third Party for manufacturing and selling the Licensed Product, Net Sales will include the Net Sales invoiced and received by SPA or its Affiliates to such Third Party distributors and the royalties or other compensation of any other kind whatsoever invoiced and received by SPA or its Affiliates to any such Third Party manufacturer, but it will not include any sales of the Licensed Product made by any such Third Party distributors or other Person.

1.24 "Order" means, in accordance with the Unoprostone Supply Agreement Sections 1.8 (*Order*), 2.4 (*Clinical Supply; Order*) and 2.5 (*Commercial Supply; Exclusivity; Forecasting; Order*), a written communication from SPA to RTU of SPA's order for purchase of a specified amount of Unoprostone or Licensed Product at a delivery date, delivery price and delivery location set forth in such written purchase order communication.

1.25 "Other Indications" means any indication for use of Unoprostone other than the Glaucoma Indication and Ocular Hypertension Indication.

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

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

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

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

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

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

1.32 "Product Label and Insert" means (i) any display of written, printed or graphic matter upon the immediate container, outside container, wrapper or other packaging of the Licensed Product or (ii) any written, printed or graphic material on or within the package from which the Licensed Product is to be dispensed and is reviewed and approved from time to time by a Regulatory Authority from time to time.

1.33 "Product Trademark" means (i) any trademark, trade dress, brand mark, service mark, brand name, logo or business symbol, Internet domain name and e-mail address, whether or not registered or any application, renewal, extension or modification thereto, that is applied to or used with the Licensed Product by RTU, its Affiliates, or any other Party that is marketing, promoting, and/or selling the Licensed Product and (ii) all goodwill associated therewith; in each case ((i) and (ii)). Corporate Names are specifically excluded, except where the name of the manufacturer is required to be mentioned on Licensed Product labels or otherwise by a Regulatory Authority. Product Trademark shall include, but

not be limited to, the mark "Rescula" as well as derivatives thereof. Product Trademarks existing as of the Effective Date include, without limitation, those Product Trademarks set forth in Exhibit C (Product Trademarks), which shall be updated from time to time.

1.34 "Product Valid Claims" means, with respect to the Licensed Product, a claim of any issued and unexpired patent included within the Licensed Patents, the enforceability of which has not been subject to one or more of any of the following: (i) irretrievable lapse, revocation or abandonment; (ii) holding of unenforceability or invalidity by a decision of a court or other appropriate body of competent jurisdiction, that is unappealable or unappealed within the time allowed for appeal; and/or (iii) disclaimer or admission of invalidity or unenforceability through reissue or re-examination or opposition, nullity action or invalidation suit response, terminal disclaimer or otherwise. The foregoing notwithstanding, in the event a claim of a patent within the Licensed Patent(s) has been held to be invalid or unenforceable, and an appeal is pending, such claim shall not be considered a Product Valid Claim until reinstated by a final decision of a court or governmental agency of competent jurisdiction.

1.35 "Promote" or "**Promotion**" means those activities normally undertaken by a pharmaceutical company's sales force and marketing team to implement marketing plans and strategies aimed at encouraging the appropriate use of a particular prescription or other pharmaceutical product, including detailing. When used as a verb, "Promote" means to engage in such activities.

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

1.37 "Recall" means a "recall" as such term is defined in Title 21, United Stated Code of Federal Regulations, Part 7.3 (as amended from time to time, or such successor Applicable Law as may take effect in the United States) or equivalent Applicable Law outside the United States, of the Licensed Product.

1.38 "Receiving Party" means the Party receiving Confidential Information; provided a Party owning certain property as provided hereunder shall be considered the Disclosing Party and the other Party shall be considered the Receiving Party regardless of which Party discloses such information.

1.39 "Regulatory Approval" means, in the SPA Territory, 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 Licensed Product, including, where applicable, pricing or reimbursement approval, or pre- and post-approval marketing authorizations, labeling approvals, import and export licenses, technical, medical and scientific licenses.

1.40 "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, Commercialization, or sale of the Licensed Product.

1.41 "Regulatory Data and Information" consists of data and information relating to a Licensed Product that is derived from any or several of the following business activities undertaken by any of the Parties at any time: (i) market and business research and intelligence; (ii) research and development of pharmaceutical and medicinal products; (iii) obtaining Commercialization approval for pharmaceutical products; and (iv) consultation with respect to any or several of the above activities.

1.42 "Regulatory Filings" means, collectively, all INDs, Drug Approval Applications, diagnostic product device approval applications, establishment license applications, drug master files, and any product approvals under Section 505 (a) and (b) of the Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. § 355(b)(4)(B)) or any update thereto or all other similar filings (including, without limitation, any counterparts of any of the foregoing in SPA Territory) as may be required by any Regulatory Authority for the Development, manufacture or Commercialization of Unoprostone or the Licensed Product; and (b) all supplements and amendments to any of the foregoing.

1.43 "Technology" means, collectively, proprietary information, know-how and data, technical or non-technical, trade secrets, materials (including tangible chemical, biological or other physical materials) or inventions, discoveries, improvements, processes, methods of use, methods of manufacturing and analysis, compositions of matter, or designs, whether or not patentable.

1.44 "Term" means the definition provided in Section 12.1.

1.45 "Territory" means (i) with respect to SPA, the United States of America and Canada, and all of their territories and possessions and any other location where the FDA or its foreign counterparts in the Territory has jurisdiction over pharmaceutical products intended for human use ("SPA Territory"), and (ii) with respect to RTU, the remaining countries in the world ("RTU Territory").

1.46 "Third Parties" means any Person other than RTU and SPA and their respective Affiliates.

1.47 "Unoprostone" (also known by the USAN name of Unoprostone isopropyl) is the composition of matter defined chemically as isopropyl [*] as further described in Exhibit A, and its salts, metabolites, as well as any active pro-drugs, isomers, tautomers, hydrates, chelates, complexes and polymorphs and all other pharmaceutically acceptable modifications as may be projected in the public domain as motivation to an medicinal chemistry expert in the drug development field.

Article 2. NDA Transfer

2.1 After the Effective Date, RTU shall cooperate with SPA for timely transfers to SPA of ownership and control of all regulatory approvals and files, owned by RTU as of the Effective Date, for the Licensed Product in the SPA Territory, at RTU's expense, with the exception of the CMC matter to be retained by RTU.

2.2 RTU shall provide SPA with transitional services relating to the regulatory approvals, which shall consist of supporting SPA's efforts to submit regulatory filings, reasonably requested by SPA in writing for a period of up to six (6) months after Effective Date, at SPA 's expense.

2.3 Prior to the Effective Date, RTU shall maintain the NDA of the Licensed Product at RTU's expense and, as from the Effective Date, SPA shall maintain the NDA of the Licensed Product at SPA's expense within the SPA Territory.

Article 3. Data Sharing

3.1. Right to Use Regulatory Data and Information.

3.1.1 Each Party (each, within this Article 3, a "**Receiving Party**") shall have a right to use of all Regulatory Data and Information developed by the other Party (each, within this Article 3, a "**Developing Party**") for the purpose specified in the Agreement in such Receiving Party's Territory. The Parties shall keep one another reasonably apprised of information pertaining to Regulatory Data and Information and may request formal disclosure of Regulatory Data and Information at any time, consent to such request shall not be unreasonably withheld.

3.1.2 The Parties anticipate that a Receiving Party may exercise its rights under this Section 3.1 at any time, and specifically at the start of Phase I Studies or at the end of Phase I Studies, Phase II Studies, Phase III Studies or Regulatory Approval.

3.1.3 If a Receiving Party exercises its right to access and use a Developing Party's Regulatory Data and Information, such Receiving Party shall be entitled to use such Regulatory Data and Information solely for the purpose of developing, obtaining regulatory approval for, marketing and selling products in such Receiving Party's Territory pursuant to the terms and conditions of this Agreement. Such rights shall include the right to refer, in any application for regulatory approvals for the Licensed Products and/or Unoprostone in respect of any country in the Receiving Party's Territory, to any and all documentation filed by the Developing Party or its sublicenses with the regulatory authorities in the Developing Party's Territory, in support of any application for regulatory approval of the Licensed Products and/or Unoprostone.

3.2 Data Sharing Intellectual Property Ownership. Subject to the rights obtained by a Party pursuant to this Article 3, the Receiving Party shall retain all the rights in any invention, technology, know-how or other intellectual property resulting from its use of the Regulatory Data and Information in compliance herewith; provided, however, that such Receiving Party shall allow the other Party to use non-exclusively in its Territory such Regulatory Data and Information without consideration solely for the purpose of developing, obtaining regulatory approval for, marketing and selling products in such Party's Territory. The provisions set forth in Article 3 shall not be the basis of any joint development program, partnership or joint venture of any kind unless separately agreed upon. Any joint development program, if any, shall be the subject of separate definitive agreements.

Article 4. Patent License Grants and Know-How Access

4.1 Patent Licenses. Subject to the terms and conditions of this Agreement, and subject to no further costs than those set forth in Article 9 below, RTU hereby grants to SPA a royalty-bearing and exclusive license, with right of sublicense as provided in Section 4.3 (*Sublicensing*), under the Licensed Patents to Develop, import, use, make, have made, export, register, Commercialize, offer for sale and sell Licensed Products throughout the SPA Territory.

4.2 License to Know-How. Subject to the terms and conditions of this Agreement, and subject to no further costs than those set forth in Article 9 below, RTU hereby grants to SPA a royalty-bearing and exclusive license, with right of sublicense as provided in Section 4.3 (*Sublicensing*), under the Licensed Know-How to Develop, import, use, make, have made, export, register, Commercialize offer for sale and sell Licensed Products throughout the SPA Territory.

4.3 Sublicensing. SPA shall have the right to sublicense its rights under Sections 4.1 (*Patent Licenses*) and 4.2 (*License to Know-How*) to Third Parties, provided that (i) the agreement in which such sublicense is granted shall conform with the terms of this Agreement as may be necessary for SPA to abide by all duties, obligations and restrictions provided under this Agreement, and (ii) RTU shall provide written consent for such sublicensing, which shall not be unreasonably withheld. In no event may SPA grant a sublicense that diminishes the rights or increases the obligations of RTU under this Agreement without the prior written consent of RTU. With reasonable promptness following execution, SPA shall provide a copy of any sublicense to RTU provided that the financial terms of such sublicense may be redacted. SPA shall be responsible hereunder for any failure of such Third Parties to comply with the terms and conditions of this Agreement as if they are directly applicable to such Third Parties.

