# 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 June 30, 2010

OR

0 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)

4520 East-West Highway, Suite 300 Bethesda, MD 20814 (Address of principal executive offices, including zip code) **30-0520478** (I.R.S. employer identification no.)

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. Please see definition 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  $\square$ 

Non accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting company o

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

As of August 2, 2010, there were 15,657,937 shares of the registrant's class A common stock outstanding and 26,191,050 shares of the registrant's class B common stock outstanding.

# Sucampo Pharmaceuticals, Inc.

# Form 10-Q Index

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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)

|   | June 201                               |        | December 31,<br>2009 |
|---|--|--------|----------------------|
| ASSETS:   |  |        |                      |
| Current assets:   |  |        |                      |
| Cash and cash equivalents   | \$ 4                                   | 42,293 | \$ 26,714            |
| Investments, current  | 3                                      | 56,163 | 72,434               |
| Product royalties receivable  |  | 9,612  | 11,023               |
| Unbilled accounts receivable  |  | 16     | 644                  |
| Accounts receivable, net  |  | 889    | 512                  |
| Deferred tax assets, net  |  | 135    | 315                  |
| Prepaid expenses and other current assets   |  | 2,209  | 3,137                |
| Total current assets  | 1                                      | 11,317 | 114,779              |
| Investments, non-current  |  | 15,935 | 19,167               |
| Property and equipment, net   |  | 2,117  | 2,242                |
| Deferred tax assets, non-current  |  | 4,255  | 3,995                |
| Other assets  |  | 3,551  | 4,788                |
| Total assets  | \$ 13                                  | 37,175 | \$ 144,971           |
| LIABILITIES AND STOCKHOLDERS' EQUITY:   |  |        |                      |
| Current liabilities:  |  |        |                      |
| Accounts payable  | \$                                     | 2,335  | \$ 3,195             |
| Accrued expenses  |  | 7,941  | 6,545                |
| Deferred revenue, current   |  | 4,298  | 10,565               |
| Income taxes payable  |  | 428    | 349                  |
| Total current liabilities   |  | 15,002 | 20,654               |
| Deferred revenue, non-current   |  | 8,296  | 8,643                |
| Other liabilities   |  | 2,098  | 2,121                |
| Total liabilities   | · · · · · · · · · · · · · · · · · · ·  | 2,000  | 31,418               |
|   | <u> </u>                               | 5,590  | 51,410               |
| Commitments (Note 7)  |  |        |                      |
| Stockholders' equity:   |  |        |                      |
| Preferred stock, \$0.01 par value; 5,000,000 shares authorized at June 30, 2010 a | nd December 31, 2009; no shares issued |        |                      |

| and outstanding at June 30, 2010 and December 31, 2009  | -          | -          |
|---|------------|------------|
| Class A common stock, \$0.01 par value; 270,000,000 shares authorized at June 30, 2010 and December 31, 2009; |            |            |
| 15,657,937 and 15,655,730 shares issued and outstanding at June 30, 2010 and December 31, 2009, respectively  | 156        | 156        |
| Class B common stock, \$0.01 par value; 75,000,000 shares authorized at June 30, 2010 and December 31, 2009;  |            |            |
| 26,191,050 shares issued and outstanding at June 30, 2010 and December 31, 2009                               | 262        | 262        |
| Additional paid-in capital  | 99,346     | 98,636     |
| Accumulated other comprehensive income  | 277        | 484        |
| Retained earnings   | 11,738     | 14,015     |
| Total stockholders' equity  | 111,779    | 113,553    |
| Total liabilities and stockholders' equity  | \$ 137,175 | \$ 144,971 |
|   |            |            |

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

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

(In thousands, except per share data)

|  | Th | Three Months Ended June 30, |    |        | Six Months Endec |         |    | d June 30, |  |
|--|----|-----------------------------|----|--------|------------------|---------|----|------------|--|
|  |    | 2010                        |    | 2009   |                  | 2010    |    | 2009       |  |
| Revenues:  |    |                             |    |        |                  |         |    |            |  |
| Research and development revenue                         | \$ | 2,789                       | \$ | 7,395  | \$               | 6,846   | \$ | 12,921     |  |
| Product royalty revenue                                  |    | 9,612                       |    | 8,914  |                  | 19,385  |    | 17,860     |  |
| Co-promotion revenue                                     |    | 1,220                       |    | 1,244  |                  | 2,075   |    | 2,140      |  |
| Contract and collaboration revenue                       |    | 154                         |    | 152    |                  | 305     |    | 298        |  |
| Total revenues   |    | 13,775                      |    | 17,705 |                  | 28,611  |    | 33,219     |  |
| Operating expenses:                                      |    |                             |    |        |                  |         |    |            |  |
| Research and development                                 |    | 4,854                       |    | 9,621  |                  | 10,220  |    | 19,586     |  |
| General and administrative                               |    | 6,604                       |    | 2,924  |                  | 12,363  |    | 6,379      |  |
| Selling and marketing                                    |    | 2,313                       |    | 2,188  |                  | 4,500   |    | 4,700      |  |
| Milestone royalties - related parties                    |    | -                           |    | 375    |                  | -       |    | 875        |  |
| Product royalties - related parties                      |    | 1,709                       |    | 1,583  |                  | 3,446   |    | 3,173      |  |
| Total operating expenses                                 |    | 15,480                      |    | 16,691 |                  | 30,529  |    | 34,713     |  |
| Income (loss) from operations                            |    | (1,705)                     |    | 1,014  |                  | (1,918) |    | (1,494)    |  |
| Non-operating income (expense):                          |    |                             |    |        |                  |         |    |            |  |
| Interest income  |    | 177                         |    | 219    |                  | 388     |    | 531        |  |
| Other income (expense), net                              |    | (135)                       |    | (608)  | _                | (227)   | _  | 214        |  |
| Total non-operating income (expense), net                |    | 42                          |    | (389)  |                  | 161     |    | 745        |  |
| Income (loss) before income taxes                        |    | (1,663)                     |    | 625    |                  | (1,757) |    | (749)      |  |
| Income tax provision                                     |    | (315)                       |    | (863)  |                  | (520)   |    | (1,264)    |  |
| Net loss   | \$ | (1,978)                     | \$ | (238)  | \$               | (2,277) | \$ | (2,013)    |  |
| Net loss per share:                                      |    |                             |    |        |                  |         |    |            |  |
| Basic net loss per share                                 | \$ | (0.05)                      | \$ | (0.01) | \$               | (0.05)  | \$ | (0.05)     |  |
| Diluted net loss per share                               | \$ | (0.05)                      | \$ | (0.01) | \$               | (0.05)  | \$ | (0.05)     |  |
| Weighted average common shares outstanding - basic       |    | 41,848                      |    | 41,844 |                  | 41,847  | _  | 41,844     |  |
| Weighted average common shares outstanding - diluted     |    | 41,848                      |    | 41,844 |                  | 41,847  |    | 41,844     |  |
| Comprehensive income (loss):                             |    |                             |    |        |                  |         |    |            |  |
| Net loss   | \$ | (1,978)                     | \$ | (238)  | \$               | (2,277) | \$ | (2,013)    |  |
| Other comprehensive income (loss):                       |    |                             |    |        |                  |         |    |            |  |
| Unrealized gain (loss) on investments, net of tax effect |    | 10                          |    | (7)    |                  | (7)     |    | (72)       |  |
| Foreign currency translation                             |    | (220)                       |    | 340    |                  | (200)   |    | 137        |  |
| Comprehensive income (loss)                              | \$ | (2,188)                     | \$ | 95     | \$               | (2,484) | \$ | (1,948)    |  |

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

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

|   |            | Class A<br>Common Stock |     |            |    |        |    | Additional<br>Paid-In |    |          | Paid-In Comprehensive |         |    | Sto     | Total<br>ckholders' |         |  |         |  |         |  |         |  |         |  |         |  |         |  |         |  |        |   |         |  |        |
|---|------------|-------------------------|-----|------------|----|--------|----|-----------------------|----|----------|-----------------------|---------|----|---------|---------------------|---------|--|---------|--|---------|--|---------|--|---------|--|---------|--|---------|--|---------|--|--------|---|---------|--|--------|
|   | Shares     | hares Amou              |     | Shares     | A  | Amount |    | Capital               |    | Capital  |                       | Capital |    | Capital |                     | Capital |  | Capital |  | Capital |  | Capital |  | Capital |  | Capital |  | Capital |  | Capital |  | Income | E | arnings |  | Equity |
| Balance at December 31, 2009                      | 15,655,730 | \$                      | 156 | 26,191,050 | \$ | 262    | \$ | 98,636                | \$ | 484      | \$                    | 14,015  | \$ | 113,553 |                     |         |  |         |  |         |  |         |  |         |  |         |  |         |  |         |  |        |   |         |  |        |
| Employee stock option expense                     | -          |                         | -   | -          |    | -      |    | 702                   |    | -        |                       | -       |    | 702     |                     |         |  |         |  |         |  |         |  |         |  |         |  |         |  |         |  |        |   |         |  |        |
| Stock issued under employee stock purchase plan   | 2,207      |                         | -   | -          |    | -      |    | 8                     |    | -        |                       | -       |    | 8       |                     |         |  |         |  |         |  |         |  |         |  |         |  |         |  |         |  |        |   |         |  |        |
| Foreign currency translation                      | -          |                         | -   | -          |    | -      |    | -                     |    | (200)    |                       | -       |    | (200)   |                     |         |  |         |  |         |  |         |  |         |  |         |  |         |  |         |  |        |   |         |  |        |
| Unrealized loss on investments, net of tax effect | -          |                         | -   | -          |    | -      |    | -                     |    | (7)      |                       | -       |    | (7)     |                     |         |  |         |  |         |  |         |  |         |  |         |  |         |  |         |  |        |   |         |  |        |
| Net loss  |            |                         | -   |            |    | -      |    | -                     |    | <u> </u> |                       | (2,277) |    | (2,277) |                     |         |  |         |  |         |  |         |  |         |  |         |  |         |  |         |  |        |   |         |  |        |
| Balance at June 30, 2010                          | 15,657,937 | \$                      | 156 | 26,191,050 | \$ | 262    | \$ | 99,346                | \$ | 277      | \$                    | 11,738  | \$ | 111,779 |                     |         |  |         |  |         |  |         |  |         |  |         |  |         |  |         |  |        |   |         |  |        |

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

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

|   | Six Months Er | nded June 30, |
|---|---------------|---------------|
|   | 2010          | 2009          |
| Cash flows from operating activities:   |               |               |
| Net loss  | \$ (2,277)    | \$ (2,013)    |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: |               |               |
| Depreciation and amortization   | 459           | 309           |
| Deferred tax provision  | (76)          | 738           |
| Stock-based compensation  | 702           | 188           |
| Amortization of premiums on investments   | 869           | 508           |
| Unrealized gain on trading securities   | -             | (2,611)       |
| Unrealized loss on settlement rights of auction rate securities                           | -             | 2,362         |
| Realized gain on trading securities   | (1,086)       | -             |
| Realized loss on settlement rights of auction rate securities                             | 1,086         | -             |
| Changes in operating assets and liabilities:  |               |               |
| Accounts receivable   | (377)         | (26)          |
| Unbilled accounts receivable  | 628           | 750           |
| Product royalties receivable  | 1,411         | 812           |
| Income taxes payable  | 79            | (936)         |
| Accounts payable  | (887)         | 601           |
| Accrued expenses  | 1,376         | 1,009         |
| Deferred revenue  | (6,806)       | 9,445         |
| Other assets and liabilities, net   | 927           | (123)         |
| Net cash provided by (used in) operating activities                                       | (3,972)       | 11,013        |
| Cash flows from investing activities:   |               |               |
| Purchases of investments  | (40,534)      | (90,882)      |
| Proceeds from sales of investments  | 12,000        | 9,504         |
| Maturities of investments   | 48,242        | 52,760        |
| Purchases of property and equipment   | (157)         | (308)         |
| Purchase of intangible assets   | -             | (2,919)       |
| Net cash provided by (used in) investing activities                                       | 19,551        | (31,845)      |
| Cash flows from financing activities:   |               |               |
| Proceeds from employee stock purchase plan  | 8             | 9             |
| Net cash provided by financing activities   | 8             | 9             |
| Effect of exchange rates on cash and cash equivalents                                     | (8)           | 184           |
| Net increase (decrease) in cash and cash equivalents                                      | 15,579        | (20,639)      |
| Cash and cash equivalents at beginning of period  | 26,714        | 62,562        |
| Cash and cash equivalents at end of period  | \$ 42,293     | \$ 41,923     |

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

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

# 1. Business Organization and Basis of Presentation

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

Sucampo Pharmaceuticals, Inc., or the Company, is an international biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds that occur naturally in the human body as a result of enzymatic, 15-PGDH, transformation of certain fatty acids. The Company is focused on developing prostones for the treatment of gastrointestinal, ophthalmic, respiratory, vascular and central nervous system diseases and other disorders for which there are unmet or underserved medical needs and significant commercial potential.

