## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

to

OR

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

For the transition period from

Commission File Number: 001-33609

# SUCAMPO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation or organization)

**4520 East-West Highway, 3rd Floor Bethesda, MD 20814** (Address of principal executive offices, including zip code) **30-0520478** (I.R.S. Employer Identification No.)

(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  $\square$  No  $\square$ 

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

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

Large accelerated filer  $\Box$ 

Accelerated filer  $\square$ 

Non accelerated filer  $\Box$ (Do not check if a smaller reporting company) Smaller reporting company  $\Box$ 

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

As of October 27, 2011, there were 15,691,314 shares of the registrant's class A common stock outstanding and 26,191,050 shares of the registrant's class B common stock outstanding.

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## Condensed Consolidated Balance Sheets (Unaudited)

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December 21

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262

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58,468 16,574

(21,630) 53,830

149,273

(In thousands of U.S. dollars, except share data)

	Sep	tember 30, 2011	December 31, 2010
ASSETS:			
-			
Current assets:			
Cash and cash equivalents	\$	55,267	\$ 49,243
Investments, current		30,718	54,524
Product royalties receivable		10,563	10,516
Unbilled accounts receivable		1,774	1,097
Accounts receivable, net		1,139	731
Prepaid and income taxes receivable		-	702
Deferred tax assets, net		6,328	243
Restricted cash, current		15,113	15,113
Prepaid expenses and other current assets		1,663	2,374
Total current assets		122,565	134,543
Investments, non-current		1,248	5,028
Property and equipment, net		1,756	2,025
Deferred tax assets, non-current		5,974	4,178
Restricted cash, non-current		2,229	-
Other assets		9,046	3,499
Total assets	\$	142,818	\$ 149,273

## LIABILITIES AND STOCKHOLDERS' EQUITY:

Current liabilities:		
Accounts payable	\$ 6,254	\$ 4,199
Accrued expenses	18,533	10,216
Deferred revenue, current	2,642	4,987
Income taxes payable	1,668	-
Notes payable, current	 20,538	 19,522
Total current liabilities	49,635	 38,924
Notes payable, non-current	46,158	44,439
Deferred revenue, non-current	7,283	8,321
Other liabilities	3,766	3,759
Total liabilities	 106,842	 95,443

## Commitments (Note 7)

Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at September 30, 2011 and December 31, 2010; no shares issued and outstanding at September 30, 2011 and December 31, 2010	-	
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at September 30, 2011 and December 31, 2010;		
15,687,553 and 15,659,917 shares issued and outstanding at September 30, 2011 and December 31, 2010,		
respectively	156	
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at September 30, 2011 and December 31, 2010;		
26,191,050 shares issued and outstanding at September 30, 2011 and December 31, 2010	262	
Additional paid-in capital	59,500	
Accumulated other comprehensive income	17,843	
Treasury stock, at cost; 42,274 shares	(149)	
Accumulated deficit	(41,636)	
Total stockholders' equity	35,976	
Total liabilities and stockholders' equity	\$ 142,818	\$ 1

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

## SUCAMPO PHARMACEUTICALS, INC. Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) (Unaudited) Three and Nine Months Ended September 30, 2011 and 2010

(In thousands of U.S. dollars, except per share data)

	Three	Three Months Ended September 30					ed Sej	September 30,	
		2011		2010		2011		2010	
Revenues:									
Research and development revenue	\$	2,885	\$	9,072	\$	6,591	\$	15,918	
Product royalty revenue		10,563		10,400		30,724		29,785	
Co-promotion revenue		769		1,282		2,768		3,357	
Contract and collaboration revenue		155		154		463		459	
Total revenues		14,372		20,908		40,546		49,519	
Operating expenses:									
Research and development		8,725		6,262		25,838		16,483	
General and administrative		7,926		6,409		29,317		19,019	
Selling and marketing		2,243		2,602		6,689		7,102	
Total operating expenses		18,894		15,273		61,844		42,604	
Income (loss) from operations		(4,522)		5,635		(21,298)		6,915	
Non-operating income (expense):		()- )		-,		( ) )		- )	
Interest income		35		114		160		505	
Interest expense		(619)		-		(1,844)		-	
Other income (expense), net		1,224		(3,384)		(2,033)		(2,560)	
Total non-operating income (expense), net		640		(3,270)		(3,717)		(2,055)	
Income (loss) before income taxes		(3,882)		2,365		(25,015)		4,860	
Income tax benefit (provision)		(196)		(418)		5,009		(1,301)	
Net income (loss)	\$	(4,078)	\$	1,947	\$	(20,006)	\$	3,559	
Net income (loss) per share:									
Basic net income (loss) per share	\$	(0.10)	\$	0.05	\$	(0.48)	\$	0.09	
							_		
Diluted net income (loss) per share	\$	(0.10)	\$	0.05	\$	(0.48)	\$	0.09	
Weighted average common shares outstanding - basic		41,877		41,849		41,864		41,848	
Weighted average common shares outstanding - diluted		41,877		41,849		41,864		41,851	
Comprehensive income (loss):									
Net income (loss)	\$	(4,078)	\$	1,947	\$	(20,006)	\$	3,559	
Other comprehensive income (loss):									
Unrealized gain on investments, net of tax effect		100		12		108		5	
Foreign currency translation		(2,121)		4,161		1,161		2,546	
Comprehensive income (loss)	\$	(6,099)	\$	6,120	\$	(18,737)	\$	6,110	

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

## SUCAMPO PHARMACEUTICALS, INC. Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited)

(In thousands of U.S. dollars, except share data)

	Cla: Commo	ss A n Stock			Class B Common Stock			dditional Paid-In	Other Comprehensive		Treasury Stock			Accumulated			Total kholders'
	Shares	Amoun	t	Shares	Shares Amount		Capital Incom		Income	Shares		Amount Defic		Deficit	Equity		
Balance at December 31, 2010	15,659,917	\$	156	26,191,050	\$	262	\$	58,468	\$	16,574	-	\$	-	\$	(21,630)	\$	53,830
Employee stock option expense	-		-	-		-		926		-	-		-		-		926
Stock issued upon exercise of stock options	25,500		-	-		-		98		-	-		-		-		98
Stock issued under employee stock purchase plan	2,136		-	-		-		8		-	-		-		-		8
Foreign currency translation	-		-	-		-		-		1,161	-		-		-		1,161
Unrealized gain on investments, net of tax effect	-		-	-		-		-		108	-		-		-		108
Treasury shares purchased, not retired	-		-	-		-		-		-	42		(149)		-		(149)
Net loss			-			-		-		-			-		(20,006)		(20,006)
Balance at September 30, 2011	15,687,553	\$	156	26,191,050	\$	262	\$	59,500	\$	17,843	42	\$	(149)	\$	(41,636)	\$	35,976

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

# SUCAMPO PHARMACEUTICALS, INC. Condensed Consolidated Statements of Cash Flows (Unaudited) Nine Months Ended September 30, 2011 and 2010 (In thousands of U.S. dollars)

	Nine Months Ended 2011	2010
	2011	2010
Cash flows from operating activities:		
Net income (loss)	\$ (20,006) \$	3,559
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,026	718
Loss on disposal of fixed assets	12	
Deferred tax provision	(7,774)	(32)
Stock-based compensation	926	88
Amortization of premiums on investments	600	1,25
Notes payable paid-in-kind interest	1,719	(1.00
Realized gain on trading securities	-	(1,08
Realized loss on settlement rights of auction rate securities	-	1,08
Changes in operating assets and liabilities:	(100)	(= 10
Accounts receivable	(408)	(5,49
Unbilled accounts receivable	(676)	(7
Product royalties receivable	(47)	62
Prepaid and income taxes receivable and payable, net	2,340	(1,41
Accounts payable	2,144	2,64
Accrued expenses	5,403	2,43
Deferred revenue	(2,994)	(10,05
Other assets and liabilities, net	656	23
Net cash used in operating activities	(17,079)	(4,99
Cash flows from investing activities:		
Purchases of investments	(20,598)	(77,49
Proceeds from sales of investments	7,380	13,20
Maturities of investments	40,205	65,24
Purchases of property and equipment	(284)	(24
Proceeds from disposals of property and equipment	79	
Purchases of intangible assets	(3,000)	
Restricted cash	(2,286)	
Issuance of notes receivable	(100)	
Net cash provided by investing activities	21,396	71
Cash flows from financing activities:		
Issuance of notes receivable, related parties	-	(71
Proceeds from exercise of stock options	98	
Proceeds from employee stock purchase plan	8	1
Purchase of treasury stock	(149)	
Dividend payments	-	(12,68
Net cash used in financing activities	(43)	(13,38
Effect of exchange rates on cash and cash equivalents	1,750	(97
Vet increase in cash and cash equivalents	6,024	(18,64
Cash and cash equivalents at beginning of period	49,243	61,42
Cash and cash equivalents at end of period	\$ 55,267 \$	
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of intangible assets included in accrued expenses	\$ 3,000 \$	
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The accompanying Notes are an integral part of these Condensed Consolidated Financial Statements.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)

#### 1. Business Organization and Basis of Presentation

#### **Description of the Business**

Sucampo Pharmaceuticals, Inc., or the Company, is an international pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds that occur naturally in the human body as a result of enzymatic, 15-PGDH, transformation of certain fatty acids. The Company believes that most prostones function as activators of selective cellular ion channels. As a result, prostones promote fluid secretion and enhance cell protection, including the recovery of cellular barrier function. This activity gives prostones wide-ranging therapeutic potential, particularly for age-related diseases. The Company is focused on developing prostone-based compounds for the treatment of gastrointestinal, ophthalmic, respiratory, vascular, and central nervous system diseases and other disorders for which there are significant unmet medical needs, underserved patients and significant commercial potential.

The therapeutic potential of prostones was first identified by one of our founders, Dr. Ryuji Ueno. To date, two prostone products have received marketing approval. AMITIZA<sup>®</sup> (lubiprostone) is a treatment approved by the U.S. Food and Drug Administration, or FDA, for chronic idiopathic constipation, or CIC, in adults of both genders and for irritable bowel syndrome with constipation, or IBS-C, in women aged 18 years and older. RESCULA<sup>®</sup> (unoprostone isopropyl) is FDA approved for the lowering of intra-ocular pressure, or IOP, in open-angle glaucoma or ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP lowering medications.

AMITIZA is being marketed and developed in the U.S. for gastrointestinal indications under a collaboration and license agreement, dated October 29, 2004, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda. The Company is primarily responsible for clinical development activities under the Takeda Agreement while Takeda is responsible for commercialization of AMITIZA. The Company and Takeda initiated commercial sales of AMITIZA in the U.S. for the treatment of CIC in April 2006 and for the treatment of IBS-C in May 2008. AMITIZA is currently being developed for the treatment of opioid-induced bowel dysfunction, or OBD. Takeda also holds marketing rights to AMITIZA in Canada, but has not yet commercialized it there. The Company has also entered into a supplemental agreement with Takeda on February 1, 2006, or the Supplemental Takeda Agreement, which consists of certain key funding streams, including reimbursements of co-promotion costs and reimbursements of the costs of miscellaneous marketing activities. The reimbursement of co-promotion costs under the Supplemental Takeda Agreement expired on May 31, 2011. Co-promotion costs after May 31, 2011 are reimbursed under the Takeda Agreement. The previous reimbursement terms of the Supplemental Takeda Agreement were centered on our sales team days in the field selling AMITIZA. The current terms are based on actual details presented to health care prescribers.

In Switzerland, lubiprostone was approved by Swissmedic, the Swiss Agency for Therapeutic Products for the long-term treatment of adult patients with CIC in November 2009. This is the first European regulatory approval and is the first prescription medicine to be approved in Switzerland for the long-term treatment of CIC. Currently, the Company is in discussion with the Swiss Federal Office of Public Health, or the BAG, for pricing approval. Initially, the Company intends to market AMITIZA, on a limited basis, in Switzerland starting in 2012.

In Japan, lubiprostone is being developed under a license, commercialization and supply agreement, or the Abbott Agreement, with Abbott Japan Co. Ltd., or Abbott. The Company has filed a new drug application, or a NDA, in Japan with the Pharmaceuticals and Medical Devices Agency, or PMDA, following the successful conclusion of a phase 3 efficacy trial and a phase 3 long-term safety trial of lubiprostone in Japanese CIC patients. The Company has had preliminary meetings with the PMDA and anticipates a decision by the Minister of Health, Labor and Welfare on the NDA in 2012. The Company continues to negotiate with third parties for the OBD indication, and Abbott will have 45 days to meet the terms and conditions of any third party bona fide offer.

Sucampo Pharma Europe, Ltd., or SPE, submitted a filing for approval of AMITIZA to treat CIC on August 4, 2011 in the United Kingdom, and the Company expects a decision by the Medicines and Healthcare products Regulatory Agency by the third quarter of 2012. The Company continues to evaluate the opportunities in the European Union based on the fact that lubiprostone is the only product approved by the FDA in the U.S. for chronic therapy for either CIC or IBS-C and that has received marketing authorization from Swissmedic in Switzerland.

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

Following the Company's acquisition of Sucampo AG, or SAG, based in Switzerland, the Company began and has continued integrating SAG for future operational efficiencies through a simplified group structure and consolidation of intellectual property. On June 10, 2011, Sucampo Manufacturing & Research AG, or SMR, a direct wholly owned subsidiary of the Company, merged into SAG and SAG assumed all existing obligations of SMR. On June 28, 2011, Sucampo AG Japan, or SAG-J, an indirect wholly owned subsidiary of the Company, merged into Sucampo Pharma, Ltd., or SPL, and SPL assumed all existing obligations of SAG-J. On September 29, 2011 the Company's subsidiaries SPA, SPL and SPE transferred certain intellectual property and licenses to SAG, and SAG entered into agreements with the subsidiaries to perform certain services related to the intellectual property, licenses and other business activities.

In April 2009, Sucampo Pharma Americas, Inc. or SPA, acquired the rights from R-Tech Ueno, Ltd. or R-Tech, a pharmaceutical research, development and manufacturing company in Japan that is majority owned by the Company's founders and a related party under the common control with SPA, to unoprostone isopropyl, which allows the Company to commercialize RESCULA in the U.S. and Canada for its approved indication and all indications for the use of unoprostone isopropyl developed by the Company and R-Tech. On September 29, 2011, SPA transferred these rights to unoprostone isopropyl to SAG. SAG entered into an agreement with SPA to perform certain activities related to those rights. On March 22, 2011, SAG entered into a license agreement with R-Tech for unoprostone isopropyl, expanding the Company's development and commercialization rights as well as its territories beyond their previously agreed territory of the United States and Canada to the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China, or the R-Tech Territory, or the SAG Territories. SAG is now evaluating the opportunities to obtain an appropriate label in the European Union and other European countries as well as obtaining reauthorization in those countries to commercialize unoprostone isopropyl.