4.4 Improvement Patents. As inventions are discovered by a Party that would be a basis for filing for an Improvement Patent, that inventing Party shall inform the other Party and the Parties will cooperate with each other before the filing, in the filing, and after filing such Improvement Patent, to assure at lowest cost, and more reasonable level of effort the widest filing globally of a patent filing most likely to be granted with the most comprehensive claims so as to best extend and improve the commercial returns from the Licensed Product. Subject to the terms and conditions of this Agreement, and subject to no further costs than those set forth in Article 9 below, RTU hereby grants to SPA a non-exclusive and royalty-free license, under any and all patents to be owned by RTU with respect to any patentable inventions made, created, developed, conceived or reduced to practice by RTU during the Term of this Agreement in relation to the Licensed Product and/or Unoprostone, to Develop, make, register, Commercialize, use and sell the Licensed Products within the SPA Territory hereunder. SPA hereby grants to RTU a non-exclusive and royalty-free license, under any and all patents to be owned by SPA (including its Affiliates and sublicensees) with respect to any patentable inventions made, created, developed, conceived or reduced to practice by SPA during the Term of this Agreement in relation to the Licensed Products and/or Unoprostone hereunder, to make, use and sell any product within the RTU Territory. SPA will notify RTU and its Affiliates within thirty (30) days in the event that SPA decides not to prepare, file, prosecute, maintain and/or defend the Improvement Patents outside of SPA Territory. RTU or its Affiliates shall then have the right and option to do so at its own responsibilities and expense and shall own any resulting patent applicable or patent. Such rights of RTU would be in addition to, and

not replace, any other rights and remedies of RTU's available by law and/or this Agreement. RTU will notify SPA and its Affiliates within thirty (30) days in the event that RTU decides not to prepare, file, prosecute, maintain and/or defend the Improvement Patents outside of SPA Territory. SPA or its Affiliates shall then have the right and option to do so at its own responsibilities and expense and shall own any resulting patent applicable or patent. Such rights of SPA would be in addition to, and not replace, any other rights and remedies of SPA's available by law and/or this Agreement.

4.5 License to Product Trademarks. Subject to and in accordance with the terms and conditions of this Agreement, and subject to no further costs than those set forth in Article 9 below, RTU hereby grants to SPA an exclusive, even as to RTU and its Affiliates in the SPA Territory, royalty-free license, with the right to sublicense to multiple tiers of Third Parties, to use all current and future Product Trademarks in connection with the performance by SPA or its Affiliates of their development and Commercialization obligations with respect to the Licensed Product, provided, however RTU shall have the right to use these future trademarks without incurring any payment obligations to SPA in RTU Territory. Notwithstanding the license to Product Trademarks granted by RTU in this Section 4.5, SPA shall have the right not to use the Licensed Product Trademarks or to use another trademark (each an "Alternative Trademark") for the Licensed Product in SPA Territory, and SPA shall own all rights to such Alternative Trademark and shall be free to use such Alternative Trademark without regard to, or accounting to, RTU except as otherwise provided herein. RTU shall have the right to use these Alternate trademarks without incurring any payment obligations to SPA in RTU Territory.

Article 5. Regulatory

5.1 Regulatory Filings; Regulatory Approvals. Subject to Articles 2 (*NDA Transfer*) and 3 (*Data Sharing*) the following provisions shall apply:

5.1.1 Ownership. Ownership and control over all aspects of the NDA other than CMC compliance for the Licensed Product and Unoprostone in the Territory shall be transferred to SPA in accordance with the provisions of Article 2 and 3 above. Upon such transfer SPA shall undertake it commercially reasonable efforts to prosecute and maintain the NDA for the Licensed Products and/or Unoprostone [for all product indications] in the Territory.

5.1.2 Preparation of Regulatory Filings; Communications.

a) *Preparation of Regulatory Filings; Review of Regulatory Filings.* Subject to all provisions above, the Parties shall reasonably cooperate and consult with each other in good faith to develop strategies for all Regulatory Filings for Unoprostone and the Licensed Product; provided that RTU shall be responsible for determining for the CMC package and shall have a right of final approval for the overall regulatory strategy. The Parties shall also be responsible within their respective Territories for implementing the regulatory strategy for clinical studies (including the interactions with Regulatory Authorities).

b) *Communications; Regulatory Meetings.* The Parties shall cooperate with each other's reasonable requests and provide support in responding to Regulatory Authorities, including providing comments on its submissions and responses within ten (10) Business Days from the time of receipt or sooner if required by Regulatory Authority.

c) *Occurrences or Information Arising out of RTU Manufacturing Activities.* During the Term, RTU will advise SPA without undue delay, however in any event within a period not to exceed seven (7) Business Days of any occurrences or information arising out of RTU's manufacturing activities that have or could reasonably be expected to have adverse regulatory compliance and/or reporting consequences concerning the Licensed Product, including actual or threatened Regulatory Authorization withdrawals or labeling changes in SPA Territory, and failure to do so shall constitute a material breach of this Agreement by RTU.

d) *Regulatory Authority Inspections.* During the Term, and subject to the Unoprostone Supply Agreement, RTU will be responsible for handling and responding to any Regulatory Authority inspections with respect to RTU's manufacture of the Licensed Product. RTU will provide to SPA any information reasonably requested by SPA and all information requested by any Regulatory Authority concerning any governmental inspection related to the Licensed Product and will allow Regulatory Authorities to conduct reasonable inspections upon the request of such Regulatory Authority and failure to do so shall constitute a material breach of this Agreement by RTU.

e) *Violations or Deficiencies Relating to the Licensed Product.* SPA without undue delay, but in any event within a period not to exceed five (5) Business Days, of any written alleged violations or deficiencies relating to the Licensed Product and the corrective action to be taken. RTU will as expeditiously as practicable take any such corrective action required to comply with the provisions of this Agreement and with the Unoprostone Supply Agreement, and failure to do so shall constitute a material breach of this Agreement by RTU. Prior to submission of any written response submitted to any applicable Regulatory Authority, SPA will have an opportunity to review any portion of the response regarding written alleged violations or deficiencies relating to the Licensed Product.

5.2 Product Labels and Inserts; Core Data Sheets. Each Party and its Affiliates shall own and be responsible for all Product Labels and Inserts for all Licensed Products in its Territory. Each Party and its Affiliates shall own and be responsible for all Core Data Sheets for all Licensed Products in its Territory.

5.3 Adverse Event Reports. SPA and its Affiliates shall be responsible for investigating Adverse Events and other required safety information associated with the use of the Licensed Product in SPA Territory in accordance with the requirements of the relevant Regulatory Authority. SPA shall be responsible for the collection, review, assessment, tracking and filing of information related to Adverse

Events, and RTU will cooperate and provide or cause any Third Party to provide such information to SPA and its Affiliates with respect thereto and failure to do so shall constitute a material breach of this Agreement by RTU. Prior to any Commercialization of the Licensed Product in the SPA Territory, the Parties shall enter into an agreement to initiate a process for the exchange of Adverse Event safety data in a mutually agreed format, including, but not limited to, post-marketing spontaneous reports received by a Party or its Affiliates in order to monitor the safety of the Licensed Product and to meet reporting requirements with any applicable Regulatory Authority (**"Pharmacovigilance Agreement"**).

5.4 Recalls and Market Withdrawals.

5.4.1 Notification. Each Party shall make every reasonable effort to notify the other Party promptly (but in no event later than forty-eight (48) hours) upon its determination that any event, incident or circumstance has occurred that may result in the need for a Recall or Market Withdrawal of the Licensed Product, in or outside of its Territory, and include in such notice the reasoning behind such determination and any supporting facts.

5.4.2 Initiation. SPA shall determine whether to voluntarily implement any Recall and upon what terms and conditions the Licensed Product shall be subject to a Recall in SPA Territory. SPA shall determine whether to voluntarily implement a Market Withdrawal in SPA Territory and upon what terms and conditions the Licensed Product shall be subject to a Market Withdrawal or otherwise temporarily or on a limited basis withdrawn from sale in SPA Territory. If a Recall is mandated by a Regulatory Authority, SPA shall initiate such a Recall to be in compliance with Applicable Law.

5.4.3 Responsibility. For all Recalls or Market Withdrawals undertaken pursuant to this Section 5.4, SPA and its Affiliates shall be solely responsible for the execution of such Recall or Market Withdrawals, and RTU shall reasonably cooperate in all such Recall or Market Withdrawal efforts. RTU shall be responsible for the costs associated with any Recall or Market Withdrawal to the extent of its attribution to the cause of such Recall or Market Withdrawal.

5.4.4 Complaints. In the case that the same lot of the Product is supplied for the SPA Territory and RTU Territory, each Party shall refer any complaints that it receives concerning the Licensed Product in the other Party's Territory to the other Party within forty-eight (48) hours of its receipt of the same or earlier if required by Applicable Law; provided that all complaints concerning suspected or actual Licensed Product tampering, contamination or mix-up (e.g. wrong ingredients) shall be delivered within twenty-four (24) hours of receipt of the same. Unless otherwise required by any Applicable Law, the Parties shall not take any other action in respect of any such complaint which it receives concerning the Licensed Product in the other Party's Territory without the prior written consent of the other Party.

Article 6. Development

6.1 General. SPA, at its sole discretion, may engage in Development of Unoprostone and/or Licensed Product in SPA Territory.

6.2 Additional Clinical Trials. SPA, at its sole discretion, may conduct clinical trials of Unoprostone and/or Licensed Product in SPA Territory, at its sole expense.

6.3 Pharmacovigilance Administration. In SPA Territory, SPA shall be responsible for all costs of pharmacovigilance administration in SPA Territory in accordance with the Pharmacovigilance Agreement (as defined in Section 5.3 above, *Adverse Events Reports*). RTU shall ensure that it, its Affiliates, or its licensees provide SPA with all information and data required to allow SPA to comply with its regulatory obligations and RTU's failure to do so shall constitute a material breach of this Agreement by RTU.

