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, 2008

OR

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

For the transition period from to

Commission File Number: 001-33609

SUCAMPO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

13-3929237 (I.R.S. employer identification no.)

4520 East-West Highway, Suite 300 Bethesda, MD 20814

(Address of principal executive offices, including zip code)

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

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

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

Large accelerated filer o

Accelerated filer o

Non-accelerated filer \square

Smaller reporting company o

(Do not check if a smaller reporting company)

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

As of November 13, 2008, there were 15,650,398 shares of the registrant's class A common stock outstanding and 26,191,050 shares of the registrant's class B common stock outstanding.

Sucampo Pharmaceuticals, Inc.

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PART I — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

SUCAMPO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets (Unaudited)

(In thousands, except share data)

	September 30 2008	, December 31, 2007
ASSETS:		
Current assets:	ф 10.0C	ф эппп
Cash and cash equivalents	\$ 13,364	
Investments, current	93,117	
Product royalties receivable	7,611	
Unbilled accounts receivable	4,664	
Accounts receivable	1,076	
Prepaid and income taxes receivable	119	
Deferred tax assets, net	1,066	
Prepaid expenses and other current assets	2,226	
Total current assets	123,243	97,418
Investments, non-current	17,626	9,400
Property and equipment, net	2,283	3 2,265
Deferred tax assets — noncurrent, net	4,566	
Other assets	401	393
Total assets	\$ 148,119	\$ 110,027
LIABILITIES AND STOCKHOLDERS' EQUITY:		
ELEBETIES THE STOCKHOLDERS EQUITION		
Current liabilities:		
Accounts payable	\$ 2,959	
Accrued expenses	12,491	
Deferred revenue — current	6,379	
Income taxes payable	1,420	
Total current liabilities	23,249	9 13,105
Deferred revenue, net of current portion	8,202	2 8,626
Other liabilities	1,615	
Total liabilities	33,066	
Commitments (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at September 30, 2008 and December 31, 2007; no		
shares issued and outstanding at September 30, 2008 and December 31, 2007	_	
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at September 30, 2008 and December 31, 2007; 15,650,398 and 15,538,518 shares issued and outstanding at September 30, 2008 and December 31, 2007,		
respectively	156	5 155
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at September 30, 2008 and December 31, 2007; 26,191,050 shares issued and outstanding at September 30, 2008 and December 31, 2007	262	2 262
Additional paid-in capital	98,272	
Accumulated other comprehensive loss	(1,416	
Retained earnings (accumulated deficit)	17,779	
Total stockholders' equity	115,053	-
Total liabilities and stockholders' equity	\$ 148,119	\$ 110,027

Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income (Unaudited)

(In thousands, except per share data)

	Three Months End	led September 30, 2007	Nine Months End	led September 30, 2007
Revenues:				
Research and development revenue	\$ 5,436	\$ 4,652	\$ 66,982	\$ 52,105
Product royalty revenue	7,718	6,998	24,699	18,869
Co-promotion revenue	1,185	1,051	3,643	3,318
Contract and collaboration revenue	142	151	425	454
Total revenues	14,481	12,852	95,749	74,746
Operating expenses:				
Research and development	11,390	7,588	35,537	22,278
General and administrative	3,863	2,116	10,591	17,286
Selling and marketing	2,680	2,779	8,398	9,806
Milestone royalties — related parties	_	_	3,531	1,500
Product royalties — related parties	1,359	1,244	4,391	3,354
Total operating expenses	19,292	13,727	62,448	54,224
(Loss) income from operations	(4,811)	(875)	33,301	20,522
Non-operating income (expense):	()-)	()	,	-,-
Interest income	655	780	1,862	1,575
Other expense, net	(15)	(228)	(16)	(192)
Total non-operating income, net	640	552	1,846	1,383
(Loss) income before income taxes	(4,171)	(323)	35,147	21,905
Income tax benefit (provision)	1,745	(151)	(7,192)	(7,980)
Net (loss) income	\$ (2,426)	<u>\$ (474)</u>	\$ 27,955	\$ 13,925
Net (loss) income per share:				
Basic net (loss) income per share	\$ (0.06)	\$ (0.01)	\$ 0.67	\$ 0.38
Diluted net (loss) income per share	\$ (0.06)	\$ (0.01)	\$ 0.67	\$ 0.38
Weighted average common shares outstanding — basic	41,813	39,312	41,768	36,447
Weighted average common shares outstanding — diluted	41,813	39,312	42,022	36,835
Comprehensive income:				
Net (loss) income	\$ (2,426)	\$ (474)	\$ 27,955	\$ 13,925
Other comprehensive (loss) income:	¥ (=, .=0)	→ ()	Ţ _ ,,555	\$ 10,0 2 0
Unrealized gain (loss) on investments, net of tax effect	374	_	(1,082)	_
Foreign currency translation	54	281	59	205
Comprehensive (loss) income	\$ (1,998)	\$ (193)	\$ 26,932	\$ 14,130

Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited)

(In thousands, except share data)

	Class Common		Clas Commo			Additional Paid-In	rumulated Other prehensive]	Retained Earnings ccumulated	Sto	Total ckholders'
	Shares	Amoun	Shares	An	nount	Capital	Loss		Deficit)		Equity
Balance at December 31,											
2007	15,538,518	\$ 15	5 26,191,050	\$	262	\$ 96,680	\$ (393)	\$	(10,176)	\$	86,528
Stock issued upon exercise											
of stock options	111,880		1 —			869	_		_		870
Employee stock option											
expense, net of tax											
benefit	_	_			_	723	_		_		723
Foreign currency											
translation	_	_				_	59		_		59
Unrealized loss on											
investments, net of tax											
effect	_	_			_	_	(1,082)		_		(1,082)
Net income	_	-			_	_	_		27,955		27,955
Balance at September 30,											
2008	15,650,398	\$ 15	6 26,191,050	\$	262	\$ 98,272	\$ (1,416)	\$	17,779	\$	115,053

Condensed Consolidated Statements of Cash Flows (Unaudited)

(In thousands)

		ded September 30,
Cook floors from an activities	2008	2007
Cash flows from operating activities: Net income	\$ 27,955	¢ 12.025
	\$ 27,955	\$ 13,925
Adjustments to reconcile net income to net cash provided by operating activities:	226	150
Depreciation and amortization	326	153
Loss on disposal of property and equipment		63
Deferred tax (benefit) provision	(4,312)	4,413
Stock-based compensation	567	6,144
Accretion of discounts on investments	(95)	
Changes in operating assets and liabilities:		
Accounts receivable	493	(2,831)
Unbilled accounts receivable	1,219	_
Product royalties receivable	1,055	(4,969)
Prepaid and income taxes receivable and payable, net	3,224	(759)
Accounts payable	(415)	1,951
Accrued expenses	3,815	1,145
Deferred revenue	4,893	(11,376)
Other assets and liabilities, net	(114)	549
Net cash provided by operating activities	38,611	8,408
Cash flows from investing activities:		
Purchases of investments	(135,584)	(86,847)
Proceeds from sales of investments	41,000	55,795
Maturities of investments	43,125	_
Purchases of property and equipment	(342)	(2,128)
Net cash used in investing activities	(51,801)	(33,180)
Cash flows from financing activities:		
Proceeds from exercise of stock options	870	_
Excess tax benefits from share-based payments	155	_
Issuance of common stock, net of offering costs	_	31,341
Net cash provided by financing activities	1,025	31,341
Effect of exchange rates on cash and cash equivalents	(30)	186
Net (decrease) increase in cash and cash equivalents	(12,195)	6,755
Cash and cash equivalents at beginning of period	25,559	22,481
Cash and cash equivalents at end of period	\$ 13,364	\$ 29,236
	3.00	

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Business Organization and Basis of Presentation

Description of the Business

Sucampo Pharmaceuticals, Inc. (Sucampo or the Company) is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. Sucampo is focused on developing prostones for the treatment of gastrointestinal, respiratory, vascular and central nervous system diseases and disorders.

The Company is party to a collaboration and license agreement with Takeda Pharmaceutical Company Limited (Takeda) to jointly develop and commercialize AMITIZA® (lubiprostone) for chronic idiopathic constipation, irritable bowel syndrome with constipation, opioid-induced bowel dysfunction and other gastrointestinal indications in the United States and Canada. In January 2006, the Company received marketing approval from the U.S. Food and Drug Administration (FDA) for AMITIZA's first indication to treat chronic idiopathic constipation in adults. Commercialization of AMITIZA began in April 2006 throughout the United States. On April 29, 2008, the Company received marketing approval from the FDA for AMITIZA to treat irritable bowel syndrome with constipation in women 18 years of age or older. Commercialization for this indication began in May 2008 throughout the United States. The Company is currently conducting Phase III pivotal clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction.

The Company's founders own directly or indirectly the majority holdings in Sucampo as well as in other companies that have contractual relationships with Sucampo. One of the Company's founders serves as the Chairman of the Board of Directors, Chief Executive Officer and Chief Scientific Officer of the Company.

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements as of and for the year ended December 31, 2007, included in the Company's Annual Report on Form 10-K. The financial information as of September 30, 2008 and for the three and nine months ended September 30, 2008 and 2007 is unaudited. In the opinion of management, all adjustments, consisting only of normal recurring adjustments or accruals, considered necessary for a fair statement of the results of these interim periods have been included. The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

The condensed consolidated financial statements include the accounts of Sucampo and its wholly-owned subsidiaries. All significant inter-company balances and transactions have been eliminated in the consolidated accounts.