Other prostone compounds in the Company's development plan include cobiprostone for the prevention of gastric ulcers and other gastrointestinal injuries in patients treated with non-steroidal anti-inflammatory drugs, or NSAIDs, for use as a treatment for chronic obstructive pulmonary disease, or COPD, oral mucositis in cancer patients and wound healing. Additionally, the Company is evaluating SPI-017 for use as a treatment of peripheral arterial disease, or PAD, and SPI-017/SPI-3608 as a potential treatment for the management of pain caused by spinal stenosis.

In September 2011, preclinical data were presented at the annual scientific meeting of the Japanese Biochemical Society, held in Kyoto, Japan, by Sachiko Tsukita, Ph.D., Professor at the Graduate School of Frontier Biosciences and Graduate School of Medicine, of Osaka University. These data demonstrate that lubiprostone significantly reduces expression of inflammatory cytokines (p<0.01) vs. the control in an animal model of inflammatory bowel disease, or IBD. In addition, lubiprostone significantly (p<0.01) protects the intestinal epithelial barrier function, as compared to the control, despite decreased expression levels of claudin4 and occludin.

In September 2011, the Company entered into a Loan Guarantee and Development Agreement, or Numab Agreement, with Numab AG, or Numab, a related party. It provides the Company with access to Numab's proprietary technology for the discovery of high-affinity antibodies against certain selected targets. The Company will have exclusive commercial rights to any biologic products successfully developed and commercialized in the course of the collaboration. The Numab Agreement presents an opportunity to maximize the Company's knowledge of a variety of targets that result in several large, underserved patient populations. By applying Numab's antibody technology to these targets, the Company plans to develop biologic products with a different mechanism of action that will be complementary to the prostone-based compounds the Company now has in development. Under the terms of the agreement, the Company will provide Numab with up to CHF 5.0 million as collateral for a loan to Numab from a third party. The Company may name up to four targets against which Numab is eligible for full time equivalent based payments and discovery success dependent fees. Any success dependent fees will result in a corresponding reduction in the amount of the available guarantee. Should Numab default its loan obligation, the collateral may be called upon to meet Numab's obligation under its loan agreement. As of September 30, 2011, the collateral of CHF 2.0 million has been deposited by the Company and Numab has utilized CHF 1.5 million of its loan available. In reviewing the amount outstanding, the Company has made an allowance of \$226,000 in respect to the collateral being called upon to meet potential loan default by Numab. If a biologic is successfully developed, Numab and the Company may enter into a license arrangement in which Numab will be entitled to clinical development milestone payments and increasing tireed royalties on net sales. The Company will be responsible for clinical development and will retain all commercial rights to any resu

In July 2011, the Company obtained the development and commercial rights to a peptide compound from CuroNZ, a New Zealand company, for a loan of \$100,000 that will augment the Company's ophthalmic development opportunities. CuroNZ will embark on a research effort for the development of the peptide compound late this year or next year.

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

#### **Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, and the rules and regulations of the Securities and Exchange Commission, or SEC, for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's Consolidated Financial Statements as of and for the year ended December 31, 2010 included in the Company's Annual Report on Form 10-K, which was filed with the SEC on March 8, 2011. The financial information as of September 30, 2011 and for the three and nine months ended September 30, 2011 and 2010 is unaudited. In the opinion of the Company's management, all adjustments, consisting only of normal recurring adjustments or accruals, considered necessary for a fair statement of the results of these interim periods have been included. The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

The Condensed Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiaries: SPL, which is based in Tokyo and Osaka, Japan, and conducts Asian operations under the direction of SAG; SPA, which is based in Bethesda, Maryland, and conducts operations in North and South America under the direction of SAG; SPE, which is based in Oxford, U.K., and conducts certain operations in Europe under the direction of SAG; SAG, which is based in Zug, Switzerland, and conducts certain operations in Europe and worldwide and directs the other subsidiaries to perform certain services related to its intellectual property, licenses and other business activities; and Ambrent Investments S.à r.l., or Ambrent, which is based in Luxembourg and conducts business in Luxembourg. The Company's reportable geographic segments are the United States, Asia, and Europe and 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 these subsidiaries. Such measures include the progress of research and development activities, collaboration and licensing efforts, commercialization activities and other factors. All significant inter-company balances and transactions have been eliminated.

In December 2010, the Company acquired SAG, a Swiss-based patent-holding company, and SAG-J, a patent maintenance company and a wholly owned subsidiary of SAG. The acquisition of SAG and its subsidiary was accounted for as a merger of companies under common control and accounted for at historical cost. The financial information of these acquired entities is included in these Condensed Consolidated Financial statements for all periods presented.

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

#### 2. Summary of Significant Accounting Policies

#### Cash and Cash Equivalents

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

#### **Restricted Cash**

Restricted cash amounted to approximately \$17.3 million and \$15.1 million at September 30, 2011 and December 31, 2010, respectively. Restricted cash represents cash required to be deposited with financial institutions in connection with the SPL and The Bank of Tokyo-Mitsubishi UFJ, Ltd. loan agreement (see Note 9 below), SAG's agreement with Numab (see Note 10 below) and operating leases.

#### Current and Non-current Investments

Current and non-current investments consist primarily of U.S. government agencies securities, U.S. commercial paper, municipal and corporate bonds, mutual funds and variable rate demand notes, or VRDNs. The Company classifies its investments into current and non-current based on their maturities and management's reasonable expectation to realize these investments in cash. The Company classifies all of its investments, as available for sale securities and reports unrealized gains or losses, net of related tax effects, in other comprehensive income.

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

#### Notes Receivable, Related Parties

Notes receivable represent amounts due from related parties and were paid in full subsequent to September 30, 2010.

#### 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 expenses, approximate their fair values based on their short maturities, independent valuations or internal assessments.

#### **Revenue Recognition**

The Company's revenues are derived primarily 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 evaluated the multiple deliverables within the collaboration and license agreements in accordance with the guidance of multiple deliverables to determine whether the delivered elements that are the obligation of the Company have value to other parties to the agreement on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate recognition of revenue is then applied to each separate unit of accounting. The Company's deliverables under the Takeda Agreement and the Abbott Agreement, including the related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 10 below.

The Company applies a time-based model of revenue recognition for cash flows associated with research and development deliverables under the Takeda Agreement. Under this model, cash flow streams related to each unit of accounting are recognized as revenue over the estimated performance period. Upon receipt of cash payments, such as development milestones, revenue is recognized to the extent the accumulated service time has occurred. The remainder is deferred and recognized as revenue ratably over the remaining estimated performance period. A change in the period of time expected to complete the deliverable is accounted for as a change in estimate and is recognized on a prospective basis. In cases where milestone payments are received after the completion of the associated development period, the Company recognizes revenue upon completion of the performance obligation. Revenue is limited to amounts that are nonrefundable and that the other party to the agreement is contractually obligated to pay to the Company. The Company recognizes reimbursable research and development costs under the Takeda Agreement as research and development revenue using a time-based model over the estimated performance period. The research and development revenue for these obligations is limited to the lesser of the actual reimbursable costs incurred or the straight-line amount of revenue recognized over the estimated performance period. Revenues are recognized for reimbursable costs only if those costs can be reasonably determined.

The Company applies a proportional-performance model using the percentage-of-completion method of revenue recognition for cash flows associated with research and development deliverables under the Abbott Agreement. Since the Company has previous research and development experience and the expected cost to complete the development can be reasonably estimated, the Company believes a proportional-performance methodology of revenue recognition is appropriate. Under this method, revenue in any period is recognized as a percentage of the total actual cost expended relative to the total estimated costs required to satisfy the performance obligations under the arrangement related to the development. Revenue recognized is limited to the amounts that are non-refundable and that the other party to the agreement is contractually obligated to pay to the Company. A change in the period of time expected to complete the deliverable is accounted for as a change in estimate and is recognized on a prospective basis. Research and development costs are not reimbursable under the Abbott Agreement.

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

The Company also entered into the Supplemental Takeda Agreement, which expired on May 31, 2011, consisted of the following key funding streams: reimbursements of co-promotion costs based upon a per-day rate and reimbursements of the costs of miscellaneous marketing activities, which the Company recognizes as revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts. Co-promotion costs after May 31, 2011 are reimbursed under the Takeda Agreement and the amounts recognized are based on amounts billed for actual details presented to health care prescribers.

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

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

The Company has determined that it is acting as a principal under the Takeda Agreement and the Supplemental Takeda Agreement, or the Takeda Agreements, and the Abbott Agreement and, as such, records revenue on a gross basis in the condensed consolidated statements of operations and comprehensive income (loss).

#### Contract Revenue

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

#### Foreign Exchange

The Company's Condensed Consolidated Financial Statements are reported in U.S. dollars. Assets and liabilities of each international subsidiaries with a non-U.S. dollar functional currency are translated to U.S. dollars at the exchange rates in effect on the balance sheet date, or the last business day of the period, if applicable. Revenues and expenses for these subsidiaries are translated to U.S. dollars using a weighted average rate for the relevant reporting period. Translation adjustments resulting from this process are included, net of tax, in accumulated other comprehensive income in the Condensed Consolidated Balance Sheets. Gains and losses that arise from exchange rate fluctuations for monetary asset and liability balances that are not denominated in an entity's functional currency are included within other income (expense), net in the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss).

#### Certain Risks, Concentrations and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents, restricted cash, investments and receivables. The Company places its cash, cash equivalents and restricted cash with highly rated financial institutions and invests its excess cash in highly rated investments. As of September 30, 2011 and December 31, 2010, approximately \$22.0 million, or 21.1%, and \$34.1 million, or 27.6%, respectively, of the Company's cash, cash equivalents, restricted cash and investments was issued or insured by the federal government or government agencies. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

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

The Company's products, AMITIZA and RESCULA, compete (or in the case of RESCULA, will compete) in a rapidly changing, highly competitive market, which is characterized by advances in scientific discovery, changes in customer requirements, evolving regulatory requirements and developing industry standards. Any failure by the Company to anticipate or to respond adequately or timely to scientific developments in its industry, changes in customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products could have a material adverse effect on the Company's business, operating results and future cash flows.

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

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

Revenues from one unrelated party, Takeda, accounted for 97.6% and 62.4%, of the Company's total revenues for the three months ended September 30, 2011 and 2010, respectively, and 96.6% and 75.0% for the nine months ended September 30, 2011 and 2010, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 98.0% and 99.9% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at September 30, 2011 and December 31, 2010, respectively. Revenues from another unrelated party, Abbott, accounted for 1.7% and 37.1% of the Company's total revenues for the three months ended September 30, 2011 and 2010, respectively, and 2.7% and 24.3% for the nine months ended September 30, 2011 and 2010, respectively. The Company depends significantly upon the collaborations with Takeda and Abbott and its activities may be impacted if these relationships are disrupted (see Note 10 below for additional details).

The Company has an exclusive supply arrangement with R-Tech to provide it with commercial and clinical supplies of its product and product candidates. Any difficulties or delays in performing the services under these arrangements may cause the Company to lose revenues, delay research and development activities or otherwise disrupt the Company's operations (see Note 8 below for additional details).

The Company has entered into the Numab Agreement. Under the terms of the agreement, the Company will provide Numab up to CHF 5.0 million as collateral for a loan to Numab from a third party. If Numab is unsuccessful with its development activities, Numab may default on the loan resulting in the loss of collateral.

#### Error in Previously Issued Financial Statements

The Company incorrectly classified certain VRDNs as cash equivalents rather than short-term investments in the financial statements reported in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010. The misclassification resulted in an immaterial error to the Company's quarterly Condensed Consolidated Balance Sheet and Statement of Cash Flows, whereby cash balances and net cash provided by investing activities were overstated by \$19.1 million for the nine months ended September 30, 2010. The September 30, 2010 cash flow statement has been revised.

#### **Recent Accounting Pronouncements**

In September 2009, the Financial Accounting Standards Board, or FASB, issued an amendment to the authoritative guidance which addresses how revenues should be allocated among products and services in a singular sales arrangement. The guidance establishes a hierarchy for determining the selling price of each product or service, with vendor-specific objective evidence, or VSOE, at the highest level, third-party evidence of VSOE at the intermediate level, and management's best estimate at the lowest level. It replaces "fair value" with "selling price" in revenue allocation guidance. It also significantly expands the disclosure requirements for multiple-deliverable revenue arrangements. This guidance is effective for agreements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company adopted the guidance effective January 1, 2011, and such adoption did not have a material impact on the Company's Condensed Consolidated Financial Statements.

In June 2011, the FASB issued an accounting update on Comprehensive Income-Topic 220: Presentation of Comprehensive Income, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, the Company must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. This update will be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. The Company is continuing to evaluate the impact that this amendment would have on its financial condition and results of operation upon adoption.

#### 3. Earnings per Share

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



### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

The computation of net income (loss) per share for the three and nine months ended September 30, 2011 and 2010 is shown below:

	Three	Months End	led S	eptember 30,	Nir	ne Months End	led September 30,			
(In thousands of U.S. dollars, except per share data)		2011	2010			2011		2010		
Basic net income (loss) per share:										
Net income (loss)	\$	(4,078)	\$	1,947	\$	(20,006)	\$	3,559		
Weighted average class A and B common shares outstanding		41,877		41,849		41,864		41,848		
Basic net income (loss) per share	\$	(0.10)	\$	0.05	\$	(0.48)	\$	0.09		
Diluted net income (loss) per share:										
Net income (loss)	\$	(4,078)	\$	1,947	\$	(20,006)	\$	3,559		
Weighted average class A and B common shares outstanding for diluted net income per share		41,877		41,849		41,864		41,851		
Diluted net income (loss) per share	\$	(0.10)	\$	0.05	\$	(0.48)	\$	0.09		

For the periods listed above, the potentially dilutive securities used in the calculations of diluted historical net loss per share as of September 30, 2011 and 2010 are shown below:

	Three Months Ende	ed September 30,	Nine Months Ended September 30				
(In thousands)	2011	2010	2011	2010			
Employee stock options	-	-	-	133			
Non-employee stock options	-	-	-	-			

For the periods listed above, the following securities were excluded from the computation of diluted net loss per share as their effect would be antidilutive as of September 30, 2011 and 2010 are shown below:

	Three Months Ended	September 30,	Nine Months Ended September				
(In thousands)	2011	2010	2011	2010			
Employee stock options	3,427	1,391	3,427	1,258			
Non-employee stock options	450	450	450	450			



#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

### 4. Current and Non-Current Investments

At September 30, 2011 and December 31, 2010, current and non-current available-for-sale investments consisted of the following securities:

	September 30, 2011								
n thousands of U.S. dollars)		Cost	U	Inrealized Gains	Unrealized Losses		Fa	ir Value	
Current:									
U.S. commercial paper	\$	2,995	\$	5	\$	-	\$	3,000	
U.S. government securities		5,251		-		(2)		5,249	
Municipal securities		2,065		-		(1)		2,064	
Corporate bonds		8,040		12		(2)		8,050	
Variable rate demand notes		12,355		-		-		12,355	
Total	\$	30,706	\$	17	\$	(5)	\$	30,718	
Non-current:									
U.S. government securities	\$	1,250	\$	-	\$	(2)	\$	1,248	
Total	\$	1,250	\$	-	\$	(2)	\$	1,248	

