

## Form 10-Q

(Mark One)

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

**For the quarterly period ended March 31, 2011**

OR

**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, 3rd Floor  
Bethesda, MD 20814**

*(Address of principal executive offices,  
including zip code)*

**30-0520478**

*(I.R.S. Employer  
Identification No.)*

**(301) 961-3400**

*(Registrant's telephone number,  
including area code)*

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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

Accelerated filer

Non accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of May 4, 2011, there were 15,660,682 shares of the registrant's class A common stock outstanding and 26,191,050 shares of the registrant's class B common stock outstanding.

Sucampo Pharmaceuticals, Inc.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

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

|  | March 31,<br>2011 | December 31,<br>2010 |
|--|-------------------|----------------------|
| <b>ASSETS:</b>   |                   |                      |
| Current assets:  |                   |                      |
| Cash and cash equivalents  | \$ 48,358         | \$ 49,243            |
| Investments, current   | 48,481            | 54,524               |
| Product royalties receivable   | 9,118             | 10,516               |
| Unbilled accounts receivable   | 2,579             | 1,097                |
| Accounts receivable, net   | 623               | 731                  |
| Prepaid and income taxes receivable  | 3,587             | 702                  |
| Deferred tax assets, net   | 99                | 243                  |
| Restricted cash  | 15,113            | 15,113               |
| Prepaid expenses and other current assets  | 1,954             | 2,374                |
| Total current assets   | <u>129,912</u>    | <u>134,543</u>       |
| Investments, non-current   | 3,007             | 5,028                |
| Property and equipment, net  | 1,993             | 2,025                |
| Deferred tax assets, non-current   | 4,324             | 4,178                |
| Other assets   | 9,467             | 3,499                |
| Total assets   | <u>\$ 148,703</u> | <u>\$ 149,273</u>    |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>   |                   |                      |
| Current liabilities:   |                   |                      |
| Accounts payable   | \$ 3,139          | \$ 4,199             |
| Accrued expenses   | 17,180            | 10,216               |
| Deferred revenue, current  | 4,763             | 4,987                |
| Notes payable, current   | 19,522            | 19,522               |
| Total current liabilities  | <u>44,604</u>     | <u>38,924</u>        |
| Notes payable, non-current   | 45,009            | 44,439               |
| Deferred revenue, non-current  | 7,872             | 8,321                |
| Other liabilities  | 3,701             | 3,759                |
| Total liabilities  | <u>101,186</u>    | <u>95,443</u>        |
| Commitments (Note 7)   |                   |                      |
| Stockholders' equity:  |                   |                      |
| Preferred stock, \$0.01 par value; 5,000,000 shares authorized at March 31, 2011 and December 31, 2010; no shares issued and outstanding at March 31, 2011 and December 31, 2010   | -                 | -                    |
| Class A common stock, \$0.01 par value; 270,000,000 shares authorized at March 31, 2011 and December 31, 2010; 15,660,682 and 15,659,917 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively | 156               | 156                  |
| Class B common stock, \$0.01 par value; 75,000,000 shares authorized at March 31, 2011 and December 31, 2010; 26,191,050 shares issued and outstanding at March 31, 2011 and December 31, 2010                               | 262               | 262                  |
| Additional paid-in capital   | 58,616            | 58,468               |
| Accumulated other comprehensive income   | 17,022            | 16,574               |
| Accumulated deficit  | (28,539)          | (21,630)             |
| Total stockholders' equity   | <u>47,517</u>     | <u>53,830</u>        |
| Total liabilities and stockholders' equity   | <u>\$ 148,703</u> | <u>\$ 149,273</u>    |