6.4 Conduct of Development.

6.4.1 Compliance. Within its Territory, each Party shall perform Development of Unoprostone and/or Licensed Product in good scientific manner and in material compliance with Applicable Law.

6.4.2 Cooperation. The Parties shall cooperate in good faith as needed in performance of Development.

6.5 Records. Each Party shall maintain records of its Development activities in sufficient detail, in good scientific manner and otherwise in a manner that reflects all work done and results achieved in the performance of Development. Each Party shall retain such records for at least five (5) years after the expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law or agreed to in writing by the Parties. Subject to Articles 10 (*Confidentiality and Non-Disclosure*) and 3 (*Data Sharing*), each Party shall provide the other Party, upon reasonable request, a copy of such records to the extent reasonably required for the performance of the requesting Party's obligations and exercise of its rights under this Agreement. Each Party agrees to maintain a policy that requires its employees and consultants to record and maintain Technology developed during the development plans in accordance with generally accepted practice in the industry.

6.6 Other Indications; Mutual Right of First Refusal. From time to time during the Term, each Party may Develop products for Other Indication(s) within each Territory and grant the other Party a non-exclusive license to Develop and Commercialize a product for such Other Indication(s) in its Territory. Each Party shall provide the other with notice of any such Other Indication(s) in writing. The Parties shall negotiate in good faith on basic terms and conditions of such license agreement. Each party shall have the right to sublicense the right set out in this section 6.6 only upon prior written consent by the other party, which consent is within the other party's full and unfettered discretion.

Article 7. Promotion of Licensed Products

7.1 Efforts. Subject to the terms and conditions of this Agreement, SPA and its Affiliates shall be solely responsible for all aspects of Commercializing the Licensed Product in SPA Territory, including, but not limited to the utilization of Third Parties to Commercialize or detail the Licensed Products. SPA shall have full discretion, without liability to RTU, in determining whether or not to Commercialize the Licensed Product in SPA Territory.

7.2 Promotional Materials. SPA shall own all Promotional Materials for the Licensed Product in SPA Territory. RTU shall provide SPA with copies of Promotional Materials, if prepared by RTU, for the Licensed Product. SPA, its Affiliates and sublicensees may use such Promotional Materials, as modified appropriately subject to the approval of RTU in writing, for use in SPA Territory for the purpose of this Agreement. SPA shall permit RTU to use copies of the Promotional Materials, including those so modified, within RTU Territory.

Article 8. Consideration

8.1 Upfront Payment. SPA or its Affiliates shall pay to RTU a non-refundable Three Million United States Dollars (US$3,000,000) (payable in Japanese Yen, converted at the spot rate at the close of the Business Day in which each such milestone payment becomes payable) within fifteen (15) days of the Effective Date.

8.2 Milestone Payments. SPA shall make each of the following non-refundable, payments to RTU, in United States dollars, but paid in Japanese Yen, converted at the spot rate at the close of the Business Day in which each such milestone payment becomes payable and each on a one (1) time basis at the end of the month following which the milestone event is achieved:

Milestone Event	Milestone Payment
Re-launch of Rescula® for Glaucoma Indication in SPA Territory	SPA to pay RTU US$500,000 in accordance with 9.2 after the occurrence of the Milestone Event
Other Indication Regulatory Approval in SPA Territory for efficacy	SPA to pay RTU US$1,000,000 in accordance with 9.2 after the occurrence of the Milestone Event
1st occurrence of Annual Net Sales in total of all indications of US$[*] or more in SPA Territory	SPA to pay RTU US$500,000 in accordance with 9.2 after the occurrence of the Milestone Event
1st occurrence of Annual Net Sales in total of all indications of US$[*] or more in SPA Territory	SPA to pay RTU US$1,000,000 in accordance with 9.2 after the occurrence of the Milestone Event
1st occurrence of Annual Net Sales in total of all indications US$[*] or more in SPA Territory	SPA to pay RTU US$2,500,000 in accordance with 9.2 after the occurrence of the Milestone Event

8.3 Third Party Royalties and Milestones. Within SPA Territory, SPA shall be solely responsible for the payment of any Third Party Royalties, milestone payments and any other payments arising from Third Party intellectual property rights claims related to the Licensed Product.

8.4 Payment Dates and Reports. Upon making the payments under Sections 9.2 (*Milestone Payments*) and 9.3 (*Third Party Royalties and Milestones*), SPA and its Affiliates shall also provide a report showing: (i) a statement identifying the Annual Net Sales of the Licensed Product in the Territory; (ii) the withholding taxes, if any, required by Applicable Law to be deducted with respect to such Net Sales; and (iii) the exchange rates, if any, used in determining the amount of United States dollars.

8.5 Audit Rights. Each Party shall keep and maintain for at least three (3) years complete and accurate records in accordance with GAAP or IFRF as the case may be in sufficient detail to allow confirmation of any payment calculations or components thereof and made hereunder. Upon the written request of a Party (herein, the "**Auditing Party**") and not more than once in each Calendar Year, the other Party (herein, the "**Audited Party**") shall permit an independent certified public accounting firm of internationally-recognized standing, selected by the Auditing Party (provided that the Auditing Party shall not without the Audited Party's prior written consent select the same public accounting firm that conducts the Auditing Party's annual financial statement audit) and reasonably acceptable to the Audited Party, at the Auditing Party's expense, to have access, with not less than thirty (30) days notice, during normal business hours, to the records of the Audited Party and its Affiliates as may be reasonably necessary to verify the accuracy of the payments hereunder for any year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm will be instructed to provide its audit report first to the Audited Party, and will be further instructed to redact any proprietary information of the Audited Party not relevant to verifying the accuracy of payments prior to providing that audit report to the Auditing Party. The accounting firm's audit report shall state whether the applicable report(s) is/are correct or not, and, if applicable, the specific details concerning any discrepancies. No other information shall be shared. If such accounting firm concludes that additional monies were owed by the Audited Party to the other, the Audited Party shall have the option to invoke the arbitration proceedings of Sub-Section 14.1.2 or pay the additional monies within thirty (30) days of the date the Audited Party receives such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by the Auditing Party; provided if an error in favor of the Auditing Party of more than ten percent (10%) is discovered, then the Audited Party shall pay the reasonable fees and expenses charged by such accounting firm. Any audit reports provided hereunder shall be the Confidential Information of the Audited Party.

8.6 Withholding Taxes. All payments made under this Agreement shall be free and clear of any and all taxes, duties, levies, fees or other charges, except for withholding taxes. Where any sum due to be paid to a Party hereunder is subject to any withholding tax, the Parties shall use commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the paying Party shall deduct any

withholding taxes from payment and pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to the receiving Party and secure and send to the receiving Party the best available evidence of such payment.

8.7 Payments. All payments due under this Agreement shall be payable in Japanese Yen, converted at the spot rate at the close of the Business Day in which each such milestone payment becomes payable. Unless specified otherwise herein or in the Unoprostone Supply Agreement, RTU will invoice SPA for Licensed Product upon RTU's delivery thereof to SPA's carrier and payments shall be due within thirty (30) days from date of receipt of invoice. All payments under this Agreement shall be by appropriate electronic funds transfer in immediately available funds to such bank account as RTU shall designate. Each payment shall reference this Agreement and identify the obligation specific as to time and Net Sales or other condition incurring the payment obligation under this Agreement that the payment satisfies. If at any time legal restrictions prevent the remittance of part or all of payments owed by a Party hereunder, the Parties shall promptly negotiate in good faith the terms for repayment under lawful means or methods.

8.8 No Other Compensation. Unless otherwise agreed to by the Parties and set forth in writing, RTU and SPA hereby agree that the terms of this Agreement and all ancillary agreements hereto (including, without limitation, the Unoprostone Supply Agreement attached hereto) shall fully define any and all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by each Party to the other in connection with the transactions contemplated herein. Neither Party has previously paid or entered into any other commitment to pay, whether orally or in writing, any employee of the other Party, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transactions contemplated herein.

Article 9. Confidentiality and Non-Disclosure

9.1 Confidentiality.

9.1.1 Nondisclosure Obligations. Except to the extent expressly permitted by this Agreement, at all times during the Term and for a period of ten (10) years following the expiration or termination hereof, the Receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than the purpose of this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party shall treat and protect the trade secret status of Confidential Information as it would its own proprietary information which in no event shall be with less than a reasonable standard of care, and take reasonable precautions to prevent the publication or unauthorized use or disclosure of Confidential Information to a Third Party, except as explicitly set forth herein, without prior, explicit, written consent of the other Party.

9.1.2 Exceptions to Confidentiality. The Receiving Party's obligations set forth in this Agreement shall not extend to any information of a Disclosing Party or information developed in the performance of this Agreement that:

a) is or hereafter becomes part of the public domain in accordance with Article 4, by public use, publication, general knowledge or the like or is made generally available in the public domain by a Third Party with right to make such publication; in each case, other than through a breach of this Agreement;

b) is received from a Third Party without restriction and with the right to disclose such information or information developed in the performance of this Agreement;

c) the Receiving Party can demonstrate by competent pre-existing written evidence properly maintained as a formal business record was already in its possession without any limitation on its use or disclosure prior to its receipt from the Disclosing Party;

d) the Receiving Party can demonstrate by competent written evidence properly maintained as a formal business record was independently developed by or for the Receiving Party without reference to, use of or disclosure of the Disclosing Party's Confidential Information or information developed in confidence in the performance of this Agreement; or

e) is released from the restrictions set forth in this Agreement by the express prior written consent of the Disclosing Party, or in the case of information developed in confidence in the performance of this Agreement, the other Party.