	December 31, 2010								
(In thousands of U.S. dollars)	Cost			Jnrealized Gains	Unrealized Losses		F	air Value	
Current:									
U.S. Treasury bills and notes	\$	1,002	\$	1	\$	-	\$	1,003	
U.S. commercial paper		999		-		-		999	
U.S. government securities		16,525		7		(4)		16,528	
Municipal securities		17,582		6		(12)		17,576	
Certificates of deposits		750		-		-		750	
Corporate bonds		6,665		5		(2)		6,668	
Variable rate demand notes		11,000		-		-		11,000	
Total	\$	54,523	\$	19	\$	(18)	\$	54,524	
Non-current:									
Corporate bonds	\$	5,019	\$	11	\$	(2)	\$	5,028	
Total	\$	5,019	\$	11	\$	(2)	\$	5,028	

The Company performs fair value measurements in accordance with the FASB's guidance for fair value measurements and disclosures, which defines fair value as the exchange price that would be received for selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy is established which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company classifies its investments into the following categories based on the three levels of inputs used to measure fair value:

Level 1: quoted prices in active markets for identical assets or liabilities;

Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

The Company's assets measured at fair value on a recurring basis, which are subject to the fair value disclosure requirements, as of September 30, 2011 and December 31, 2010 are as follows:

	Fair Value Measurements at Reporting Date Using							
September 30, 2011	In Mai id	ed Prices Active rkets for entical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs		Tetel		
(In thousands of U.S. dollars)	<u>(L</u>	evel 1)	(Level 2)	(Level 3)		Total		
U.S. government securities	\$	6,497	\$-	\$-	\$	6,497		
U.S. commercial paper		-	3,000	-		3,000		
Corporate bonds		8,050	-	-		8,050		
Municipal securities		2,064	-	-		2,064		
Money market funds		15,755	-	-		15,755		
Variable rate demand notes	_	12,355	-	-		12,355		
Total assets measured at fair value	\$	44,721	\$ 3,000	\$ -	\$	47,721		

	Fair Value Measurements at Reporting Date Using							
December 31, 2010 (In thousands of U.S. dollars)	In Mai id A	ed Prices Active rkets for entical Assets evel 1)	( Obs I	nificant Other servable nputs evel 2)	Significant Unobservabl Inputs (Level 3)	e		Total
U.S. Treasury bills and notes	\$	1,003	\$	-	\$	-	\$	1,003
U.S. government securities		16,528		-		-		16,528
U.S. commercial paper		-		999		-		999
Corporate bonds		11,696		-		-		11,696
Municipal securities		17,576		-		-		17,576
Certificates of deposits		-		750		-		750
Money market funds		780		-		-		780
Variable rate demand notes		11,000		-		-		11,000
Total assets measured at fair value	\$	58,583	\$	1,749	\$	-	\$	60,332

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

#### 5. Intangible Assets

In April 2009, SPA entered into an agreement with R-Tech to acquire all patents and other intellectual property rights related to RESCULA for its FDA approved indication and any new indications for unoprostone isopropyl in the U.S. and Canada. Although RESCULA eye drops have been approved by the FDA since 2000, RESCULA is not currently marketed in the U.S. or Canada. In September 2011, SPA transferred those rights to SAG, and SAG entered into an agreement with SPA to perform certain activities related to those rights. The Company plans to re-launch RESCULA in the U.S. for its approved indication after approval of an enhanced label from the FDA.

Under the terms of the 2009 R-Tech agreement, SPA made an upfront payment of \$3.0 million and may be required to pay up to \$5.5 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of \$500,000 is payable upon the re-launch of RESCULA for the treatment of glaucoma which is considered as being probable; therefore, this amount is recorded as part of the initial cost of the acquired assets. The Company allocated the acquisition cost between an intangible asset of \$3.4 million and a non-current prepaid inventory of \$85,000. As of September 30, 2011, both of which are reflected in other non-current assets in the accompanying condensed consolidated balance sheets. The Company is amortizing the \$3.4 million over the ten-year life of the license agreement, which management believes approximates the useful life of the underlying rights and data. Amortization expense was \$256,000 for the nine months ended September 30, 2011 and 2010. The annual amortization expense will be approximately \$342,000 through April 2019.

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

On March 22, 2011, SAG entered into a license agreement with R-Tech for unoprostone isopropyl, expanding the Company's development and commercialization rights as well as its territories beyond their previously agreed territory of the United States and Canada to the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China, or the R-Tech Territory, or the SAG Territories. This alliance ensures state of the art global development and commercialization between SAG and R-Tech for all current and potential indications.

SAG made an upfront payment to R-Tech of \$3.0 million, which is reflected in other non-current assets in the accompanying condensed consolidated balance sheets, and may be required to pay up to \$103.0 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of \$3.0 million is payable upon the earlier of product approval within the SAG Territories or by March 15, 2012, which is included within non-current assets, and the liability is reflected in accrued expenses in the accompanying condensed consolidated balance sheet. SAG will be responsible for all development, regulatory, and commercialization activities. The Company is amortizing the \$6.0 million over the 10-year life of the license agreement, which management believes approximates the useful life of the underlying rights and data. Amortization expense was \$300,000 for the nine months ended September 30, 2011. The annual amortization expense will be approximately \$600,000 through March 2021.

#### 6. Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2011 and December 31, 2010:

	September 30,		December 31,	
(In thousands of U.S. dollars)	2011		2010	
Research and development costs	\$	4,852	\$	4,146
Employee compensation		1,691		1,795
Selling and marketing costs		76		305
Legal service fees		7,805		2,620
RESCULA milestones		3,500		500
Other accrued expenses		609		850
Total	\$	18,533	\$	10,216

## 7. Commitments

#### **Operating Leases**

1. (110 1.1)

The Company leases office space in the United States, the United Kingdom, Japan and Switzerland under operating leases ranging through 2017. Total future minimum, non-cancelable lease payments under operating leases were as follows as of September 30, 2011:

(In thousands of U.S. dollars)	
2011 (October - December)	\$ 407
2012	1,399
2013	995
2014	1,024
2015	1,052
2016 and thereafter	 1,222
Total minimum lease payments	\$ 6,099

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

Rent expense for all operating leases was approximately \$376,000 and \$342,000 for the three months ended September 30, 2011 and 2010, respectively, and \$1.1 million and \$1.0 million for the nine months ended September 30, 2011 and 2010, respectively.

#### **Research and Development Costs**

The Company routinely enters into agreements with third-party contract research organizations, or 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.

#### 8. Related Party Transactions

#### R-Tech Ueno, Ltd.

In addition to the unoprostone isopropyl agreements described in Note 5 above, the Company is a party to other development and exclusive supply agreements with R-Tech covering various compounds and territories The Company's founders, Drs. Ueno and Kuno, directly or indirectly, own a majority of the stock of R-Tech.

The Company recorded the following expenses under its agreements with R-Tech for the three and nine months ended September 30, 2011 and 2010:

	Three Months Ended September 30,					Nine Months Ended September 3				
(In thousands of U.S. dollars)	2011 2010					2011	2010			
Clinical supplies	\$	-	\$	68	\$	-	\$	121		
Other research and development services		93		(1)		100		65		
Commercial supplies		21		152		144		304		
	\$	114	\$	219	\$	244	\$	490		

The following table summarizes the amounts included in deferred revenue resulting from the deferral of upfront payments relating to the exclusive supply agreements with R-Tech as of September 30, 2011 and December 31, 2010:

	Sept	tember 30,	Dec	ember 31,
(In thousands of U.S. dollars)		2011		2010
Deferred revenue, current	\$	434	\$	433
Deferred revenue, non-current		5,193		5,839
	\$	5,627	\$	6,272

The Company recognized approximately \$105,000 of revenue relating to its agreements with R-Tech for each of the three months ended September 30, 2011 and 2010, which was recorded as contract and collaboration revenue in the accompanying condensed consolidated statements of operations and comprehensive income (loss).

#### Numab, AG

The Company entered into the Numab Agreement, as described in Note 1 above. Dr. Peter Lichtlen, Senior Medical Officer and Vice President of European Operations, is a shareholder in Numab.



#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

#### 9. Notes Payable

In November 2010, SPL entered into a ¥1,000,000, approximating \$12.0 million as of the closing date, secured term loan agreement with The Bank of Tokyo-Mitsubishi UFJ, Ltd, or the Bank. The loan agreement provides for the extension of credit for the period of one year, which can be renewed annually upon the agreement of the Company, SPL and the Bank. Borrowings may be used to finance research and development activities, for working capital needs and for the general corporate purposes of SPL. The loan bears annual interest based on the three-month Tokyo Interbank Offer Rate, or TIBOR, plus 1% and is reset quarterly. The interest rate for the first nine months of 2011 is 1.34%. The outstanding loan balances included in the accompanying Condensed Consolidated Balance Sheets were \$13.0 and \$12.0 million as of September 30, 2011 and December 31, 2010, respectively. In connection with the loan agreement, the Company and the Bank executed a guarantee agreement, which provides full guarantee by the Company on behalf of SPL's obligation to the Bank. The loan agreement includes representations, covenants, and events of default customary for financing transactions of this type. Additionally, the Company agreed to maintain an amount of collateral that would not fall below 90.0% of the initial balance throughout the term of the loan. The Company deposited \$14.9 million with the Bank, and the deposit bears annual interest of 0.4%, which is recorded as restricted cash in the accompanying Condensed Consolidated Balance Sheets as of September 30, 2011 and December 31, 2010.

#### Subordinated Unsecured Promissory Notes

In connection with the December 2010 acquisition of SAG and SAG-J, Ambrent issued a subordinated unsecured promissory note, or notes, to each of the Ueno Trust and Kuno Trust, a related party. Each of the notes was issued with an initial principal balance of approximately \$25.9 million, or approximately \$51.9 million in the aggregate. The interest rate for the notes is equal to the per annum rate of interest determined on the basis of the sum of London Interbank Offered Rate, or LIBOR, plus 4.0%, and will be reset every six months on December 1st and June 1st of each year, the first reset occurred on June 1, 2011. The interest rate beginning June 1, 2011 is 4.4%.

The notes provide for a semi-annual repayment schedule of interest and principal over a seven-year period on each June 1st and December 1st, provided that, until December 1, 2012, all accrued and unpaid interest will not be paid in cash and will instead be added to the principal balance of the notes, and Ambrent will make only two scheduled principal payments on December 1, 2011 and December 1, 2012. For the nine months ended September 30, 2011, approximately \$1.7 million of interest expense was added to the principal balance of the notes as paid-in-kind.

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

Notes payable consist of the following as of September 30, 2011 and December 30, 2010:

(In thousands of U.S. dollars)	Sept	tember 30, 2011	Dec	ember 31, 2010
Loan agreement, The Bank of Tokyo-Mitsubishi UFJ, Ltd	\$	13,038	\$	12,022
Promissory notes, Sellers of SAG		53,658		51,939
	\$	66,696	\$	63,961
Notes payable, current	\$	20,538	\$	19,522
Notes payable, non-current		46,158		44,439
	\$	66,696	\$	63,961

The aggregated scheduled maturities of notes payable were as follows as of September 30, 2011:

(In thousands of U.S. dollars)	September 30, 2011
Due in one year	\$ 20,538
Due in two years	7,500
Due in three years	8,114
Due in four years	8,337
Due in five years	8,570
Thereafter	13,637
	\$ 66,696

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

#### **10.** Collaboration and License Agreements

#### Abbott Agreement

In February 2009, SPL entered into the Abbott Agreement, an exclusive 19-year license, commercialization and supply agreement with Abbott to develop and commercialize lubiprostone for the treatment of CIC in Japan. SPL assigned the Abbott Agreement to SAG, and SAG entered into an agreement with SPL to perform certain activities. Additionally, the agreement grants Abbott the right of first refusal to any additional indications for which lubiprostone is developed in Japan under all relevant patents, know-how and trademarks. SPL is currently negotiating with third parties for a licensing arrangement for the OBD indication. Payments under the terms of the Abbott Agreement include a non-refundable upfront payment and non-refundable development and commercial milestone payments based on achieving specified development, regulatory and sales goals.

SPL has received a total of \$22.5 million in up-front and development milestone payments through September 30, 2011 under the Abbott Agreement. As a result of the assignment of the agreement to SAG and subject to future development and commercial milestones, SAG will receive additional development milestone and commercial milestone payments under the Abbott Agreement, although there can be no assurance that SAG will receive any such payments.

The following table summarizes the cash streams and related revenue recognized or deferred under the Abbott Agreement for the nine months ended September 30, 2011:

(In thousands of U.S. dollars) Collaboration revenue:	Def Dece	mount ferred at ember 31, 2010	for t Montl Septe	Received he Nine hs Ended nber 30, 011	Reco t Mor	Revenue ognized for he Nine nths Ended tember 30, 2011	Curr for Mor	Foreign ency Effects • the Nine nths Ended tember 30, 2011	De	Amount eferred at tember 30, 2011
Up-front payment associated with the Company's obligation to participate in joint committees	\$	868	\$		\$	39	\$	57	\$	886
Research and development revenue:										
Up-front payment	\$	707	\$	-	\$	443	\$	21	\$	285
Development milestone payment	\$	948		-		593		27	\$	382
Total	\$	1,655	\$		\$	1,036	\$	48	\$	667

#### Takeda commercialization and license agreement

In October 2004, the Company entered into the Takeda Agreement and on February 1, 2006, the Company entered into the Supplemental Takeda Agreement, together, the Takeda Agreements. Payments to the Company under the Takeda 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. SAG has requested Takeda's consent to the assignment of the Takeda Agreements and other related agreements to SAG, but as of the filing of this report, SAG has not received such consent.

The Company has received a total of \$150.0 million in up-front and development milestone payments through September 30, 2011 under the Takeda Agreement. Subject to the potential arbitration award, future development and commercial milestones, the Company will receive additional development milestone and commercial milestone payments under the Takeda Agreement, although there can be no assurance that the Company will receive any such payments.



#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

On March 12, 2010, the Company submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Takeda Agreement, which specifies that New York law will govern the procedural and substantive aspects of the arbitration. The opening submission and witness statements have been filed by the Company, and Takeda has submitted its responsive brief and witness statements. The Company's reply brief and witness statements are currently scheduled to be filed in November 2011. The hearing on the Company's claims is currently scheduled to conclude by the end of December 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. The Company has spent and expects to spend significant resources in the dispute with Takeda, and these arbitration proceedings may require the continuing attention of the Company's senior management.