The therapeutic potential of prostones was first identified by one of the Company's founders, Dr. Ryuji Ueno. To date, two prostone products have received marketing approval. Amitiza<sup>®</sup> (lubiprostone) is an FDA-approved treatment for two gastrointestinal indications: (i) chronic idiopathic constipation, or CIC, in adults of both genders and all ages and (ii) irritable bowel syndrome with constipation, or IBS-C, in adult women. Rescula<sup>®</sup> (unoprostone isopropyl) is FDA-approved for the treatment of open-angle glaucoma and ocular hypertension.

Amitiza is being marketed and developed in the U.S. for gastrointestinal indications under a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda. The Company is primarily responsible for development activities under the agreement. The Company and Takeda initiated commercial sales of Amitiza in the U.S. for the treatment of CIC in April 2006 and for the treatment of IBS-C in May 2008. Amitiza is currently being developed for the treatment of opioid-induced bowel dysfunction, or OBD.

In Japan, lubiprostone is being developed for gastrointestinal indications under a license, commercialization and supply agreement with Abbott Japan Co. Ltd., or Abbott.

The Company continues to evaluate the opportunities to obtain an appropriate label in the European Union consistent with the fact that lubiprostone is approved by the FDA in the U.S. for chronic therapy for either CIC or IBS-C and received marketing authorization from Swissmedic, the Swiss Agency for Therapeutic Products, in November 2009 for CIC.

In April 2009, the Company acquired the rights to Rescula that allow the Company to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension and any new indication developed by the Company, including retinitis pigmentosa and dry aged-related macular degeneration, or dry AMD. The Company plans to re-launch Rescula in the U.S. for the treatment of open-angle glaucoma and ocular hypertension. Additionally, the Company plans to initiate clinical trials of Rescula for the treatment of dry AMD in early 2011.

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

#### **Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, and the rules and regulations of the Securities and Exchange Commission, or SEC, for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements as of and for the year ended December 31, 2009 included in the Company's Annual Report on Form 10-K. The financial information as of June 30, 2010 and for the three and six months ended June 30, 2010 and 2009 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.

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

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: Sucampo Pharma Ltd., based in Tokyo and Osaka, Japan, through which the Company conducts its Asian operations; Sucampo Pharma Americas, Inc., based in Bethesda, Maryland, through which the Company conducts operations in North and South America; and Sucampo Pharma Europe Ltd., based in Oxford, U.K., through which the Company conducts operations in Europe and the rest of the world. All inter-company balances and transactions have been eliminated. In April 2010, the Company incorporated another wholly owned subsidiary, Sucampo Manufacturing & Research AG, in Wollerau, Switzerland, whose operations will focus on managing specific manufacturing, commercial, research and intellectual property activities and whose activity and accounts are included in the consolidated financial statements.

# 2. Summary of Significant Accounting Policies

#### Cash and Cash Equivalents

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

# **Current and Non-current Investments**

Current and non-current investments consist primarily of U.S. Treasury bills and notes, U.S. government agencies securities, municipal and corporate bonds, mutual funds and auction rate securities, or ARS. The Company classifies its investments into current and non-current based on their maturities and management's reasonable expectation to realize these investments in cash. The Company classifies all of its investments, except ARS, as available for sale securities and reports unrealized gains or losses, net of related tax effects, in other comprehensive income. Pursuant to the Company's acceptance of settlement rights for its investments in ARS in October 2008, the Company classifies its investments in ARS as trading securities and records gains or losses resulting from the changes in fair values of its ARS and related settlement rights in other income (expense), net. The fair value of the settlement rights related to ARS is recorded in non-current other assets. The fair value of the settlement rights abeen derived from the par value of the Company's investment in ARS and the fair value of ARS as of the recognition date, since the settlement rights obligate the broker to redeem the ARS at par value. The redemption of the remaining ARS and the related settlement rights are described in Note 4 below.

#### Fair Value

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, restricted cash, current and non-current investments, receivables, accounts payable and accrued expenses, approximate their fair values based on their short maturities, independent valuations or internal assessments.

# **Revenue Recognition**

The Company's revenues are derived primarily from collaboration and license agreements and include up-front payments, development milestone payments, reimbursements of development and co-promotion costs and product royalties.

The Company evaluated the multiple deliverables within the collaboration and license agreements in accordance with the guidance of multiple deliverables to determine whether the delivered elements that are the obligation of the Company have value to other parties to the agreement on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate recognition of revenue is then applied to each separate unit of accounting. The Company's deliverables under the Takeda and Abbott agreements, including the related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 9.

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

# Notes to Condensed Consolidated Financial Statements (Unaudited)

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

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

The Takeda supplemental agreement consists of the following key funding streams: reimbursements of co-promotion costs based upon a per-day rate up to a specific annual amount and reimbursements of the costs of miscellaneous marketing activities, which the Company recognizes as revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts.

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

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

Contract revenue relates to development, manufacturing and consulting activities with a related party, R-Tech Ueno, Ltd. or R-Tech, a Japanese manufacturing and research and development company that is majority owned by the Company's founders. The contract revenue includes upfront payments received for exclusive manufacturing and supply agreements which are accounted for under the time-based model.

# 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. In accordance with its investment policy, the Company places its cash, cash equivalents and restricted cash with highly rated financial institutions and invests its excess cash in highly rated investments. As of June 30, 2010 and December 31, 2009, approximately \$62.7 million, or 54.7%, and \$60.7 million, or 51.2%, respectively, of the Company's cash, cash equivalents, restricted cash and investments was issued or insured by the federal government or government agencies. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits. On June 8, 2010, the issuer of the Company's remaining ARS redeemed the security at par value of \$10.0 million.

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

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

# Notes to Condensed Consolidated Financial Statements (Unaudited)

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

Revenues from one unrelated party, Takeda, accounted for 88.1% and 79.2% of the Company's total revenues for the three months ended June 30, 2010 and 2009, respectively, and 84.3% and 87.5% for the six months ended June 30, 2010 and 2009, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 99.7% and 96.5% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at June 30, 2010 and December 31, 2009, respectively. Revenues from another unrelated party, Abbott, accounted for 11.1% and 20.2% of the Company's total revenues for the three months ended June 30, 2010 and 2009, respectively, and 15.0% and 11.9% for the six months ended June 30, 2010 and 2009, respectively. The Company depends significantly upon the collaborations with Takeda and Abbott and its activities may be impacted if these relationships are disrupted (Note 9).

The Company has an exclusive supply arrangement with R-Tech to provide it with commercial and clinical supplies of its product and product candidates. Additionally, in April 2009, the Company acquired from R-Tech all patents and other intellectual property rights related to Rescula in the U.S. and Canada. R-Tech also provides certain preclinical and other research and development services. Any difficulties or delays in performing the services under these arrangements may cause the Company to lose revenues, delay research and development activities or otherwise disrupt the Company's operations (Note 8).

The Company has previously entered into a restated license agreement with a related party, Sucampo AG, or SAG, to grant the Company a royaltybearing, exclusive, worldwide license to develop prostone compounds, other than Rescula. SAG is a Swiss-patent holding company and an entity whollyowned by the Company's founders. The Company's success depends, in part, on SAG's ability to obtain and maintain proprietary protection for the intellectual property rights relating to the prostone technology and products (Note 8).

#### Reclassifications

Certain amounts in the prior year financial statements have been reclassified to conform to the current year presentation. The Company reclassified money market funds of approximately \$186,000 from current investments to cash and cash equivalents as of June 30, 2009. The Company has adjusted the cash flow statement for the quarter ended June 30, 2009 accordingly.

#### **Recent Accounting Pronouncements**

In June 2009, the FASB issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities, or VIEs. The elimination of the concept of qualifying special-purpose entities, or QSPEs, removes the exception from applying the consolidation guidance within this amendment. This amendment requires an enterprise to perform a qualitative analysis when determining whether or not it must consolidate a VIE. The amendment also requires an enterprise to continuously reassess whether it must consolidate a VIE. Additionally, the amendment requires enhanced disclosures about an enterprise's involvement with VIEs and any significant change in risk exposure due to that involvement, as well as how its involvement with VIEs impacts the enterprise's financial statements. Finally, an enterprise will be required to disclose significant judgments and assumptions used to determine whether or not to consolidate a VIE. This amendment is effective for financial statements issued for fiscal years beginning after November 15, 2009. The Company adopted the guidance effective January 1, 2010 and such adoption did not have an impact on the condensed consolidated financial statements.

In September 2009, the FASB issued an amendment to the authoritative guidance which addresses how revenues should be allocated among products and services in a singular sales arrangement. The guidance establishes a hierarchy for determining the selling price of each product or service, with vendor-specific objective evidence, or VSOE, at the highest level, third-party evidence of VSOE at the intermediate level, and management's best estimate at the lowest level. It replaces "fair value" with "selling price" in revenue allocation guidance. It also significantly expands the disclosure requirements for multiple-deliverable revenue arrangements. This guidance will be effective prospectively for agreements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is continuing to evaluate the impact that this amendment would have on its financial condition and results of operation upon adoption.

# Notes to Condensed Consolidated Financial Statements (Unaudited)

In January 2010, the FASB issued authoritative guidance on improving the disclosures about fair value measurements. This statement requires additional disclosures about fair value measurements including transfers in and out of Levels 1 and 2 and a higher level of disaggregation for the different types of financial instruments. For the reconciliation of Level 3 fair value measurements, information about purchases, sales, issuances and settlements should be presented separately. This statement is effective for annual and interim reporting periods beginning after December 15, 2009 for most of the new disclosures and for periods beginning after December 15, 2010 for the new Level 3 disclosures. The Company adopted the relevant guidance effective January 1, 2010 and such adoption did not have a material impact on the condensed consolidated financial statements.

In March 2010, the FASB issued authoritative guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. Under this statement, an accounting policy election can be made to recognize arrangement consideration received for achieving specified performance measures during the period in which the milestones are achieved, provided certain criteria are met. This statement is limited to transactions involving research or development. This statement is effective for annual and interim reporting periods beginning on or after June 15, 2010 and may be early adopted. Since the Company elected to continue to use the existing revenue models, the relevant guidance has not been adopted.