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

9.1.3 Authorized Disclosures. Each Party may disclose Confidential Information and/or Information developed in confidence in the performance of this Agreement to the extent that such disclosure is:

a) made in response to a valid relevant unappealed or unappealable order of a court of competent jurisdiction or other Regulatory Authority or any political subdivision or regulatory body thereof of competent jurisdiction; provided that the Receiving Party shall first have, if reasonably possible, given notice to the Disclosing Party and given the Disclosing Party, at such Disclosing Party's own expense, a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information and/or Information developed in confidence in the performance of this Agreement or documents that are the subject of such order be held in confidence by

such court or Regulatory Authority or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such order shall be limited only to that information which is legally required, in the opinion of legal counsel to the Receiving Party, to be disclosed in such response to such court or governmental order;

b) otherwise required by Applicable Law or the requirements of a major national securities exchange, in the opinion of legal counsel to the Receiving Party, provided that the Party disclosing such Confidential Information shall exercise its commercially reasonable efforts to obtain a protective order or other reliable assurance that confidential treatment will be accorded and if possible give the other Party a reasonable opportunity to review and comment on any such disclosure in advance thereof (but not less than five (5) Business Days, if possible, prior to the date of such disclosure);

c) made to an applicable Regulatory Authority as useful or required in connection with any filing, application or request for Regulatory Approval; provided that reasonable measures shall be taken to assure confidential treatment and narrowest possible use and disclosure of such information;

d) (i) reasonably necessary in filing or prosecution of patents or other intellectual and/or industrial property rights covering the manufacture, use or sale of Unoprostone or the Licensed Product(s) or (ii) reasonably necessary in defending litigation related to Licensed Patents if such litigation relates to this Agreement, and in each case of (i) and (ii), provided that the Receiving Party or Party disclosing information developed in confidence in the performance of this Agreement, if such disclosure is non-confidential, gives reasonable advance notice to the Disclosing Party, or other Party in the case of information developed in confidence in the performance of this Agreement, of such disclosure; and

e) to the extent necessary, and subject to subcontracting provisions set forth in this Agreement, to its Affiliates, directors, officers, employees, consultants, sublicensees of SPA or RTU (or bona fide potential sublicensees of SPA or RTU), vendors and clinicians, under written agreements of confidentiality substantially similar or at least as restrictive as those set forth in this Agreement, who have a need to know such information in connection with a Party performing its obligations or exercising its rights under this Agreement; provided, that either Party may enter into such written agreements that provide for shorter timeframes for maintaining confidentiality than those set forth in this Agreement with the written consent of the other Party.

9.2 Patient Information. The Parties shall abide (and cause their respective Affiliates to abide), and take (and cause their respective Affiliates to take) all reasonable and appropriate actions to ensure that

all Third Parties conducting or assisting with any clinical development activities hereunder in accordance with, and subject to the terms of, this Agreement, shall abide, to the extent applicable, by all Applicable Law concerning the confidentiality or protection of patient identifiable information and other patient protected health information, the confidentiality of Confidential Information and the patentability of any concepts, ideas, or inventions developed incident to the performance of this Agreement.

9.3 Use of Name and Disclosure of Terms. Each Party shall keep the existence of, the terms of and the transactions and the subject matter covered by this Agreement confidential and shall not disclose such information to any Third Party through a press release, publication, promotional material, other form of publicity or otherwise, or, except as expressly permitted in this Agreement, mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates in any manner without the prior written consent of the other Party in each instance. The restrictions imposed by this Section shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law, rule or regulation or the requirements of a major national securities exchange or another similar regulatory body, provided that any such disclosure shall be governed by this Article and that the other Party is given a reasonable opportunity to review and comment on any such press release or public communication in advance thereof (but not less than five (5) Business Days prior to the date of disclosure). Further, the restrictions imposed on each Party under this Section are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to this Article. Each Party agrees that it shall obtain its own legal advice with regard to its compliance with securities laws, rules and regulations, and will not rely on any statements made by the other Party relating to such securities laws, rules and regulations.

Article 10. Intellectual Property Rights

10.1 RTU Intellectual Property Rights. As between the Parties, RTU and its Affiliates shall have sole and exclusive ownership of all right, title and interest (subject to the licenses granted in this Agreement) in and to any and all Licensed Patents (in case of joint patent with SPA, those rights shall include only the RTU portion of the joint rights), Licensed Know-How and Product Trademarks in the SPA Territory.

10.2 Patent Filing Prosecution and Maintenance. Subject to Article 2 (*NDA Transfer)* RTU, acting through patent counsel of its choice, and at its own sole discretion, as to which claims, shall be responsible for the preparation, filing, prosecution, maintenance and/or defense of the Licensed Patents in SPA Territory. RTU will notify SPA and its Affiliates within thirty (30) days in the event that RTU decides not to prepare, file, prosecute, maintain and/or defend the Licensed Patents in SPA Territory. SPA or its Affiliates shall then have the right and option to do so at its own expense and shall own any resulting patent applicable or patent. Such rights of SPA would be in addition to, and not replace, any other rights and remedies of SPA's available by law and/or this Agreement.

10.3 Information and Cooperation. RTU shall (i) provide SPA with copies of all patent applications filed with respect to the Licensed Product and other material submissions and correspondence with the

U.S. Patent and Trademark Office and other patent offices, in sufficient time to allow for review and comment by SPA, (ii) provide SPA and its patent counsel with an opportunity to consult with RTU and its patent counsel regarding the filing and contents of any such application, amendment, submission or response and (iii) provide notice of filing of new Licensed Patents to SPA within ten (10) Business Days of such filing. RTU hereby agrees that the advice and suggestions of SPA and its patent counsel shall be taken into reasonable consideration by RTU and its patent counsel in connection with each filing.

10.4 Product Trademarks. RTU shall be responsible for the filing, prosecution, defense and maintenance before all trademark offices of all Product Trademarks and using commercially reasonable efforts to ensure Product Trademarks exist in SPA Territory, and are kept in good standing for an initial period of ten (10) years with three (3) ten (10) year automatic renewals. If, at the end of the Term, SPA wishes to continue to sell the Licensed Product under the Product Trademark, RTU shall grant SPA an exclusive license in SPA Territory to continue to use the Product Trademark for an additional ten (10) years with the option to renew for two (2) additional terms of ten (10) years each. If RTU chooses not to prepare, file, prosecute, maintain or defend Product Trademarks in SPA Territory, then SPA or its Affiliates shall have the right and option to do so at its own expense. At SPA's request, RTU shall register domain names containing the Rescula trademark. SPA shall be responsible for the filing, prosecution, defense and maintenance before all trademark offices of all Alternative Trademarks.

10.5 Intellectual Property Legal Actions.

10.5.1 Notice of Third Party Infringement, Opposition or Interference. In the event (ia) either Party becomes aware of any possible infringement, opposition of or interference with any Licensed Patent Rights or Licensed Know-How relating to the Licensed Product or any Product Trademark in the SPA Territory, (ii) either Party becomes aware of the submission by any Third Party of regulatory filing in SPA Territory for a product that includes the manufacture, use or sale of Unoprostone, or (iii) either Party becomes aware of any infringement, interference, opposition, or a nullity action being filed against any Licensed Patent by a Third Party (each, an "**Infringement**"), that Party shall promptly notify the other Party and provide it with all details of such Infringement of which it is aware (each, an "**Infringement Notice**").

10.5.2 SPA's Right to Enforce. In the event of an Infringement, RTU shall have the first right and option to initiate legal proceedings or take other commercially reasonable steps regarding such Infringement. If RTU does not take or initiate commercially reasonable steps to initiate legal proceedings or take other actions regarding the Infringement within ten (10) days from any Infringement Notice, then SPA or its Affiliates shall have the right and option to do so at its own expense.

10.5.3 No Settlement and Allocation of Damages. Neither Party shall settle any Infringement claim or proceeding under this Article that would limit the rights of a Party hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. If either SPA and/or RTU collects any settlement or judgment from any

Third Party Infringers, the Parties shall first allocate any such amounts to each Party equal to their respective attorneys' fees and litigation costs. Any additional amounts collected shall be payable to SPA.

10.5.4 Right to Represent. RTU and its Affiliates shall have the right, at their own expense, to participate and be represented by counsel that it selects, in any legal proceedings or other action instituted under this Article by SPA.

10.5.5 Cooperation. In any action, suit or proceeding instituted under this Article, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such action, suit or proceeding, the other Party shall join therein and shall be represented using counsel of its own choice, at the requesting Party's expense.

Article 11. Term and Termination

11.1 Term

11.1.1 If no Order is submitted from SPA to RTU, or no Clinical Trials are initiated from two (2) years of the Effective Date, then this Agreement shall terminate without further consideration or notice; OR

11.1.2 With respect to each Licensed Product, the term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Agreement, shall expire upon the later of (i) a period of ten (10) years, or (ii) the expiry of all Product Valid Claims in SPA Territory with respect to such Licensed Product, or (iii) the loss of Data Exclusivity with respect to such Licensed Product. If this Agreement expires (*i.e.*, not terminated pursuant to Section 11.2, *Termination for Material Breach*), then, at RTU's request, the Parties shall negotiate in good faith the terms by which SPA could continue to promote or co-promote and distribute the Licensed Product or SPA will sell back to RTU, and RTU will repurchase from SPA, at SPA's actual cost, remaining inventory with greater than twelve (12) months remaining shelf life.