The following table summarizes the cash streams and related revenue recognized or deferred under the Takeda Agreements for the nine months ended September 30, 2011:

(In thousands of U.S. dollars)	Def Dece	mount Terred at Ember 31, 2010	for Mo	h Received r the Nine nths Ended tember 30, 2011	Re Mo	Revenue cognized for the Nine onths Ended ptember 30, 2011	Ro the	Change in Accounts eceivable for Nine Months Ended eptember 30, 2011*	D	Amount eferred at otember 30, 2011
Collaboration revenue:										
Up-front payment associated with the Company's obligation to participate in joint committees	\$	1,470	\$		\$	110	\$		\$	1,360
Research and development revenue:										
Reimbursement of research and development expenses	\$	3,042	\$	3,040	\$	5,555	\$	857	\$	1,384
Product royalty revenue	\$		\$	30,677	\$	30,724	\$	47	\$	-
Co-promotion revenue	\$	-	\$	2,657	\$	2,768	\$	111	\$	-

\* Includes billed and unbilled accounts receivable.

In September 2011, the Company signed the Numab Agreement. Under the terms of the agreement, the Company will provide Numab up to CHF 5.0 million as collateral for a loan to Numab from a third party. The Company may name up to four targets against which Numab will use its proprietary technology to discover high-affinity antibodies and to develop these to an investigational new drug, or IND, ready stage. Numab is eligible for research support payments and discovery success dependent fees. If a biologic is successfully developed, Numab and the Company may enter into a license agreement in which Numab will be entitled to clinical development milestone payments and increasing tiered royalties on net sales. The Company will be responsible for clinical development and will retain all commercial rights to any resulting biologic product.

#### 11. Stock Option Plans

The following table summarizes the employee stock option activity for the nine months ended September 30, 2011 under the Company's 2001 Incentive Plan:

	Shares	E	Weighted Average xercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2010	345,100	\$	10.44		
Options expired	(154,700)		10.99		
Options outstanding, September 30, 2011	190,400		10.00	4.58	\$
Options exercisable, September 30, 2011	190,400		10.00	4.58	\$

## Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

The following table summarizes the employee stock option activity for the nine months ended September 30, 2011 under the Company's Amended and Restated 2006 Stock Incentive Plan, or 2006 Incentive Plan:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2010	1,201,650	\$ 5.69		
Options granted	2,321,920	4.35		
Options exercised	(25,500)	3.85		
Options forfeited	(202,955)	4.50		
Options expired	(58,300)	6.93		
Options outstanding, September 30, 2011	3,236,815	4.80	9.04	\$
Options exercisable, September 30, 2011	598,996	6.75	7.34	\$ -

During the nine months ended September 30, 2011, the Company made a grant of time-based and market condition options to all eligible employees and independent directors. The aggregate options total 2,321,920 shares of the Company's class A common stock, consisting of 784,976 shares of time-based options and 1,536,944 shares of market condition options. The market condition options (a) vest in certain percentages based on the attainment of specific stock price targets over a 30-day trading period so long as the individual is in continuous service with the Company on each such date, (b) have an exercise price equal to the closing price of the Company's class A common stock on the Nasdaq Global Market on the date of grant, and (c) must vest within a term of four years from such date. These options must be exercised within a term of ten years from the date of grant. The percentages and target prices are: 40.0% at \$8.00 per share, 40.0% at \$12.00 per share and 20.0% at \$16.00 per share. The Company determined that the market condition options should be classified as equity instruments, and selected, in accordance with GAAP, a lattice option-pricing model to estimate the fair value of those options. A lattice option-pricing model produces an estimated fair value of the option based on the assumed changes in the price of the underlying share over successive periods of time.

The time-based stock options (a) vest in equal annual installments over the four-year period commencing on the first anniversary of the date of grant (*i.e.*, the first 25.0% of the stock option grant would vest on the first anniversary of the date of grant) so long as the individual is in continuous service with the Company on each such date and (b) have an exercise price equal to the closing price of the Company's class A common stock on the Nasdaq Global Market on the date of grant. These options must be exercised within a term of ten years from such date. All options that were granted on May 2, 2011 have an exercise price equal to the fair market value of the stock price, or \$4.41 per share of class A common stock, on the date of the grant.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2011 and the year ended December 31, 2010 were \$4.35 and \$2.05, respectively. As of September 30, 2011, approximately \$3.9 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards are expected to be recognized over a weighted average period of 3.42 years.

The Company granted 510,000 stock options with an exercise price of \$5.85 per share to non-employees in August 2005 under the Company's 2001 Incentive Plan. As of September 30, 2011 and December 31, 2010, 450,000 of these options were outstanding and exercisable. These non-employee stock options vested immediately and have a weighted average exercise price per share of \$5.85 and \$5.85, respectively, and remaining contractual life of 3.59 and 5.33 years, respectively, as of September 30, 2011 and December 31, 2010.

#### **Employee Stock Purchase Plan**

Under the Company's 2006 Employee Stock Purchase Plan, or ESPP, a total of 2,136 and 3,208 shares of class A common stock were purchased during the nine months ended September 30, 2011 and 2010, respectively. The ESPP is non-compensatory and intended to qualify as an Employee Stock Purchase Plan as defined in Section 423 of the Internal Revenue Code of 1986, as amended, and in accordance with GAAP guidance that requires estimates in the fair value of share-based payment awards on the date of the grant using an option-pricing model and recognizing the expense over the required service periods in the accompanying condensed consolidated statement of operations and comprehensive income (loss). The Company received \$8,132 and \$11,018 upon purchase of shares under the ESPP for the nine months ended September 30, 2011 and 2010, respectively.

#### Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

#### 12. Income Taxes

For the three months ended September 30, 2011 and 2010, the Company recorded a tax provision of \$196,000 and \$418,000, respectively. For the nine months ended September 30, 2011 and 2010, the Company recorded a tax benefit of \$5.0 million and a tax provision of \$1.3 million, respectively. The tax provision for the three months ended September 30, 2011 includes discrete items of approximately \$267,000, and the discrete release of \$1.6 million of valuation allowance on the deferred tax assets expected to be realizable at December 31, 2011 by the subsidiary in Japan. As a result of the transfer of certain intellectual property to the Company's Swiss subsidiary on September 29, 2011 and the associated service agreements between the Company's Swiss subsidiary and other subsidiaries, management expects that the Company's Japanese subsidiary will generate sufficient taxable income to utilize certain net operating losses prior to expiration and has released the associated valuation allowance. The tax benefit for the nine months ended September 30, 2011 primarily pertains to the taxable loss generated by the Company's U.S. subsidiary for which a tax benefit is being recognized, and the release of a valuation allowance by the Company's Japanese subsidiary. Also, included in the benefit for the nine months ended September 30, 2011 are the changes for the effective tax rate, discrete items, and valuation allowance release that occurred during the quarter ended September 30, 2011. Certain of the Company's other subsidiaries based in Europe and Japan incurred pre-tax losses for the three and nine months ended September 30, 2011 and 2010, for which no tax benefit was recognized.

The Company has estimated its annual effective tax rate for the full fiscal year 2011 and 2010 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 recognized on certain of 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 FASB's guidance for uncertainty in income taxes that requires the application of a more likely than not threshold to the recognition and derecognition of uncertain tax positions.

The Company had an outstanding non-current income tax liability of approximately \$1,475,000, including interest, for uncertain tax positions as of September 30, 2011. 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 September 30, 2011 mainly pertains to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes, as well as uncertain tax positions related to related party interest in foreign jurisdictions.

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 twelve months, except for recurring accruals on existing uncertain tax positions.

#### 13. Segment Reporting

The Company has determined that it has three reportable segments based on the Company's method of internal reporting, which disaggregates business by geographic location. These segments are the Americas, Europe and Asia. The Company evaluates the performance of these segments based on income (loss) from operations, as well as other factors, including the progress of its research and development activities. The reportable segments have historically derived their revenue from joint collaboration and strategic alliance agreements. Transactions between the segments consist primarily of loans and the provision of research and development services. Following is a summary of financial information by reportable geographic segment for the three and nine months ended September 30, 2011 and 2010.

## Notes to Condensed Consolidated Financial Statements (Unaudited) – (Continued)

(In thousands of U.S. dollars)	An	nericas	Europe	Asia	С	onsolidated
Three Months Ended September 30, 2011						
Research and development revenue	\$	2,658	\$ -	\$ 227	\$	2,885
Product royalty revenue		10,563	-	-		10,563
Co-promotion revenue		769	-	-		769
Contract and collaboration revenue		141	 	 14		155
Total revenues		14,131	 -	241	_	14,372
Research and development expenses		6,552	965	1,208		8,725
Depreciation and amortization		215	167	(6)		376
Other operating expenses		9,014	 403	 376		9,793
Loss from operations		(1,650)	(1,535)	(1,337)		(4,522)
Interest income		32	2	1		35
Interest expense		-	(576)	(43)		(619)
Other non-operating expense		(10)	 1,463	 (229)		1,224
Loss before income taxes	\$	(1,628)	\$ (646)	\$ (1,608)	\$	(3,882)
Capital expenditures	\$	15	\$ 3	\$ 86	\$	104
Three Months Ended September 30, 2010						
Research and development revenue	\$	1,325	\$ -	\$ 7,747	\$	9,072
Product royalty revenue		10,400	-	-		10,400
Co-promotion revenue		1,282	-	-		1,282
Contract and collaboration revenue		141	-	13		154
Total revenues		13,148	-	7,760		20,908
Research and development expenses		3,074	285	2,903		6,262
Depreciation and amortization		228	16	10		254
Other operating expenses		7,857	557	343		8,757
Income (loss) from operations		1,989	(858)	 4,504		5,635
Interest income		112	1	1		114
Other non-operating income (expense), net		(10)	(3,205)	(169)		(3,384)
Income (loss) before income taxes	\$	2,091	\$ (4,062)	\$ 4,336	\$	2,365
Capital expenditures	\$	74	\$ 	\$ 11	\$	85

## Notes to Condensed Consolidated Financial Statements (Unaudited)

(In thousands of U.S. dollars)		Americas		Europe		Asia	Co	nsolidated
Nine Months Ended September 30, 2011								
Research and development revenue	\$	5,555	\$	-	\$	1,036	\$	6,591
Product royalty revenue		30,724		-		-		30,724
Co-promotion revenue		2,768		-		-		2,768
Contract and collaboration revenue		424		-		39		463
Total revenues		39,471		-		1,075		40,546
Research and development expenses		19,465		2,352		4,021		25,838
Depreciation and amortization		668		325		33		1,026
Other operating expenses		33,232		807		941		34,980
Loss from operations		(13,894)		(3,484)		(3,920)		(21,298)
Interest income		155		3		2		160
Interest expense		-		(1,719)		(125)		(1,844)
Other non-operating expense		(21)		(1,779)		(233)		(2,033)
Loss before income taxes	\$	(13,760)	\$	(6,979)	\$	(4,276)	\$	(25,015)
Capital expenditures	\$	93	\$	6,003	\$	188	\$	6,284
Nine Months Ended September 30, 2010								
Research and development revenue	\$	3,898	\$	-	\$	12,020	\$	15,918
Product royalty revenue	Ψ	29,785	Ψ	-	Ψ	-	Ψ	29,785
Co-promotion revenue		3,357		-		-		3,357
Contract and collaboration revenue		424		-		35		459
Total revenues	_	37,464	_	-	-	12,055	-	49,519
Research and development expenses		6,979		563		8,941		16,483
Depreciation and amortization		668		22		28		718
Other operating expenses		23,122		1,373		908		25,403
Income (loss) from operations		6.695	_	(1,958)		2,178	-	6,915
Interest income		499		2		4		505
Other non-operating income (expense), net		(42)		(2,196)		(322)		(2,560)
Income (loss) before income taxes	\$	7,152	\$	(4,152)	\$	1,860	\$	4,860
Capital expenditures	\$	228	\$	2	\$	15	\$	245
As of September 30, 2011								
Property and equipment, net	\$	1,430	\$	18	\$	308	\$	1,756
	\$		\$		\$			
Identifiable assets, net of intercompany loans and investments	\$	93,069	\$	36,885	\$	12,864	\$	142,818
As of December 31, 2010								
Property and equipment, net	\$	1,750	\$	24	\$	251	\$	2,025
Identifiable assets, net of intercompany loans and investments	\$	102,096	\$	30,789	\$	16,388	\$	149,273

## 14. Supplemental Information

The following is additional information on SAG and the Company for the nine months ended September 30, 2010 as well as on the Company, which incorporates results of SAG, for the nine months ended September 30, 2011 and 2010.

## Notes to Condensed Consolidated Financial Statements (Unaudited) - (Continued)

						Consolidating Information				
	Nine	e Months End	led S	September 30,	Nir	ptember 30,				
(In thousands of U.S. dollars)		2011		2010	2010			2010		
							Co	onsolidated		
	0	Consolidated I	Including SAG			SAG		luding SAG		
Income Statement										
Revenues	\$	40,546	\$	49,519	\$	-	\$	49,519		
Operating expenses		(61,844)		(42,604)		6,000		(48,604)		
Non-operating income (expense)		(3,717)		(2,055)		(2,214)		159		
Income (loss) before income taxes		(25,015)		4,860		3,786		1,074		
Income tax benefit (provision)		5,009		(1,301)		(358)		(943)		
Net income (loss)		(20,006)		3,559		3,428		131		
Cash Flows										
Operating activities		(17,079)		(4,993)		2,644		(7,637)		
Investing activities		21,396		712		2		710		
Financing activities		(43)		(13,388)		(13,399)		11		
Effect of exchange rates on cash and cash equivalents		1,750		(979)		(1,421)		442		
Net increase in cash and cash equivalents		6,024		(18,648)		(12,174)		(6,474)		
Cash and cash equivalents at beginning of period		49,243		61,420		34,706		26,714		
Cash and cash equivalents at end of period		55,267		42,772		22,532		20,240		

						Consolidating	g Info	rmation														
	Three Months Ended September 30,			Th	ree Months End	nded September 30,																
		2011	2010		2010		2010		2010		2010		2010		2010		2010		2010		2010 2010	
	Co	onsolidated 1	solidated Including SAG			SAG		onsolidated cluding SAG														
Income Statement																						
Revenues	\$	14,372	\$	20,908	\$	-	\$	20,908														
Operating expenses		(18,894)		(15,273)		2,802		(18,075)														
Non-operating income (expense)		640		(3,270)		(3,268)		(2)														
Income (loss) before income taxes		(3,882)		2,365		(466)		2,831														
Income tax benefit (provision)		(196)		(418)		5		(423)														
Net income (loss)		(4,078)		1,947		(461)		2,408														

#### 15. Subsequent events

On October 26, 2011, the Company entered into a settlement agreement with Covance Inc., or Covance, that performed the clinical trials for the OBD indication and against which the Company had filed the lawsuit under seal in the Circuit Court for Montgomery County, Maryland on December 9, 2010. Under the terms of the settlement agreement, the Covance will pay the Company \$10.0 million and forgive the payment by the Company of outstanding payables of \$1.1 million. The cash payment is due within ten days of the date of the settlement agreement. The cash was received by the Company on November 4, 2011. As a result of the settlement agreement, the lawsuit will be dismissed with prejudice.