2. Summary of Significant Accounting Policies

Current and Non-Current Investments

Current and non-current investments consist primarily of U.S. Treasury bills and notes and auction rate securities. The Company's investments in these securities are classified as available-for-sale securities under Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115).

The available-for-sale securities are accounted for at fair market value and unrealized gains and losses on these securities, if any, are included in accumulated other comprehensive loss in stockholders' equity. The fair value of the securities is measured in accordance with SFAS No. 157, "Fair Value Measurements" (SFAS 157), which was adopted by the Company on January 1, 2008. SFAS 157 addresses how companies should measure fair value when they are required to use a fair value measure for recognition and disclosure purposes under generally accepted accounting principles. The Company assesses the recoverability of its available-for-sale securities and, if impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. Other-than-temporary impairments are included in the condensed consolidated statement of operations and comprehensive (loss) income. Any future fluctuation in fair value related to these instruments that the Company deems to be temporary, including any recoveries of previous write-downs, will be recorded to other comprehensive income.

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

The adoption of SFAS 157 did not materially affect the Company's financial condition, its results of operations, or its cash flows. SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. See additional disclosures related to the determination of the fair value of the Company's investments (see Note 4).

The Company also adopted SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115" (SFAS 159), which permits entities to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis, on January 1, 2008. The adoption of SFAS 159 did not materially affect the Company's financial condition, results of operations, or cash flows as the Company has not elected to account for any assets or liabilities at fair value on an instrument-by-instrument basis.

Certain Risks, Concentrations and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents, restricted cash, investments and receivables. The Company places its cash and cash equivalents, restricted cash and investments with highly rated financial institutions. At September 30, 2008 and December 31, 2007, the Company had approximately \$98.1 million and \$85.9 million, respectively, of cash and cash equivalents, restricted cash and investments in excess of government insured limits. The Company's uninsured cash, cash equivalents and investments as of September 30, 2008 consist primarily of \$70.8 million of T-bills and notes and \$18.9 million of money market funds guaranteed under the U.S. Treasury's Temporary Guarantee Program. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

At September 30, 2008, the Company holds \$21.0 million of investments in auction rate securities at fair value and has recorded a cumulative unrealized loss of \$1.9 million, or \$1.2 million net of tax effect, as of September 30, 2008 related to these investments. This unrealized loss was recorded as other comprehensive loss during the nine months ended September 30, 2008.

On October 16, 2008, the Company accepted the settlement rights offered by the Company's broker under a settlement agreement between the broker and the SEC and various state regulatory authorities. The settlement rights allow the Company to redeem auction rate securities at par within a specified period. Based on this settlement, the Company received \$3.4 million on November 3, 2008, representing the par value of its tax-exempt auction rate securities and has the right to request the redemption of the remaining auction rate securities at par value of an additional \$19.4 million within, the two-year period starting June 30, 2010. As the settlement was accepted subsequent to September 30, 2008, the Company's consolidated financial statements as of September 30, 2008 do not reflect any contingent gains, valuation adjustments or any other amounts relating to the settlement rights. The Company has, however, classified auction rate securities as current and non-current investments as of September 30, 2008 based on the expected redemption dates. The Company does not anticipate having to sell these securities in order to operate its business before the expected redemption dates.

The Company's product, AMITIZA, and other candidates under development require approval from the FDA or other international regulatory agencies prior to commercial sales. For those product candidates 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 product, AMITIZA, competes in a rapidly changing, highly competitive market, which is characterized by advances in scientific discovery, changes in customer requirements, evolving regulatory requirements and developing industry standards. Any failure by the Company to anticipate or to respond adequately to scientific developments in its industry, changes in customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services could have a material adverse effect on the Company's business, operating results and future cash flows.

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

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, research and development efforts to develop new products, payments received under contractual agreements with other parties, the status of competitive products and market acceptance of the Company's new products by physicians and patients. The Company plans to continue financing operations with product royalty revenue as well as with cash received from milestones and other revenue related to its joint collaboration and license agreement and the supplemental agreement entered into with Takeda (see Note 9).

The Company depends significantly upon the collaboration with Takeda and the Company's activities may be affected if this relationship is disrupted. Revenues from Takeda accounted for more than 99% of the Company's total revenues for the three months ended September 30, 2008 and 2007 and the nine months ended September 30, 2008 and 2007. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 98% and 99% of the Company's accounts receivable, unbilled accounts receivable and product royalties receivable at September 30, 2008 and December 31, 2007, respectively (see Note 9).

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

The Company has previously entered into a restated license agreement with Sucampo AG (SAG) to grant the Company a royalty-bearing, exclusive, worldwide license to develop prostone compounds, including AMITIZA and cobiprostone. SAG is a Swiss-patent holding company and an affiliate. The Company's success depends, in part, on SAG's ability to obtain and maintain proprietary protection for the intellectual property rights relating to the prostone technology and products (see Note 8).

Deferred Revenue

Deferred revenue represents payments received or receivables for licensing fees, option fees, consulting, research and development contracts and related cost sharing and supply agreements that are deferred until revenue can be recognized under the Company's revenue recognition policy. Deferred revenue is classified as current if management believes the Company will be able to recognize the deferred amount as revenue within 12 months of the balance sheet date. During the second quarter of 2008, the Company agreed to receive quarterly prepayments from Takeda for its research and development expenses under the agreements with Takeda. As of September 30, 2008, approximately \$1.9 million of deferred revenue relates to these prepayments (see Note 6).

Reclassifications

Certain amounts in the previously issued financial statements have been reclassified to conform with the current presentation. The Company reclassified expenses that have been previously included within general and administrative expenses to research and development expenses. Such expenses primarily include salaries and other employee benefits of personnel who oversee the research and development process, and allocated depreciation and rent expenses and insurance costs. The Company also reclassified allocated depreciation and rent expenses and insurance costs from general and administrative expenses to selling and marketing expenses. During the three months ended September 30, 2007, the Company reclassified \$828,000 and \$84,000 of general and administrative expenses to research and development expenses and selling and marketing expenses, respectively. During the nine months ended September 30, 2007, the Company reclassified approximately \$2.2 million and \$154,000 of general and administrative expenses to research and development expenses and selling and marketing expenses, respectively.

Cumulative Out-of-Period Adjustment

The Company recorded a cumulative adjustment of approximately \$148,000 during the nine months ended September 30, 2008 to recognize additional research and development expenses that have not been recorded in prior periods. The error resulted from incorrect accounting for investigator services for the Phase IIb study of lubiprostone for adult chronic idiopathic constipation initiated in Japan in the fourth quarter of 2007. The effect of this adjustment on the consolidated financial statements was not material for the year ended December 31, 2007 or for the period in which it was recorded, as the adjustment consisted of insignificant amounts related to each of these periods.

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

Changes in Estimate

In June 2006, a joint committee comprised of representatives of the Company and Takeda (the Joint Commercialization Committee) granted approval for the Company and Takeda to begin three studies related to funding arrangements discussed in the collaboration and license agreement and its supplement. The Company accounts for these three required deliverables as a single unit of accounting for revenue recognition purposes. Effective April 1, 2008, as a result of lower-than-expected patient enrollment in one of the studies, the Joint Commercialization Committee approved an increase in funding for patient recruitment. Additionally, the Company concluded that the estimated completion of these trials would be extended from June 2009 to December 2009. As such, the Company determined that the recognition period for associated research and development revenue should be extended. The related research and development revenue is limited to the lesser of the actual cumulative reimbursable costs incurred or the cumulative straight-line amount of revenue recognized over the estimated performance period. As a result of the extended completion date and an increase of total expected reimbursable costs, the Company deferred approximately \$1.9 million and \$3.6 million in research and development revenue for the three and nine months ended September 30, 2008, respectively. The Company expects to recognize the deferred revenue of \$3.6 million in 2009. Under the provision of SFAS No. 154, "Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3" (SFAS 154), the Company will recognize this as a change in estimate on a prospective basis from April 1, 2008.

During the three months ended September 30, 2008, as additional historic information became available, the Company refined its estimated rebates, discounts and other expenses deducted from Takeda's gross sales in order to calculate Takeda's net sales and product royalties due from Takeda to the Company. As a result of this, the Company recorded a reduction to its product royalty revenues of \$644,000 during the three months ended September 30, 2008.

The above changes in estimate have the following impact on net income and basic and diluted net income per share for the three and nine months ended September 30, 2008:

(In thousands, except per share data)	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2008
Decrease in revenue and income before income taxes	\$(2,570)	\$(4,263)
Impact on basic net (loss) income per share	(0.03)	(0.02)
Impact on diluted net (loss) income per share	(0.03)	(0.02)

Recent Accounting Pronouncements

In June 2007, the Emerging Issues Task Force (EITF) issued EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" (EITF 07-3), which provides guidance to research and development companies on how to account for the nonrefundable portion of an advance payment made for research and development activities. The Company adopted EITF 07-3 as of January 1, 2008 and there was no material impact upon its adoption.

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141 (revised 2007), "Business Combinations" (SFAS 141R) and SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51" (SFAS 160). SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141R and SFAS 160 will be applied to acquisitions that close in years beginning after December 15, 2008. Early adoption is not permitted. SFAS 141R and SFAS 160 will not have any impact on the Company's future consolidated financial statements unless it undertakes an acquisition in the future.

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

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

In February 2008, the FASB agreed to delay the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, to fiscal years beginning after November 15, 2008. The Company adopted SFAS 157 with respect to its financial assets and liabilities as of January 1, 2008 and does not expect that the adoption of SFAS 157 for its nonfinancial assets and liabilities will have a significant impact on its financial position or results from operations.

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, except when their inclusion would be anti-dilutive.