#### 3. Earnings per Share

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

The computation of net income (loss) per share for the three and six months ended June 30, 2010 and 2009 is shown below:

|  | Th | ree Months H | d June 30, | Six Months Ended June 30, |    |         |      |         |
|--|----|--------------|------------|---------------------------|----|---------|------|---------|
| (in thousands, except per share data)        |    | 2010         |            | 2009                      |    | 2010    | 2009 |         |
| Basic net loss per share:                    |    |              |            |                           |    |         |      |         |
| Net loss                                     | \$ | (1,978)      | \$         | (238)                     | \$ | (2,277) | \$   | (2,013) |
|  |    |              |            |                           |    |         |      |         |
| Weighted average class A and B common shares |    |              |            |                           |    |         |      |         |
| outstanding                                  |    | 41,848       |            | 41,844                    |    | 41,847  |      | 41,844  |
|  |    |              |            |                           |    |         |      |         |
| Basic net loss per share                     | \$ | (0.05)       | \$         | (0.01)                    | \$ | (0.05)  | \$   | (0.05)  |
|  |    |              |            |                           |    |         |      |         |
| Diluted net loss per share:                  |    |              |            |                           |    |         |      |         |
| Net loss                                     | \$ | (1,978)      | \$         | (238)                     | \$ | (2,277) | \$   | (2,013) |
|  |    |              |            |                           |    |         | -    |         |
| Weighted average class A and B common shares |    |              |            |                           |    |         |      |         |
| outstanding for diluted net income per share |    | 41,848       |            | 41,844                    |    | 41,847  |      | 41,844  |
|  |    |              |            |                           | -  |         |      |         |
| Diluted net loss per share                   | \$ | (0.05)       | \$         | (0.01)                    | \$ | (0.05)  | \$   | (0.05)  |
| outstanding for diluted net income per share | \$ | 41,848       | \$         | 41,844                    |    | 41,847  | \$   | 41,844  |

For the periods listed above, the following securities were excluded from the computation of diluted net loss per share as their effect would be antidilutive as of June 30, 2010 and 2009:

# Notes to Condensed Consolidated Financial Statements (Unaudited)

|                            | June  | 30,  |
|----------------------------|-------|------|
| (In thousands)             | 2010  | 2009 |
| Employee stock options     | 1,400 | 670  |
| Non-employee stock options | 450   | 450  |

# 4. Current and Non-Current Investments

At June 30, 2010 and December 31, 2009, current and non-current available-for-sale investments consisted of the following securities:

|                               | June 30, 2010 |        |                     |    |                      |      |            |
|-------------------------------|---------------|--------|---------------------|----|----------------------|------|------------|
| (In thousands)                | Cost          |        | Unrealized<br>Gains |    | Unrealized<br>Losses |      | Fair Value |
| Current:                      |               |        |                     |    |                      |      |            |
| U.S. Treasury bills and notes | \$            | 1,004  | \$                  | -  | \$                   | -    | \$ 1,004   |
| U.S. commercial paper         |               | 5,181  |                     | 2  |                      | -    | 5,183      |
| U.S. government securities    |               | 13,016 |                     | 12 |                      | (5)  | 13,023     |
| Municipal securities          |               | 16,600 |                     | 6  |                      | (9)  | 16,597     |
| Certificates of deposits      |               | 1,750  |                     | 1  |                      | -    | 1,751      |
| Corporate bonds               |               | 18,585 |                     | 27 |                      | (7)  | 18,605     |
| Total                         | \$            | 56,136 | \$                  | 48 | \$                   | (21) | \$ 56,163  |
|                               |               |        |                     |    |                      |      |            |
| Non-current:                  |               |        |                     |    |                      |      |            |
| U.S. government securities    | \$            | 6,703  | \$                  | 5  | \$                   | (7)  | \$ 6,701   |
| Municipal securities          |               | 3,358  |                     | 8  |                      | -    | 3,366      |
| Certificates of deposits      |               | 250    |                     | -  |                      | (1)  | 249        |
| Corporate bonds               |               | 5,625  |                     | -  |                      | (6)  | 5,619      |
| Total                         | \$            | 15,936 | \$                  | 13 | \$                   | (14) | \$ 15,935  |

|                               | December 31, 2009 |        |    |                     |    |                      |    |           |
|-------------------------------|-------------------|--------|----|---------------------|----|----------------------|----|-----------|
| (In thousands)                |                   | Cost   |    | Unrealized<br>Gains |    | Unrealized<br>Losses |    | air Value |
| Current:                      |                   |        |    |                     |    |                      |    |           |
| U.S. Treasury bills and notes | \$                | 2,999  | \$ | -                   | \$ | -                    | \$ | 2,999     |
| U.S. commercial paper         |                   | 1,000  |    | -                   |    | -                    |    | 1,000     |
| U.S. government securities    |                   | 26,020 |    | 16                  |    | (6)                  |    | 26,030    |
| Municipal securities          |                   | 25,339 |    | 4                   |    | (7)                  |    | 25,336    |
| Certificates of deposits      |                   | 1,250  |    | -                   |    | (1)                  |    | 1,249     |
| Corporate bonds               |                   | 15,782 |    | 38                  |    | -                    |    | 15,820    |
| Total                         | \$                | 72,390 | \$ | 58                  | \$ | (14)                 | \$ | 72,434    |
|                               |                   |        |    |                     |    |                      |    |           |
| Non-current:                  |                   |        |    |                     |    |                      |    |           |
| U.S. government securities    | \$                | 6,065  | \$ | 7                   | \$ | (12)                 | \$ | 6,060     |
| Municipal securities          |                   | 1,802  |    | 4                   |    | -                    |    | 1,806     |
| Certificates of deposits      |                   | 500    |    | -                   |    | (2)                  |    | 498       |
| Corporate bonds               |                   | 1,891  |    | 1                   |    | (3)                  |    | 1,889     |
| Auction rate securities       |                   | 10,000 |    | -                   |    | (1,086)              |    | 8,914     |
| Total                         | \$                | 20,258 | \$ | 12                  | \$ | (1,103)              | \$ | 19,167    |

The Company records unrealized gains and losses resulting from changes in the fair value of the auction rate securities and related settlement rights within other income (loss). On June 8, 2010, the issuer of the Company's remaining ARS redeemed the security at par value of \$10.0 million, which terminated the related settlement rights.

# Notes to Condensed Consolidated Financial Statements (Unaudited)

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

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

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

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

The Company's assets measured at fair value on a recurring basis, which are subject to the fair value disclosure requirements, are as follows:

|                                     | Fair Value Measurements at Reporting Date Usin                |        |  |       |   |   |    |        |  |
|-------------------------------------|---|--------|--|-------|---|---|----|--------|--|
| June 30, 2010                       | Quoted Prices in<br>Active Markets<br>for identical<br>Assets |        | Significant<br>Other<br>Observable<br>Inputs |       | Significant<br>e Unobservable<br>Inputs |   |    |        |  |
| (In thousands)                      | (Level 1)   |        | (Level 2)                                    |       | l 2) (Level 3)                          |   |    | Total  |  |
| U.S. Treasury bills and notes       | \$  | 1,004  | \$   | -     | \$                                      | - | \$ | 1,004  |  |
| U.S. government securities          |   | 19,723 |  | -     |   | - |    | 19,723 |  |
| U.S. commercial paper               |   | -      |  | 5,183 |   | - |    | 5,183  |  |
| Corporate bonds                     |   | 24,225 |  | -     |   | - |    | 24,225 |  |
| Municipal securities                |   | 19,963 |  | -     |   | - |    | 19,963 |  |
| Certificates of deposits            |   | -      |  | 2,000 |   | - |    | 2,000  |  |
| Total assets measured at fair value | \$  | 64,915 | \$   | 7,183 | \$                                      | - | \$ | 72,098 |  |

|  | Fair Value Measurements at Reporting Date                                  |        |    |   |    |  |    |        |
|--|--|--------|----|---|----|--|----|--------|
| December 31, 2009<br>(In thousands)            | Quoted Prices in<br>Active Markets<br>for identical<br>Assets<br>(Level 1) |        |    | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) |    | Significant<br>Unobservable<br>Inputs<br>(Level 3) |    | Total  |
| U.S. Treasury bills and notes                  | \$   | 2,999  | \$ | -   | \$ | -  | \$ | 2,999  |
| U.S. government securities                     |  | 32,090 |    | -   |    | -  |    | 32,090 |
| U.S. commercial paper                          |  | -      |    | 1,000   |    | -  |    | 1,000  |
| Corporate bonds                                |  | 17,709 |    | -   |    | -  |    | 17,709 |
| Municipal securities                           |  | 27,142 |    | -   |    | -  |    | 27,142 |
| Auction rate securities                        |  | -      |    | -   |    | 8,914  |    | 8,914  |
| Settlement rights for auction rate securities* |  | -      |    | -   |    | 1,086  |    | 1,086  |
| Certificates of deposits                       |  | -      |    | 1,747   |    | -  |    | 1,747  |
| Total assets measured at fair value            | \$   | 79,940 | \$ | 2,747   | \$ | 10,000   | \$ | 92,687 |

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

# Notes to Condensed Consolidated Financial Statements (Unaudited)

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

The fair value of the Company's auction rate security holdings and settlement rights as of December 31, 2009 were estimated based on an internal pricing model and categorized in Level 3 of the fair value hierarchy. The pricing model takes into consideration the characteristics of the underlying securities as well as multiple inputs, including counterparty credit quality, expected timing of redemptions and the yield premium that a market participant would require over otherwise comparable securities. These inputs require significant management judgment.

#### 5. Intangible Assets

In April 2009, the Company entered into two agreements with R-Tech to acquire all patents and other intellectual property rights related to Rescula for glaucoma and ocular hypertension and any new indications in the U.S. and Canada. Although Rescula eye drops have been approved by the FDA for the treatment of open-angle glaucoma and ocular hypertension since 2000, Rescula is not currently marketed in the U.S. or Canada.

Under the terms of the R-Tech agreements, the Company made an upfront payment of \$3.0 million and may be required to pay up to \$5.5 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of \$500,000 is payable upon the re-launch of Rescula for the treatment of glaucoma which is considered as being probable; therefore, this amount is recorded as part of the initial cost of the acquired assets. The Company allocated the acquisition cost between an intangible asset of \$3.4 million and a non-current prepaid inventory of \$85,000, both of which are reflected in other non-current assets in the accompanying consolidated balance sheet as of June 30, 2010. The Company is amortizing the \$3.4 million over the 10-year life of the license agreement, which management believes approximates the useful life of the existing underlying rights and data. Amortization expense was \$171,000 and \$57,000 for the six months ended June 30, 2010 and 2009, respectively. The annual amortization expense will be approximately \$342,000 through April 2019.

# 6. Accrued Expenses

Accrued expenses consisted of the following as of:

| (In thousands)                 | J  | une 30,<br>2010 | ember 31,<br>2009 |
|--------------------------------|----|-----------------|-------------------|
| Research and development costs | \$ | 2,500           | \$<br>3,624       |
| Employee compensation          |    | 1,473           | 879               |
| Selling and marketing costs    |    | 129             | 731               |
| Other accrued expenses         |    | 3,839           | 1,311             |
| Total                          | \$ | 7,941           | \$<br>6,545       |

#### 7. Commitments

#### **Operating Leases**

The Company leases office space in the U.S., the United Kingdom and Japan under operating leases ranging through 2017. Total future minimum, noncancelable lease payments under operating leases, which do not include future sub-lease receipts of approximately \$30,000, were as follows as of June 30, 2010:

# Notes to Condensed Consolidated Financial Statements (Unaudited)

| (In thousands)               |             |
|------------------------------|-------------|
| 2010 (July - December)       | \$<br>715   |
| 2011                         | 1,169       |
| 2012                         | 966         |
| 2013                         | 994         |
| 2014                         | 1,024       |
| 2015 and thereafter          | 2,275       |
| Total minimum lease payments | \$<br>7,143 |

Rent expense for all operating leases was approximately \$313,000 and \$341,000 for the three months ended June 30, 2010 and 2009, respectively, and \$645,000 and \$642,000 for the six months ended June 30, 2010 and 2009, respectively.

# **Research and Development Costs**

The Company routinely enters into agreements with third-party clinical research organizations, or CROs, to oversee clinical research and development studies provided on an outsourced basis. The Company is not generally contractually obligated to pay the CRO if the service or reports are not provided. Total future estimated costs through 2013 under these agreements as of June 30, 2010 were approximately \$6.0 million. This amount does not include expected costs relating to the third phase 3 study for Amitiza in OBD and the phase 2 studies for Rescula, for which the CRO agreements have not been finalized as of June 30, 2010.