#### 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. (the "Company," "we," "us," or "our") and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Quarterly Report Form 10-Q and in our other Securities and Exchange Commission, or SEC, filings, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, which we filed with the SEC on March 8, 2011. You should also read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements as of and for the year ended December 31, 2010 included in our Annual Report on Form 10-K.

#### Overview

We are an international pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds that occur naturally in the human body as a result of enzymatic, 15-PGDH, transformation of certain fatty acids.

We believe that most prostones function as activators of selective cellular ion channels. As a result, prostones promote fluid secretion and enhance cell protection, including the recovery of cellular barrier function. This activity gives prostones wide-ranging therapeutic potential, particularly for age-related diseases. We are focused on developing prostone-based compounds for the treatment of gastrointestinal, ophthalmic, respiratory, vascular, central nervous system diseases and other disorders for which there are significant unmet medical needs, underserved patients and significant commercial potential.

The therapeutic potential of prostones was first identified by one of our founders, Dr. Ryuji Ueno. To date, two prostone products have received marketing approval. AMITIZA<sup>®</sup> (lubiprostone) is a treatment approved by the U.S. Food and Drug Administration, or FDA, for chronic idiopathic constipation, or CIC, in adults of both genders and for irritable bowel syndrome with constipation, or IBS-C, in women aged 18 years and older. RESCULA<sup>®</sup> (unoprostone isopropyl) is FDA-approved for the lowering of intra-ocular pressure, or IOP, in open-angle glaucoma or ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP lowering medications.

We generate revenue mainly from product royalties, development milestone payments, and clinical development activities. We expect to continue to incur significant expenses for the next several years as we continue our research and development activities and as we seek regulatory approvals for additional indications for AMITIZA, RESCULA and other compounds both in the U.S. and other countries. Additionally, we expect to expand our international operations.

AMITIZA is being marketed and developed in the U.S. for gastrointestinal indications under a collaboration and license agreement, dated October 29, 2004, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda. We are primarily responsible for clinical development activities under the Takeda Agreement while Takeda is responsible for commercialization of AMITIZA. We and Takeda initiated commercial sales of AMITIZA in the U.S. for the treatment of CIC in April 2006 and for the treatment of IBS-C in May 2008. AMITIZA is currently being developed for the treatment of opioid-induced bowel dysfunction, or OBD. Takeda also holds marketing rights to AMITIZA in Canada, but has not yet commercialized it there. We also entered into a supplemental agreement with Takeda on February 1, 2006, or the Supplemental Takeda Agreement, which consists of certain key funding streams, including reimbursements of co-promotion costs and reimbursements of the costs of miscellaneous marketing activities. The reimbursement of co-promotion costs under the Supplemental Takeda Agreement terms of the Supplemental Takeda Agreement were centered on our sales team days in the field selling AMITIZA. The current terms are based on actual presentation of details in front of health care prescribers.

As a result of the transfer of certain intellectual property and licenses to Sucampo AG, or SAG, SAG has requested Takeda's consent to the assignment of the Supplemental Takeda Agreement and other related agreements to SAG but as of the filing of this report SAG has not received such consent.

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Takeda Agreement, which specify that New York law will govern the procedural and substantive aspects of the arbitration. The opening submission and witness statements have been filed by us and Takeda has submitted its responsive brief and witness statements. Our reply brief and witness statements are currently scheduled to be filed in November 2011. The hearing on our claims is currently scheduled to conclude by the end of December 2011. It is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. We have spent and expect to spend significant resources in the dispute with Takeda, and these arbitration proceedings may require the continuing attention of our senior management.

In Switzerland, lubiprostone was approved by Swissmedic, the Swiss Agency for Therapeutic Products for the long-term treatment of adult patients with CIC in November 2009. This is the first European regulatory approval and is the first prescription medicine to be approved in Switzerland for the long-term treatment of CIC. Currently we are in discussion with the Swiss Federal Office of Public Health, or the BAG, for pricing approval. Initially, we intend to market AMITIZA, on a limited basis, in Switzerland starting in 2012.

In Japan, lubiprostone is being developed under a license, commercialization and supply agreement, or the Abbott Agreement, with Abbott Japan Co. Ltd., or Abbott. We have filed a new drug application, or NDA, in Japan with the Pharmaceuticals and Medical Devices Agency, or PMDA, following the successful conclusion of a phase 3 efficacy trial and a phase 3 long-term safety trial of lubiprostone in Japanese CIC patients. We have had preliminary meetings with PMDA and anticipate a decision by the Ministry of Health, Labor and Welfare, or MHLW, on the NDA in 2012. We continue to negotiate with third parties for the OBD indication, and Abbott will have forty-five days to meet the terms and conditions of any third party bona fide offer.

Sucampo Pharma Europe, Ltd., or SPE, submitted a filing for approval of AMITIZA to treat CIC on August 4, 2011 in the United Kingdom, and we expect a decision by the Medicines and Healthcare products Regulatory Agency, or MHRA, by the third quarter of 2012. We continue to evaluate the European Union based on the fact that lubiprostone is the only product approved by the FDA in the U.S. for chronic therapy for either CIC or IBS-C that has received marketing authorization from Swissmedic in Switzerland.

We hold all other development and commercialization rights to lubiprostone in all other territories worldwide.

Following our acquisition of SAG, based in Switzerland, we began and have continued integrating SAG for future operational efficiencies through a simplified group structure and consolidation of intellectual property. On June 10, 2011, Sucampo Manufacturing & Research AG, or SMR, a direct wholly owned subsidiary of us, merged into SAG, and SAG assumed all existing obligations of SMR. On June 28, 2011, Sucampo AG Japan, or SAG-J, an indirect wholly owned subsidiary of us, merged into Sucampo Pharma, Ltd., or SPL, and SPL assumed all existing obligations of SAG-J. On September 29, 2011, our subsidiaries SPA, SPL and SPE transferred certain intellectual property and licenses to SAG, and SAG entered into agreements with the subsidiaries to perform certain services for the subsidiaries related to the intellectual property, licenses and other business activities.

In April 2009, Sucampo Pharma Americas, Inc. or SPA, acquired the rights from R-Tech Ueno, Ltd. or R-Tech, a pharmaceutical research, development and manufacturing company in Japan that is majority owned by our founders and a related party under the common control with SPA, to unoprostone isopropyl, which allows us to commercialize RESCULA in the U.S. and Canada for its approved indication and all indications for the use of unoprostone isopropyl developed by us and R-Tech, which we intend to do during 2012. On September 29, 2011, SPA transferred those rights to SAG. SAG entered into an agreement with SPA to perform certain activities related to those rights. On March 22, 2011, SAG entered into a license agreement with R-Tech for unoprostone isopropyl, expanding our development and commercialization rights as well as our territories beyond our previously agreed territory of the United States and Canada to the rest of the world, with the exception of Japan, Korea, Taiwan and the People's Republic of China, or the R-Tech Territory, or the SAG Territories. SAG is now evaluating the opportunities to obtain an appropriate label in the European Union and other European countries as well as obtaining reauthorization in those countries to commercialize unoprostone isopropyl.

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

Drs. Ryuji Ueno and Sachiko Kuno, together, directly or indirectly, own a majority of the stock of R-Tech. Drs. Ueno and Kuno also are our controlling stockholders and are married to each other. Dr. Ueno is our Chief Executive Officer and Chairman of the Board of Directors. Dr. Kuno is a member of our Board of Directors and our advisor on international business development.

#### **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 pursuing development of a third gastrointestinal indication of AMITIZA for the treatment of OBD in patients with chronic non-cancer pain, a constipation-related gastrointestinal indication. Our third phase 3 study of lubiprostone to evaluate its effectiveness as a treatment of OBD was initiated in December 2010, and subsequent to the quarter end, we enrolled a total of 447 patients in our third phase 3 clinical trial of lubiprostone in patients with OBD caused by their chronic use of pain medications for non-malignant pain, excluding those taking methadone. If successful, the data from the trials will enable a filing of a NDA with the FDA and the regulatory authorities in other territories during 2012.

In July 2011, data from our 48-week long-term safety study of lubiprostone 24 mcg twice per day in CIC patients was published in Digestive Disease Sciences (Dig Dis Sci 2011 56:2639-2645). These data demonstrate that lubiprostone was well tolerated and bowel symptoms consistently improved over 48 weeks in adult patients with CIC. Of the 248 patients who entered the trial, 127 (51.0%) completed the trial. A dose reduction was observed in 17.0% of the patients, resulting in an average study medication exposure across the study of approximately 1.7 capsules (or approximately 40.8 mcg) per day. The most common treatment-related adverse events, or AEs, were nausea (19.8%), diarrhea (9.7%), abdominal distension (6.9%), headache (6.9%), and abdominal pain (5.2%). Most nausea events were rated as "mild" or "moderate" by patients and discontinuations due to nausea was 5.2%. No deaths were reported and of the 16 reported serious AEs, one was considered possibly treatment related. Average changes in serum electrolytes were not clinically relevant at any time point during the study. On average, lubiprostone significantly (p<0.0001) reduced patient-reported constipation severity, abdominal bloating and abdominal discomfort across 48 weeks when compared to baseline.

#### AMITIZA (lubiprostone) in Japan

We have filed a NDA in Japan with PMDA following the successful conclusion of a phase 3 efficacy trial and a phase 3 long-term safety trial of lubiprostone in Japanese CIC patients. We have had preliminary meetings with PMDA and anticipate a decision by the MHLW on the NDA in 2012.

We did not reach agreement with Abbott on the terms and conditions for a license for the OBD indication. We are now negotiating with third parties, and Abbott will have 45 days to meet the terms and conditions of any third party bona fide offer.

#### AMITIZA (lubiprostone) in other countries

We filed for approval of AMITIZA in the United Kingdom for the treatment of CIC on August 4, 2011. We expect a decision from the MHRA in the third quarter of 2012.

We continue to negotiate with the Federal Office of Public Health in Switzerland, or the BAG, for pricing approval. Initially, we intend to market AMITIZA, on a limited basis, in Switzerland starting in 2012.

We continue to evaluate the opportunities to obtain approvals in the other countries of Europe for chronic therapy of CIC patients.

#### AMITIZA (lubiprostone) in other indications

In September 2011, preclinical data were presented at the annual scientific meeting of the Japanese Biochemical Society, held in Kyoto, Japan, by Sachiko Tsukita, Ph.D., Professor at the Graduate School of Frontier Biosciences and Graduate School of Medicine, of Osaka University. These data demonstrate that lubiprostone significantly reduces expression of inflammatory cytokines (p<0.01) vs. the control in an animal model of inflammatory bowel disease, or IBD. In addition, lubiprostone significantly (p<0.01) protects the intestinal epithelial barrier function, as compared to the control, despite decreased expression levels of claudin4 and occludin.

#### RESCULA (unoprostone isopropyl)

As a result of the 2009 and 2011 agreements with R-Tech, we have evaluated the requirements to reactivate RESCULA's licenses and revisions to the label in the European countries in which the licenses have been registered and approved but have lapsed. We plan on filing for re-approval and revisions to the label in 2012. In addition, we may develop RESCULA as a treatment for an array of ophthalmic diseases including dry age-related macular degeneration, or dry AMD, and diabetic retinopathy. We initiated an exploratory clinical study for the ophthalmic indication of dry AMD in the second quarter of 2011, which is intended to evaluate the effects of RESCULA in a small number of patients with dry AMD. We anticipate results from the study in December of this year. If this study is successful, we plan to initiate a dose-ranging phase 2 trial in a significantly larger number of patients to evaluate the effectiveness of RESCULA to prevent the progression of dry AMD to wet AMD. We are currently designing that trial protocol and plan to initiate that trial in the first half of 2012.

On July 8, 2011, we also obtained the development and commercial rights to a peptide compound from CuroNZ, a New Zealand company, for a loan of \$100,000 that will augment our ophthalmic development opportunities. CuroNZ will embark on a research effort for the development of the peptide compound late this year or next year. The loan is included in other assets in the condensed consolidated balance sheets.

#### Pipeline

The table below summarizes the development status of AMITIZA, RESCULA and several other prostone-based product candidates. We currently hold all of the commercialization rights to the prostone compounds in our product pipeline, other than for commercialization of AMITIZA in the U.S., Canada and Japan, which is covered by the Takeda Agreements and the Abbott Agreement, and for RESCULA, for which we hold the rights in the SAG territories. Commercialization may take several years after successful completion of studies.

Target Indication	<b>Development Phase</b>	Next Milestone
Chronic idiopathic constipation (CIC) (adults of all ages)	Marketed in the U.S.	
	Approved in Switzerland	Complete pricing negotiations with Swiss government health agency
	New Drug Application (NDA) submitted in 2010 to authorities (PMDA) in Japan, and updated in early 2011 with results of long-term safety study	Approval of NDA, to be followed by pricing negotiations with government
Irritable bowel syndrome with constipation (adult women) (IBS-C)	Marketed in the U.S.; phase 4 study on higher dosage and with additional male subjects	
Chronic idiopathic constipation (CIC) (pediatric, patients with renal impairment and patients with hepatic impairment)	Phase 4 pediatric, revised label to reflect renal and hepatic impairment reduced dosage	
Inflammatory bowel disease (IBD)	Preclinical	
Mixed irritable bowel syndrome (IBS-M)	Proof of concept study under design	
Opioid-induced bowel dysfunction (OBD) in patients with chronic non-cancer pain	Two phase 3 efficacy trial results reported; third phase 3 efficacy trial ongoing	Top-line results of third phase 3 efficacy trial anticipated near year- end 2011
Opioid-induced bowel dysfunction (OBD) in cancer patients	Phase 2/3 clinical trial design underway	Initiation of phase 2/3 clinical trial
Dry age-related macular degeneration (dry AMD)	Exploratory clinical study at a single site ongoing to evaluate choroidal blood flow in dry AMD patients	Treatment phase of study to complete during 2011
	Phase 2b trial protocol under design	Phase 2b dose-ranging trial in dry AMD
Glaucoma and ocular hypertension	Approved in the U.S.	Limited commercialization
<i>Gastrointestinal</i> Oral mucositis	Preclinical	Phase 1 trial
Prevention of non-steroidal anti- inflammatory drug (NSAID)- induced ulcers	Phase 2a trial results reported	
<i>Pulmonary</i> Chronic obstructive pulmonary disease (COPD)	Preclinical	Finalize inhaled formulation
Dermatology		
Wound Healing	Preclinical	Phase 1 trial
Spinal stenosis	Preclinical	Phase 1 trial
Spinal stenosis	Preclinical	Phase 1 trial
	Chronic idiopathic constipation (CIC) (adults of all ages)Irritable bowel syndrome with constipation (adult women) (IBS-C)Chronic idiopathic constipation (CIC) (pediatric, patients with renal impairment and patients with hepatic impairment)Inflammatory bowel disease (IBD)Mixed irritable bowel syndrome (IBS-M)Opioid-induced bowel dysfunction (OBD) in patients with chronic non- cancer painOpioid-induced bowel dysfunction (OBD) in cancer patientsDry age-related macular degeneration (dry AMD)Glaucoma and ocular hypertension Gastrointestinal Oral mucositisPrevention of non-steroidal anti- inflammatory drug (NSAID)- induced ulcersPulmonary Chronic obstructive pulmonary disease (COPD)Dermatology Wound HealingSpinal stenosis	Chronic idiopathic constipation (CIC) (aduits of all ages)Marketed in the U.S.Approved in SwitzerlandNew Drug Application (NDA) submitted in 2010 to authorities (PMDA) in Japan, and updated in early 2011 with results of long-term safety studyIrritable bowel syndrome with constipation (adult women) (IBS-C)Marketed in the U.S.; phase 4 study on higher dosage and with additional male subjectsChronic idiopathic constipation (CIC) (pediatric, patients with renal impairment and patients with hepatic impairment and patients with hepatic impairment with hepatic impairment with chronic non- (BS-M)Phase 4 pediatric, revised label to reflect renal and hepatic impairment reduced dosageOpioid-induced bowel dysfunction (OBD) in patients with chronic non- cancer painPreclinicalOpioid-induced bowel dysfunction (OBD) in cancer patientsTwo phase 3 efficacy trial results reported; third phase 3 efficacy trial ongoingDry age-related macular degeneration (dry AMD)Exploratory clinical study at a single site ongoing to evaluate choroidal blood flow in dry AMD patients Phase 2b trial protocol under designGlaucoma and ocular hypertensionPreclinicalGastrointestinal oral mucositisPreclinicalPulmonary Chronic obstructive pulmonary 

#### **Our Preclinical Research**

We have proceeded with Numab AG, or Numab, to collaborate on the discovery of high-affinity antibodies for a certain target and anticipate a determination of whether such discovery is successful by the second quarter of 2012. If successful, we will be required to pay a success fee of CHF 3.0 million to Numab. This payment will reduce our collateral deposit on the loan guarantee and development agreement with Numab, or Numab Agreement, and will require Numab and us to negotiate the terms of a commercialization arrangement.