The computation of net income per share for the three and nine months ended September 30, 2008 and 2007 is shown below:

	Three Months End		Nine Months Ended September 2008 20		
(In thousands, except per share data) Basic net (loss) income per share:	2008	2007	2008	2007	
•	f (2.42C)	¢ (474)	ተ 37 0 55	¢ 12.025	
Net (loss) income	\$ (2,426)	<u>\$ (474)</u>	\$ 27,955	\$ 13,925	
Weighted average class A and B common shares outstanding	41,813	37,252	41,768	35,753	
Conversion of series A preferred stock to class A common shares					
outstanding	_	2,060	_	694	
	41,813	39,312	41,768	36,447	
Basic net (loss) income per share	<u>\$ (0.06)</u>	\$ (0.01)	\$ 0.67	\$ 0.38	
Diluted net (loss) income per share:					
Net (loss) income	\$ (2,426)	\$ (474)	\$ 27,955	\$ 13,925	
Weighted average class A and B common shares outstanding for diluted net					
income per share	41,813	39,312	41,768	36,447	
Assumed exercise of stock options under the treasury stock method	_	_	254	388	
	41,813	39,312	42,022	36,835	
Diluted net (loss) income per share	\$ (0.06)	<u>\$ (0.01)</u>	\$ 0.67	\$ 0.38	

The potentially dilutive securities used in the calculations of diluted historical net income per share as of the nine months ended September 30, 2008 and 2007 are as follows:

	Septem	ber 30,
(In thousands)	2008	2007
Employee stock options	381	641
Non-employee stock options	450	510

Potentially dilutive securities representing approximately 407,000 and nil shares of common stock for the three months ended September 30, 2008 and 2007, respectively, were excluded from the computation of diluted earnings per share for the periods because their effect would have been anti-dilutive.

4. Current and Non-Current Investments

At September 30, 2008 and December 31, 2007, current and non-current available-for-sale investments consisted of the following securities:

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

	September 30, 2008				
~ · · · · · ·	-	Unrealized	Unrealized	F : X/ 1	
(In thousands) Current:	Cost	Gains	Losses	<u>Fair Value</u>	
	f 70.71 <i>C</i>	¢ 115	¢	¢ 70.021	
U.S. Treasury bills and notes	\$ 70,716	\$ 115	\$ —	\$ 70,831	
Auction rate securities	3,475	_	(104)	3,371	
Money market funds	18,915			18,915	
Total	\$ 93,106	\$ 115	\$ (104)	\$ 93,117	
Non-current:					
Auction rate securities	\$ 19,400	\$ —	\$ (1,774)	\$ 17,626	
		December	31, 2007		
		Unrealized	Unrealized		
(In thousands)	Cost	Gains	Losses	Fair Value	
Current:					
Auction rate securities	\$ 51,500	\$ —	\$ —	\$ 51,500	
Money market funds	52	<u></u> _		52	
Total	\$ 51,552	<u> </u>	\$ —	\$ 51,552	
				·	
Non-current:					
Auction rate securities	\$ 9,400	<u>\$</u>	<u>\$ —</u>	\$ 9,400	

The Company's assets measured at fair value on a recurring basis, which are subject to the disclosure requirements of SFAS 157, at September 30, 2008 were as follows:

	Fair Value Measurements at Reporting Date Using							
		ed Prices in	G! !f!	. 6.1		gnificant		
	Ident	Markets for tical Assets	Observa	ant Other ble Inputs		observable Inputs		Total as of otember 30,
(In thousands)	(1	Level 1)	(Le	vel 2)		Level 3)		2008
U.S. Treasury bills and notes	\$	70,831	\$	_	\$	_	\$	70,831
Auction rate securities						20,997		20,997
Other available-for-sale securities		18,915		<u> </u>		<u> </u>		18,915
Total assets measured at fair value	\$	89,746	\$		\$	20,997	\$	110,743

Based on market conditions, the Company changed its valuation methodology for auction rate securities to a valuation method that includes market and income approaches during the first quarter of 2008. Accordingly, these securities changed from Level 1 to Level 3 within SFAS 157's valuation hierarchy at the time of the Company's initial adoption of SFAS 157 at January 1, 2008. The Level 2 securities consist of the auction rate securities that were redeemed at par during 2008. The following table presents the Company's assets measured at fair value on a recurring basis using significant observable inputs (Level 2) and significant unobservable inputs (Level 3) as defined in SFAS 157 during the nine months ended September 30, 2008:

(In thousands)	 ection Rate Securities
Balance at January 1, 2008	\$ 9,400
Transfers to Level 2	(3,900)
Transfers to Level 3	51,500
Total gains (losses) (realized or unrealized):	
Included in earnings	_
Included in other comprehensive loss	(1,878)
Purchases	5,100
Settlements	(39,225)
Balance at September 30, 2008	\$ 20,997

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

5. Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	September 30, 	December 31, 2007		
Research and development costs	\$ 7,717	\$ 4,422		
Selling and marketing costs	352	384		
Employee compensation	1,589	1,867		
Legal service fees	268	226		
Product royalty liability — related party	1,706	1,536		
Other accrued expenses	859	295		
	\$ 12,491	\$ 8,730		

6. Deferred Revenue

Total deferred revenue consists of the following:

(In thousands)	Sep	tember 30, 2008		mber 31, 2007
Deferred revenue — current	\$	6,379	\$	1,062
Deferred revenue, net of current portion		8,202		8,626
	\$	14,581	\$	9,688

During the second quarter of 2008, the Company agreed to receive quarterly prepayments from Takeda for its research and development expenses under the agreements with Takeda. As of September 30, 2008, approximately \$1.9 million of deferred revenue relates to these prepayments. As a result of the change in estimate (see Note 2) resulting from an extended completion date and an increase of total expected reimbursable costs of certain clinical studies, the Company deferred approximately \$3.6 million in research and development revenue as of September 30, 2008.

7. Commitments

Operating Leases

The Company leases office space in the United States, United Kingdom and Japan under operating leases through 2017. Total future minimum, non-cancelable lease payments under operating leases, which do not include future sublease receipts of \$299,000, are as follows as of September 30, 2008:

(In thousands)	
2008	\$ 402
2009	1,520
2010	1,049
2011	938
2012	963
2013 and thereafter	4,243
Total minimum lease payments	\$ 9,115

Rent expense for all operating leases was \$296,000 and \$288,000 for the three months ended September 30, 2008 and 2007, respectively, and \$874,000 and \$751,000 for the nine months ended September 30, 2008 and 2007, respectively.

Research and Development Costs

The Company routinely enters into agreements with clinical research organizations (CROs), to oversee clinical research and development studies provided on an outsourced basis and assist in other research and development activities. The Company generally is not contractually obligated to pay the third party if the service or reports are not provided. Total future estimated costs under these agreements as of September 30, 2008 were approximately \$14.3 million.

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

8. Related Party Transactions

R-Tech Ueno, Ltd.

The Company is a party to multiple exclusive clinical and commercial supply agreements with R-Tech, whereby R-Tech manufactures and supplies AMITIZA and other prostone compounds for Sucampo. Also, R-Tech sells commercial supplies of AMITIZA directly to Takeda, which are not recorded in the books of Sucampo.

The following table summarizes the Company's transactions with R-Tech towards these services:

	Three Months Ended September 30, 2008 2007		<u>N</u>	ine Months 2008	Ended Septe	ember 30, 2007	
(In thousands)			 	_		_	
Clinical supplies	\$	38	\$ 1,357	\$	553	\$	2,899
Other research and development services		62	 67	_	111		85
	\$	100	\$ 1,424	\$	664	\$	2,984

The following table summarizes the amounts included in deferred revenue resulting from the deferral of upfront payments relating to the exclusive supply agreements with R-Tech:

(In thousands)	tember 30, 2008	ember 31, 2007
Deferred revenue — current	\$ 419	\$ 419
Deferred revenue, net of current portion	 6,549	6,862
	\$ 6,968	\$ 7,281

The Company recognized approximately \$105,000 of previously deferred revenue relating to its agreements with R-Tech for the three months ended September 30, 2008 and 2007 and approximately \$314,000 for the nine months ended September 30, 2008 and 2007, which was recorded as contract and collaboration revenue in the condensed consolidated statements of operations and comprehensive (loss) income.

Sucampo AG License Agreements

During the three months ended March 31, 2008, the Company submitted a Marketing Authorization Application (MAA) for lubiprostone, 24 micrograms, for the indication of chronic idiopathic constipation in adults in nine European countries using the decentralized procedure. The submission of the MAA triggered the obligation on the part of the Company under the license agreement with SAG to make a \$1.0 million payment to SAG. The Company recorded the expense as milestone royalties — related parties in the first quarter of 2008 and paid the milestone in the fourth quarter of 2008.

The Company expensed approximately \$1.4 million and \$1.2 million in product royalties — related parties under the license agreement with SAG for the three months ended September 30, 2008 and 2007, respectively, and approximately \$4.4 million and \$3.4 million for the nine months ended September 30, 2008 and 2007, respectively, based on current AMITIZA sales.

9. Collaboration and License Agreements with Takeda

On October 29, 2004, the Company entered into a 16-year collaboration and license agreement with Takeda to exclusively co-develop, commercialize and sell products that contain lubiprostone for gastroenterology indications in the United States and Canada. On February 1, 2006, the Company entered into a supplemental agreement with Takeda, which amended the responsibilities of both the Company and Takeda for the co-promotion of AMITIZA and clarified the responsibilities and funding arrangements for other marketing services to be performed by both parties. Payments to the Company under these agreements include a non-refundable up-front payment, non-refundable development and commercial milestone payments, reimbursement of certain development and co-promotion costs and product royalties.