# 8. Related Party Transactions

# R-Tech Ueno, Ltd.

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

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

|   | Three Months Ended June 30, |      |    | 5     | l June 30, |      |    |       |
|---|-----------------------------|------|----|-------|------------|------|----|-------|
| (In thousands)                          |                             | 2010 | _  | 2009  |            | 2010 |    | 2009  |
| Clinical supplies                       | \$                          | 91   | \$ | 577   | \$         | 203  | \$ | 1,620 |
| Other research and development services |                             | 83   |    | 3,034 |            | 147  |    | 3,039 |
|   | \$                          | 174  | \$ | 3,611 | \$         | 350  | \$ | 4,659 |

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)                | J  | une 30,<br>2010 | Dec | ember 31,<br>2009 |
|-------------------------------|----|-----------------|-----|-------------------|
| Deferred revenue, current     | \$ | 432             | \$  | 431               |
| Deferred revenue, non-current |    | 6,035           |     | 6,256             |
|                               | \$ | 6,467           | \$  | 6,687             |

The Company recognized approximately \$105,000 of revenue relating to its agreements with R-Tech for each of the three months ended June 30, 2010 and 2009, and approximately \$209,000 for the six months ended June 30, 2010 and 2009, which was recorded as contract and collaboration revenue in the accompanying condensed consolidated statements of operations and comprehensive income (loss).

# Notes to Condensed Consolidated Financial Statements (Unaudited)

#### Sucampo AG License Agreements

The Company expensed approximately \$375,000 in milestone royalties – related parties expense under our sublicense agreement with SAG for the three months ended June 30, 2009, reflecting 5% of the \$7.5 million development payment received from Abbott. The Company expensed approximately \$875,000 in milestone royalties – related parties expense under our sublicense agreement with SAG for the six months ended June 30, 2009, reflecting 5% of the \$10.0 million upfront payment and the \$7.5 million development payments received from Abbott. There was no corresponding expense in 2010.

The Company expensed approximately \$1.7 million and \$1.6 million in product royalties – related parties under the license agreement with SAG for the three months ended June 30, 2010 and 2009, respectively, and approximately \$3.4 million and \$3.2 million for the six months ended June 30, 2010 and 2009, respectively, reflecting 3.2% of Amitiza net sales in the U.S. during each of these periods.

# 9. Collaboration and License Agreements

# Abbott license, commercialization and supply agreement

In February 2009, the Company entered into an exclusive 15-year license, commercialization and supply agreement with Abbott to develop and commercialize lubiprostone for the treatment of CIC in Japan. Additionally, the agreement grants Abbott the right of first refusal to any additional indications for which lubiprostone is developed in Japan under all relevant patents, know-how and trademarks. Payments to the Company under the terms of the agreement include a non-refundable upfront payment and non-refundable development and commercial milestone payments based on achieving specified development, regulatory and sales goals.

The Company has received a total of \$17.5 million in up-front and development milestone payments through June 30, 2010 under this agreement. Subject to future development and commercial milestones, the Company will receive additional development milestone and commercial milestone payments under this agreement with Abbott, although there can be no assurance that the Company will receive any such payments.

The following table summarizes the cash streams and related revenue recognized or deferred under the license, commercialization and supply agreement with Abbott for the six months ended June 30, 2010:

| (In thousands)   | De | Amount<br>eferred at<br>cember 31,<br>2009 | 1  | sh Received<br>for the Six<br>onths Ended<br>June 30,<br>2010 | Ree<br>the | Revenue<br>cognized for<br>Six Months<br>ded June 30,<br>2010 | Eff         | reign Currency<br>ects for the Six<br>iths Ended June<br>30,<br>2010 |    | Amount<br>Deferred at<br>June 30,<br>2010 |
|--|----|--|----|---|------------|---|-------------|--|----|---|
| Collaboration revenue:<br>Up-front payment associated with the Company's | ¢  | 812  | ¢  |   | ¢          | 22  | ¢           | 33   | ¢  | 822                                       |
| obligation to participate in joint committees                            | 2  | 812  | 3  | -   | 3          | 23  | <u>&gt;</u> | 33   | Þ  | 822                                       |
| Research and development revenue:  |    |  |    |   |            |   |             |  |    |   |
| Up-front payment   | \$ | 3,991                                      | \$ | -   | \$         | 2,313   | \$          | 93   | \$ | 1,771                                     |
| Development milestone payment  | \$ | 3,366                                      |    | -   |            | 1,951   |             | 78   | \$ | 1,493                                     |
| Total  | \$ | 7,357                                      | \$ | -   | \$         | 4,264   | \$          | 171  | \$ | 3,264                                     |

# Takeda commercialization and license agreement

In October 2004, the Company entered into a 16-year collaboration and license agreement with Takeda to exclusively co-develop, commercialize and sell products that contain lubiprostone for gastroenterology indications in the United States and Canada. On February 1, 2006, the Company entered into a supplemental agreement with Takeda, which amended the responsibilities of both the Company and Takeda for the co-promotion of Amitiza and clarified the 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)

The Company has received a total of \$150.0 million in up-front and development milestone payments through June 30, 2010 under these agreements. Subject to future development and commercial milestones, the Company will receive additional development milestone and 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.

On March 12, 2010, the Company submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between the Company and Takeda dated October 29, 2004. The Company is disappointed with the level of U.S. sales of Amitiza being generated by Takeda and what the Company believes to be other failures of performance by Takeda under the agreements. The Company believes that Takeda materially breached its agreement, without limitation, by its continuing failure to exercise its best efforts to commercialize Amitiza and maximize net sales revenue, and its ongoing refusal to collaborate and provide the Company with information to which the Company is entitled under the agreement. The Company also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only the Company and the Amitiza brand, but also consumers. The Company is seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. The respective arbitrators for both the Company and Takeda have been confirmed and both parties have selected a third arbitrator. If the third arbitrator is confirmed, then it will comprise the panel that will conduct the arbitration proceedings. The Company spent and expects to spend significant resources in the dispute with Takeda and these legal proceedings may require the continuing attention of the Company's senior management.

The following table summarizes the cash streams and related revenue recognized or deferred under the collaboration and license agreements with Takeda for the six months ended June 30, 2010:

| (In thousands)   | Amount<br>Deferred at<br>December 31,<br>2009 | Cash Received<br>for the Six<br>Months Ended<br>June 30,<br>2010 | Revenue<br>Recognized for<br>the Six Months<br>Ended June 30,<br>2010 | Change in Accounts<br>Receivable for the<br>Six Months Ended<br>June 30,<br>2010* | Amount<br>Deferred at<br>June 30,<br>2010 |
|--|---|--|---|---|---|
| Collaboration revenue:   |   |  |   |   |   |
| Up-front payment associated with the Company's obligation to participate in joint committees | \$ 1,617                                      | <u>\$</u>  | <u>\$ 73</u>  | <u>\$</u>   | <u>\$ 1,544</u>                           |
| Research and development revenue:  |   |  |   |   |   |
| Reimbursement of research and development expenses   | \$ 2,734                                      | <u>\$ 965</u>  | \$ 2,573  | <u>\$ (628)</u>   | <u>\$ 498</u>                             |
| Product royalty revenue  | <u>\$</u>                                     | \$ 20,796  | \$ 19,385   | <u>\$ (1,411</u> )  | <u>\$</u>                                 |
| Co-promotion revenue   | <u>\$</u>                                     | \$ 2,028   | \$ 2,075  | <u>\$ 47</u>  | <u>\$</u>                                 |

# Includes billed and unbilled accounts receivable.

As a result of the mixed results of the Company's phase 3 efficacy trials for Amitiza in OBD that were completed in 2009 and a subsequent meeting with the FDA in April 2010, the Company agreed with Takeda to conduct another phase 3 efficacy trial of Amitiza for the treatment of OBD in order to file its sNDA for this indication. Accordingly, the Company concluded that the estimated completion of the OBD program would be extended from late 2010 to mid-2012 and, therefore, the recognition period for associated research and development revenue would be extended. Additionally, since Takeda funds the first \$50.0 million of the development expenses for the OBD program and the Company and Takeda share equally development costs that exceed that amount, the estimated future additional revenue and expenses reflect this arrangement. This change in estimate did not have material impact on the financial statements for the three months ended June 30, 2010.

# Notes to Condensed Consolidated Financial Statements (Unaudited)

# 10. Stock Option Plans

The following table summarizes the employee stock option activity for the six months ended June 30, 2010 under the Company's 2001 Incentive Plan:

|  | Shares   | Weighted Average<br>Exercise Price Per<br>Share |      | Exercise Price Per Contractual Term |           | Aggregate<br>Intrinsic Value |
|--|----------|---|------|-------------------------------------|-----------|------------------------------|
| Options outstanding, December 31, 2009 | 358,700  | \$ 1  | 0.43 |                                     |           |                              |
| Options expired                        | (13,600) | 1   | 0.00 |                                     |           |                              |
| Options outstanding, June 30, 2010     | 345,100  | 1   | 0.44 | 3.62                                | <u>\$</u> |                              |
| Options exercisable, June 30, 2010     | 345,100  | 1   | 0.44 | 3.62                                | \$        |                              |

The following table summarizes the employee stock option activity for the six months ended June 30, 2010 under the Company's 2006 Incentive Plan:

|  | Shares    | Weighted Average<br>Exercise Price Per<br>Share | 0    | Aggregate<br>Intrinsic Value |
|--|-----------|---|------|------------------------------|
| Options outstanding, December 31, 2009 | 509,800   | \$ 8.58   |      |                              |
| Options granted                        | 546,000   | 3.77  |      |                              |
| Options forfeited                      | (3,000)   | 14.12   |      |                              |
| Options outstanding, June 30, 2010     | 1,052,800 | 6.07  | 8.89 | \$                           |
| Options exercisable, June 30, 2010     | 405,617   | 7.42  | 8.44 | \$ -                         |

The weighted average grant date fair value of options granted during the six months ended June 30, 2010 and the year ended December 31, 2009 were \$1.89 and \$2.73, respectively. As of June 30, 2010, approximately \$1.6 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards are expected to be recognized over a weighted average period of 2.50 years.

During the three months ended June 30, 2010, the Company granted (i) annual stock options for 80,000 shares of class A common stock to its independent directors and (ii) fully vested stock options for 177,000 shares of class A common stock to its non-executive employees, both under the 2006 Incentive Plan.

The Company granted 510,000 stock options with an exercise price of \$5.85 per share to non-employees in August 2005 under the 2001 Incentive Plan. As of June 30, 2010 and December 31, 2009, 450,000 options were outstanding and exercisable. These non-employee stock options vested immediately. These options have a weighted average exercise price of \$5.85 as of June 30, 2010 and December 31, 2009 and a remaining contractual life of 4.84 and 5.33 years, respectively, as of June 30, 2010 and December 31, 2009.

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

Under the 2006 Employee Stock Purchase Plan, or ESPP, a total of 2,207 and 1,526 shares of class A common stock were purchased during the six months ended June 30, 2010 and 2009, respectively. The ESPP is non-compensatory and is intended to qualify as an Employee Stock Purchase Plan as defined in Section 423 of the Internal Revenue Code of 1986 and in accordance with GAAP guidance that requires estimates in the fair value of share-based payment awards on the date of the grant using an option-pricing model and recognizing the expense over the required service periods in the accompanying condensed consolidated statement of operations and comprehensive income (loss). The Company received \$7,452 and \$8,910 upon purchase of shares under the ESPP for the six months ended June 30, 2010 and 2009, respectively.