#### **Results of Operations**

#### Comparison of three months ended September 30, 2011 and September 30, 2010

#### Revenues

The following table summarizes our revenues for the three months ended September 30, 2011 and 2010:

	_	Ended 30,		
(In thousands of U.S. dollars)		2011	_	2010
Research and development revenue	\$	2,885	\$	9,072
Product royalty revenue		10,563		10,400
Co-promotion revenue		769		1,282
Contract and collaboration revenue		155		154
Total	\$	14,372	\$	20,908

Total revenues were \$14.4 million for the three months ended September 30, 2011 compared to \$20.9 million for the three months ended September 30, 2010, a decrease of \$6.5 million or 31.3%.

Research and development revenue was \$2.9 million for the three months ended September 30, 2011 compared to \$9.1 million for the three months ended September 30, 2010, a decrease of \$6.2 million or 68.2%. The decrease was primarily due to lower activity of our Japanese development program for lubiprostone under the Abbott Agreement, while we await a response to the NDA filing. The revenue recognized under the Abbott Agreement decreased to \$227,000 for the three months ended September 30, 2011 from \$7.7 million for the three months ended September 30, 2010. We are recognizing the revenue from the payments from Abbott using a percentage-of-completion model over the estimated term of the CIC development program. The revenue recognized under the Takeda Agreement increased to \$2.7 million for the three months ended September 30, 2011 from \$1.3 million for the three months ended September 30, 2010. We are recognizing the revenue from the payments from Takeda using a time-based model over the estimated performance period.

Product royalty revenue represents royalty revenue earned on net sales, as reported by Takeda, of AMITIZA in the United States. For the three months ended September 30, 2011 and 2010, we recognized \$10.6 million and \$10.4 million, respectively, of product royalty revenue, an increase of \$163,000 or 1.6%.

Co-promotion revenues represent partial reimbursement by Takeda of co-promotion costs for our specialty sales force. For each of the three months ended September 30, 2011 and 2010, we recognized \$769,000 and \$1.3 million, respectively, of co-promotion revenues for partial reimbursement of sales force costs. The difference represents the change of reimbursement under the Takeda Agreement and the Supplemental Takeda Agreement.

#### **Research and Development Expenses**

The following summarizes our research and development expenses for the three months ended September 30, 2011 and 2010:

	 Three Months F September 3			
(In thousands of U.S. dollars)	 2011		2010	
Direct costs:				
AMITIZA	\$ 6,788	\$	4,990	
Cobiprostone	87		162	
SPI-017	157		348	
RESCULA	851		235	
Other	534		27	
Total	8,417		5,762	
Indirect costs	308		500	
Total	\$ 8,725	\$	6,262	

Total research and development expenses for the three months ended September 30, 2011 were \$8.7 million compared to \$6.3 million for the three months ended September 30, 2010, an increase of \$2.4 million or 39.3%. The increase was primarily due to expenses associated with the third phase 3 trial of lubiprostone for OBD patients and remonitoring costs which are 50.0% reimbursed by Takeda, as well as increases in other development activities. Due to the method adopted for revenue recognition, certain expenses are reimbursed and included as revenue, as described in the accounting policies, there may be timing differences between the costs incurred and the recognition of cost reimbursement.

#### General and Administrative Expenses

The following summarizes our general and administrative expenses for the three months ended September 30, 2011 and 2010:

	Three Mon Septeml			
(In thousands of U.S. dollars)		2011		2010
Salaries, benefits and related costs	\$	1,554	\$	1,382
Legal, consulting and other professional expenses		4,434		3,404
Stock-based compensation		263		138
Other expenses		1,675		1,485
Total	\$	7,926	\$	6,409

General and administrative expenses were \$7.9 million for the three months ended September 30, 2011, compared to \$6.4 million for the three months ended September 30, 2010, an increase of \$1.5 million or 23.7%. The increase is due primarily to the increase in legal, consulting and other professional expenses, which relate primarily to costs incurred in connection with the on-going legal matters, including our dispute with Takeda and a separate dispute with a Covance Inc., and SAG integration as discussed in Item 1 of Part II of this Quarterly Report on Form 10-Q.

## 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, and represent costs of market research and analysis and other selling and marketing expenses. Selling and marketing expenses. Selling and marketing expenses were \$2.2 million for the three months ended September 30, 2011, compared to \$2.6 million for the three months ended September 30, 2010, a decrease of \$359,000 or 13.8%. The decrease in selling and marketing expenses relates primarily to the timing of pre-commercialization activities for RESCULA in the U.S. Part of the AMITIZA co-promotion expenses are funded by Takeda and recorded as co-promotion revenue.

#### Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the three months ended September 30, 2011 and 2010:

	Three Mon Septem		
(In thousands of U.S. dollars)	2011	_	2010
Interest income	\$ 35	\$	114
Interest expense	(619)		-
Other income (expense), net	1,224		(3,384)
Total	\$ 640	\$	(3,270)

Interest income was \$35,000 for the three months ended September 30, 2011, compared to \$114,000 for the three months ended September 30, 2010, a decrease of \$79,000, or 69.3%. The decrease was primarily due to lower prevailing interest rates earned by our investments and a shift in the composition of our portfolio from auction rate securities, or ARS, which bear higher interest rates, to other types of investments. Our investment in ARS was redeemed in June 2010.

Interest expense was \$619,000 for the three months ended September 30, 2011, including \$576,000 on the notes payable issued for the December 2010 SAG acquisition and \$43,000 on the notes payable issued on SPL's borrowings.

Other income was \$1.2 million for the three months ended September 30, 2011, compared to other expense of \$3.4 million for the three months ended September 30, 2010, an increase of \$4.6 million. The majority of the increase belongs to non-cash foreign exchange losses in 2010 that are unrealized and relate to amounts held within subsidiaries.

#### Income Taxes

We recorded a tax provision of \$196,000 and \$418,000 for the three months ended September 30, 2011 and 2010, respectively. The tax provision for the three months ended September 30, 2011 includes discrete items of approximately \$267,000, and the discrete release of \$1.6 million of valuation allowance on the deferred tax assets expected to be realizable at December 31, 2011 by the subsidiary in Japan. During the three months ended September 30, 2011, the Company determined that it was more likely than not that a portion of the deferred tax assets of its subsidiary in Japan would be realizable as a result of a change in its forecasted income. Certain of our other subsidiaries, based in Europe and Japan, incurred a pre-tax loss for the three months ended September 30, 2011, for which no tax benefit was recognized. As of September 30, 2011, we had an outstanding non-current income tax liability of approximately \$1,475,000, including interest, for uncertain tax positions which represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in our condensed consolidated financial statements. The liability for uncertain tax positions as of September 30, 2011 was mainly a result of our interpretation of nexus in certain states related to revenue sourcing for state income tax purposes, as well as uncertain tax positions related to related party interest in foreign jurisdictions.

#### Comparison of nine months ended September 30, 2011 and September 30, 2010

#### Revenues

The following table summarizes our revenues for the nine months ended September 30, 2011 and 2010:

	Nine Months Ended September 30,			
(In thousands of U.S. dollars)		2011		2010
Research and development revenue	\$	6,591	\$	15,918
Product royalty revenue		30,724		29,785
Co-promotion revenue		2,768		3,357
Contract and collaboration revenue		463		459
Total	\$	40,546	\$	49,519

Total revenues were \$40.5 million for the nine months ended September 30, 2011 compared to \$49.5 million for the nine months ended September 30, 2010, a decrease of \$9.0 million or 18.1%.



Research and development revenue was \$6.6 million for the nine months ended September 30, 2011 compared to \$15.9 million for the nine months ended September 30, 2010, a decrease of \$9.3 million or 58.6%. The decrease was primarily due to lower activity of our Japanese development program for lubiprostone under with the Abbott Agreement, while we await a response to the NDA filing. The revenue recognized under the Abbott Agreement decreased to \$1.0 million for the nine months ended September 30, 2011 from \$12.0 million for the nine months ended September 30, 2010. We are recognizing the revenue from the payments from Abbott using a percentage-of-completion model over the estimated term of the CIC development program. The revenue recognized under the Takeda Agreement increased to \$5.6 million for the nine months ended September 30, 2011 from \$3.9 million for the nine months ended September 30, 2010. We are recognized under the rakeda Agreement increased to \$5.6 million for the nine months ended September 30, 2011 from \$3.9 million for the nine months ended September 30, 2010. We are recognized under the rakeda Agreement increased to \$5.6 million for the nine months ended September 30, 2011 from \$3.9 million for the nine months ended September 30, 2010. We are recognizing the revenue from the payments from Takeda using a time-based model over the estimated performance period.

Product royalty revenue represents royalty revenue earned on net sales, as reported by Takeda, of AMITIZA in the United States. For the nine months ended September 30, 2011 and 2010, we recognized \$30.7 million and \$29.8 million, respectively, of product royalty revenue, an increase of \$939,000 or 3.2%.

Co-promotion revenues represent partial reimbursement by Takeda of co-promotion costs for our specialty sales force. For each of the nine months ended September 30, 2011 and 2010, we recognized \$2.8 million and \$3.4 million, respectively, of co-promotion revenues for partial reimbursement of sales force costs.

#### **Research and Development Expenses**

The following summarizes our research and development expenses for the nine months ended September 30, 2011 and 2010:

	Nine Months September			
(In thousands of U.S. dollars)	2011		2010	
Direct costs:				
AMITIZA	\$ 20,186	\$	12,001	
Cobiprostone	263		468	
SPI-017	284		1,891	
RESCULA	1,614		525	
Other	2,293		94	
Total	 24,640		14,979	
Indirect costs	 1,198		1,504	
Total	\$ 25,838	\$	16,483	

Total research and development expenses for the nine months ended September 30, 2011 were \$25.8 million compared to \$16.5 million for the nine months ended September 30, 2010, an increase of \$9.3 million or 56.8%. The increase was primarily due to expenses associated with the third phase 3 trial of lubiprostone for OBD patients and remonitoring costs which are 50.0% reimbursed by Takeda, as well as increases in other development activities. Due to the method adopted for revenue recognition, certain expenses are reimbursed and included as revenue, as described in the accounting policies, there may be timing differences between the costs incurred and the recognition of cost reimbursement.

We routinely enter into agreements with third-party contract research organizations, or CROs, to oversee clinical research and development studies provided on an outsourced basis. We are not generally contractually obligated to pay the CRO if the service or reports are not provided. Total future estimated costs through 2013 under these agreements as of September 30, 2011 were approximately \$9.4 million.

#### General and Administrative Expenses

The following summarizes our general and administrative expenses for the nine months ended September 30, 2011 and 2010:

	Nine Months Ended September 30,					
(In thousands of U.S. dollars)		2011		2010		
Salaries, benefits and related costs	\$	4,912	\$	4,343		
Legal, consulting and other professional expenses		19,323		10,207		
Stock-based compensation		663		475		
Other expenses		4,419		3,994		
Total	\$	29,317	\$	19,019		

General and administrative expenses were \$29.3 million for the nine months ended September 30, 2011, compared to \$19.0 million for the nine months ended September 30, 2010, an increase of \$10.3 million or 54.1%. The increase is primarily to the increase in legal, consulting and other professional expenses, which relate primarily to costs incurred in connection with the on-going legal matters, including separate disputes with Takeda and Covance, and SAG integration activities as discussed in Item 1 of Part II of this Quarterly Report on Form 10-Q.

#### 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, and represent costs of market research and analysis and other selling and marketing expenses. Selling and marketing expenses were \$6.7 million for the nine months ended September 30, 2011, compared to \$7.1 million for the nine months ended September 30, 2010, a decrease of \$413,000 or 5.8%. The decrease in selling and marketing expenses relates primarily to the timing of pre-commercialization activities for RESCULA in the U.S. Part of the AMITIZA co-promotion expenses are funded by Takeda and recorded as co-promotion revenue.

#### Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the nine months ended September 30, 2011 and 2010:

	-	Nine Months Ended September 30,				
(In thousands of U.S. dollars)	2011	2010				
Interest income	\$ 16	0 \$ 505				
Interest expense	(1,844	4) -				
Other expense, net	(2,03)	3) (2,560)				
Total	\$ (3,71)	7) \$ (2,055)				

Interest income was \$160,000 for the nine months ended September 30, 2011, compared to \$505,000 for the nine months ended September 30, 2010, a decrease of \$345,000, or 68.3%. The decrease was primarily due to lower prevailing interest rates earned by our investments and a shift in the composition of our portfolio from auction rate securities, or ARS, which bear higher interest rates, to other types of investments. Our investment in ARS was redeemed in June 2010.

Interest expense was \$1.8 million for the nine months ended September 30, 2011, including \$1.7 million on the notes payable issued for the December 2010 SAG acquisition and \$125,000 on the notes payable issued on SPL's borrowings.

Other expense was \$2.0 million for the nine months ended September 30, 2011, compared to \$2.6 million for the nine months ended September 30, 2010, a decrease of \$527,000. The majority of the decrease belongs to non-cash foreign exchange losses that are unrealized and relate to amounts held within subsidiaries.