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

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

|  | <b>Three Months Ended March 31,</b> |                 |
|--|-------------------------------------|-----------------|
|  | <b>2011</b>                         | <b>2010</b>     |
| <b>Revenues:</b>   |                                     |                 |
| Research and development revenue                         | \$ 1,964                            | \$ 4,057        |
| Product royalty revenue                                  | 9,118                               | 9,773           |
| Co-promotion revenue                                     | 938                                 | 855             |
| Contract and collaboration revenue                       | 154                                 | 151             |
| Total revenues   | <u>12,174</u>                       | <u>14,836</u>   |
| <b>Operating expenses:</b>                               |                                     |                 |
| Research and development                                 | 9,220                               | 5,366           |
| General and administrative                               | 9,697                               | 5,894           |
| Selling and marketing                                    | 2,418                               | 2,187           |
| Total operating expenses                                 | <u>21,335</u>                       | <u>13,447</u>   |
| Income (loss) from operations                            | (9,161)                             | 1,389           |
| <b>Non-operating income (expense):</b>                   |                                     |                 |
| Interest income  | 70                                  | 213             |
| Interest expense   | (611)                               | -               |
| Other income (expense), net                              | (135)                               | 607             |
| Total non-operating income (expense), net                | <u>(676)</u>                        | <u>820</u>      |
| Income (loss) before income taxes                        | (9,837)                             | 2,209           |
| Income tax benefit (provision)                           | 2,928                               | (409)           |
| Net income (loss)  | <u>\$ (6,909)</u>                   | <u>\$ 1,800</u> |
| <b>Net income (loss) per share:</b>                      |                                     |                 |
| Basic net income (loss) per share                        | \$ (0.17)                           | \$ 0.04         |
| Diluted net income (loss) per share                      | \$ (0.17)                           | \$ 0.04         |
| Weighted average common shares outstanding - basic       | <u>41,851</u>                       | <u>41,847</u>   |
| Weighted average common shares outstanding - diluted     | <u>41,851</u>                       | <u>41,849</u>   |
| <b>Comprehensive income (loss):</b>                      |                                     |                 |
| Net income (loss)  | \$ (6,909)                          | \$ 1,800        |
| <b>Other comprehensive income (loss):</b>                |                                     |                 |
| Unrealized gain (loss) on investments, net of tax effect | 11                                  | (17)            |
| Foreign currency translation                             | 437                                 | (745)           |
| Comprehensive income (loss)                              | <u>\$ (6,461)</u>                   | <u>\$ 1,038</u> |

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 |               | Class B<br>Common Stock |               | Additional<br>Paid-In<br>Capital | Accumulated<br>Other<br>Comprehensive<br>Income | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity |
|---|-------------------------|---------------|-------------------------|---------------|----------------------------------|---|------------------------|----------------------------------|
|   | Shares                  | Amount        | Shares                  | Amount        |                                  |   |                        |                                  |
| Balance at December 31, 2010                      | 15,659,917              | \$ 156        | 26,191,050              | \$ 262        | \$ 58,468                        | \$ 16,574                                       | \$ (21,630)            | \$ 53,830                        |
| Employee stock option expense                     | -                       | -             | -                       | -             | 145                              | -   | -                      | 145                              |
| Stock issued under employee stock purchase plan   | 765                     | -             | -                       | -             | 3                                | -   | -                      | 3                                |
| Foreign currency translation                      | -                       | -             | -                       | -             | -                                | 437   | -                      | 437                              |
| Unrealized gain on investments, net of tax effect | -                       | -             | -                       | -             | -                                | 11  | -                      | 11                               |
| Net loss  | -                       | -             | -                       | -             | -                                | -   | (6,909)                | (6,909)                          |
| Balance at March 31, 2011                         | <u>15,660,682</u>       | <u>\$ 156</u> | <u>26,191,050</u>       | <u>\$ 262</u> | <u>\$ 58,616</u>                 | <u>\$ 17,022</u>                                | <u>\$ (28,539)</u>     | <u>\$ 47,517</u>                 |