# Notes to Condensed Consolidated Financial Statements (Unaudited)

# 11. Income Taxes

For the three months ended June 30, 2010 and 2009, the Company recorded a tax provision of \$315,000 and \$863,000, respectively. For the six months ended June 30, 2010 and 2009, the Company recorded a tax provision of \$520,000 and \$1.3 million, respectively. The tax provision for the three and six months ended June 30, 2010 and 2009 primarily pertained to taxable income generated by the Company's U.S. subsidiary. The Company's other subsidiaries based in Europe and Japan incurred pre-tax losses for the three and six months ended June 30, 2010, for which no tax benefit was recognized.

The Company has estimated its annual effective tax rate for the full fiscal year 2010 and 2009 and applied that rate to its income before income taxes in determining its income tax provision for the interim periods. There is no tax benefit recognized on the net operating losses incurred in the foreign jurisdictions due to the lack of evidence supporting the Company's ability to use these losses in the future.

#### Uncertain Tax Positions

The Company applies the FASB's guidance for uncertainty in income taxes that requires the application of a more likely than not threshold to the recognition and derecognition of uncertain tax positions.

The Company had an outstanding non-current income tax liability of approximately \$788,000 for uncertain tax positions as of June 30, 2010. The amount represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in the Company's condensed consolidated financial statements, and is reflected in other liabilities in the accompanying condensed consolidated balance sheets. The liability for uncertain tax positions as of June 30, 2010 mainly pertained to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes.

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

# 12. Segment Reporting

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



# Notes to Condensed Consolidated Financial Statements (Unaudited)

| (In thousands)                            | Δ  | mericas    | Europe      | Asia          |    | ercompany<br>iminations | ſ  | onsolidated |
|---|----|------------|-------------|---------------|----|-------------------------|----|-------------|
| Three Months Ended June 30, 2010          |    | lillericas | <br>Lurope  | <br>Asid      | En | mmations                |    | onsonuateu  |
| Research and development revenue          | \$ | 1,269      | \$<br>-     | \$<br>1,520   | \$ | -                       | \$ | 2,789       |
| Product royalty revenue                   |    | 9,612      | -           | -             |    | -                       |    | 9,612       |
| Co-promotion revenue                      |    | 1,220      | -           | -             |    | -                       |    | 1,220       |
| Contract and collaboration revenue        |    | 141        | -           | 285           |    | (272)                   |    | 154         |
| Total revenues                            | _  | 12,242     | -           | 1,805         | _  | (272)                   |    | 13,775      |
| Research and development expenses         |    | 1,996      | 142         | 2,988         |    | (272)                   |    | 4,854       |
| Depreciation and amortization             |    | 222        | 3           | 6             |    | -                       |    | 231         |
| Other operating expenses                  | _  | 9,707      | <br>468     | <br>220       |    | -                       |    | 10,395      |
| Income (loss) from operations             |    | 317        | (613)       | (1,409)       |    | -                       |    | (1,705)     |
| Interest income                           |    | 254        | -           | 1             |    | (78)                    |    | 177         |
| Other non-operating income (expense), net |    | 3          | (49)        | (167)         |    | 78                      |    | (135)       |
| Income (loss) before income taxes         | \$ | 574        | \$<br>(662) | \$<br>(1,575) | \$ | -                       | \$ | (1,663)     |
| Capital expenditures                      | \$ | 63         | \$<br>1     | \$<br>(1)     | \$ | -                       | \$ | 63          |
|   |    |            |             |               |    |                         |    |             |
| Three Months Ended June 30, 2009          |    |            |             |               |    |                         |    |             |
| Research and development revenue          | \$ | 3,825      | \$<br>-     | \$<br>3,570   | \$ | -                       | \$ | 7,395       |
| Product royalty revenue                   |    | 8,914      | -           | -             |    | -                       |    | 8,914       |
| Co-promotion revenue                      |    | 1,244      | -           | -             |    | -                       |    | 1,244       |
| Contract and collaboration revenue        |    | 142        | <br>-       | 220           |    | (210)                   | _  | 152         |
| Total revenues                            |    | 14,125     | -           | 3,790         |    | (210)                   |    | 17,705      |
| Research and development expenses         |    | 5,807      | 177         | 3,847         |    | (210)                   |    | 9,621       |
| Depreciation and amortization             |    | 182        | 3           | 2             |    | -                       |    | 187         |
| Other operating expenses                  |    | 6,154      | <br>302     | <br>427       |    | -                       |    | 6,883       |
| Income (loss) from operations             |    | 1,982      | (482)       | (486)         |    | -                       |    | 1,014       |
| Interest income                           |    | 292        | -           | (1)           |    | (72)                    |    | 219         |
| Other non-operating income (expense), net | _  | (36)       | <br>(334)   | <br>(310)     | _  | 72                      |    | (608)       |
| Income (loss) before income taxes         | \$ | 2,238      | \$<br>(816) | \$<br>(797)   | \$ | -                       | \$ | 625         |
| Capital expenditures                      | \$ | 3,068      | \$<br>3     | \$<br>29      | \$ | -                       | \$ | 3,100       |

# Notes to Condensed Consolidated Financial Statements (Unaudited)

| (In thousands)AmericasEuropeAsiaEliminationsConsolidatedSix Months Ended June 30, 2010<   |
|---|
| Research and development revenue \$ 2,573 \$ - \$ 4,273 \$ - \$ 6,846   Product royalty revenue 19,385 19,385   Co-promotion revenue 2,075 2,075   Contract and collaboration revenue 282 - 570 (547) 305   Total revenues 24,315 - 4,843 (547) 28,611   Research and development expenses 4,369 361 6,037 (547) 28,611   Depreciation and amortization 440 6 13 - 459   Other operating expenses 18,712 720 418 - 19,850   Income (loss) from operations 794 (1,087) (1,625) - (1,918)   Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ (1,810) \$ - \$ (1,757) |
| Product royalty revenue 19,385 - - 19,385   Co-promotion revenue 2,075 - - 2,075   Contract and collaboration revenue 282 - 570 (547) 305   Total revenues 24,315 - 4,843 (547) 28,611   Research and development expenses 4,369 361 6,037 (547) 10,220   Depreciation and amortization 440 6 13 - 459   Other operating expenses 18,712 720 418 - 19,850   Income (loss) from operations 794 (1,087) (1,625) - (1,918)   Interest income 527 - 2 (141) 388   Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ 4.141 (227)   |
| Co-promotion revenue $2,075$ $2,075$ Contract and collaboration revenue $282$ - $570$ $(547)$ $305$ Total revenues $24,315$ - $4,843$ $(547)$ $28,611$ Research and development expenses $4,369$ $361$ $6,037$ $(547)$ $10,220$ Depreciation and amortization $440$ 6 $13$ - $459$ Other operating expenses $18,712$ $720$ $418$ - $19,850$ Income (loss) from operations $794$ $(1,087)$ $(1,625)$ - $(1,918)$ Interest income $527$ - $2$ $(141)$ $388$ Other non-operating income (expense), net $(33)$ $(148)$ $(187)$ $141$ $(227)$ Income (loss) before income taxes $$1,288$ $$(1,235)$ $$(1,810)$ $$<$ $$(1,757)$                         |
| Contract and collaboration revenue 282 - 570 (547) 305   Total revenues 24,315 - 4,843 (547) 28,611   Research and development expenses 4,369 361 6,037 (547) 10,220   Depreciation and amortization 440 6 13 - 459   Other operating expenses 18,712 720 418 - 19,850   Income (loss) from operations 794 (1,087) (1,625) - (1,918)   Interest income 527 - 2 (141) 388   Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ (1,810) \$ - \$ (1,757)  |
| Total revenues $24,315$ - $4,843$ $(547)$ $28,611$ Research and development expenses $4,369$ $361$ $6,037$ $(547)$ $10,220$ Depreciation and amortization $440$ $6$ $13$ - $459$ Other operating expenses $18,712$ $720$ $418$ - $19,850$ Income (loss) from operations $794$ $(1,087)$ $(1,625)$ - $(1,918)$ Interest income $527$ - $2$ $(141)$ $388$ Other non-operating income (expense), net $(33)$ $(148)$ $(187)$ $141$ $(227)$ Income (loss) before income taxes $$1,288$ $$(1,235)$ $$(1,810)$ $$ $(1,757)$  |
| Research and development expenses 4,369 361 6,037 (547) 10,220   Depreciation and amortization 440 6 13 - 459   Other operating expenses 18,712 720 418 - 19,850   Income (loss) from operations 794 (1,087) (1,625) - (1,918)   Interest income 527 - 2 (141) 388   Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ - \$ (1,757)   |
| Depreciation and amortization 440 6 13 - 459   Other operating expenses 18,712 720 418 - 19,850   Income (loss) from operations 794 (1,087) (1,625) - (1,918)   Interest income 527 - 2 (141) 388   Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ (1,810) \$ - \$ (1,757)   |
| Other operating expenses 18,712 720 418 - 19,850   Income (loss) from operations 794 (1,087) (1,625) - (1,918)   Interest income 527 - 2 (141) 388   Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ (1,810) \$ - \$ (1,757)  |
| Income (loss) from operations 794 (1,087) (1,625) - (1,918)   Interest income 527 - 2 (141) 388   Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ (1,810) \$ - \$ (1,757)   |
| Interest income 527 - 2 (141) 388   Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ 1,810 \$ - \$ (1,757)   |
| Other non-operating income (expense), net (33) (148) (187) 141 (227)   Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ (1,810) \$ - \$ (1,757)   |
| Income (loss) before income taxes \$ 1,288 \$ (1,235) \$ (1,810) \$ (1,757)   |
|   |
| Capital expenditures   \$ 154   \$ 1   \$ 2   \$ -   \$ 157   |
|   |
|   |
| Six Months Ended June 30, 2009  |
| Research and development revenue   \$ 8,977 \$ - \$ 3,944 \$ - \$ 12,921  |
| Product royalty revenue 17,860 17,860   |
| Co-promotion revenue 2,140 2,140  |
| Contract and collaboration revenue 283 - 435 (420) 298  |
| Total revenues 29,260 - 4,379 (420) 33,219  |
| Research and development expenses   13,778   329   5,899   (420)   19,586   |
| Depreciation and amortization 299 6 4 - 309   |
| Other operating expenses 12,641 630 1,547 - 14,818  |
| Income (loss) from operations 2,542 (965) (3,071) - (1,494)   |
| Interest income 651 - 2 (122) 531   |
| Other non-operating income (expense), net 208 (370) 254 122 214   |
| Income (loss) before income taxes \$ 3,401 \$ (1,335) \$ (2,815) \$ - \$ (749)  |
| Capital expenditures \$ 3,195 \$ 3 \$ 29 \$ - \$ 3,227  |
|   |
| As of June 30, 2010   |
| Property and equipment, net \$ 1,892 \$ 28 \$ 197 \$ - \$ 2,117   |
|   |
| Identifiable assets, net of intercompany loans and investments \$ 129,759 \$ 6,316 \$ 3,900 \$ (2,800) \$ 137,175   |
|   |
| As of December 31, 2009   |
| Property and equipment, net \$ 2,008 \$ 34 \$ 200 \$ - \$ 2,242   |
| Identifiable assets, net of intercompany loans and investments \$ 134,714 \$ 864 \$ 11,294 \$ (1,901) \$ 144,971  |

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

This Quarterly Report on Form 10-Q contains forward-looking statements regarding Sucampo Pharmaceuticals, Inc. (the "Company," "we," "us," or "our") and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements. 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, 2009 included in our Annual Report on Form 10-K.

#### Overview

We are an international biopharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds that occur naturally in the human body as a result of enzymatic, 15-PGDH, transformation of certain fatty acids. We believe that most prostones function as activators of cellular ion channels and do not function in the same manner as prostaglandins. As a result, prostones promote fluid secretion and enhance cell protection, including the recovery of cellular barrier function. This activity gives prostones wide-ranging therapeutic potential, particularly for age-related diseases. We are focused on developing prostones for the treatment of gastrointestinal, ophthalmic, respiratory, vascular and central nervous system diseases and other disorders for which there are unmet or underserved medical needs and significant commercial potential.