11.2 Termination.

11.2.1 Termination for Material Breach. In the event of an alleged material breach of this Agreement by a Party, the other Party must give the Party that is allegedly in default notice thereof if such non-breaching party intends to terminate the Agreement pursuant to this Section 11.2.1. Any dispute regarding an alleged material breach of this Agreement shall be resolved in accordance with this Article. It is the Parties' express intent that consideration shall first and foremost be given to remedying any breach of this Agreement through the payment of monetary damages or such other legal or equitable remedies as shall be appropriate under the circumstances, as decided, in each case, according to the provisions of Section 14.1.2 (*Dispute Resolution)*, and that there shall only be a limited right to terminate this Agreement as a matter of last resort. If,

however, a Party receives a notice of material breach that relates solely to the payment of amounts due hereunder, and (i) there is no dispute as to the amounts owed and (ii) such breach for non-payment is not cured within ninety (90) days after receipt of such notice, the notifying Party shall be entitled to immediately terminate this Agreement by giving written notice to the defaulting Party. In the event that the neutral (as defined in Section 14.1.2 (*Dispute Resolution*)), in accordance with the procedures set forth in Section 14.1.2, has rendered a ruling that a Party has materially breached this Agreement, which ruling specified the remedies imposed on such breaching Party for such breach, and the breaching Party has failed to comply with the terms of such adverse ruling within the time period specified therein for compliance, or if such compliance cannot be fully achieved by such date, the breaching Party has failed to commence compliance and/or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible, or in the event the material breach cannot be remedied, then in each case the non-breaching Party shall then in each case the non-breaching Party shall have the following rights:

a) if SPA is the breaching Party that failed to cure such breach or, if applicable comply with an adverse ruling and if the basis for such breach is SPA's failure to abide by a material obligation under this Agreement, RTU may terminate this Agreement with respect only to such specific Licensed Product(s) to which such breach relates to by delivering written notice to SPA after the expiration of the period during which SPA was to comply as set forth in the adverse ruling (if applicable) or may at its option continue this Agreement in effect and seek monetary or relief against SPA in an amount commensurate with the damages suffered; and

b) if RTU is the breaching Party that failed to cure such breach or, if applicable, comply with an adverse ruling and if the basis for such breach is RTU's failure to abide by a material obligation under this Agreement, SPA may terminate this Agreement with respect only to such specific Licensed Product(s) to which such breach relates to by delivering written notice to RTU after the expiration of the period during which RTU was to comply as set forth in the adverse ruling (if applicable) or may at its option continue this Agreement in effect and seek monetary or relief against RTU in an amount commensurate with the damages suffered.

11.2.2 Termination for Insolvency. In the event a Party files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

11.2.3 Termination for Licensed Product Withdrawal or Material Adverse Event. In the event the Licensed Product is withdrawn from the market by a Regulatory Authority in any country in the

world or a material Adverse Event occurs, then SPA may terminate this Agreement effective immediately upon written notice to RTU.

11.3 Consequences of Termination of Agreement in its Entirety. Upon any termination of this Agreement by a Party pursuant to Sub-Sections 11.2.1 or 11.2.2:

11.3.1 the licenses granted by RTU to SPA under this Agreement shall terminate and any and all rights and properties (including Regulatory Filings) provided to SPA hereunder shall revert to RTU;

11.3.2 with respect to all Clinical Studies or post approval studies for any Licensed Product(s) being conducted as of the effective date of termination, the applicable Party shall end such Clinical Studies or post approval studies with respect to enrolled subjects in an orderly and prompt manner in accordance with Applicable Law, including any required follow up treatment with previously enrolled subjects, and all other Development, Commercialization and Promotion activities under this Agreement shall promptly cease.

11.3.3 each Party shall return, or if allowed by the other Party destroy (and soon thereafter provide to the other Party written certification evidencing such destruction), all data, files, records and other materials in its possession or control relating to the other Party's Technology, or containing or comprising the other Party's Confidential Information.

11.4 Consequences of Termination of Agreement with respect to a Licensed Product. Upon any termination of this Agreement with respect to a Licensed Product by a Party pursuant to Sub-Sections

11.4.1 the licenses granted by RTU to SPA under this Agreement shall terminate with respect to such terminated Licensed Product(s);

11.4.2 with respect to all Clinical Studies or post approval studies for such terminated Licensed Product being conducted as of the effective date of termination, the applicable Party shall end such Clinical Studies or post approval studies with respect to enrolled subjects in an orderly and prompt manner in accordance with Applicable Law, including any required follow up treatment with previously enrolled subjects, and all other Development, Commercialization and Promotion activities under this Agreement shall promptly cease.

11.5 Surviving Provisions. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination of this Agreement only to the extent expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of Articles 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, and 14 and all defined terms referenced in such Articles as will provide agreed meanings used in such Articles shall survive and govern any after termination claims, liabilities, disputes and rights and, to the extent applicable, all other Articles referenced in any such Article shall survive such termination. Without limiting the generality of the foregoing, the obligations of confidentiality non-disclosure and non use set forth in Article 9 of this Agreement and Intellectual Property set forth in Article 10 and Indemnification set forth in Article 13 shall survive for not less than ten (10) years past effective termination of this Agreement.

11.6 Continued Obligations. Upon expiration or termination of this Agreement, in whole or in part, for any reason, nothing herein shall be construed to release either Party from any accrued rights or obligations that matured prior to the effective date of such expiration or termination, nor preclude either Party from pursuing any right or remedy it may have hereunder or at law or in equity with respect to any breach of this Agreement.

Article 12. Representations and Warranties

12.1 Mutual Representations and Warranties. SPA and RTU each represents and warrants to the other, as of the Effective Date, as follows:

12.1.1 Corporate Power. Such Party is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.

12.1.2 Due Authorization. Such Party (i) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

12.1.3 Binding Agreement. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with the terms hereof subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

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

12.2 Compliance with Applicable Law. SPA and RTU each represents and warrants to the other that it shall comply, in all material respects, with Applicable Law relating to such Party's rights, duties, responsibilities and obligations set forth in this Agreement.

12.3 Intellectual Property – RTU Representations and Warranties.

12.3.1 Right to Grant Licenses. RTU represents and warrants to SPA that it has the right to grant to SPA rights and licenses within the scope set forth in this Agreement that is free and clear of any licenses, sublicenses and all encumbrances and RTU will not enter into an agreement that is inconsistent with the rights and licenses granted to SPA in this Agreement. RTU represents and

warrants that no agreements exist with Third Parties that limits or restricts use of the Licensed Patents.

12.3.2 No Existing Claims or Infringement. RTU represents and warrants that, to the best of its knowledge, with respect to all relevant patents and patent applications, trademarks and trademark applications in relation to the Licensed Patents and Product Trademarks, that all patents are valid and in good standing, all assignments for patents and patent applications have been appropriately obtained and recorded, all inventors have been correctly and appropriately listed, no inventorship disputes exist, and there is no claim or demand of any Person pertaining to, or any proceeding which is pending or to the best of its knowledge threatened, that challenges RTU's interest in or the validity of, scope of , infringement of or enforceability of the Licensed Patents or Product Trademarks or makes any adverse claim of inventorship or ownership thereof. None of the relevant patents and patent applications, trademarks and trademark applications in the Licensed Patents and Product Trademarks are the subject of any ongoing infringement by any Third Party or any pending or, to RTU's knowledge, threatened adverse claim, judgment, injunction, order, decree or agreement restricting its use in connection with the Licensed Product.

12.3.3 Disclosure and Delivery. RTU represents and warrants that at the time of disclosure and delivery of the Licensed Patents and Product Trademarks to SPA, RTU shall, to the best of its knowledge, have the full right and legal capacity to disclose and license the Licensed Patents and Trademark Applications without violating the rights of Third Parties.

12.3.4 Maintaining Existing Licenses and Rights. RTU represents and warrants that RTU shall maintain all rights and licenses executed by RTU as of the Effective Date that materially affect SPA's rights set forth in this Agreement. All such licenses are listed in Exhibit B (*Licensed Patents*) to this Agreement. In the event RTU receives notice that it is in breach of any such rights or license, RTU represents and warrants that it shall give prompt written notice to SPA and take all actions to cure such breach, including at SPA's option, allowing SPA to cure such breach if possible without impairing SPA's legal rights and remedies set forth in this Agreement. RTU represents and warrants that RTU shall use commercially reasonable efforts to ensure Product Trademarks exist in each country in SPA Territory and are kept in good standing for an initial period of ten (10) years with ten (10) year automatic renewals, as listed in Exhibit D (Product Trademarks) to this Agreement, which shall be updated from time to time.

12.3.5 Future Authorizations. RTU shall obtain and maintain during the Term all authorizations, consents and approvals, governmental or otherwise, necessary for RTU to grant the rights and licenses granted by RTU under this Agreement.

12.4 No Debarment. Each Party certifies that as of the Effective Date, neither it, nor any of its employees or agents that will be performing hereunder have ever been or are currently, or are the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a

Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual. Each Party further agrees that if, during the Term, it, or any of its employees or agents, become, or are the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual, such Party shall notify the other and shall prohibit such employee or agent from performing on its behalf under this Agreement. This provision shall survive termination or expiration of this Agreement for a period of ten (10) years. For purposes of this provision, the following definitions shall apply:

12.4.1 "**Debarred Individual**" means an individual who has been debarred by the Food and Drug Administration (FDA) pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug product application or is similarly debarred under corresponding Applicable Law outside of the United States but in the SPA Territory.

12.4.2 "**Debarred Entity**" means a corporation, partnership or association that has been debarred by the Food and Drug Administration (FDA) pursuant to 21 U.S.C. §335a(a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity or is similarly debarred under corresponding Applicable Law outside of the United States but in the SPA Territory..

12.4.3 "**Excluded Individual**" or "**Excluded Entity**" means (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA) or is similarly debarred under corresponding Applicable Law outside of the United States but in the SPA Territory..

12.4.4 "**Convicted Individual**" or "**Convicted Entity**" means an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a(a) or 42 U.S.C. §1320a — 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible or is similarly debarred under corresponding Applicable Law outside of the United States but in the SPA Territory..

12.5 No Litigation. RTU represents and warrants that there is no threatened, pending or settled litigation with respect to the Unoprostone or the Licensed Product or that may affect in any way RTU's ability to grant the rights and licenses granted by RTU under this Agreement.

12.6 No Additional Material Information. RTU represents and warrants that, to the best of its knowledge, there is no material information that has not been provided to SPA that may be relevant to the transaction contemplated by this Agreement.

12.7 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE MANUFACTURE OF LICENSED PRODUCT, ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY 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 NONINFRINGEMENT.

12.8 Limited Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, EXCEPT IN CIRCUMSTANCES OF INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES, OR WITH RESPECT TO (I) INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS SET FORTH IN ARTICLE 13 (INDEMNIFICATION; INSURANCE), NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS OR LOST REVENUES, OR COST/EXPENSE OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY.