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

The Company has received a total of \$150.0 million in up-front and development milestone payments through September 30, 2008 under these agreements. In June 2007, the Company submitted the supplemental new drug application (sNDA) to the FDA for irritable bowel syndrome with constipation and received a \$30.0 million milestone from Takeda that was recognized as revenue in the second quarter of 2007. The Company received a \$50.0 million milestone from Takeda as a result of the FDA's approval on April 29, 2008 of the sNDA for irritable bowel syndrome with constipation in women 18 years of age and older and recognized the payment as research and development revenue in the second quarter of 2008. Subject to future development and commercial milestones, the Company is potentially entitled to receive up to \$10.0 million in additional development milestone payments and up to \$50.0 million in commercial milestone payments, under the collaboration and license agreements with Takeda, although there can be no assurance that the Company will receive any such payments.

The following table summarizes the cash streams and related collaboration and research and development revenue recognized under the collaboration and license agreements with Takeda for the nine months ended September 30, 2008:

(In thousands)	Amount Deferred at December 31, 2007	Cash Received for the Nine Months Ended September 30, 2008	Revenue Recognized for the Nine Months Ended September 30, 2008	Change in Accounts Receivable for the Nine Months Ended September 30, 2008	Amount Deferred at September 30, 2008
Collaboration revenue:					
Up-front payment associated with the Company's obligation to participate in joint committees with					
Takeda	\$ 1,911	\$ —	\$ 110	s —	\$ 1,801
Idkeud	\$ 1,911	Ф —	\$ 110	<u> </u>	\$ 1,001
Research and development revenue:					
Development milestones	\$ —	\$ 50,000	\$ 50,000	\$ —	\$ —
Reimbursement of research and development expenses		24,653	16,982	(2,191)	5,480
Total	<u> </u>	\$ 74,653	\$ 66,982	\$ (2,191)	\$ 5,480
Product royalty revenue	<u> </u>	\$ 25,755	\$ 24,699	\$ (1,056)	<u> </u>
	Accounts Receivable at December 31,	Cash Received for the Nine Months Ended September 30,	Revenue Recognized for the Nine Months Ended September 30,	Accounts Receivable at September 30,	Amount Deferred at September 30,
(In thousands) Research and development revenue:	2007*	2008	2008	2008*	2008
Development milestones	\$ —	\$ 50,000	\$ 50,000	\$ —	\$ —
Reimbursement of research and development expenses	\$ 6,887	\$ 24,653	\$ 16,982	\$ 4,696	\$ 5,480
Reinfoursement of research and development expenses	\$ 0,007	\$ 24,033	\$ 10,962	\$ 4,090	3 3,400
Product royalty revenue	\$ 8,667	\$ 25,755	\$ 24,699	\$ 7,611	<u> </u>
Co-promotion revenue	\$ 360	\$ 3,212	\$ 3,643	\$ 791	<u> </u>

Includes billed and unbilled accounts receivable.

In connection with the Company's MAA filing for lubiprostone in Europe, the Company agreed with Takeda to make a one-time payment of approximately \$1.8 million, which will permit the Company to use in Europe, the Middle East and Africa certain data and information developed under the Takeda Agreement relating to the use of lubiprostone to treat chronic idiopathic constipation. The Company recognized this payment as a research and development expense in the first quarter of 2008.

10. Stock Option Plan

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

The following table summarizes the employee stock option activity for the nine months ended September 30, 2008 under the Company's 2001 Incentive Plan:

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2007	640,900	\$ 10.24		
Options exercised	(51,880)	10.00		
Options forfeited	(34,850)	10.00		
Options expired	(48,750)	10.00		
Options outstanding, September 30, 2008	505,420	10.30	6.07	<u> </u>
Options exercisable, September 30, 2008	490,545	10.31	6.02	\$ —

The following table summarizes the employee stock option activity for the nine months ended September 30, 2008 under the Company's 2006 Incentive Plan:

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2007	267,500	\$ 14.44		
Options granted	44,000	9.66		
Options forfeited	(17,250)	14.12		
Options expired	(11,750)	14.12		
Options outstanding, September 30, 2008	282,500	13.87	8.27	<u> </u>
Options exercisable, September 30, 2008	60,750	14.47	7.96	\$

The weighted average grant date fair value of options granted during the nine months ended September 30, 2008 and the year ended December 31, 2007 were \$5.25 and \$7.19, respectively. As of September 30, 2008, approximately \$1.2 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 2.35 years.

The following table summarizes the non-employee stock option activity for the nine months ended September 30, 2008 under the Company's 2001 Incentive Plan:

(In thousands, except share and per share data)	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2007	510,000	\$ 5.85		
Options exercised	(60,000)	5.85		
Options outstanding, September 30, 2008	450,000	5.85	6.58	\$ 1,206
Options exercisable, September 30, 2008	450,000	5.85	6.58	\$ 1,206

11. Income Taxes

For the three months ended September 30, 2008 and 2007, the Company's consolidated effective tax rate was 41.8% and 46.6%, respectively. For the nine months ended September 30, 2008 and 2007, the Company's consolidated annualized effective tax rate was 20.5% and 36.4%, respectively. As a result of the FDA approval of the sNDA in April 2008 for irritable bowel syndrome with constipation and the related impact on projected income in 2008 and future years based on the \$50.0 million milestone payment and expected product royalties, the Company believes that its U.S. deferred tax assets will likely be realized. Accordingly, the tax provision recorded during the nine months ended September 30, 2008 reflects a discrete release of U.S. deferred tax asset valuation allowances of \$4.8 million and a reduction in the projected 2008 effective tax rate applied to the 2008 pre-tax income for the nine months ended September 30, 2008.

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

12. Uncommitted Line of Credit

On March 5, 2008, the Company entered into a line of credit providing for uncommitted borrowings of up to \$30.0 million. The lender has no obligation to make advances under this line of credit but may do so in its sole discretion. The line of credit is collateralized by our current and non-current investments. Advances made under this line of credit will bear an interest rate based on LIBOR plus a predetermined percentage based on the amount of the advance and other conditions. Borrowings under this line of credit are due upon the demand of the lender and the lender can make a repayment demand at its sole option at any time for any or no reason. As of September 30, 2008, the Company had not drawn down any funds under this line of credit.

13. Segment Reporting

The Company has determined that it has three reportable geographic segments based on the Company's method of internal reporting, which disaggregates business by geographic location. These segments are the United States, Europe and Japan. 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 intercompany loans and the provision of research and development services. Following is a summary of financial information by reportable geographic segment.

(In thousands)	Unit	ted States	E	urope	Japan			ercompany iminations	C	Consolidated
Three Months Ended September 30, 2008		_							_	
Research and development revenue	\$	5,436	\$	_	\$	_	\$	_	\$	5,436
Product royalty revenue		7,718		_		_		_		7,718
Co-promotion revenue		1,185		_		_		_		1,185
Contract and collaboration revenue		142				213		(213)		142
Total revenues		14,481		_		213		(213)		14,481
Depreciation and amortization		110		1		3		_		114
Other operating expenses		17,819		469		1,100	_	(210)	_	19,178
Loss from operations		(3,448)		(470)		(890)		(3)		(4,811)
Interest income		678		1		2		(26)		655
Other non-operating expense, net		(6)		(17)	_	(21)		29	_	(15)
Loss before income taxes	\$	(2,776)	\$	(486)	\$	(909)	\$		<u>\$</u>	(4,171)
Capital expenditures	\$	5	\$	35	\$		\$	_	\$	40
									=	
Three Months Ended September 30, 2007										
Research and development revenue	\$	4,652	\$	_	\$	_	\$	_	\$	4,652
Product royalty revenue		6,998		_		_		_		6,998
Co-promotion revenue		1,051		_		_		_		1,051
Contract and collaboration revenue		142				219	_	(210)	_	151
Total revenues		12,843		_		219		(210)		12,852
Depreciation and amortization		85		1		7				93
Other operating expenses		12,587		520		737		(210)		13,634
Income (loss) from operations		171		(521)		(525)		_		(875)
Interest income		782		_		3		(5)		780
Other non-operating income (expense), net		(69)		(16)		(148)	_	5	_	(228)
Income (loss) before income taxes	\$	884	\$	(537)	\$	(670)	\$	_	\$	(323)
Capital expenditures	\$	788	\$		\$		\$		\$	788

Notes to Condensed Consolidated Financial Statements (Unaudited) — (Continued)