The therapeutic potential of prostones was first identified by Dr. Ryuji Ueno. To date, two prostone products have received marketing approval. Amitiza<sup>®</sup> (lubiprostone) is an FDA-approved treatment for two gastrointestinal indications: (i) chronic idiopathic constipation, or CIC, in adults of both genders and all ages and (ii) irritable bowel syndrome with constipation, or IBS-C, in adult women. Rescula<sup>®</sup> (unoprostone isopropyl) is FDA-approved for the treatment of open-angle glaucoma and ocular hypertension.

We generate revenue through product royalties, development milestone payments, and clinical development activities. We expect to continue to incur significant expenses for the next several years as we continue our research and development activities, seek regulatory approvals for additional indications for Amitiza, Rescula and other compounds both in the U.S. and other countries and expand our international operations. We hold an exclusive worldwide royalty-bearing license from Sucampo AG, or SAG, a Swiss patent-holding company, to develop and commercialize Amitiza and all other prostone compounds covered by patents and patent applications held by SAG. We are obligated to assign to SAG all patentable improvements that we make in the field of prostones, which in turn SAG is obligated to license back to us on an exclusive basis.

In the United States, Amitiza is being marketed and developed under a collaboration and license agreement with Takeda Pharmaceutical Company Limited, or Takeda, for gastrointestinal indications. In Japan, lubiprostone is developed under a license, commercialization and supply agreement with Abbott Japan Co. Ltd., or Abbott.

In April 2009, we acquired the rights to Rescula that allow us to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension and any new indication developed by us.

Under the Takeda agreement, Takeda is primarily responsible for the sales and marketing of Amitiza in the U.S. and Canada. Takeda currently sells Amitiza in the U.S., mainly to office-based specialty and primary care physicians and reimburses us a part of our co-promotion expenses. We currently copromote Amitiza in the U.S. through a specialty sales force focused on the institutional marketplace, including specialist physicians based in academic medical centers and long-term care and veteran's affairs facilities. Takeda records all sales of Amitiza and we receive a tiered royalty based on net sales. We are primarily responsible for Amitiza research and development efforts and hold the new drug application, or NDA. Takeda reimburses us for a significant portion of our research and development activities.

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



Our founders, Drs. Ryuji Ueno and Sachiko Kuno, together, directly or indirectly, own all of the stock of SAG, and a majority of the stock of R-Tech Ueno, or R-Tech, as described more fully in Note 8 to the condensed consolidated financial statements. Drs. Ueno and Kuno also are our controlling stockholders and are married to each other. Dr. Ueno is our chief executive officer and chairman of the Board of Directors. Dr. Kuno is a member of our Board of Directors, our advisor on international business development and is a member of the Board of Directors of R-Tech.

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between us and Takeda Pharmaceuticals Company Limited dated October 29, 2004. We are disappointed with the level of U.S. sales of Amitiza being generated by Takeda and other failures of performance by Takeda under the agreements. We believe that Takeda materially breached its agreement, without limitation, by its continuing failure to exercise its best efforts to commercialize Amitiza and maximize net sales revenue, and its ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only us and the Amitiza brand, but also consumers. We are seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. The respective arbitrators for both us and Takeda have been confirmed and both parties have selected a third arbitrator. If the third arbitrator is confirmed, then it will comprise the panel that will conduct the arbitration proceedings. We spent and expect to spend significant resources in the dispute with Takeda and these legal proceedings may require the continuing attention of our senior management.

# **Our Clinical Development Programs**

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

*Amitiza (lubiprostone) in the United States and Canada.* We currently are pursuing development of a third gastrointestinal indication of Amitiza for the treatment of opioid-induced bowel dysfunction, or OBD, in patients with non-malignant pain, a constipation-related gastrointestinal indication. In July 2009, we reported top-line results for the two identically-designed efficacy studies conducted by a clinical research organization, or CRO, one of which met the primary endpoint by demonstrating a statistically significant change from baseline in the frequency of spontaneous bowel movements, or SBM, at week 8 of treatment when compared to placebo. We have advised the CRO of our concerns over its conduct of the studies. Based on a recent meeting with the FDA, we will conduct one additional phase 3 efficacy study in order to submit a supplemental new drug application, or sNDA, for the OBD indication, which we plan to initiate in late 2010.

*Amitiza (lubiprostone) in Japan.* In June 2010, we reported that the phase 3 efficacy trial of lubiprostone in Japanese CIC patients met the primary endpoint by demonstrating a statistically significant (p<0.001) change in the frequency of SBMs at the end of week 1 of treatment when compared to placebo.

In August 2010, we reported the interim results through 24 weeks of our fully enrolled 48-week phase 3 clinical trial to evaluate the long-term safety of lubiprostone in Japanese CIC patients. Those results showed that lubiprostone was safe and well-tolerated. As of this interim analysis, a total of 7.7% of patients experienced moderate adverse drug reactions, 65.6% experienced mild adverse drug reactions and no severe adverse drug reactions were reported. The two most common adverse drug reactions reported were diarrhea (32.5% of patients) and nausea (26.3% of patients). The nausea was transient in duration and the majority of patients experiencing nausea remained on treatment. Data from patients' daily diary cards showed improvements from baseline in all efficacy endpoints, including bowel movements frequency, straining, incomplete evacuation, stool consistency, abdominal bloating and abdominal discomfort. Patients' quality of life, or QOL, as measured by the IBS-QOL and SF-36 questionnaires, also showed improvement from baseline at Week 24. Top-line data from this 48-week long-term safety study are expected to be available during the fourth quarter of 2010.

*Amitiza (lubiprostone) in other countries.* We have retained full rights to develop and commercialize Amitiza for the rest of the world's markets outside of the U.S., Canada and Japan. In November 2009, we obtained a marketing authorization for lubiprostone in Switzerland for the long-term treatment of adult patients with CIC. This is the first European regulatory approval for us. Amitiza is the first prescription medicine to be approved in Switzerland for the long-term treatment of CIC and we are currently pursuing the pricing approval with the Swiss authorities. We continue to evaluate the opportunities to obtain an appropriate label in the E.U. for chronic therapy of CIC and OBD.

*Rescula*. Under our agreement with R-Tech, we hold the exclusive rights to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension and any new indication developed by us. We also have the right of first refusal to commercialize Rescula in the U.S. and Canada for any additional indications for which unoprostone is developed by R-Tech. Currently, we intend to develop Rescula as a treatment for ophthalmic diseases including retinitis pigmentosa (an orphan indication), dry age-related macular degeneration, or dry AMD, and diabetic retinopathy. We anticipate initiating two phase 2 trials to evaluate Rescula as a potential treatment for (i) retinitis pigmentosa and (ii) dry AMD in 2011. We also plan to re-launch Rescula in the U.S. for the treatment of open-angle glaucoma and ocular hypertension.

*Cobiprostone.* In July 2009, we reported top-line results from our phase 2a clinical trial of orally administered cobiprostone for the prevention of gastric ulcers and other gastrointentinal injuries in patients treated with non-steroidal anti-inflammatory drugs, or NSAIDs. Cobiprostone patients experienced an overall statistically significant reduction in the number of gastric erosions through the treatment period of 12 weeks as compared to placebo patients. In addition, the high dose cobiprostone group experienced a 50.0% reduction in the overall incidence of gastric ulcers when compared to patients taking placebo. We are evaluating a phase 2b study to complement the findings of earlier studies. We also are designing a preclinical study of cobiprostone for use as a treatment for chronic obstructive pulmonary disease, or COPD, and as a potential treatment for wound healing.

*SPI-017* is currently in preclinical and clinical testing in peripheral arterial diseases as well as central nervous system disorders. We have recently completed a phase 1 clinical program of the intravenous formulation of SPI-017 for peripheral arterial disease, or PAD, in Japan and plan to initiate a phase 2 study for this indication in late 2010.

*SPI-3608*: A novel prostone, SPI-3608, will continue to undergo preclinical testing. Based on preclinical results seen to date, this compound may have potential as a treatment for spinal stenosis.

#### **Results of Operations**

# Comparison of three months ended June 30, 2010 and June 30, 2009

#### Revenues

The following table summarizes our revenues for the three months ended June 30, 2010 and 2009:

|                                    | Th  | Three Months End<br>June 30, |           |  |  |  |
|------------------------------------|-----|------------------------------|-----------|--|--|--|
| (In thousands)                     | 201 | 0                            | 2009      |  |  |  |
| Research and development revenue   | \$  | 2,789 \$                     | \$ 7,395  |  |  |  |
| Product royalty revenue            |     | 9,612                        | 8,914     |  |  |  |
| Co-promotion revenue               |     | 1,220                        | 1,244     |  |  |  |
| Contract and collaboration revenue |     | 154                          | 152       |  |  |  |
| Total                              | \$  | 13,775 \$                    | \$ 17,705 |  |  |  |

Total revenues were \$13.8 million for the three months ended June 30, 2010 compared to \$17.7 million for the three months ended June 30, 2009, a decrease of \$3.9 million or 22.2%.

Research and development revenue was \$2.8 million for the three months ended June 30, 2010 compared to \$7.4 million for the three months ended June 30, 2009, a decrease of \$4.6 million or 62.3%. The decrease was primarily due to reduced revenue recognized in respect to the OBD program for Amitiza in the U.S., partially offset by \$1.5 million in revenue recognized under the agreement with Abbott in Japan. The research and development revenue recognized under the agreement with Abbott in Japan. The research and development revenue recognized under the agreement with Takeda decreased to \$1.3 million for the three months ended June 30, 2010 from \$3.8 million for the three months ended June 30, 2009, reflecting a completion of the initial two phase 3 efficacy trials in July 2009 funded by Takeda and the change in estimated costs and timeline to complete the OBD program, including an additional phase 3 efficacy trial. Since Takeda funds the first \$50.0 million of the development expenses for the OBD program and we and Takeda share equally development costs that exceed that amount, we expect to fund about 50.0% of the upcoming phase 3 trial. The research and development revenue recognized under the agreement with Abbott decreased to \$1.5 million for the three months ended June 30, 2010 from \$3.6 million for the three months ended June 30, 2010 from \$3.6 million for the three months ended June 30, 2010 from \$3.6 million for the three months ended June 30, 2010 from \$3.6 million for the three months ended June 30, 2010 from \$3.6 million for the three months ended June 30, 2010 from \$3.6 million for the three months ended June 30, 2010 from \$3.6 million for the three months ended June 30, 2009, reflecting the progress of the Japanese development program for lubiprostone. We are recognizing the revenue from the payments from Abbott using a percentage-of-completion model over the estimated term of the CIC development program.

Product royalty revenue represents royalty revenue earned on net sales of Amitiza in the United States. For the three months ended June 30, 2010 and 2009, we recognized \$9.6 million and \$8.9 million, respectively, of product royalty revenue, an increase of \$698,000 or 7.8%, reflecting mainly a higher price per pill and a slight increase in volume.

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force. For each of the three months ended June 30, 2010 and 2009, we recognized \$1.2 million of co-promotion revenues for reimbursement of our sales force costs.

# **Research and Development Expenses**

The following summarizes our research and development expenses for the three months ended June 30, 2010 and 2009:

|                | Three Mon<br>June |          |
|----------------|-------------------|----------|
| (In thousands) | 2010              | 2009     |
| Direct costs:  |                   |          |
| Amitiza        | \$ 3,223          | \$ 7,579 |
| Cobiprostone   | 162               | 687      |
| SPI-017        | 733               | 679      |
| Rescula        | 174               | 58       |
| Other          | 21                | 110      |
| Total          | 4,313             | 9,113    |
|                |                   |          |
| Indirect costs | 541               | 508      |
| Total          | \$ 4,854          | \$ 9,621 |

Total research and development expenses for the three months ended June 30, 2010 were \$4.9 million compared to \$9.6 million for the three months ended June 30, 2009, a decrease of \$4.7 million or 49.5%. The decrease was primarily due to the completion in July 2009 of the initial two phase 3 pivotal clinical trials for the treatment of OBD, the completion in July 2009 of the phase 2 clinical trial of cobiprostone for the prevention of NSAID-induced ulcers and a slight increase in overall preclinical and basic development costs related to SPI-017 and pre-clinical compounds.