Article 13. Indemnification; Insurance

13.1 Indemnification by SPA. SPA agrees to indemnify, defend and hold harmless RTU and its Affiliates and their respective employees, agents, officers, directors and permitted assigns ("**RTU Indemnitees**") from and against any Third Party claims, judgments, expenses (including reasonable attorneys' fees), damages and awards (collectively a "**Third Party Claim**") arising out of or resulting from the following events:

13.1.1 improper storage or handling of the Unoprostone or the Licensed Product by SPA or its Affiliates or sublicensees including but not limited to failure to comply with CMC specifications, practices or procedures filed in support of the NDA for the Licensed Products;

13.1.2 SPA's negligence or willful misconduct in regard to its performance, or non-performance, under this Agreement including but not limited to its compliance with cGMP law and regulations and filed CMC requirements of the NDA for the Licensed Products; or

13.1.3 a breach of any of SPA's representations or warranties hereunder;

except, in the respective events, to the extent that such Third Party Claim arises out of or results from the gross negligence or willful misconduct of any RTU Indemnitee;

13.1.4 any personal injury and /or product liability of arising from the inherent safety of the Drug Substance, Drug Product or Commercial Product.

13.2 Indemnification by RTU. RTU agrees to indemnify, defend and hold harmless SPA and its Affiliates and their respective employees, agents, officers, directors and permitted assigns ("**SPA**

Indemnitees") from and against any Third Party Claim arising out of or resulting from the following events:

13.2.1 improper storage, handling, manufacturing, formulation or contamination of the Unoprostone or the Licensed Product by RTU or its Affiliates Agreement including but not limited to its compliance with cGMP law and regulations and filed CMC requirements of the NDA for the Licensed Products;

13.2.2 Infringement of Third Party intellectual property rights by the manufacture, use or sale of Licensed Products pursuant to the terms and conditions of this Agreement or the filing and prosecution of any Licensed Patents or Licensed Know-How or any Product Trademark;

13.2.3 failure by RTU or any Affiliate or subcontractor of RTU to supply Licensed Product in accordance with the Specifications and Applicable Law including but not limited to its compliance with cGMP law and regulations and filed CMC requirements of the NDA for the Licensed Products;

13.2.4 any product liability claims arising from quality defect of the Product;

13.2.5 Non-Conforming Product as set forth in Unoprostone Supply Agreement, Section 2.3.2;

13.2.6 RTU's and/or its subcontractors' negligence or willful misconduct in regard to its performance, or non-performance, under this Agreement; or

13.2.7 a breach of any of RTU's representations or warranties hereunder;

except, in the respective events, to the extent that such Third Party Claim arises out of or results from the gross negligence or willful misconduct of any SPA Indemnitee.

13.3 Procedures for Indemnification. The obligations of an indemnifying Party under Section 13.1 and Section 13.2 shall be governed by and contingent upon the following:

13.3.1 Notice of Claim. Each Party shall give the other Party prompt written notice of any Third Party Claim (an "Indemnification Claim Notice"). Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of the loss claimed (to the extent that the nature and amount of such loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any such Third Party Claim. The indemnifying Party shall not be required to provide indemnification notice with respect to a Third Party Claim to the extent that the defense of such Third Party Claim is materially prejudiced by the failure to give timely notice by the indemnified Party or the intentional misconduct of the indemnified Party.

13.3.2 Assumption of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the indemnified Party within fourteen (14) days after the indemnifying Party's receipt of an Indemnification Claim Notice or sooner if necessary. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be

construed as an acknowledgement that the indemnifying Party is liable to indemnify any SPA Indemnitees or RTU Indemnitees (as applicable) in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any indemnified Party's claim for indemnification.

13.3.3 Control of the Defense. Upon the assumption of the defense of a Third Party Claim by the indemnifying Party:

a) the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party, which shall be reasonably acceptable to the indemnified Party;

b) the indemnified Party shall promptly deliver to the indemnifying Party all original notices and documents (including court papers) received by the indemnified Party in connection with the Third Party Claim; and

c) except as expressly provided in Section 13.3.4, the indemnifying Party shall not be liable to the indemnified Party for any legal expenses subsequently incurred by such indemnified Party or any SPA Indemnitee or RTU Indemnitee (as applicable) in connection with the analysis, defense or settlement of the Third Party Claim. To the extent that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless an Indemnitee from and against the Third Party Claim, the indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including reasonable attorneys' fees and costs of suit) and any loss incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such indemnified Party or Indemnitee.

13.3.4 Right to Participate in the Defense. Without limiting Section 13.3.2 or Section 13.3.3, any SPA Indemnitee or RTU Indemnitee (as applicable) shall be entitled to participate in, but not control, the defense of a Third Party Claim and to retain counsel of its choice for such purpose; provided that such retention shall be at its own expense unless, (i) the indemnifying Party has failed to assume the defense and retain counsel in accordance with Section 13.3.2 (in which case the indemnified Party shall control the defense), or (ii) the interests of the Indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under Applicable Law, ethical rules or equitable principles.

13.3.5 Settlement. The indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of any Third Party Claim, on such terms as the indemnifying Party, in its reasonable discretion, shall deem appropriate; provided that:

a) the sole relief provided is the payment of money damages;

b) the consent, settlement or other disposition does not, and will not, result in a finding or admission of any negligence, intentional malfeasance, violation of any Applicable Law or any violation of the rights of any person and does not effect on any other claims that may be made against the indemnified Party;

c) the consent, settlement or other disposition does not, and will not, result in the indemnified Party's rights under this Agreement being adversely affected; and

d) the consent, settlement or other disposition does not, and will not, result in the indemnified Party becoming subject to injunctive or other relief or otherwise will adversely affect the business of the indemnified Party in any manner.

With respect to all other Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.3.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Third Party Claim with the prior written consent of the indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Third Party Claim by an indemnified Party that is reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

13.3.6 Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the indemnified Party shall, and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the indemnified Party for any out-of-pocket expenses in connection therewith.

13.4 Insurance. Each Party shall obtain and carry in full force and effect the minimum insurance requirements set forth herein, which shall protect Indemnitees with respect to events covered by Section 13.1 and Section 13.2. Such insurance (i) shall be primary insurance with respect to each Party's own participation under this Agreement, (ii) shall be issued by a recognized insurer rated by A.M. Best "A-VII" (or its equivalent) or better, or an insurer pre-approved in writing by the other Party, (c) shall list the other Party as an additional named insured thereunder, and (d) shall require thirty (30) days written

notice to be given to the other Party prior to any cancellation, non-renewal or material change thereof. The types of insurance, and minimum limits shall be General liability insurance with a minimum limit of [*] per occurrence and [*] in aggregate. General liability insurance shall include, at a minimum, Professional Liability, Clinical Trial Insurance and, beginning at least thirty (30) days prior to First Commercial Sale of the Licensed Product, product liability insurance. Upon request by a Party, the other Party shall provide Certificates of Insurance evidencing compliance with this Section. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement during any period in which such Party continues to make, to have made, to use, to offer for sale, to sell or to import a product that was the Licensed Product under this Agreement, and thereafter for a period of five (5) years. Notwithstanding the foregoing, either Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies.

Article 14. Miscellaneous

14.1 Governing Law; Dispute Resolution.

14.1.1 Governing Law. This Agreement and all disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the substantive laws of New York, United States of America, without regard to conflict of laws principles, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. The Parties hereby exclude the application of or reference to the United Nations Convention on Contracts for the International Sale of Goods from this Agreement.

14.1.2 Dispute Resolution.

a) *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.

b) *Arbitration.* Any dispute, controversy or claim that arises out of or relates to this Agreement that is not resolved under Section 14.1.2(a) 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 Section 14.1.2(c) 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 professional knowledge of and experience in the regulation of and terms of trade of the ethical pharmaceutical industry.

c) *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:

(i) The arbitrators may not award or assess punitive damages against either party; and

(ii) 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.

14.2 Notices.

14.2.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing and in English, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand with written confirmation of receipt, by telefax with written confirmation of receipt issued by other means than by automated telefax response or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Sub-Section 14.2.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed by other means than automated telefax response) or upon receipt (at the place of delivery) if sent by an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered by internationally recognized overnight delivery service that maintains records of delivery as soon as practicable thereafter. This Section is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

14.2.2 Addresses for Notice.

For SPA: Sucampo Pharma Americas Inc.
4520 East West Highway
3rd Floor
Bethesda, MD 20814
USA

Attention: Legal Department
Fax: 301 961 3440

For RTU: R-Tech Ueno, Ltd.
4-1, Techno-Park
Sanda, Hyogo, 669-1339
Japan
Attention: Mr. Ryu Hirata
Facsimile Number: 81-795-60-7180

14.3 Equitable Relief. The Parties acknowledge and agree that the restrictions set forth in Article 10 (*Confidentiality and Non-Disclosure*) are reasonable and necessary to protect the legitimate interests of the Parties and that neither Party would have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of Article 10 (*Confidentiality and Non-Disclosure*) may result in irreparable injury to the other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of Article 10 (*Confidentiality and Non-Disclosure*) by a Party, the other Party may be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. Nothing in this Section is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

14.4 Amendment; Waiver. This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a written instrument signed by duly authorized representatives of each Party or, in the case of waiver, signed by duly authorized representatives of the Party or Parties waiving compliance. The delay or failure of any Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

14.5 No Third Party Beneficiaries. Except as set forth in Section 13.1 (*Indemnification by SPA)* and Sub-Section 13.2.2, the provisions of this Agreement are for the sole benefit of the Parties and their permitted successors and permitted assigns and none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, without limitation, any employee or creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement

or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

14.6 Relationship of the Parties. Nothing in this Agreement shall be construed (i) to create or imply a partnership, association, joint venture or fiduciary duty between the Parties, (ii) to make either Party the agent of the other for any purpose, (iii) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, or (d) to give either Party the right to bind the other or to create any duties or obligations between the Parties, except as expressly set forth herein. All Persons employed by a Party shall be employees of such Party and not of the other Party and all costs/expenses and obligations incurred by reason of such employment shall be for the account and expense of such Party. The Parties agree that the rights and obligations under this Agreement are not intended to constitute a partnership or similar arrangement that will require separate reporting for tax purposes in SPA Territory.