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)

|  | <b>Three Months Ended March 31,</b> |                  |
|--|-------------------------------------|------------------|
|  | <b>2011</b>                         | <b>2010</b>      |
| <b>Cash flows from operating activities:</b>   |                                     |                  |
| Net income (loss)  | \$ (6,909)                          | \$ 1,800         |
| <b>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</b> |                                     |                  |
| Depreciation and amortization  | 249                                 | 230              |
| Loss on disposal of fixed assets   | -                                   | 1                |
| Deferred tax provision   | (12)                                | 138              |
| Stock-based compensation   | 145                                 | 145              |
| Amortization of premiums on investments  | 292                                 | 461              |
| Notes payable paid-in-kind interest  | 570                                 | -                |
| <b>Changes in operating assets and liabilities:</b>  |                                     |                  |
| Accounts receivable  | 108                                 | 395              |
| Unbilled accounts receivable   | (1,482)                             | 217              |
| Product royalties receivable   | 1,398                               | 1,250            |
| Prepaid and income taxes receivable and payable, net   | (2,893)                             | (453)            |
| Accounts payable   | (1,065)                             | (1,152)          |
| Accrued expenses   | 3,902                               | (318)            |
| Deferred revenue   | (640)                               | (3,461)          |
| Other assets and liabilities, net  | 290                                 | 568              |
| Net cash used in operating activities  | <u>(6,047)</u>                      | <u>(179)</u>     |
| <b>Cash flows from investing activities:</b>   |                                     |                  |
| Purchases of investments   | (8,790)                             | (35,778)         |
| Proceeds from sales of investments   | 1,248                               | 1,500            |
| Maturities of investments  | 15,335                              | 24,917           |
| Purchases of property and equipment  | (133)                               | (95)             |
| Proceeds from disposals of property and equipment  | -                                   | 3                |
| Purchases of intangible assets   | (3,000)                             | -                |
| Net cash provided by (used in) investing activities  | <u>4,660</u>                        | <u>(9,453)</u>   |
| <b>Cash flows from financing activities:</b>   |                                     |                  |
| Issuance of notes receivable   | -                                   | (717)            |
| Proceeds from employee stock purchase plan   | 3                                   | 5                |
| Net cash provided by (used in) financing activities  | <u>3</u>                            | <u>(712)</u>     |
| Effect of exchange rates on cash and cash equivalents  | <u>499</u>                          | <u>(792)</u>     |
| Net decrease in cash and cash equivalents  | (885)                               | (11,136)         |
| Cash and cash equivalents at beginning of period   | 49,243                              | 61,420           |
| Cash and cash equivalents at end of period   | <u>\$ 48,358</u>                    | <u>\$ 50,284</u> |
| <b>Supplemental disclosure of non-cash investing and financing activities:</b>                   |                                     |                  |
| Purchase of intangible assets included in accrued expenses                                       | <u>\$ 3,000</u>                     | <u>\$ -</u>      |

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

## Notes to Condensed Consolidated Financial Statements (Unaudited)

**1. Business Organization and Basis of Presentation***Description of the Business*

Sucampo Pharmaceuticals, Inc., or the Company, is an international pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostones. Prostones are a class of compounds that occur naturally in the human body as a result of enzymatic, 15-PGDH, transformation of certain fatty acids. The Company 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 our founders, Dr. Ryuji Ueno. To date, two prostone products have received marketing approval. AMITIZA® (lubiprostone) is a treatment approved by the U.S. Food and Drug Administration, or FDA, for chronic idiopathic constipation, or CIC, in adults of both genders and for irritable bowel syndrome with constipation, or IBS-C, in women aged 18 years and older. RESCULA® (unoprostone isopropyl) is FDA approved for the lowering of intra-ocular pressure, or IOP, in open-angle glaucoma or ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP lowering medications.

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

In Japan, lubiprostone is being developed under a license, commercialization and supply agreement, or the Abbott Agreement, with Abbott Japan Co. Ltd., or Abbott. The Company plans to file for approval in the United Kingdom for CIC and continues to evaluate the opportunities to obtain an appropriate label in the European Union based on the fact that lubiprostone is the only product approved by the FDA in the U.S. for chronic therapy for either CIC or IBS-C and received marketing authorization from Swissmedic, the Swiss Agency for Therapeutic Products, in November 2009 for CIC. The Company holds all development and commercialization rights to lubiprostone except in the U.S., Canada and Japan.