# General and Administrative Expenses

The following summarizes our general and administrative expenses for the three months ended June 30, 2010 and 2009:

|   | Three |       |    | Ended |
|---|-------|-------|----|-------|
| (In thousands)                                    |       | 2010  |    | 2009  |
| Salaries, benefits and related costs              | \$    | 1,423 | \$ | 751   |
| Legal, consulting and other professional expenses |       | 3,503 |    | 911   |
| Other expenses                                    |       | 1,678 |    | 1,262 |
| Total   | \$    | 6,604 | \$ | 2,924 |

General and administrative expenses were \$6.6 million for the three months ended June 30, 2010, compared to \$2.9 million for the three months ended June 30, 2009, an increase of \$3.7 million or 125.9%. The increase in salaries, benefits and related costs was primarily attributable to an increase in the number of key personnel and in the incentive compensation plans for 2010. The increase in legal, consulting and other professional expenses relates primarily to costs incurred in connection with the ongoing legal matters.

# 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 \$2.3 million for the three months ended June 30, 2010, compared to \$2.2 million for the three months ended June 30, 2009, an increase of \$125,000 or 5.7%. Part of the Amitiza co-promotion expenses are funded by Takeda and recorded as co-promotion revenue.

# **Product Royalties – Related Parties**

Product royalties – related parties expense, representing 3.2% of Amitiza net sales for the respective periods payable to SAG, increased to \$1.7 million for the three months ended June 30, 2009, which was consistent with the increase of net sales and product royalty revenue.

# Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the three months ended June 30, 2010 and 2009:

|                             |    | Three Months Ended<br>June 30, |    |       |
|-----------------------------|----|--------------------------------|----|-------|
| (In thousands)              | 2  | 010                            |    | 2009  |
| Interest income             | \$ | 177                            | \$ | 219   |
| Other income (expense), net |    | (135)                          |    | (608) |
| Total                       | \$ | 42                             | \$ | (389) |

Interest income was \$177,000 for the three months ended June 30, 2010, compared to \$219,000 for the three months ended June 30, 2009, a decrease of \$42,000, or 19.2%. The decrease was primarily due to lower prevailing interest rates earned by our investments and a shift in the composition of our portfolio from auction rate securities, or ARS, which bear higher interest rates, to other types of investments. The increase in other income was primarily attributable to foreign exchange gains and losses. Our investment in ARS was redeemed in June 2010.

# **Income Taxes**

We recorded a tax provision of \$315,000 and \$863,000 for the three months ended June 30, 2010 and 2009, respectively. The tax provision for the three months ended June 30, 2010 mainly pertained to taxable income generated by our U.S. subsidiary. Our other subsidiaries, based in Europe and Japan, incurred a pre-tax loss for the three months ended June 30, 2010, for which no tax benefit was recognized. As of June 30, 2010, we had an outstanding non-current income tax liability of approximately \$788,000 for uncertain tax positions which represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in our condensed consolidated financial statements. The liability for uncertain tax positions as of June 30, 2010 was mainly a result of our interpretation of nexus in certain states related to revenue sourcing for state income tax purposes.

# Comparison of six months ended June 30, 2010 and June 30, 2009

# Revenues

The following table summarizes our revenues for the six months ended June 30, 2010 and 2009:

|                                    |           | June 30, |        |  |  |  |
|------------------------------------|-----------|----------|--------|--|--|--|
| (In thousands)                     | 2010      |          | 2009   |  |  |  |
| Research and development revenue   | \$ 6,846  | \$       | 12,921 |  |  |  |
| Product royalty revenue            | 19,385    |          | 17,860 |  |  |  |
| Co-promotion revenue               | 2,075     |          | 2,140  |  |  |  |
| Contract and collaboration revenue | 305       |          | 298    |  |  |  |
| Total                              | \$ 28,611 | \$       | 33,219 |  |  |  |

Six Months Ended

Total revenues were \$28.6 million for the six months ended June 30, 2010 compared to \$33.2 million for the six months ended June 30, 2009, a decrease of \$4.6 million or 13.9%.

Research and development revenue was \$6.8 million for the six months ended June 30, 2010 compared to \$12.9 million for the six months ended June 30, 2009, a decrease of \$6.1 million or 47.0%. The decrease was primarily due to reduced revenue recognized in respect to the OBD program for Amitiza in the U.S., partially offset by \$4.3 million in revenue recognized under the agreement with Abbott in Japan. The research and development revenue recognized under the agreement with Takeda decreased to \$2.6 million for the six months ended June 30, 2010 from \$9.0 million for the six months ended June 30, 2009, generally reflecting a completion of the initial two phase 3 efficacy trials in July 2009 funded by Takeda and the change in estimated costs and timeline to complete the OBD program, including an additional phase 3 efficacy trial. Since Takeda funds the first \$50.0 million of the development expenses for the OBD program and we and Takeda share equally development costs that exceed that amount, we expect to fund about 50.0% of the upcoming phase 3 trial. The research and development revenue recognized under the agreement with Abbott increased to \$4.3 million for the six months ended June 30, 2010 from \$3.9 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2010 from \$4.3 million for the six months ended June 30, 2009, reflecting the progress of the Japanese development program for lubiprostone. We are recognizing the revenue from the payments from Abbott using a percentage-of-completion model over the estimated term of the CIC development program.

Product royalty revenue represents royalty revenue earned on net sales of Amitiza in the United States. For the six months ended June 30, 2010 and 2009, we recognized \$19.4 million and \$17.9 million, respectively, of product royalty revenue, an increase of \$1.5 million or 8.5%, reflecting mainly a higher price per pill and a slight increase in volume.

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force. For each of the six months ended June 30, 2010 and 2009, we recognized \$2.1 million of co-promotion revenues for reimbursement of our sales force costs.

# **Research and Development Expenses**

The following summarizes our research and development expenses for the six months ended June 30, 2010 and 2009:

|                | Six Mon<br>Jun |           |
|----------------|----------------|-----------|
| (In thousands) | 2010           | 2009      |
| Direct costs:  |                |           |
| Amitiza        | \$ 6,997       | \$ 14,350 |
| Cobiprostone   | 307            | 1,577     |
| SPI-017        | 1,542          | 2,316     |
| Rescula        | 292            | 58        |
| Other          | 82             | 254       |
| Total          | 9,220          | 18,555    |
|                |                |           |
| Indirect costs | 1,000          | 1,031     |
| Total          | \$ 10,220      | \$ 19,586 |

Total research and development expenses for the six months ended June 30, 2010 were \$10.2 million compared to \$19.6 million for the six months ended June 30, 2009, a decrease of \$9.4 million or 47.8%. The decrease was primarily due to the completion in July 2009 of the two phase 3 pivotal clinical trials for the treatment of OBD, the completion in July 2009 of the phase 2 clinical trial of cobiprostone for the prevention of NSAID-induced ulcers and a reduction in overall preclinical and basic development costs related to SPI-017.

# General and Administrative Expenses

The following summarizes our general and administrative expenses for the six months ended June 30, 2010 and 2009:

|   | Six Months Ended<br>June 30, |        |    | ded   |
|---|------------------------------|--------|----|-------|
| (In thousands)                                    |                              | 2010   |    | 2009  |
| Salaries, benefits and related costs              | \$                           | 2,668  | \$ | 1,909 |
| Legal, consulting and other professional expenses |                              | 6,738  |    | 1,989 |
| Other expenses                                    |                              | 2,957  |    | 2,481 |
| Total   | \$                           | 12,363 | \$ | 6,379 |

General and administrative expenses were \$12.4 million for the six months ended June 30, 2010, compared to \$6.4 million for the six months ended June 30, 2009, an increase of \$6.0 million or 93.8%. The increase in salaries, benefits and related costs was primarily attributable to an increase in the number of key personnel and in the incentive compensation plans for 2010. The increase in legal, consulting and other professional expenses relates primarily to costs incurred in connection with the ongoing legal matters.

# 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 \$4.5 million for the six months ended June 30, 2010, compared to \$4.7 million for the six months ended June 30, 2009, a decrease of \$200,000 or 4.3%. The decrease in the selling and marketing expenses was primarily due to a reduction in market research expenses in 2010. Part of the Amitiza co-promotion expenses are funded by Takeda and recorded as co-promotion revenue.

# **Product Royalties - Related Parties**

Product royalties – related parties expense, representing 3.2% of Amitiza net sales for the respective periods payable to SAG, increased to \$3.4 million for the six months ended June 30, 2010 from \$3.2 million for the six months ended June 30, 2009, which was consistent with the increase of net sales and product royalty revenue.

# Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the six months ended June 30, 2010 and 2009:

|                             | Six Months Ended<br>June 30, |    | ded  |
|-----------------------------|------------------------------|----|------|
| (In thousands)              | 2010                         |    | 2009 |
| Interest income             | \$<br>388                    | \$ | 531  |
| Other income (expense), net | <br>(227)                    |    | 214  |
| Total                       | \$<br>161                    | \$ | 745  |

Interest income was \$388,000 for the six months ended June 30, 2010 compared to \$531,000 for the six months ended June 30, 2009, a decrease of \$143,000, or 26.9%. The decrease was primarily due to lower prevailing interest rates earned by our investments and a shift in the composition of our portfolio from ARS, which bear higher interest rates, to other types of investments. Our investment in ARS was redeemed in June 2010. The change in other income (expense) was primarily attributable to foreign exchange gains and losses.

# **Income Taxes**

We recorded a tax provision of \$520,000 and \$1.3 million for the six months ended June 30, 2010 and 2009, respectively. The tax provision for the six months ended June 30, 2010 mainly pertained to taxable income generated by our U.S. subsidiary. Our other subsidiaries, based in Europe and Japan, incurred a pre-tax loss for the six months ended June 30, 2010, for which no tax benefit was recognized. As of June 30, 2010, we had an outstanding non-current income tax liability of approximately \$788,000 for uncertain tax positions which represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in our condensed consolidated financial statements. The liability for uncertain tax positions as of June 30, 2010 was mainly a result of our interpretation of nexus in certain states related to revenue sourcing for state income tax purposes.

# **Reportable Geographic Segments**

We have determined that we have three reportable segments based on our method of internal reporting, which disaggregates business by geographic location. These segments are the Americas, Europe and Asia. We evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors, including the progress of research and development activities.

The financial results of our segments reflect their varying stages of development. Our Americas segment recorded income before taxes of \$1.3 million for the six months ended June 30, 2010, compared to income before taxes of \$3.4 million for the six months ended June 30, 2009. These results primarily reflect the completion of the initial two phase 3 clinical trials of Amitiza for the treatment of OBD and cobiprostone for the prevention of NSAID-induced ulcers in 2009 offset by an increase in general and administrative expenses.

Our segment in Europe recorded a loss before taxes of \$1.2 million for the six months ended June 30, 2010, compared to a loss before taxes of \$1.3 million for the six months ended June 30, 2009.