14.7 Assignment and Successors. This Agreement is personal to both Parties and neither Party shall sell, transfer, assign, delegate, pledge or otherwise dispose – other than SPA's right to sublicense under Article 4 (*Patent License Grants and Know-How Access)* of its rights or delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which shall not be unreasonably withheld, excepting always that each Party may, on providing written notice to the other Party, assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, without the written consent of the other Party to any of its Affiliates, or to any purchaser of all or substantially all of its assets and/or all or substantially all of its assets to which this Agreement relates or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation. Any permitted assignee of all of a Party's rights under this Agreement shall be deemed to be a party to this Agreement as though named herein; provided with respect to an assignment to an Affiliate, such assigning Party shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. Any attempted assignment or delegation in violation of this Section shall be void.

14.8 Binding Effect. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party, provided that such Party, if it survives, shall remain jointly and severally liable for the performance of such delegated obligations under this Agreement.

14.9 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties under this Agreement which is not within the reasonable control of the Party affected, not due to malfeasance, and which, with the exercise of due diligence could not have been avoided (**"Force Majeure"**), including, without limitation, fire, explosion, flood, earthquake, war, accident, strike, riot, terrorist attacks, civil commotion, acts of God, or the like, will not excuse such Party from the performance of its obligations or duties under this Agreement, but will suspend such performance during the continuation of Force Majeure. The Party prevented from

performing its obligations or duties because of Force Majeure shall be required to, as soon as reasonably possible, notify the other Party hereto of the occurrence and particulars of such Force Majeure and shall be required to provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure and with notice of the termination thereof. The Party so affected shall use reasonable efforts to avoid or remove such causes of nonperformance. Upon termination of Force Majeure, the obligation to perform any previously suspended obligation or duty shall promptly recommence.

14.10 Headings; References. Article, Section and Subsection headings are inserted for convenience of reference only and do not form a part of this Agreement. Unless otherwise specified, (i) references in this Agreement to any Article, Section or Exhibit shall mean references to such Article, Section or Exhibit of this Agreement, (ii) references in any section to any clause are references to such clause of such section, and (iii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or as amended if expressly stated in this Agreement.

14.11 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The term “including” as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties acknowledge and agree that: (i) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (ii) the terms and provisions of this Agreement shall be construed fairly as to all Parties and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

14.12 Severability. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions or parts thereof of this Agreement, or the application hereof to any circumstances, to be illegal, invalid or to be unenforceable in a final non-appealable order, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, in each case provided that the basic purpose and structure of this Agreement is not altered.

14.13 Entire Agreement. This Agreement and the Unoprostone Supply Agreement, and all subsequent related agreements, constitute the entire agreement between the Parties with respect to the subject matter of the Agreement. This Agreement supersedes all prior agreements and understandings, whether written or oral, with respect to the subject matter of the Agreement, including all confidentiality agreements entered in to between the Parties with respect to the subject matters hereof. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement. All Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In

the event of any inconsistency between any such Exhibits and this Agreement, the terms of this Agreement shall govern.

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

14.15 Expenses. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective attorneys and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

14.16 Further Assurance. Each Party shall perform all further acts and things and execute and deliver such further documents as may be reasonable and necessary or as the other Party may reasonably require to give effect to this Agreement.

14.17 License Survival During Bankruptcy. All rights and licenses granted under or pursuant to any Section of this Agreement are and shall otherwise be deemed to be "intellectual property" as that term is defined in Section 101(56) of Title 11, United States Code (the "Bankruptcy Code") or in other corresponding definitions under corresponding foreign bankruptcy codes under other Applicable Law in other country(ies) in the SPA Territory. Upon and after any Insolvency Event involving any Party, the other Party shall retain and may fully exercise all of its respective rights and elections under the applicable insolvency law, including, without limitation, rights and elections under Section 365(n) of the Bankruptcy Code or in other corresponding sections under corresponding foreign bankruptcy codes under other Applicable Law in other country(ies) in the SPA Territory to the extent applicable. Furthermore, upon and after any Insolvency Event involving any Party, the other Party shall be entitled to (i) a complete duplicate of, or complete access to, any such intellectual property, and such intellectual property, if not already in its possession, shall be promptly delivered to the non-insolvent Party, unless the insolvent Party elects to continue, and continues, to perform all of its obligations under this Agreement, and (ii) elect to refrain from treating this Agreement as terminated with respect to the intellectual property rights granted to it under this Agreement and instead retain its rights to such intellectual property, as such rights existed immediately before the Insolvency Event and without interference, for the duration of the term of this Agreement.

14.18 Press Release. Subject to Section 10.3 (*Use of Name and Disclosure of Terms)*, the Parties shall issue the Press Release attached hereto as Exhibit E(Press Release) on the Execution Date of this Agreement.

IN WITNESS WHEREOF, each of the Parties to this Agreement has caused one of its duly authorized representatives to execute this Agreement where provided below effective this 23 day of April 2009, on its behalf and in evidence of its intention to be bound to the terms, obligations, representations and warranties of this Agreement as set forth above.

For and on behalf of
Sucampo Pharma Americas, Inc.
By Its Duly Authorized Representative

Signature /s/ Gayle Dolecek
Name Gayle Dolecek, PD, MPH
Title SVP, Research and Development
Date April 23, 2009

For and On Behalf of
R Tech Ueno, Ltd.
By Its Duly Authorized Representative

Signature /s/ Yukiko Hashitera
Name Yukiko Hashitera
Title President
Date April 23, 2009

Exhibit A

Description of Unoprostone Isopropyl

Generic name:	Unoprostone Isopropyl (USAN)
Chemical names:	[*]
CAS No.:	120373-24-2
Structural Formula:	[*]

Exhibit B

[Separately filed with the Securities and Exchange Commission]

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Confidential

Exhibit C Licensed Patents

Title	Country	Application No	Filling Date	Patent No	Issue Date	Expiration date
Prostaglandins of the F series	USA	07/945594	9/16/1992	5221763	6/22/1993	7/15/2012
	Canada	565406	4/28/1988	1324129	11/9/1993	11/9/2010
Treatment of Ocular Hypertension with a Synergistic Combination for Ocular Administration	USA	07/703660	5/21/1991	5208256	5/4/1993	5/21/2011
	Canada	2042972-1	5/22/1991	2042972	10/15/1996	5/21/2011
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION	USA	07/704570	5/21/1991	5166175	11/24/1992	5/21/2011
	Canada	2042937-2	5/21/1991	2042937	4/30/2002	5/21/2011
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION FOR OPHTHALMIC USE	USA	07/899170	6/15/1992	5175189	12/29/1992	5/21/2011
	Canada	2042936-4	5/21/1991	2042936	4/30/2002	5/21/2011
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION	USA	08/031875	3/16/1993	5397797	3/14/1995	3/14/2012
	Canada	2042934-8	5/21/1991	2042934	4/23/2002	5/21/2011
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION	USA	08/487637	6/7/1995	5547968	8/20/1996	8/20/2013
	Canada	2061907-4	2/26/1992	2061907	4/8/2003	2/26/2012
INCREASING THE CHOROIDAL BLOOD FLOW	USA	07/867359	4/13/1992	5221690	6/22/1993	4/13/2012
	Canada	2065889-4	4/13/1992	2065889	8/27/2002	4/13/2012
TREATMENT OF OCULAR HYPERTENSION	USA	08/162386	12/7/1993	5432174	7/11/1995	8/24/2012
PROCESS FOR PRODUCTION OF PROSTAGLANDIN INTERMEDIATES	USA	07/937949	9/1/1992	5274130	12/28/1993	9/1/2012

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Confidential

Exhibit C Licensed Patents

Title	Country	Application No	Filling Date	Patent No	Issue Date	Expiration date
STABILIZATION OF A PROSTANOIC ACID COMPOUND	USA	08/202132	2/25/1994	5523461	6/4/1996	2/25/2014
Treatment of Optic Nerve Disorder with Prostanoic Acid Compounds	USA	08/613048	3/8/1996	5773471	6/30/1998	3/8/2016
	Canada	[*]	[*]			
TREATMENT OF OCULAR HYPERTENSION WITH A SYNERGISTIC COMBINATION	USA	09/220847	12/28/1998	6329426	12/1/2001	9/30/2018
PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF HYPERTENSION AND GLAUCOMA	Canada	2356912	12/25/1998	23536912	2/24/2009	12/25/2018
Apotosis Inhibitor	USA	09/816655	3/26/2001	7129272	10/31/2006	3/26/2021
	Canada	[*]	[*]			
Treatment of Ocular Hypertension and Glaucoma	USA	09/900021	7/9/2001	6458836	10/1/2002	7/9/2021
Treatment of Ocular Hypertension and Glaucoma	Canada	[*]	[*]			
CONTROL OF INTRAOCULAR PRESSURE DURING SURGERY	USA	09/645361	8/25/2000	6414021	7/2/2002	8/25/2020
[*]	USA	[*]	[*]			
	Canada	[*]	[*]			
[*]	USA	[*]	[*]			
	Canada	[*]	[*]			
[*]	USA(pro)	[*]	[*]			

Exhibit D

List of Trademarks **RESCULA**

Country	Application No.	Category	Application Date	Registration No.
USA	77/470526	Class 5	2008.5.9	
Canada	806022	Class 5	1996.3.4	806022

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit E

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Sucampo Acquires Rights to Rescula® for U.S. and Canada

Strengthens Sucampo's Prostone Product Portfolio
Potential for Label Expansion in Dry AMD

Bethesda, Maryland, and Tokyo, Japan — April 23, 2009 — Sucampo Pharmaceuticals, Inc., (NASDAQ: SCMP) and R-Tech Ueno, Ltd. (RTU) (Osaka Exchange Hercules code: 4573), today announced that Sucampo Pharma Americas, Inc. (SPA), a wholly owned subsidiary of Sucampo Pharmaceuticals Inc., licensed from RTU the commercialization rights to Rescula® (unoprostone isopropyl) in the United States and Canada, including all associated patents and other intellectual property. In addition, RTU will be the exclusive supplier of finished product to Sucampo.