(In thousands)	United States	Europe	Japan	Intercompany Eliminations	Consolidated
Nine Months Ended September 30, 2008					
Research and development revenue	\$ 66,982	\$ —	\$ —	\$ —	\$ 66,982
Product royalty revenue	24,699	_	_	_	24,699
Co-promotion revenue	3,643	_	_	_	3,643
Contract and collaboration revenue	425		630	(630)	425
Total revenues	95,749	_	630	(630)	95,749
Depreciation and amortization	318	1	7	_	326
Other operating expenses	55,324	2,891	4,537	(630)	62,122
Income (loss) from operations	40,107	(2,892)	(3,914)	_	33,301
Interest income	1,924	6	5	(73)	1,862
Other non-operating (expense) income, net	(39)	(30)	(20)	73	(16)
Income (loss) before income taxes	\$ 41,992	\$ (2,916)	\$ (3,929)	<u> </u>	\$ 35,147
Capital expenditures	\$ 304	\$ 35	\$ 3	<u> </u>	\$ 342
Nine Months Ended September 30, 2007			_		
Research and development revenue	\$ 52,105	\$ —	\$ —	\$ —	\$ 52,105
Product royalty revenue	18,869	_	_	_	18,869
Co-promotion revenue	3,318	_	_	(22.0)	3,318
Contract and collaboration revenue	424		660	(630)	454
Total revenues	74,716	_	660	(630)	74,746
Depreciation and amortization	143	1	9	_	153
Other operating expenses	52,201	829	1,671	(630)	54,071
Income (loss) from operations	22,372	(830)	(1,020)	_	20,522
Interest income	1,573	_	7	(5)	1,575
Other non-operating income (expense), net	(64)	(25)	(108)	5	(192)
Income (loss) before income taxes	\$ 23,881	\$ (855)	\$ (1,121)	<u> </u>	\$ 21,905
Capital expenditures	\$ 2,128	<u> </u>	<u> </u>	\$	\$ 2,128
As of September 30, 2008					
Property and equipment, net	\$ 2,167	\$ 32	\$ 84	\$ —	\$ 2,283
Identifiable assets	\$ 158,420	\$ 2,160	\$ 5,364	\$ (17,825)	\$ 148,119
As of December 31, 2007					
Property and equipment, net	\$ 2,182	<u>\$</u>	\$ 83	<u> </u>	\$ 2,265
Identifiable assets	\$ 114,490	\$ 2,381	\$ 1,987	\$ (8,831)	\$ 110,027
	16				

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

This Quarterly Report on Form 10-Q contains forward-looking statements regarding Sucampo Pharmaceuticals, Inc. ("Sucampo," the "Company," "we," "us," or "our") and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements. You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements as of and for the year ended December 31, 2007 included in our Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. In January 2006, we received marketing approval from the U.S. Food and Drug Administration, or FDA, for our first product, AMITIZA, for the treatment of chronic idiopathic constipation in adults. On April 29, 2008, the FDA approved AMITIZA for its second indication, the treatment of irritable bowel syndrome with constipation in women 18 years of age or older.

We and Takeda Pharmaceutical Company Limited, or Takeda, are party to a collaboration and license agreement and a related supplemental agreement, or, collectively, the Takeda Agreements, to jointly develop and commercialize AMITIZA for chronic idiopathic constipation, irritable bowel syndrome with constipation, opioid-induced bowel dysfunction and other gastrointestinal indications in the United States and Canada. We have the right to co-promote AMITIZA along with Takeda in these markets. We and Takeda initiated commercial sales of AMITIZA in the United States for the treatment of chronic idiopathic constipation in adults in April 2006. Under the Takeda Agreements, Takeda records all product revenue and we receive a royalty on net product revenues for such sales.

Drs. Ryuji Ueno and Sachiko Kuno, our founders, own directly or indirectly the majority holdings in Sucampo as well as in other companies that have contractual relationships with Sucampo. One of the founders serves as the Chairman of the Board of Directors, Chief Executive Officer and Chief Scientific Officer of Sucampo.

We hold an exclusive worldwide royalty-bearing license from Sucampo AG, or SAG, a Swiss patent-holding company and an entity wholly owned by our founders, to develop and commercialize AMITIZA and all other prostone compounds covered by patents and patent applications held by SAG. We are obligated to assign to SAG all patentable improvements that we make in the field of prostones, which SAG is obligated in turn to license back to us on an exclusive basis. AMITIZA, cobiprostone and SPI-017 are covered by perpetual licenses that cannot be terminated unless we default in our payment obligations to SAG. If we have not committed specified development efforts to any prostone compound other than AMITIZA, cobiprostone and SPI-017 by the end of a specified period, which ends on the later of June 30, 2011 or the date upon which Drs. Ryuji Ueno and Sachiko Kuno, our founders, no longer control our company, then the commercial rights to that compound will revert to SAG, subject to a 15-month extension in the case of any compound that we designate in good faith as planned for development within that extension period.

We first generated product royalty revenue for commercial sales of AMITIZA in the second quarter of 2006. Although we reported net income for the years ended December 31, 2007 and 2006, we have historically incurred operating losses, resulting principally from costs incurred in our research and development programs and from our general and administrative expenses. We expect to continue to incur significant and increasing expenses for the next several years as we continue to expand our research and development activities, seek regulatory approvals for additional indications for AMITIZA and for other compounds in the United States and abroad, expand our international operations and augment our sales and marketing capabilities. While we expect future profitability, whether we are able to sustain profitability will depend upon our ability to generate revenues and receive payments under our contracts with Takeda or similar future arrangements. In the near term, our ability to generate product revenues will depend primarily on the successful commercialization and continued development of additional indications for AMITIZA.

As a result of the FDA approval of AMITIZA for the treatment of the irritable bowel syndrome with constipation in women 18 years and older, we received a development milestone payment of \$50.0 million from Takeda in the second quarter of 2008 and we recognized the payment as research and development revenue. Consequently, in accordance with the restated license agreement with SAG, we paid and recorded as research and development expense a \$2.5 million milestone royalty to SAG during the nine months ended September 30, 2008, reflecting 5% of the \$50.0 million development milestone payment that we received from Takeda.

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 connection with our marketing approval for AMITIZA for the treatment of chronic idiopathic constipation in adults, we committed to the FDA to conduct post-marketing studies to evaluate the safety of the product in pediatric patients, in patients with renal impairment and in patients with hepatic impairment, which were initiated in January 2007. In connection with our marketing approval for AMITIZA for the treatment of irritable bowel syndrome with constipation in adult women, we committed to the FDA to conduct a post-marketing study to evaluate the safety and efficacy for the treatment of irritable bowel syndrome in pediatric patients ages 6 to 17. In addition, we committed to conduct a post-marketing study in male and female patients with irritable bowel syndrome with constipation utilizing a higher dose than currently recommended for this indication. We are also developing AMITIZA to treat opioid-induced bowel dysfunction. We commenced Phase III pivotal clinical trials of AMITIZA for the treatment of opioid-induced bowel dysfunction in September 2007 and we expect to complete these trials by the end of 2009 and file the supplemental new drug application (sNDA) with the FDA in 2010. Our collaboration and co-promotion arrangement with Takeda also covers these additional indications for AMITIZA and Takeda funds a majority of AMITIZA's development program in the United States.

In February 2008, we submitted a Marketing Approval Application, or MAA, for lubiprostone, 24 micrograms, or mcg, for the indication of chronic idiopathic constipation in adults in the United Kingdom. The MAA was submitted using the decentralized procedure with the United Kingdom, through its Medicines and Healthcare Products Regulatory Agency, serving as the reference member state, with additional applications subsequently submitted to the member states of Belgium, Denmark, France, Germany, Ireland, the Netherlands, Spain and Sweden. In May 2008, we received notification that all of the MAAs have been received and validated by the individual regulatory agencies. In June 2008, we submitted a MAA for lubiprostone, 24 micrograms, for the indication of chronic idiopathic constipation in adults in Switzerland.

In September 2008, we announced positive results from our multi-center Phase 2b dose-ranging study in Japan to evaluate the safety and efficacy of lubiprostone for treating chronic idiopathic constipation in adults. We plan to initiate Phase III clinical trials in Japan in mid-2009.

- Cobiprostone. We are developing orally administered cobiprostone to treat various gastrointestinal and liver disorders, including non-steroidal anti-inflammatory drug-induced ulcers, portal hypertension, non-alcoholic fatty liver disease and gastrointestinal disorders associated with cystic fibrosis. We also are planning to develop an inhaled formulation of cobiprostone for the treatment of respiratory symptoms of cystic fibrosis and chronic obstructive pulmonary disease. Our near term focus is on the development of cobiprostone as a treatment for non-steroidal anti-inflammatory drug-induced ulcers. We commenced a Phase II clinical trial of cobiprostone for the treatment of non-steroidal anti-inflammatory drug-induced ulcers in the third quarter of 2007. We expect to enroll approximately 120 patients in this clinical trial, which we plan to complete in mid-2009. We also initiated a Phase II proof-of-concept study of cobiprostone for the treatment of portal hypertension in patients with liver cirrhosis in July 2008 and we expect to complete the trials by the end of 2009.
- *SPI-017*. We are developing SPI-017 to treat vascular disease and central nervous system disorders. We are initially focused on developing an intravenous formulation of this product candidate for the treatment of peripheral arterial disease. We also are developing an oral formulation of SPI-017 for the treatment of Alzheimer's disease and a topical formulation for wound healing. We plan to initiate Phase I clinical trials of the intravenous and oral formulation of SPI-017 by the end of 2008.

Results of Operations

Reclassifications

We have reclassified certain amounts in the previously issued financial statements to conform with the current presentation. We reclassified expenses that have been previously included within general and administrative expenses to research and development expenses. Such expenses primarily include salaries and other employee benefits of personnel who oversee research and development projects, and allocated depreciation and rent expenses and insurance costs. We also reclassified allocated depreciation and rent expenses and insurance costs from general and administrative expenses to selling and marketing expenses. During the three months ended September 30, 2007, we reclassified \$828,000 and \$84,000 of general and administrative expenses to research and development expenses and selling and marketing expenses, respectively. During the nine months ended September 30, 2007, we reclassified approximately \$2.2 million and \$154,000 of general and administrative expenses to research and development expenses and selling and marketing expenses, respectively.

Comparison of three months ended September 30, 2008 and September 30, 2007

Revenues

The following table summarizes our revenues for the three months ended September 30, 2008 and 2007:

		Months Ended tember 30,
(In thousands)	2008	2007
Research and development revenue	\$ 5,436	\$ 4,652
Product royalty revenue	7,718	6,998
Co-promotion revenue	1,185	1,051
Contract and collaboration revenue	142	151
Total	\$ 14,481	\$ 12,852

Total revenues were \$14.5 million for the three months ended September 30, 2008 compared to \$12.9 million for the three months ended September 30, 2007, an increase of \$1.6 million or 12.4%.