Our segment in Asia recorded a loss before taxes of \$1.8 million for the six months ended June 30, 2010, compared to a loss before taxes of \$2.8 million during the six months ended June 30, 2009. These results primarily reflect the milestone royalty payments to SAG of \$875,000 during the six months ended June 30, 2009 from the payments received from Abbott in 2009.

|                                  |    |          |             |             | Int | tercompany  |    |             |
|----------------------------------|----|----------|-------------|-------------|-----|-------------|----|-------------|
| (In thousands)                   | A  | Americas | Europe      | Asia        | E   | liminations | С  | onsolidated |
| Three Months Ended June 30, 2010 |    |          |             |             |     |             |    |             |
| Total revenues                   | \$ | 12,242   | \$<br>-     | \$<br>1,805 | \$  | (272)       | \$ | 13,775      |
| Income (loss) before taxes       |    | 574      | (662)       | (1,575)     |     | -           |    | (1,663)     |
| Three Months Ended June 30, 2009 |    |          |             |             |     |             |    |             |
| Total revenues                   | \$ | 14,125   | \$<br>-     | \$<br>3,790 | \$  | (210)       | \$ | 17,705      |
| Income (loss) before taxes       |    | 2,238    | (816)       | (797)       |     | -           |    | 625         |
|                                  |    |          |             |             |     |             |    |             |
| Six Months Ended June 30, 2010   |    |          |             |             |     |             |    |             |
| Total revenues                   | \$ | 24,315   | \$<br>-     | \$<br>4,843 | \$  | (547)       | \$ | 28,611      |
| Income (loss) before taxes       |    | 1,288    | (1,235)     | (1,810)     |     | -           |    | (1,757)     |
|                                  |    |          |             |             |     |             |    |             |
| Six Months Ended June 30, 2009   |    |          |             |             |     |             |    |             |
| Total revenues                   | \$ | 29,260   | \$<br>-     | \$<br>4,379 | \$  | (420)       | \$ | 33,219      |
| Income (loss) before taxes       |    | 3,401    | (1,335)     | (2,815)     |     | -           |    | (749)       |
|                                  |    |          |             |             |     |             |    |             |
| Identifiable Assets              |    |          |             |             |     |             |    |             |
| As of June 30, 2010              | \$ | 129,759  | \$<br>6,316 | \$<br>3,900 | \$  | (2,800)     | \$ | 137,175     |
| As of December 31, 2009          |    | 134,714  | 864         | 11,294      |     | (1,901)     |    | 144,971     |
|                                  |    |          |             |             |     |             |    |             |

# Liquidity and Capital Resources

# Sources of Liquidity

We require cash principally to meet our operating expenses. Historically, we have financed our operations with a combination of upfront payments, milestone and royalty payments and research and development expense reimbursements received from Takeda, Abbott and other parties, private placements of equity securities and our initial public offering.

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

| (In thousands)            | J  | ,       |    | ember 31,<br>2009 |
|---------------------------|----|---------|----|-------------------|
| Cash and cash equivalents | \$ | 42,293  | \$ | 26,714            |
| Investments, current      |    | 56,163  |    | 72,434            |
| Investments, non-current  |    | 15,935  |    | 19,167            |
| Total                     | \$ | 114,391 | \$ | 118,315           |

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.

Our total cash, cash equivalents, short and long-term investments decreased by \$3.9 million to \$114.4 million at June 30, 2010 from \$118.3 million at December 31, 2009 mainly due to the use of cash in our operating activities.

As of June 30, 2010, our short-term investments consisted of corporate bonds, U.S. government securities, U.S. Treasury notes and bills, U.S. corporate commercial paper, municipal securities, certificates of deposits and money market funds which have short-term maturities of one year or less. Our non-current investments consisted of corporate bonds, U.S. government securities, municipal securities and certificates of deposits.

# **Cash Flows**

The following table summarizes our cash flows for the six months ended June 30, 2010 and 2009:

|   | <br>Six Months Ended June 3 |    |          |
|---|-----------------------------|----|----------|
| (In thousands)                            | 2010                        | _  | 2009     |
| Cash provided by (used in):               |                             |    |          |
| Operating activities                      | \$<br>(3,972)               | \$ | 11,013   |
| Investing activities                      | 19,551                      |    | (31,845) |
| Financing activities                      | 8                           |    | 9        |
| Effect of exchange rates                  | (8)                         |    | 184      |
| Net increase in cash and cash equivalents | \$<br>15,579                | \$ | (20,639) |

# Six Months Ended June 30, 2010

Net cash used in operating activities was \$4.0 million for the six months ended June 30, 2010. This reflected a net loss of \$2.3 million, a decrease in deferred revenue of \$6.8 million relating to the previously received funds under Takeda and Abbott agreements that were recognized as revenue during the period, offset in part by changes in other operating assets and liabilities.

Net cash provided by investing activities of \$19.6 million for the six months ended June 30, 2010 primarily reflected our proceeds from the sales and maturities of investments, offset in part by purchases of investments.

Net cash provided by financing activities of \$8,000 for the six months ended June 30, 2010 resulted from the proceeds we received under our employee stock purchase plan.

# Six Months Ended June 30, 2009

Net cash provided by operating activities was \$11.0 million for the six months ended June 30, 2009. This reflected a net loss of \$2.0 million, an increase in deferred revenue of \$9.4 million, and changes in other operating assets and liabilities. The increase in deferred revenue primarily related to a \$10.0 million upfront payment from Abbott upon execution of the license and commercialization agreement by Sucampo Japan in February 2009 and a \$7.5 million development milestone payment from Abbott for the initiation of a phase 3 study in Japan, offset by amortization of revenues in the period.

Net cash used in investing activities of \$31.8 million for the six months ended June 30, 2009 primarily reflected our proceeds from the sales and maturities of investments, offset in part by purchases of investments.

Net cash provided by financing activities of \$9,000 for the six months ended June 30, 2009 resulted from proceeds we received under our employee stock purchase plan.

#### **Off-Balance Sheet Arrangements**

As of June 30, 2010, we did not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4) of Regulation S-K under the Securities Act of 1933, as amended.

# **Funding Requirements**

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

- fund our share of the ongoing development program of Amitiza in the U.S.;
- fund development and regulatory efforts in Europe and Asia for lubiprostone;
- fund development and regulatory activities for Rescula in the U.S. and Canada;
- fund research and development activities for other prostone compounds, including cobiprostone and SPI-017;
- fund the expansion of our commercialization activities in the U.S. and the initiation of commercialization efforts in non-U.S. markets;
- fund capital expenditures to support the growth of our business;
- fund activities to resolve our ongoing legal matters; and
- fund the purchase of shares of our class A common stock up to \$10.0 million, if we elect to do so, pursuant to our board-approved stock repurchase program.

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

- the revenue from Amitiza and Rescula;
- the future expenditures we may incur to increase revenue from Amitiza or in our disputes with Takeda;
- 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. At June 30, 2010, we have sufficient liquidity for more than the next 12 months.

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



# Effects of Foreign Currency

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

# **Recent Accounting Pronouncements**

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

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

#### Foreign Exchange Risk

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

# **Interest Rate Risk**

Our exposure to market risks associated with changes in interest rates relates primarily to the increase or decrease in the amount of interest income earned on our investment portfolio. We ensure the safety and preservation of invested funds by attempting to limit default risk, market risk and reinvestment risk. We attempt to mitigate default risk by investing in investment grade securities. A hypothetical one percentage point decline in interest rates would not have materially affected the fair value of our interest-sensitive financial instruments as of June 30, 2010.

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

#### Credit Risk

Our exposure to credit risk consists of cash and cash equivalents, restricted cash, investments and receivables. We place our cash, cash equivalents and restricted cash with what we believe to be highly rated financial institutions and invest the excess cash in highly rated investments. As of June 30, 2010 and December 31, 2009, approximately 54.7% and 51.2%, respectively, of our cash, cash equivalents, restricted cash and investments is issued or insured by the federal government or government agencies. We have not experienced any losses on these accounts related to amounts in excess of insured limits.

On June 8, 2010, the issuer of our remaining ARS redeemed the security at par value of \$10.0 million, which terminated the related settlement rights.

#### Item 4. Controls and Procedures

# a) Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of June 30, 2010. In designing and evaluating such controls, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2010, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified under applicable rules of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

# b) Changes in Internal Controls

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2010 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

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Collaboration and License Agreement between us and Takeda Pharmaceuticals Company Limited dated October 29, 2004. We are disappointed with the level of U.S. sales of Amitiza being generated by Takeda and what we believe to be other failures of performance by Takeda under the agreements. We believe that Takeda materially breached its agreement, without limitation, by its continuing failure to exercise its best efforts to commercialize Amitiza and maximize net sales revenue, and its ongoing refusal to collaborate and provide us with information to which we are entitled under the agreement. We also claimed that Takeda's conduct, including, without limitation, its dealings with pharmacy benefit managers/managed care organizations, has injured not only us and the Amitiza brand, but also consumers. We are seeking all appropriate relief, including production by Takeda of all information to which we are entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. The respective arbitrators for both us and Takeda have been confirmed and both parties have selected a third arbitrator. If the third arbitrator is confirmed, then it will comprise the panel that will conduct the arbitration proceedings. We spent and expect to spend significant resources in the dispute with Takeda and these legal proceedings may require the continuing attention of our senior management.

# Item 1A. Risk Factors

Our business is subject to certain risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our common stock. For a discussion of these risks, please refer to the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2009, filed by us with the SEC on March 15, 2010.

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

On December 11, 2008, we announced a stock repurchase program pursuant to which we are authorized to purchase up to \$10.0 million of our class A common stock from time to time in open market transactions. During the quarter ended June 30, 2010, we did not purchase any shares under this program.

#### Item 3. Defaults Upon Senior Securities.

None.

**Item 4. RESERVED** 

# Item 6. Exhibits

# (a) Exhibits

| Exhibit<br>Number | Description   | Reference  |
|-------------------|---|--|
| 3.1               | Certificate of Incorporation  | Exhibit 3.1 to the Company's Current Report on Form 8-K (filed December 29, 2008)              |
| 3.2               | Certificate of Amendment  | Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2008)              |
| 3.3               | Restated Bylaws   | Exhibit 3.3 to the Company's Current Report on Form 8-K (filed December 29, 2008)              |
| 4.1               | Specimen Stock Certificate evidencing the shares of class A common stock  | Exhibit 4.1 to Registration Statement No. 333-135133, Amendment No. 5 (filed February 1, 2007) |
| 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  |
|                   | 33  |  |

# 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.

| August 5, 2010 | By: | /s/ RYUJI UENO<br>Ryuji Ueno, M.D., Ph.D., Ph.D.<br>Chief Executive Officer, Chief Scientific Officer and<br>Chairman of the Board of Directors<br>(Principal Executive Officer) |
|----------------|-----|--|
| August 5, 2010 | By: | /s/ JAN SMILEK<br>Jan Smilek<br>Chief Financial Officer<br>(Principal Financial and Accounting Officer)  |

# Sucampo Pharmaceuticals, Inc. Exhibit Index

| Exhibit<br>Number | Description   | Reference  |
|-------------------|---|--|
| 3.1               | Certificate of Incorporation  | Exhibit 3.1 to the Company's Current Report on Form 8-K (filed December 29, 2008)              |
| 3.2               | Certificate of Amendment  | Exhibit 3.2 to the Company's Current Report on Form 8-K (filed December 29, 2008)              |
| 3.3               | Restated Bylaws   | Exhibit 3.3 to the Company's Current Report on Form 8-K (filed December 29, 2008)              |
| 4.1               | Specimen Stock Certificate evidencing the shares of class A common stock  | Exhibit 4.1 to Registration Statement No. 333-135133, Amendment No. 5 (filed February 1, 2007) |
| 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  |
|                   | 35  |  |

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

I, Ryuji Ueno, certify that:

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

Date: August 5, 2010

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(F)) for the registrant and have:
  - (a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrants fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2010

/s/ JAN SMILEK

Jan Smilek Chief Financial Officer (Principal Financial and Accounting Officer)

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

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

- (1) The Quarterly Report on Form 10-Q for the period ended June 30, 2010 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: August 5, 2010

/s/ RYUJI UENO

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

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

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

- (1) The Quarterly Report on Form 10-Q for the period ended June 30, 2010 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: August 5, 2010

/s/ JAN SMILEK

Jan Smilek Chief Financial Officer (Principal Financial and Accounting Officer)