We recorded a tax benefit of \$5.0 million and a provision of \$1.3 million for the nine months ended September 30, 2011 and 2010, respectively. The tax benefit for the nine months ended September 30, 2011 mainly pertains to the taxable loss generated by our U.S. subsidiary for which a tax benefit is being recognized and the discrete valuation allowance release in Japan during the three months ended September 30, 2011. Certain of our other subsidiaries, based in Europe and Japan, incurred a pre-tax loss for the nine months ended September 30, 2011, for which no tax benefit was recognized. As of September 30, 2011, we had an outstanding non-current income tax liability of approximately \$1,475,000, including interest, for uncertain tax positions which represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in our condensed consolidated financial statements. The liability for uncertain tax positions as of September 30, 2011 was mainly a result of our interpretation of nexus in certain states related to revenue sourcing for state income tax purposes, as well as uncertain tax positions related to related party interest in foreign jurisdictions.

#### **Reportable Geographic Segments**

We have determined that we have three reportable segments based on our method of internal reporting, which disaggregates business by geographic location. These segments are the Americas, Europe and Asia. We evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors, including the progress of research and development activities. The financial results in these three segments based on geographic locations for the three and nine months ended September 30, 2011 are summarized in the table below.

The financial results of our segments reflect their varying stages of development. Our Americas segment recorded a loss before taxes of \$1.6 million for the three months ended September 30, 2011 compared to income before taxes of \$2.1 million for the three months ended September 30, 2010. Our Americas segment recorded a loss before taxes of \$1.8 million for the nine months ended September 30, 2011 compared to income before taxes of \$7.2 million for the nine months ended September 30, 2011 compared to income before taxes of \$7.2 million for the nine months ended September 30, 2010. These results primarily reflect the expenses associated with initiating the additional phase 3 trial of lubiprostone for OBD in chronic non-cancer pain patients and the increased expenses in legal matters, including our dispute with Takeda.

Our segment in Europe recorded a loss before taxes of \$646,000 for the three months ended September 30, 2011 compared to loss before taxes of \$4.1 million for the three months ended September 30, 2010. Our segment in Europe recorded a loss before taxes of \$7.0 million for the nine months ended September 30, 2011 compared to loss before taxes of \$4.2 million for the nine months ended September 30, 2010. These results primarily reflect the on-going regulatory submission for AMITIZA, the interest accruing on the loan notes issued for the December 2010 SAG acquisition and non-cash foreign exchange gains and losses.

Our segment in Asia recorded a loss before taxes of \$1.6 million for the three months ended September 30, 2011 compared to income before taxes of \$4.3 million during the three months ended September 30, 2010. Our segment in Asia recorded a loss before taxes of \$4.3 million for the nine months ended September 30, 2011 compared to income before taxes of \$1.9 million during the nine months ended September 30, 2010. These results primarily reflect the reduction of revenue recognized during the three and nine months ended September 30, 2011 from the payments received from Abbott in 2009 and 2010.

(In thousands of U.S. dollars)	A	mericas	Europe		Asia	Co	nsolidated
Three Months Ended September 30, 2011				_			
Total revenues	\$	14,131	\$ -	\$	241	\$	14,372
Loss before taxes		(1,628)	(646)		(1,608)		(3,882)
Three Months Ended September 30, 2010							
Total revenues	\$	13,148	\$ -	\$	7,760	\$	20,908
Income (loss) before taxes		2,091	(4,062)		4,336		2,365
Nine Months Ended September 30, 2011							
Total revenues	\$	39,471	\$ -	\$	1,075	\$	40,546
Loss before taxes		(13,760)	(6,979)		(4,276)		(25,015)
Nine Months Ended September 30, 2010							
Total revenues	\$	37,464	\$ -	\$	12,055	\$	49,519
Income (loss) before taxes		7,152	(4,152)		1,860		4,860
Identifiable assets							
As of September 30, 2011	\$	93,069	\$ 36,885	\$	12,864	\$	142,818
As of December 31, 2010		102,096	30,789		16,388		149,273

# Liquidity and Capital Resources

## Sources of Liquidity

We require cash principally to meet our operating expenses. We finance our operations principally from cash and cash equivalents and to a lesser extend from the sale of securities through the exercise of stock options. Revenues generated from operations principally consist of a combination of upfront payments, milestone and royalty payments and research and development expense reimbursements received from Takeda, Abbott and other parties.

Our cash, cash equivalents, restricted cash and investments consisted of the following as of September 30, 2011 and December 31, 2010:

(In thousands of U.S. dollars)	Sept	tember 30, 2011	Dec	ember 31, 2010
Cash and cash equivalents	\$	55,267	\$	49,243
Restricted cash, current		15,113		15,113
Restricted cash, non-current		2,229		-
Investments, current		30,718		54,524
Investments, non-current		1,248		5,028
Total	\$	104,575	\$	123,908

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

As of September 30, 2011 and December 31, 2010, our restricted cash consisted primarily of the collateral to SPL's loan with The Bank of Tokyo-Mitsubishi UFJ, Ltd. and the SAG's agreement with Numab.

As of September 30, 2011, our short-term investments consisted of U.S. government agencies securities, U.S. commercial paper, municipal and corporate bonds, variable rate demand notes and certificates of deposits that have short-term maturities of one year or less.

## Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2011 and 2010:

	Ni	Nine Months Ended September 30,		
(In thousands of U.S. dollars)		2011		2010
Cash provided by (used in):				
Operating activities	\$	(17,079)	\$	(4,993)
Investing activities		21,396		712
Financing activities		(43)		(13,388)
Effect of exchange rates		1,750		(979)
Net decrease in cash and cash equivalents	\$	6,024	\$	(18,648)

# Nine Months Ended September 30, 2011

Net cash used in operating activities was \$17.1 million for the nine months ended September 30, 2011. This reflected net loss of \$20.0 as well as changes in other operating assets and liabilities.

Net cash provided by investing activities of \$21.4 million for the nine months ended September 30, 2011 primarily reflected our proceeds from the sales and maturities of investments, offset in part by purchases of investments, intangible assets and movements in restricted cash.



Net cash used in financing activities of \$43,000 for the nine months ended September 30, 2011 primarily reflected purchases under the stock repurchase program, offset in part by the proceeds we received under our employee stock purchase plan.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for nine months ended September 30, 2011 was an increase of \$1.8 million.

## Nine Months Ended September 30, 2010

Net cash used in operating activities was \$5.0 million for the nine months ended September 30, 2010. This reflected net income of \$3.6 million, a decrease in deferred revenue of \$10.1 million and a decrease in accounts receivable of \$5.5 million as well as changes in other operating assets and liabilities.

Net cash provided by investing activities of \$712,000 million for the nine months ended September 30, 2010 primarily reflected our proceeds from the sales and maturities of investments, offset in part by purchases of investments.

Net cash used in financing activities of \$13.4 million for the nine months ended September 30, 2010 resulted from the dividends paid by SAG prior to the acquisition but included under accounting for common control and the issuance of related party notes receivable, offset in part by the proceeds we received under our employee stock purchase plan.

The effect of exchange rates on the cash balances of currencies held in foreign denominations for the nine months ended September 30, 2010 was a decrease of \$1.0 million.

# **Off-Balance Sheet Arrangements**

As of September 30, 2011, we did not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4) of Regulation S-K under the Securities Act of 1933, as amended.

### **Funding Requirements**

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

- $\cdot\,$  our share of the ongoing development program of AMITIZA in the U.S.;
- development and regulatory efforts in Europe and Asia for lubiprostone;
- development and regulatory activities for unoprostone isopropyl in the U.S., Canada and the rest of the world except Japan, Korea, Taiwan and The People's Republic of China;
- · development, marketing and manufacturing activities at SAG;
- activities to resolve our ongoing legal matters;
- research and development activities for other prostone compounds, including cobiprostone and SPI-017;
- other business development activities, including partnerships, alliances and investments in or acquisitions of other businesses, products and technologies;
- $\cdot\,$  the initiation of commercialization efforts in non-U.S. markets;
- $\cdot$  the expansion of our commercialization activities in the U.S.;
- continuing purchase of shares of our class A common stock up to \$2.0 million pursuant to the recently implemented repurchase program, and if we elect to do so, increasing the repurchase program up to the \$10.0 million previously approved by our Board; and
- $\cdot\,$  the satisfaction of the conditions of our loan note obligations.
- the revenue from AMITIZA and RESCULA;

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

- the future expenditures we may incur to increase revenue from AMITIZA or in our dispute with Takeda;
- $\cdot\,$  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
- $\cdot\,$  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. At September 30, 2011, we have sufficient liquidity for the next twelve months.

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

#### Effects of Foreign Currency

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

#### **Recent Accounting Pronouncements**

Recent accounting pronouncements applicable to our financial statements are described in Note 2 to the accompanying Condensed Consolidated Financial Statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q.

## 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 a hypothetical one percentage point fluctuation in the U.S. dollar exchange rate would materially affect the fair value of our foreign currency sensitive assets and investments as of September 30, 2011. We do not currently hedge our foreign currency transactions.

## **Interest Rate Risk**

We are subject to interest rate risks associated with fluctuations in interest rates. Our interest income is more sensitive to fluctuations in the interest rates in the U.S. than to changes in interest rates in other markets. Our interest expense is more sensitive to fluctuations in LIBOR and TIBOR than to changes in other interest rates. We ensure the safety and preservation of invested funds by attempting to limit default risk, market risk and reinvestment risk. We attempt to mitigate default risk by investing in investment grade securities. A hypothetical one percentage point decline in interest rates would not have materially affected the fair value of our interest-sensitive financial instruments as of September 30, 2011.

We do not use derivative financial instruments for trading or speculative purposes. However, we regularly invest excess cash in overnight repurchase agreements that are subject to changes in short-term interest rates. We believe that the market risk arising from holding these financial instruments is minimal.

### **Credit Risk**

Our exposure to credit risk consists of cash and cash equivalents, restricted cash, investments and receivables. We place our cash, cash equivalents and restricted cash with what we believe to be highly rated financial institutions and invest the excess cash in highly rated investments. As of September 30, 2011 and December 31, 2010, approximately 21.1% and 27.6%, respectively, of our cash, cash equivalents, restricted cash and investments is issued or insured by the federal government or government agencies. We have not experienced any losses on these accounts related to amounts in excess of insured limits.

### Item 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 Principal Accounting 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, or the Exchange Act) as of September 30, 2011. In designing and evaluating such controls, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based upon the evaluation we carried out, our Chief Executive Officer and Principal Accounting Officer have concluded that, as of September 30, 2011, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified under the applicable rules and forms of the SEC, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Principal Accounting Officer, as appropriate, to allow timely decisions regarding required disclosures.

### b) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2011 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

As previously reported in our Quarterly Reports on Forms 10-Q, on March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Takeda Agreement between us and Takeda, which specify that New York law will govern the procedural and substantive aspects of the arbitration. The opening submission and witness statements have been filed by us and Takeda has submitted its responsive brief and witness statements. Our reply brief and witness statements are currently scheduled to be filed in November 2011. The arbitration hearing on our claims is currently scheduled to conclude by the end of December 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. We have spent and expect to spend significant resources in the dispute with Takeda, and these arbitration proceedings may require the continuing attention of our senior management.

As previously reported in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, on December 9, 2010, we filed an amended lawsuit under seal in the Circuit Court for Montgomery County, Maryland against Covance that performed the clinical trials for the OBD indication. On October 26, 2011, we entered into a settlement agreement with Covance, which provides that they will pay us \$10.0 million and forgive the payment by us of outstanding payables of \$1.1 million. The cash payment is due within ten days of the date of the settlement agreement. The cash was received on November 4, 2011. As a result of the settlement agreement, the lawsuit will be dismissed with prejudice.

#### Item 1A. Risk Factors.

Our business is subject to certain risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our common stock. For a discussion of these risks, please refer to the "Risk Factors" section, Part 1, Item 1A, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed by us with the SEC on March 8, 2011. There have not been any material changes from the risk factors as previously disclosed in our Form 10-K.

### 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. On September 8, 2011, our Board of Directors authorized the repurchase of up to an aggregate of \$2.0 million of our Class A common stock out of the \$10.0 million authorized by the Board of Directors on December 9, 2008. During the quarter ended September 30, 2011, we purchased 42,274 shares of our class A common stock under this program at a cost of \$149,060.

## Item 3. Defaults Upon Senior Securities.

None.

Item 4. (Removed and Reserved).

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, 2008)
3.2	Certificate of Amendment	Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2008)
3.3	Restated Bylaws	Exhibit 3.3 to the Company's Current Report on Form 8-K (filed December 29, 2008)
4.1	Specimen Stock Certificate evidencing the shares of class A common stock	Exhibit 4.1 to Registration Statement No. 333-135133, Amendment No. 5 (filed February 1, 2007)
10.1	Form of Sucampo Pharmaceuticals, Inc. Duration and Performance- Based Stock Option Incentive Award	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed May 6, 2011)
10.2	Settlement and Mutual Release Agreement, dated October 26, 2011, between Sucampo Pharmaceuticals, Inc. and Covance Inc.	Included herewith
101.[INS]†	XBRL Instance Document	Included herewith
101.[SCH]†	XBRL Taxonomy Extension Schema Document	Included herewith
101.[CAL]†	XBRL Taxonomy Extension Calculation Linkbase Document	Included herewith
101.[LAB]†	XBRL Taxonomy Extension Label Linkbase Document	Included herewith
101.[PRE]†	XBRL Taxonomy Extension Presentation Linkbase Document	Included herewith
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 †Attached as Ex	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 whibit 101 to this report are documents formatted in XBRL (Extensible	Included herewith e Business Reporting Language). Users of this data are advised that,

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

# SIGNATURES

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

	Sucampo Pharmaceuticals, Inc.		
November 9, 2011	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)		
November 9, 2011	By: /s/ CARY J. CLAIBORNE Cary J. Claiborne Chief Financial Officer		
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# Sucampo Pharmaceuticals, Inc. Exhibit Index

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## SETTLEMENT AND MUTUAL RELEASE AGREEMENT

THIS SETTLEMENT AND MUTUAL RELEASE AGREEMENT (this "*Release*") is made and entered into as of October \_\_\_, 2011, by and among (i) Sucampo Pharmaceuticals, Inc. ("*Sucampo*"), a Delaware corporation, and (ii) Covance Inc. ("*Covance*"), a Delaware corporation. The parties referred to in clauses (1)(a) and (1)(b) are referred to collectively in this Release as the "*Parties*." This Release shall be effective as of October \_\_\_, 2011 (the "*Effective Date*").