Research and development revenue was \$5.4 million for the three months ended September 30, 2008 compared to \$4.7 million for the three months ended September 30, 2007, an increase of \$0.7 million or 14.9%. This increase was primarily due to revenue recognized related to the on-going opioid-induced bowel dysfunction Phase III pivotal trials funded by Takeda. During the three months ended September 30, 2008, we deferred an additional \$1.9 million of research and development revenue as a result of a change, in the second quarter of 2008, in the estimated completion date and an increase in total expected reimbursable costs associated with these trials.

Product royalty revenue represents royalty revenue earned on net sales of AMITIZA in accordance with the Takeda Agreements. For the three months ended September 30, 2008 and 2007, we recognized \$7.7 million and \$7.0 million, respectively, of product royalty revenue, an increase of \$0.7 million or 10%. The increase reflects the continuing acceptance by patients and physicians of AMITIZA® 24 mcg for the treatment of chronic idiopathic constipation in adults and sales of AMITIZA 8 mcg for irritable bowel syndrome with constipation in adult women. The product royalty revenue for the three months ended September 30, 2008 was also burdened somewhat by lower restocking orders for AMITIZA 8 mcg reflecting the draw-down of the inventory from the initial stocking of AMITIZA 8 mcg completed during the second quarter of 2008. We recognized royalty of approximately \$1.9 million in the second quarter of 2008 for the portion of the 8 mcg product with no right of return. Additionally, during the three months ended September 30, 2008, we recorded a reduction of product royalty revenues of \$644,000 resulting from a change in estimate relating to rebates, discounts and other expenses.

Co-promotion revenues represent reimbursement by Takeda of certain co-promotion costs for our specialty sales force and costs associated with miscellaneous marketing activities in connection with the commercialization of AMITIZA. For the three months ended September 30, 2008 and 2007, we recognized \$1.2 million and \$1.1 million, respectively, of co-promotion revenues for reimbursement of sales force costs.

Research and Development Expenses

The following summarizes our research and development expenses for the three months ended September 30, 2008 and 2007:

		Months Ended tember 30,
(In thousands)	2008	2007
Direct costs:		
AMITIZA	\$ 8,166	\$ 5,563
Cobiprostone	1,180	875
SPI - 017	616	278
Other		458
Total	10,711	7,174
Indirect costs	679	414
Total	\$ 11,390	\$ 7,588

Total research and development expenses for the three months ended September 30, 2008 were \$11.4 million compared to \$7.6 million for the three months ended September 30, 2007, an increase of \$3.8 million or 50%. This increase was due to our on-going clinical development programs of AMITIZA for the treatment of opioid-induced bowel dysfunction, chronic idiopathic constipation in Japan and cobiprostone for the treatment of non-steroidal anti-inflammatory drug-induced ulcers and portal hypertension in patients with liver cirrhosis, and preclinical and basic development costs associated with SPI-017.

General and Administrative Expenses

The following summarizes our general and administrative expenses for the three months ended September 30, 2008 and 2007:

	September 30,	
(In thousands)	2008	2007
Salaries, benefits and related costs	\$ 1,156	\$ 882
Legal and consulting expenses	852	638
Stock-based compensation	51	9
Founders' stock-based award	_	(1,000)
Other operating expenses	1,804	1,587
Total	\$ 3,863	\$ 2,116

General and administrative expenses were \$3.9 million for the three months ended September 30, 2008 compared to \$2.1 million for the three months ended September 30, 2007, an increase of \$1.8 million or 85.7%. This increase was primarily due to an adjustment to the founders' stock-based award during the three months ended September 30, 2007 and due to an increase in operational headcount, an increase in expenses associated with our new office space and an increase in overall costs associated with the compliance and regulatory requirements of being a publicly traded company with international operations for the three months ended September 30, 2008.

Selling and Marketing Expenses

Selling and marketing expenses represent costs we incur to co-promote AMITIZA, including salaries, benefits and related costs of our sales force and other sales and marketing personnel, costs of market research and analysis and other selling and marketing expenses. Selling and marketing expenses were \$2.7 million for the three months ended September 30, 2008 compared to \$2.8 million for the three months ended September 30, 2007, a decrease of \$0.1 million or 3.6%. The decrease was primarily due to reduced marketing expenses in the long-term care market, which we support with our internal sales force.

Product Royalties — Related Parties

Product royalties — related parties expense represent 3.2% of AMITIZA net sales for the respective periods payable to SAG and increased to \$1.4 million for the three months ended September 30, 2008 from \$1.2 million for the three months ended September 30 2007 in line with the increase of product royalty revenue.

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the three months ended September 30, 2008 and 2007:

		Three Months Ended September 30,		ed
(In thousands)	2	2008		2007
Interest income	\$	655	\$	780
Other expense, net		(15)		(228)
Total non-operating income, net	\$	640	\$	552

Interest income was \$655,000 for the three months ended September 30, 2008 compared to \$780,000 for the three months ended September 30, 2007, a decrease of \$125,000 or 16.0%. The decrease was primarily due to a decrease in yield earned by our investments as we moved our investment portfolio mix from auction rate securities to U.S. Government securities.

Income Taxes

For the three months ended September 30, 2008 and 2007, our consolidated effective tax rate was 41.8% and 46.6%, respectively. For the three months ended September 30, 2008, we recorded a tax benefit of \$1.7 million. For the three months ended September 30, 2007, we recorded a tax provision of \$151,000.

Comparison of nine months ended September 30, 2008 and September 30, 2007

Revenues

The following table summarizes our revenues for the nine months ended September 30, 2008 and 2007:

	ıtıns Ended ıber 30,
2008	2007
\$ 66,982	\$ 52,105
24,699	18,869
3,643	3,318
425	454
\$ 95,749	\$ 74,746
	Septen 2008 \$ 66,982 24,699 3,643 425

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Total revenues were \$95.7 million for the nine months ended 2008 compared to \$74.7 million for the nine months ended September 30, 2007, an increase of \$21.0 million or 28.1%.

Research and development revenue was \$67.0 million for the nine months ended September 30, 2008 compared to \$52.1 million for the nine months ended September 30, 2007, an increase of \$14.9 million or 28.6%. The increase was primarily due to the \$50.0 million development milestone earned and received from Takeda in May 2008 upon FDA approval of AMITIZA for the treatment of the irritable bowel syndrome with constipation in adult women compared to the \$30.0 million development milestone earned from Takeda upon filing of the sNDA for AMITIZA to treat irritable bowel syndrome with constipation in June 2007. The increase was partially offset by a deferral of approximately \$3.6 million in research and development revenue as a result of a change in the second quarter of 2008 of the estimated completion date and an increase in total expected reimbursable costs associated with the ongoing clinical trials for opioid-induced bowel dysfunction. The increase in research and development revenue was partly offset by the recognition of \$11.0 million of AMITIZA-related deferred revenue during the first six months of 2007 resulting from payments previously received from Takeda for development of AMITIZA to treat chronic idiopathic constipation and irritable bowel syndrome with constipation. We recognized revenue for this development work ratably over the estimated performance period, which was completed in June 2007 when we filed the sNDA for the irritable bowel syndrome with constipation indication, and there is no corresponding amount in 2008.

Product royalty revenue represents royalty revenue earned on net sales of AMITIZA in accordance with the Takeda Agreements. For the nine months ended September 30, 2008 and 2007, we recognized \$24.7 million and \$18.9 million, respectively, of product royalty revenue, an increase of \$5.8 million or 30.7%. The increase reflects the continuing acceptance by patients and physicians of AMITIZA® 24 mcg for the treatment of chronic idiopathic constipation in adults and sales of AMITIZA 8 mcg for irritable bowel syndrome with constipation in adult women, including the royalty revenue of approximately \$1.9 million recognized during the three months ended June 30, 2008 from the initial stocking of AMITIZA 8 mcg in May 2008. Additionally, during the nine months ended September 30, 2008, we recorded a reduction of product royalty revenues of \$644,000 resulting from a change in estimate relating to rebates, discounts and other expenses.

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force and costs associated with miscellaneous marketing activities in connection with the commercialization of AMITIZA. For the nine months ended September 30, 2008 and 2007, we recognized \$3.6 million and \$3.3 million, respectively, of co-promotion revenues for reimbursement of sales force costs.

Research and Development Expenses

The following summarizes our research and development expenses for the nine months ended September 30, 2008 and 2007:

		onths Ended ember 30,
(In thousands)	2008	2007
Direct costs:		
AMITIZA	\$ 27,192	\$ 16,272
Cobiprostone	3,450	3,101
SPI - 017	2,232	1,033
Other	1,048	863
Total	33,922	21,269
Indirect costs	1,615	1,009
Total	<u>\$ 35,537</u>	\$ 22,278

Total research and development expenses for the nine months ended September 30, 2008 were \$35.5 million compared to \$22.3 million for the nine months ended September 30, 2007, an increase of \$13.2 million or 59.2%. This increase was due to our ongoing clinical development programs of AMITIZA for the treatment of opioid-induced bowel dysfunction, chronic idiopathic constipation in Japan and cobiprostone for the treatment of non-steroidal anti-inflammatory drug-induced ulcers and portal hypertension in patients with liver cirrhosis, and preclinical and basic development costs associated with SPI-017. We also incurred filing and data purchase costs of approximately \$2.5 million, which were necessary to submit our European MAAs during the nine months ended September 30, 2008.