Rescula was approved by the U.S. Food and Drug Administration (FDA) for the treatment of open-angle glaucoma and ocular hypertension in 2000. In addition to these approved indications, Sucampo management believes that Rescula has the potential to be a treatment for dry age-related macular degeneration (dry AMD). As a result, Sucampo plans to initiate a phase 2 clinical trial with Rescula for dry AMD in 2010.

Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman and Chief Executive Officer of Sucampo Pharmaceuticals, said, "We are very pleased to add Rescula to Sucampo's product portfolio, alongside Amitiza®. We look forward to re-launching Rescula for its currently approved indications and to developing it as a potential treatment for dry AMD. We believe Rescula will be an important and integral part of our product portfolio. Both Rescula and Amitiza are created from the prostone technology whose therapeutic potential I discovered in the 1980s and is also the basis for Sucampo's clinical and preclinical pipeline compounds. Rescula targets disorders caused by the aging process, which is consistent with the commercial focus of Sucampo and one of my abiding passions."

Ms. Yukiko Miyake-Hashitera, President and Chief Executive Officer of R-Tech Ueno Ltd., said, "I am very pleased with this agreement as it provides an opportunity for Rescula to significantly impact the quality of vision and quality of life of patients both in the U.S. and Canada. I have the utmost confidence that the potential of Rescula will be fully maximized."

Gayle Dolecek, P.D., M.P.H., Senior Vice President of Research & Development, Sucampo Pharmaceuticals, said, “Rescula’s safety profile and novel mechanism of action are two of its product attributes that provide a rationale for new indications. Its existing FDA approval status and safety profile should facilitate entry into clinical trials for dry AMD patients. If those trials are successful, Rescula will provide us the opportunity to meet the unmet medical needs of a substantial patient population.”

Stanley G. Miele, Senior Vice President of Sales & Marketing, Sucampo Pharmaceuticals, said, “This agreement provides Sucampo’s sales team with a second prostone product. As part of our future re-launch of Rescula, we will continue focusing on the Amitiza market segments we now serve, while establishing relationships and a collaborative approach with specialists who treat ocular disorders. This is a very nice fit for our commercial team.”

Terms of the Agreement

Under the terms of the agreement, Sucampo will hold the exclusive rights to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension. Sucampo also will have the right to develop Rescula for additional indications. Sucampo also will have the right of first refusal to commercialize in the U.S. and Canada any additional indications for which Rescula is developed by RTU. RTU will be exclusively responsible for supply of Rescula to Sucampo for the U.S. and Canada.

Sucampo will make an upfront payment to RTU of $3.0 million and will be responsible for additional milestone payments based on the achievement of specified development and commercialization goals. Sucampo will be responsible for the development, regulatory, and commercialization activities and expenses for Rescula in the U.S. and Canada.

As of April 1, 2009, RTU held six percent of the outstanding common stock of Sucampo Pharmaceuticals’ outstanding shares. Dr. Ueno, Chairman and Chief Executive Officer of Sucampo Pharmaceuticals, Inc., and his wife, Dr. Sachiko Kuno directly and indirectly own a majority of the capital stock of RTU. Dr. Ueno and Dr. Kuno do not hold any management or board positions with RTU. Dr. Ueno and Dr. Kuno are both members of the board of directors of Sucampo Pharmaceuticals and together directly or indirectly hold a substantial majority of the common stock of Sucampo Pharmaceuticals.

About Rescula (unoprostone isopropyl)

Rescula (unoprostone isopropyl) is a synthetic docosanoid that is administered topically as a liquid eye drop that activates the BK channels in cells within the retina. Sucampo management believes that this activation of BK channels lowers intraocular pressure (IOP) by increasing the outflow of aqueous humor. Clinical studies have shown that in patients with a mean baseline IOP of 23 mm Hg, unoprostone isopropyl lowers IOP by approximately 3 to 4 mm Hg throughout the day.

In clinical and preclinical studies Rescula has: increased ocular blood flow to the optic nerve and in the choroid; maintained visual field; delayed retinal degeneration induced by rhodoposin by inhibiting apoptosis; inhibited topographic and blood changes in an ischemic optic nerve head; and lowered intraocular pressure. SPA believes that these clinical effects suggest that Rescula could potentially be effective in the treatment of other ocular diseases.

Rescula received its first marketing approval in Japan in 1994 for the treatment of glaucoma and ocular hypertension.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Rescula is a registered trademark of RTU and has been licensed to Sucampo for use in the U.S. and Canada.

Amitiza is a registered trademark of Sucampo Pharmaceuticals, Inc.

About dry age-related macular degeneration (dry AMD)

More than 8 million people in the U.S. currently have age-related macular degeneration (AMD), a disease which causes damage to the retina resulting in loss of vision. AMD is the leading cause of irreversible blindness in adults, worldwide. The prevalence of AMD in the U.S. is expected to increase by more than 50 percent, to approximately 12 million by 2020. More than 85 percent of all people with intermediate and advanced AMD have the dry form, [1]

AMD is a disease associated with aging that gradually destroys sharp, central vision. Central vision is needed for seeing objects clearly and for common daily tasks such as reading and driving. AMD affects the macula, the part of the eye that allows the seeing of fine detail. The macula is located in the center of the retina, the light-sensitive tissue at the back of the eye. The retina instantly converts light, or an image, into electrical impulses or nerve signals, which are sent to the brain. Dry AMD occurs when the light-sensitive cells in the macula slowly break down, gradually blurring central vision in the affected eye. As dry AMD progresses, patients may see a blurred spot in the center of their vision. Over time, as less of the macula functions, central vision is gradually lost in the affected eye. The most common symptom of dry AMD is slightly blurred vision and a need for more light to read and do other tasks. Dry AMD generally affects both eyes, but vision can be lost in one eye while the other eye seems unaffected. [2] Currently, no drugs have been approved by regulatory authorities for the treatment of dry AMD.

About glaucoma

Glaucoma is a group of diseases that can damage the eye's optic nerve, or retina, resulting in vision loss and blindness. Glaucoma occurs when the normal fluid pressure inside the eyes slowly rises. However, with early treatment, one can often protect one's eyes against serious vision loss.

It is estimated that over 4 million Americans have glaucoma and that it accounts for 9 to 12 percent of all cases of blindness in the U.S. [3]

For more information visit: http://nei.nih.gov/health and http://www.glaucoma.org

Sources:

1. Retina Today, January/February 2007
2. National Eye Institute, Facts about Age-Related Macular Degeneration [NEI Health Information]

3 Glaucoma Research Foundation, Glaucoma Facts and Stats

About Sucampo Pharmaceuticals

Sucampo Pharmaceuticals, Inc., a biopharmaceutical company based in Bethesda, Maryland, focuses on the development and commercialization of medicines based on prostones. The therapeutic potential of prostones, which are bio-lipids that occur naturally in the human body, was first identified by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo Pharmaceuticals' Chairman and Chief Executive Officer. Dr. Ueno founded Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, Ph.D., founding Chief Executive Officer and currently Advisor, International Business Development and a Director.

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Sucampo markets Amitiza® (lubiprostone) 24 mcg in the U.S. for chronic idiopathic constipation in adults and Amitiza 8 mcg in the U.S. to treat irritable bowel syndrome with constipation in adult women. Sucampo also is developing the drug for additional gastrointestinal disorders with large potential markets. In addition, Sucampo has a robust pipeline of compounds with the potential to target underserved diseases, inclusive of age-related diseases, affecting millions of patients worldwide. Sucampo Pharmaceuticals, Inc. has three wholly owned subsidiaries: Sucampo Pharma Europe, Ltd., located in the UK; Sucampo Pharma, Ltd., located in Japan; and, Sucampo Pharma Americas, Inc., located in Maryland. To learn more about Sucampo Pharmaceuticals and its products, visit www.sucampo.com.

About R-Tech Ueno

R-Tech Ueno was founded in 1989 by Ryuji Ueno, M.D. Ph.D., Ph.D., and has been a pharmaceutical venture corporation focusing on research, development, manufacturing and sales promotion of prescription drugs mainly in the area of ophthalmic diseases. Products which we manufacture are Rescula eye drops, glaucoma and ocular hypertension drug and Amitiza capsules, Chronic Idiopathic Constipation and Irritable Bowel Syndrome drug. Utilizing the highest level of expertise in the field of ophthalmology, our “physicians oriented new drug innovation” is making advances into the development of new drugs that target ophthalmic diseases with no currently effective medications. We also offer comprehensive support services to venture companies which seek new drug development. R-Tech Ueno was listed on the Hercules, Osaka Stock Exchange on April 9, 2008. R-Tech Ueno contributes to the society and progress by developing effective pharmaceutical products which are derived from our own innovative ideas.

To learn more about R-Tech Ueno Ltd. and its products, visit http://www.rtechueno.com/en/index.php

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Sucampo Pharmaceuticals are forward-looking statements made under the provisions of The Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words “project,” “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “should,” “would,” “could,” “will,” “may” or other similar expressions. Forward-looking statements include statements about potential growth in the prevalence of particular diseases or conditions, including dry AMD, the commercial relaunch of Rescula and the ability of Sucampo to commercialize and market it, the potential utility of Rescula to treat additional indications and future clinical trials. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those described in Sucampo Pharmaceuticals’ filings with the Securities and Exchange Commission (SEC), including the annual report on Form 10-K for the year ended December 31, 2008 and other periodic reports filed with the SEC. Any forward-looking statements in this press release represent Sucampo Pharmaceuticals’ views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Sucampo Pharmaceuticals anticipates that subsequent events and developments will cause its views to change. However, while Sucampo Pharmaceuticals may elect to update these forward-looking statements publicly at some point in the future, Sucampo Pharmaceuticals specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

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EXHIBIT 31.1

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

I, Ryuji Ueno, 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: May 11, 2009

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

EXHIBIT 31.2

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

I, Jan Smilek, 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: May 11, 2009

/s/ JAN SMILEK
Jan Smilek
Chief Financial Officer
(Principal Financial and Accounting 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 period ended March 31, 2009 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: May 11, 2009

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

EXHIBIT 32.2

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

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

(1) The Quarterly Report on Form 10-Q for the period ended March 31, 2009 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: May 11, 2009

/s/ JAN SMILEK
Jan Smilek
Chief Financial Officer
(Principal Financial and Accounting Officer)