# **RECITALS**

WHEREAS, Sucampo is a biopharmaceutical company that in 2007 initiated a clinical trial program to assess the efficacy and safety of its drug Amitiza® (lubiprostone) in the treatment of patients with Opioid-induced Bowel Dysfunction ("OBD");

WHEREAS, Covance is engaged in the business of providing clinical research services, data management, and related services for the pharmaceutical, biotechnology, and medical device industries;

WHEREAS, the Parties entered into an Agreement for Clinical Trials Services in connection with Sucampo Protocol Number SPI/0211OBD-0631 and Covance Project Number 102416 ("Trial 0631") on or about March 2, 2007 and subsequently amended this Agreement;

WHEREAS, the Parties entered into an Agreement for Clinical Trials Services in connection with Sucampo Protocol Number SPI/0211OBD-0632 and Covance Project Number 102579 ("Trial 0632") on or about March 2, 2007 and subsequently amended this Agreement;

WHEREAS, the Parties entered into an Agreement for Clinical Trials Services in connection with Sucampo Protocol Number SPI/0211OBD-06S1 and Covance Project Number 102580 ("Trial 06S1") on or about March 2, 2007 and subsequently amended this Agreement;

WHEREAS, certain disputes have arisen between Sucampo, on the one hand, and Covance, on the other hand, in connection with Trial 0631, Trial 0632, and Trial 06S1;

WHEREAS, the Parties state that this Release is a settlement of disputed claims and shall not be construed as an admission by either Party that it has violated the law, breached any contract, committed a tort, or failed to fulfill any duty;

WHEREAS, the Parties desire to resolve and effect a full and final settlement in respect of all of the Parties' respective rights and obligations between them in connection with Trial 0631, Trial 0632, and Trial 06S1, on the basis set forth below.

WITNESSETH: In consideration of the mutual promises hereinafter set forth and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### **TERMS OF AGREEMENT**

- 1. Defined Terms. As used in this Release, the following terms have the meanings ascribed thereto below:
- (a) the term "Sucampo" shall mean Sucampo Pharmaceuticals, Inc., a corporation organized and existing under the law of the State of Delaware, with its principal place of business located at 4520 East West Highway, Third Floor, Bethesda, Maryland 20814, and all of its respective parents, partners, joint venturers, successors, assigns, subsidiaries, affiliates, officers, directors, members, contractors, agents and employees;
- (b) the term "*Covance*" shall mean Covance Inc., a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 210 Carnegie Center, Princeton, New Jersey 08540, and all of its respective parents, partners, joint venturers, successors, assigns, subsidiaries, affiliates, officers, directors, members, contractors, agents and employees;
- (c) the term "*Claim*" shall mean any claim, liability, cause of action, or other demand of any kind or character (including, without limitations, direct and indirect claims for direct, consequential or punitive damages, costs and attorneys' fees), and whether based on contract (express or implied), tort (including negligence), or any federal, state or local law, order, rule or regulation;
- (d) the term "*Business Day*" shall mean any other day other than a Saturday, a Sunday or a day on which national banks in Washington, D.C., or New York, New York, are not open for the normal conduct of banking business;
- (e) the term "*Trial 0631*" shall mean the clinical trial of Amitiza (lubiprostone) conducted by the Parties according to the Protocol titled "A Multicenter, Randomized, Placebo-controlled, Double-blinded Study of the Efficacy and Safety of Lubiprostone in Patients with Opioid-induced Bowel Dysfunction";
- (f) the term "*Trial 0632*" shall mean the clinical trial of Amitiza (lubiprostone) conducted by the Parties according to the Protocol titled "A Multicenter, Randomized, Placebo-controlled, Double-blinded Study of the Efficacy and Safety of Lubiprostone in Patients with Opioid-induced Bowel Dysfunction";
- (g) the term "*Trial 06S1*" shall mean the clinical trial of Amitiza (lubiprostone) conducted according to the Protocol titled "A Multi-center, Open-labeled Study of the Long-term Safety and Efficacy of Lubiprostone in Patients with Opioid-induced Bowel Dysfunction";

- (h) the term "OBD Trials" shall mean Trial 0631, Trial 0632, and Trial 06S1 collectively; and
- (i) the term "*Agreements*" shall mean the three Agreements for Clinical Trials Services in connection with the OBD Trials that the Parties entered on or about March 2, 2007 and subsequently amended.

### 2. Settlement Terms.

- (a) Covance's Payment Obligation. Covance shall pay to Sucampo the sum of ten million dollars (\$10,000,000.00) within 10 business days of the Effective Date.
- (b) Covance's Release Obligation. As of the Effective Date, Covance forgives, releases and discharges Sucampo from any and all payments of monies due and owing to Covance in the amount of \$1,031,770.95.
- *(c) Stipulation of Dismissal with Prejudice.* Within 10 business days of the Effective Date, the Parties shall sign and Sucampo shall file a Stipulation of Dismissal with Prejudice of Montgomery County Circuit Court Case Number 337725-V.

### 3. Release by Sucampo.

- (a) Release. Except as provided in Section 3(b), as of the Effective Date, Sucampo hereby forever releases and discharges Covance from any and all Claims (including counterclaims, demands, actions, causes of action, suits, costs, damages, losses, compensation, penalties, liabilities and/or obligations of any kind or nature whatsoever), whether known or unknown, suspected or unsuspected, or hereafter discovered, which arise out of or are in any way connected to the OBD Trials or the Agreements.
- (b) Exceptions. The releases contained in Section 3(a) shall not release Covance from any Claim by Sucampo arising out of (i) a misrepresentation or breach of warranty under this Release, (ii) a default by Covance in performing any of its obligations under this Release, or (iii) the surviving provisions of the Agreements listed in Section 10 of this Release below. The releases contained in Section 3(a) shall not release Takeda Pharmaceuticals Company, Ltd., a corporation organized and existing under the laws of Japan, and Takeda Pharmaceuticals North America, Inc. (collectively "Takeda"), a corporation organized and existing under the laws of Delaware with its principal place of business located at One Takeda Way, Deerfield, Illinois 60069, from the claims asserted by Sucampo in the currently pending matter captioned In the Matter of Sucampo Pharmaceuticals, Inc. et al. v. Takeda Pharmaceutical Company Limited, Respondent, ICC Case No. 17 006/VRO, International Court of Arbitration, International Chamber of Commerce (the "Takeda Arbitration"). Provided, however, that Sucampo shall defend, indemnify, and hold harmless Covance from and against all claims, counterclaims, or third-party claims for contribution that are asserted, now or in the future, in the Takeda Arbitration.

## 4. Release by Covance.

- (a) Release. Except as provided in Section 4(b), as of the Effective Date, Covance hereby forever releases and discharges Sucampo from any and all Claims (including counterclaims, demands, actions, causes of action, suits, costs, damages, losses, compensation, penalties, liabilities and/or obligations of any kind or nature whatsoever), whether known or unknown, suspected or unsuspected, or hereafter discovered, which arise out of or are in any way connected to the OBD Trials or the Agreements.
- (b) *Exceptions*. The releases contained in <u>Section 4(a)</u> shall not release Sucampo from any Claim by Covance arising out of (i) a misrepresentation or breach of warranty under this Release, (ii) a default by Sucampo in performing any of its obligations under this Release, or (iii) the surviving provisions of the Agreements listed in <u>Section 10</u> of this Release below.

## 5. Notices.

- (a) Manner of Giving Notice. Each notice, request, demand, consent, approval or other communication (hereafter in this Section referred to collectively as "Notices" or "notices" and referred to singly as a "Notice" or a "notice") which any Party is required or permitted to give to another Party pursuant to this Release shall be in writing and shall be deemed to have been duly and sufficiently given if
  - (i) personally delivered with proof of delivery thereof (any notice so delivered shall be deemed to have been received at the time so delivered),
  - (ii) sent by Federal Express or other similar overnight courier (any notice so delivered shall be deemed to have been received on the next Business Day following receipt by the courier), or
  - (iii) sent by telecopy or facsimile machine which automatically generates a transmission report that states the date and time of the transmission, the length of the document transmitted and the telephone number of the recipient's telecopy or facsimile machine (with a copy thereof sent in accordance with <u>Section 5(b)</u>), addressed to the Parties at their respective address designated pursuant to <u>Section 5(b)</u>.

Any notice delivered pursuant to <u>Subsection 5(a)(iii)</u> shall be deemed to have been received (i) on the date of transmission, if so transmitted before 5:30 p.m. (local time of the recipient) on a Business Day, or (ii) on the next Business Day, if so transmitted on or after 5:30 p.m. (local time of the recipient) on a Business Day or if transmitted on a day other than a Business Day.

(b) Addresses for Notices. All notices shall be addressed to the parties at the following addresses

(i) if to Sucampo:

Sucampo Pharmaceuticals, Inc. 4520 East West Highway Third Floor Bethesda, Maryland 20852 Attention: Mr. Thomas J. Knapp Telecopier No.: (301) 961-3440 Telephone No.: (301) 961-3400

(ii) if to Covance:

Covance Inc. 210 Carnegie Center Princeton, New Jersey 08540 Attention: General Counsel Telecopier No.: (609) 419-2585 Telephone No.: (609) 452-4585

with a copy to Sidley Austin LLP:

Prentice H. Marshall, Jr. Sidley Austin LLP One South Dearborn Chicago, Illinois 60603 Telecopier No.: (312) 853-7036 Telephone No.: (312) 853-7248

Any Party may, by notice given pursuant to this Section, change the Person or Persons and/or address or addresses, or designate an additional Person or Persons or an additional address or addresses, for its notices, but notice of a change of address shall be effective only upon receipt. Each Party agrees that it will not refuse or reject delivery of any notice given under this Release, that it will acknowledge, in writing, receipt of the same upon request by the other Party and that any notice rejected or refused by it shall be deemed for all purposes of this Release to have been received by the rejecting Party on the date so refused or rejected, as conclusively established by the records of the U.S. Postal Service or the courier service.



(c) Notice Given by Counsel. All Notices that are required or permitted to be given by any Party pursuant to this Release may be given by such Party or its legal counsel, who are hereby authorized by such Party to do so on its behalf.

## 6. Representations, Warranties and Covenants.

- (a) Each Party represents and warrants, as of the date hereof and as of the Effective Date, that it has all requisite corporate power to execute and deliver this Release and perform its obligations hereunder and that this Release has been duly authorized, executed and delivered by such Party.
- (b) Each Party represents and warrants that no third party, including but not limited to Takeda, has asserted any legal or equitable right, title, or interest to all or any portion of the Claim released herein, nor is either Party aware of any such assertion, and that no part of the Claim released herein has been assigned, encumbered, transferred, or subrogated.
- (c) Sucampo and Covance warrant and represent that neither has pursued nor intends to pursue any Claim or legal action against any third party for loss or damage allegedly sustained as a result of the OBD Trials or the Agreements. Sucampo covenants that if it pursues a claim against any third party for loss or damage allegedly sustained as a result of or in connection with the OBD Trials or the Agreements, then it will waive all rights it has to recovery against such third party for any loss or damage found to be attributable to Covance.

7. Integration. This Release sets forth all (and is intended by all parties hereto to be an integration of all) of the promises, agreements, conditions, understandings, warranties and representations among the parties hereto with respect to the subject matter of this Release, and there are no promises, agreement, conditions, understanding, warranties, or representations, oral or written, express or implied, among them other than as set forth herein.

8. *Amendment*. This Release may be amended only by a written amendment signed by both parties.

**9.** *Governing Law.* It is the intention of the parties that all questions with respect to the construction of this Release and the rights and liabilities of the parties hereto shall be determined in accordance with the laws of the State of Delaware, without regard to its or any other jurisdiction's conflict of laws principles.

**10.** Survival of Certain Contractual Obligations. Subsections 11.0, 11.1, 11.2, and 11.3 of each Agreement for Clinical Trials Services shall survive the execution of this Release, notwithstanding any terms herein to the contrary. Further, section 13 of each Agreement for Clinical Trials Services shall survive the execution of this Release only with respect to any claim, suit, action, proceeding, arbitration or investigation alleging bodily injury or death brought by a third party.

# 11. Confidentiality.

- (a) Each Party agrees not to disclose the terms of this Release, or any facts and circumstances underlying the Parties' allegations concerning the OBD Trials, to any third party, unless a Party or its representatives reasonably deem such disclosure to be required under applicable law and regulations, by subpoena or court order, in a proceeding to enforce this Release, or as appropriate to comply with the rules, regulations and requirements of government agencies, state and federal courts, or a Party's financial auditors or insurance carriers. For a period of eighteen (18) months from the Effective Date, prior to making any disclosure that a Party believes is required to be made by the rules, regulations or requirements of the U.S. Food and Drug Administration ("FDA") and which disclosure states that the non-disclosing Party did not comply with the rules, regulations of the FDA in connection with the OBD Trials or Agreements, the disclosing Party shall notify the other Party of its intended disclosure at least ten (10) days in advance; if such advance notice is not practicable, the disclosing Party shall provide notice as soon as practicable before or after the disclosure.
- (b) To the extent that any applicable law, regulation, court rule, or court order requires that any of the terms of this Release be disclosed to a court for any purpose, the Parties agree, represent, and warrant that they will take all appropriate actions to have any document, including any transcript of any hearing, disclosing any such information, ordered sealed by the court.

**12. Severability**. If any provision of this Release is held to be void or unenforceable, in whole or in part, (a) such holding shall not affect the validity and enforceability of the remainder of this Release, including any other provision, section or subsection, and (b) the Parties agree to attempt in good faith to reform such void or unenforceable provision to the extent necessary to render such provision enforceable and to carry out its original intent.

**13.** *Incontestability; Arm's Length Negotiations.* In consideration of the mutual agreements contained herein, each Party does hereby agree that this Release, and each and every provision hereof, is and shall be enforceable by and between them according to its terms. This Release is the product of arm's length negotiations and the terms of this Release have been completely read and fully understood and voluntarily accepted by each Party.

**14.** *Binding Effect.* This Release shall be binding upon, and inure to the benefit of, the Parties hereto and their respective successors and assigns.

**15.** *Counterparts.* This Release may be signed in several counterparts, all of which together shall constitute one agreement binding on all Parties hereto.

End of this page; signatures continued on next page

IN WITNESS WHEREOF, the Parties have signed this Release as of the day and year first above written, but with the intention that it shall become effective on and as of the Effective Date.

# SUCAMPO PHARMACEUTICALS, INC.

By\_

Thomas J. Knapp, SVP, General Counsel & Corporate Secretary

COVANCE INC.

By\_

William Klitgaard, Corporate Senior Vice President and Chief Financial Officer

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

I, Ryuji Ueno, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Sucampo Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(F)) for the registrant and have:
  - (a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrants fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2011

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

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

I, Cary J. Claiborne, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Sucampo Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(F)) for the registrant and have:
  - (a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrants fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2011

/s/ CARY J. CLAIBORNE

Cary J. Claiborne (Chief Financial Officer)

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

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

- (1) The Quarterly Report on Form 10-Q for the period ended September 30, 2011 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2011

/s/ RYUJI UENO

Ryuji Ueno, M.D., Ph.D., Ph.D. Chief Executive Officer (Principal Executive Officer)

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

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

- (1) The Quarterly Report on Form 10-Q for the period ended September 30, 2011 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2011

/s/ CARY J. CLAIBORNE

Cary J. Claiborne (Chief Finanical Officer)