General and Administrative Expenses

The following summarizes our general and administrative expenses for the nine months ended September 30, 2008 and 2007:

		Nine Months Ended September 30,	
(In thousands)	2008	2007	
Salaries	\$ 3,277	\$ 2,772	
Legal and consulting expenses	2,101	2,005	
Stock-based compensation	153	(194)	
Founders' stock-based award	_	9,187	
Other	5,060	3,516	
Total	\$ 10,591	\$ 17,286	

General and administrative expenses were \$10.6 million for the nine months ended September 30, 2008 compared to \$17.3 million for the nine months ended September 30, 2007, a decrease of \$6.7 million or 38.7%. This decrease was primarily due to a one-time expense of \$9.2 million related to a stock-based award granted to the founders recorded in 2007, partially offset by an increase in operational headcount, an increase in expenses associated with our new office space and an increase in overall costs associated with the compliance and regulatory requirements of being a publicly traded company with international operations.

Selling and Marketing Expenses

Selling and marketing expenses represent costs we incur to co-promote AMITIZA, including salaries, benefits and related costs of our sales force and other sales and marketing personnel, costs of market research and analysis and other selling and marketing expenses. Selling and marketing expenses were \$8.4 million for the nine months ended September 30, 2008 compared to \$9.8 million for the nine months ended September 30, 2007, a decrease of \$1.4 million or 14.3%. This decrease was primarily due to cost savings related to completing our initial build-out of our own internal dedicated sales force to provide AMITIZA to patients in long-term care facilities, as well as in medical schools and university hospitals, which was completed during the second quarter of 2007 and reduced marketing expenses in the long-term care market.

Milestone Royalties — Related Parties

Milestone royalties — related parties expense was \$3.5 million for the nine months ended September 30, 2008. We are obligated to pay SAG a \$1.0 million milestone in connection with our first NDA filing, or comparable foreign regulatory filing, such as an MAA, in each of the three following territories covered by the license agreement with SAG: North, Central and South America (including the Caribbean); Asia; and the rest of the world. Our MAA filed in February 2008 represented the first such filing for the rest-of-the-world territory. As a result of our sNDA approval for AMITIZA to treat irritable bowel syndrome with constipation, we paid SAG \$2.5 million, reflecting 5% of the \$50.0 million development milestone payment that we received from Takeda in May 2008. We recorded \$1.5 million in milestone royalties — related parties expense for the nine months ended September 30, 2007, reflecting the 5% we owed SAG in respect of the \$30.0 million development milestone earned from Takeda during that period upon the filing of our sNDA.

Product Royalties — Related Parties

Product royalties — related parties expense was \$4.4 million for the nine months ended September 30, 2008 compared to \$3.4 million for the nine months ended September 30, 2007, an increase of \$1.0 million or 29.4%, in line with the increase of product royalty revenue.

Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the nine months ended September 30, 2008 and 2007:

	September	
(In thousands)	2008	2007
Interest income	\$ 1,862	\$ 1,575
Other expense, net	(16)	(192)
Total non-operating income, net	<u>\$ 1,846</u>	\$ 1,383

Interest income was \$1.9 million for the nine months ended September 30, 2008 compared to \$1.6 million for the nine months ended September 30, 2007, an increase of \$0.3 million or 18.8%. The increase was primarily due to an increase in the funds available for investment in 2008 compared to 2007, partially offset by a decrease in yield earned by our investments as our investment portfolio mix moved from auction rate securities to U.S. Government securities.

Income Taxes

For the nine months ended September 30, 2008 and 2007, our consolidated effective tax rate was 20.5% and 36.4%, respectively. For the nine months ended September 30, 2008 and 2007, we recorded a tax provision of \$7.2 million and \$7.9 million, respectively. As a result of the FDA approval of the sNDA for irritable bowel syndrome with constipation in adult women and the related impact on projected income in 2008 and future years from the \$50.0 million milestone payment received in May 2008 and expected product royalties, we believe that our U.S. deferred tax assets will likely be realized. Accordingly, the tax provision recorded for the nine months ended September 30, 2008 reflects a discrete release of U.S. deferred tax asset valuation allowances of \$4.8 million and a reduction in the projected 2008 effective tax rate applied to our pre-tax income.

Reportable Geographic Segments

We have determined that we have three reportable geographic segments based on our method of internal reporting, which disaggregates business by geographic location. These segments are the United States, Europe and Japan. We evaluate the performance of these segments based on income (loss) from operations, as well as other factors, including the progress of research and development activities. The following is a summary of financial information by reportable segment.

(In thousands)	United States	Europe	Japan	Intercompany Eliminations	Consolidated
Three Months Ended September 30, 2008					
Total revenues	\$ 14,481	\$ —	\$ 213	\$ (213)	\$ 14,481
Loss from operations	(3,448)	(470)	(890)	(3)	(4,811)
Three Months Ended September 30, 2007					
Total revenues	\$ 12,843	\$ —	\$ 219	\$ (210)	\$ 12,852
Income (loss) from operations	171	(521)	(525)	_	(875)
Nine Months Ended September 30, 2008					
Total revenues	\$ 95,749	\$ —	\$ 630	\$ (630)	\$ 95,749
Income (loss) from operations	40,107	(2,892)	(3,914)	_	33,301
Nine Months Ended September 30, 2007					
Total revenues	\$ 74,716	\$ —	\$ 660	\$ (630)	\$ 74,746
Income (loss) from operations	22,372	(830)	(1,020)	_	20,522
Identifiable Assets					
At September 30, 2008	\$158,420	\$ 2,160	\$ 5,364	\$(17,825)	\$148,119
At December 31, 2007	114,490	2,381	1,987	(8,831)	110,027

Liquidity and Capital Resources

Sources of Liquidity

We require cash principally to meet our operating expenses. We have financed our operations with a combination of private placements of equity securities, our initial public offering, up-front payment, milestone and royalty payments and research and development expense reimbursements received from Takeda and R-Tech Ueno, Ltd., a Japanese pharmaceutical manufacturer and affiliate. We have raised net proceeds of \$55.3 million from private equity financings and net proceeds of \$28.2 million from our initial public offering. We have also received an aggregate of \$215.3 million in up-front, milestone and expense reimbursement payments from Takeda.

Our cash, cash equivalents and investments consist of the following assets at fair value:

(In thousands)	September 30,	December 31, 2007
Cash and cash equivalents	\$ 13,364	\$ 25,559
Investments, current	93,117	51,552
Investments, non-current	17,626	9,400
	\$ 124,107	\$ 86,511

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

At September 30, 2008, we continue to hold \$21.0 million of investments in auction rate securities at fair value and recorded an unrealized loss of \$1.9 million, or \$1.2 million net of tax effect, as of September 30, 2008, related to these investments. This unrealized loss was recorded as other comprehensive loss during the nine months ended September 30, 2008.

On October 16, 2008, we accepted the settlement rights offered by our broker under a settlement agreement between the broker and the SEC and various state regulatory authorities. The settlement rights allow us to redeem auction rate securities at par within a specified period. Based on this settlement, we received \$3.4 million on November 3, 2008, representing the par value of our tax-exempt auction rate securities, and we have the right to request the redemption of the remaining auction rate securities at par value of an additional \$19.4 million within the two-year period starting June 30, 2010. As the settlement was accepted subsequent to September 30, 2008, our consolidated financial statements as of September 30, 2008 do not reflect any contingent gains, valuation adjustments or any other amounts relating to the settlement rights. We have, however, classified auction rate securities as current and non-current investments as of September 30, 2008 based on the expected redemption dates. We do not anticipate having to sell these securities in order to operate its business before the expected redemption dates.

On March 5, 2008, we entered into a line of credit providing for uncommitted borrowings of up to \$30.0 million. The lender has no obligation to make advances under this line of credit but may do so in its sole discretion. The line of credit is collateralized by our current and non-current investments. Advances made under this line of credit will bear an interest rate based on LIBOR plus a predetermined percentage based on the amount of the advance and other conditions. Borrowings under this line of credit are due upon the demand of the lender and the lender can make a repayment demand at its sole option at any time for any or no reason. As of September 30, 2008, we had not drawn down any funds under this line of credit.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2008 and 2007:

	Septem	
(In thousands)	2008	2007
Cash (used in) provided by:		
Operating activities	\$ 38,611	\$ 8,408
Investing activities	(51,801)	(33,180)
Financing activities	1,025	31,341
Effect of exchange rates	(30)	186
Net (decrease) increase in cash and cash equivalents	\$ (12,195)	\$ 6,755

Nine Months Ended September 30, 2008

Net cash provided by operating activities was \$38.6 million for the nine months ended September 30, 2008 and reflected net income of \$28.0 million, a change of \$3.2 million in net prepaid and income taxes receivable and payable, an increase in accrued expenses of \$3.8 million and an increase of \$4.9 million in deferred revenue, offset by a non-cash reversal of deferred tax asset valuation allowances of \$4.3 million and changes in other operating assets and liabilities.

Net cash used in investing activities of \$51.8 million for the nine months ended September 30, 2008 primarily reflected our net purchases of investments as a result of our investment of the \$50.0 million milestone payment received from Takeda in the second quarter of 2008.

Net cash provided by financing activities of \$1.0 million for the nine months ended September 30, 2008 resulted from the exercise of stock options.

Nine Months Ended September 30, 2007

Net cash provided by operating activities was \$8.4 million for the nine months ended September 30, 2007. This reflected net income of \$13.9 million, which was offset by an increase in product royalties receivable of \$5.0 million, an increase in accounts receivable of \$2.8 million and a decrease in deferred revenue of \$11.4 million. The decrease in deferred revenue primarily related to the amortization of deferred research and development revenue over the performance period of the development of AMITIZA.

Net cash used in investing activities of \$33.2 million for the nine months ended September 30, 2007 primarily reflected our net purchases of investments as a result of our investment of the \$30.0 million milestone payment received from Takeda in the second quarter of 2007 and approximately \$2.1 million of purchases of property and equipment associated with the move of our offices in the United States in July 2007.

Net cash provided by financing activities was \$31.3 million for the nine months ended September 30, 2007 and reflected primarily proceeds from our initial public offering, net of certain offering costs.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4) of Regulation S-K promulgated under the Securities Act of 1933, as amended.

Funding Requirements

We will need substantial amounts of capital to continue growing our business. We will require this capital to:

- fund our 30% share of the two post-marketing studies of AMITIZA to evaluate its safety in patients with renal impairment and patients with hepatic impairment;
- fund regulatory efforts in Europe and Japan for AMITIZA;
- fund development and regulatory activities for cobiprostone and SPI-017;
- fund research and development activities for prostone compounds other than AMITIZA, cobiprostone and SPI-017;
- fund the expansion of our commercialization activities in the United States and the initiation of commercialization efforts in non-U.S. markets;
- fund costs for capital expenditures to support the growth of our business.

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

- the revenue from AMITIZA;
- the future expenditures we may incur to increase revenue from AMITIZA;
- the cost and time involved to pursue our research and development programs;
- our ability to establish collaborative arrangements and to enter into licensing agreements and contractual arrangements with others; and
- any future change in our business strategy.

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

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 may dilute the ownership of our equity investors.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We do not use derivative financial instruments for trading or speculative purposes. However, we regularly invest excess cash in overnight deposits that are subject to changes in short-term interest rates.

Our exposure to market risks associated with changes in interest rates relates primarily to the increase or decrease in the amount of interest income earned on our investment portfolio. We mitigate default risk by investing in investment grade securities. A hypothetical one percentage point adverse move in interest rates along the entire interest rate yield curve would not have materially affected the fair value of our interest sensitive financial instruments as of September 30, 2008.

Our exposure to credit risk consists of cash and cash equivalents, restricted cash investments and receivables. We place our cash and cash equivalents, restricted cash and investments with highly rated financial institutions. Our uninsured cash, cash equivalents and investments as of September 30, 2008 consist primarily of \$70.8 million of U.S. Treasury and notes and \$18.9 million of money market funds guaranteed under the U.S. Treasury's Temporary Guarantee Program.

(In thousands)	Sep	tember 30, 2008
Cash and cash equivalents	\$	13,364
Investments		110,743
Restricted cash		213
Less: amounts subject to federally insured limits		(26,239)
Total amounts in excess of federally insured limits	\$	98,081

Our investments in the auction rate securities and related risks are further described in Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources."

Item 4. Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, performed an evaluation of the effectiveness of the design and operation of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of September 30, 2008. Based upon this evaluation, our Principal Executive Officer and Principal Financial Officer have concluded that, as of September 30, 2008, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified under applicable rules of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

b) Changes in Internal Controls

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Except for the risk factors listed below, we do not believe there have been material changes to the risk factors affecting our business that we included in our Annual Report on Form 10-K for the year ended December 31, 2007.

The recent downturn in the global economy and the recent pressure on capital markets increase the possibility of and may exacerbate the impact of any adverse effects on our financial position and business prospects.

The recent downturn in the U.S. economy and economics around the world and the extraordinary pressure being placed on both debt and equity markets have led to significant retraction in the U.S. businesses, sudden and severe decreases in the prices of U.S. equities generally and a severe shortage in available credit. These factors have made it more difficult, in general, for companies to expand or maintain their current operations and have increased the likelihood that certain companies will fail. Although we cannot say with certainty the impact the current economic crises has had on us to date or may have on us in the future, continued pressure on the U.S. economy and its capital markets may have the effect of, among other things, reducing demand for our products generally, increasing the cost to manufacture our products, or making it more difficult for us to raise capital or enter into strategic relationships, each of which could have a materially negative impact on our business or business prospects. The economic downturn may also lead to, or accelerate, a decrease in the trading price of our class A common stock.

We depend significantly upon Takeda's sales force to market AMITIZA. In addition to its own sales force, Takeda has been utilizing a sales force within an affiliated joint venture for this purpose, and the joint venture was recently terminated. Any disruptions in the marketing of AMITIZA by the Takeda sales force as a result of this development could cause a decline in our revenues.

Under our collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda markets AMITIZA broadly to office-based specialty physicians and primary care physicians. For this purpose, Takeda has been utilizing its own sales force and a sales force within an affiliated joint venture, TAP Pharmaceutical Products, Inc., or TAP, which Takeda jointly owned with Abbot Pharmaceuticals, or Abbott. Takeda and Abbott recently announced that they have terminated the TAP joint venture. Takeda has informed us that the TAP sales force marketing AMITIZA will become a Takeda sales force following the termination of the joint venture. These developments could cause some short-term distraction and dislocation in the Takeda sales force promoting AMITIZA, which could cause some disruption in the marketing of AMITIZA and in turn lead to declining or deferred sales of AMITIZA. While we expect any such disruptions would be temporary and short-term, we cannot assure you that will be the case. Any longer-term disruptions could cause a material decline in our revenues.

The resignations of our chief financial officer, our vice president of business development and company operations and our executive vice president of commercial operations could be disruptive to our business, and our inability to replace them on a timely basis could compromise our ability to manage our company.

Mariam E. Morris, our former chief financial officer, resigned her position with us effective July 31, 2008. Kei S. Tolliver, our former vice president of business development and company operations, resigned her position effective as of May 31, 2008. In addition, Brad Fackler, our executive vice president, commercial operations, resigned his position effective as of October 10, 2008 and agreed to remain as an employee at Sucampo for a period of time to assist in the transition of responsibilities. Our failure to successfully transition the responsibilities of these employees to other employees could make it difficult for us to pursue our business strategy.

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

Use of Proceeds from Initial Public Offering of Class A Common Stock

In August 2007, we completed an initial public offering of class A common stock pursuant to a registration statement on Form S-1 (Registration No. 333-135133) which the Securities and Exchange Commission, or SEC, declared effective on August 2, 2007. Pursuant to the registration statement, we registered the offering and sale of an aggregate of 4,312,500 shares of our class A common stock, of which 3,125,000 shares were sold by us and 625,000 shares were sold by a selling stockholder, at a price of \$11.50 per share. S&R Technology Holdings, LLC, or S&R, which is wholly owned by our founders, Drs. Kuno and Ueno, granted to the underwriters an option to purchase an additional 562,500 shares of our class A common stock at the initial public offering price of \$11.50 per share to cover over-allotments, if any. The initial closing of the offering occurred on August 2, 2007. The underwriters exercised their over-allotment option and purchased an additional 562,500 shares of class A common stock from S&R on August 29, 2007. We did not receive any proceeds from the sale of these shares by S&R. The managing underwriters for the offering were Cowen and Company, LLC, CIBC World Markets Corp. and Leerink Swann & Co., Inc.

We raised a total of \$28.2 million in net proceeds from our initial public offering. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10% or more of our common stock or to any affiliate of ours, and none of the expenses we incurred in connection with the offering or the underwriting discounts and commissions were paid, directly or indirectly, to any such persons. We did, however, contemporaneously with the closing of our initial public offering, make payments of approximately \$3.1 million in the aggregate to Ryuji Ueno, a director, officer and 10% stockholder, and Sachiko Kuno, a 10% stockholder, in settlement of special stock and cash awards that had been made to them in June 2007.

We have used all proceeds from our initial public offering in line with the use of proceeds as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

Item 3. Defaults Upon Senior Securities.

None.

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

No matters were submitted to a vote of security holders during the quarter ended September 30, 2008.

Item 5. Other Information.

None.

Item 6. Exhibits

(a) Exhibits

Exhibit

Number	Description	Reference
3.1	Restated Certificate of Incorporation	Exhibit 3.1 to the Company's Current Report on Form 8-K (filed August 8, 2007)
3.2	Form of Restated Bylaws	Exhibit 3.4 to Registration Statement No. 333-135133, Amendment No. 2 (filed October 20, 2006)
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	Indemnification Agreement by and between the Company and Andrew J. Ferrara	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed July 22, 2008)
10.2	Separation Agreement and General Release by and between the Company and Mariam E. Morris	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed July 28, 2008)
10.3	Consulting Agreement by and between the Company and Mariam E. Morris	Exhibit 10.2 to the Company's Current Report on Form 8-K (filed July 28, 2008)
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002	Included herewith
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Included herewith
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SIGNATURES

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

Sucampo Pharmaceuticals, Inc.

November 14, 2008 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 14, 2008 By: /s/ JAN SMILEK

Jan Smilek

Vice President, Finance and Acting Chief

Financial Officer

(Principal Financial Officer)

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Sucampo Pharmaceuticals, Inc. Exhibit Index

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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)) 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) 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
 - (c) 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 14, 2008 /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, Jan Smilek, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Sucampo Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) 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) 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
 - (c) 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 14, 2008 /s/ JAN SMILEK

Jan Smilek
Vice President, Finance
Acting Chief Financial Officer
(Principal Financial Officer)

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

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

- (1) The Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 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 14, 2008

/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 quarter ended September 30, 2008 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 14, 2008 /s/ JAN SMILEK

Jan Smilek
Vice President, Finance
Acting Chief Financial Officer
(Principal Financial Officer)