In April 2009, the Company acquired the rights from a related party under common control, R-Tech Ueno, Ltd. or R-Tech, a pharmaceutical research, development and manufacturing company in Japan, that is majority owned by our founders, to unoprostone isopropyl which allow the Company to commercialize RESCULA in the U.S. and Canada for its approved indication and all indications for the use of unoprostone isopropyl developed by the Company and R-Tech. On March 22, 2011, Sucampo Manufacturing & Research AG, or SMR, a wholly-owned subsidiary of the Company, entered into a license agreement with R-Tech for unoprostone isopropyl, expanding the rights of the Company's subsidiaries beyond their previously agreed territory of the United States and Canada (those rights are held by Sucampo Pharma Americas, Inc.) to all countries in Europe and the rest of the world except Japan, Korea, Taiwan and the People's Republic of China, or SMR Territories. The Company is evaluating the opportunities to obtain an appropriate label in the European Union and other European countries as well as obtaining reauthorization in those countries to commercialize unoprostone isopropyl.

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

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

***Basis of Presentation***

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

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: Sucampo Pharma Ltd., based in Tokyo and Osaka, Japan, through which the Company conducts its Asian and Oceania operations; Sucampo Pharma Americas, Inc., based in Bethesda, Maryland, through which the Company conducts its operations in North and South America; Sucampo Pharma Europe Ltd., based in Oxford, U.K., in which we conduct certain operations in Europe; Sucampo AG, or SAG, and Sucampo Manufacturing & Research AG, based in Switzerland (through which the Company conducts certain operations in Europe and the rest of the world); Sucampo AG Japan, based in Osaka, Japan; and Ambrent Investments S.à r.l., based in Luxembourg. All significant inter-company balances and transactions have been eliminated.

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

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

**2. Summary of Significant Accounting Policies**

***Cash and Cash Equivalents***

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

***Restricted Cash***

Restricted cash amounted to approximately \$15.1 million at March 31, 2011 and December 31, 2010. Restricted cash represents cash required to be deposited with financial institutions in connection with the Sucampo Pharma, Ltd. and The Bank of Tokyo-Mitsubishi UFJ, Ltd. loan agreement and operating leases.

***Current and Non-current Investments***

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

***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.



**Notes to Condensed Consolidated Financial Statements (Unaudited) – (Continued)****Revenue Recognition**

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

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

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

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

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

The Company has also entered into the Supplemental Takeda Agreement, which consists of the following key funding streams: reimbursements of co-promotion costs based upon a per-day rate and reimbursements of the costs of miscellaneous marketing activities, which the Company recognizes as revenue as the related costs are incurred and Takeda becomes contractually obligated to pay the amounts.

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

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

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

*Contract Revenue*

Contract revenue relates to development and consulting activities with R-Tech and is 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. 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 March 31, 2011 and December 31, 2010, approximately \$33.0 million, or 28.7%, and \$34.1 million, or 27.6%, respectively, of the Company's cash, cash equivalents, restricted cash and investments was issued or insured by the federal government or government agencies. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits.

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

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

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

Revenues from one unrelated party, Takeda, accounted for 94.8% and 80.7%, of the Company's total revenues for the three months ended March 31, 2011 and 2010, respectively. Accounts receivable, unbilled accounts receivable and product royalties receivable from Takeda accounted for 99.9% of the Company's total accounts receivable, unbilled accounts receivable and product royalties receivable at March 31, 2011 and December 31, 2010. Revenues from another unrelated party, Abbott, accounted for 4.3% and 18.6% of the Company's total revenues for the three months ended March 31, 2011 and 2010, respectively. The Company depends significantly upon the collaborations with Takeda and Abbott and its activities may be impacted if these relationships are disrupted (see Note 10 below for additional details).

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

*Error in Previously Issued Financial Statements*

The Company incorrectly classified certain VRDNs as cash equivalents rather than short-term investments in its previously filed financial statements for the quarter ended March 31, 2010. The misclassification resulted in an immaterial error to the Company's quarterly balance sheet and statement of cash flows, whereby cash balances and net cash provided by investing activities were overstated by \$14.8 million for the first quarter of 2010. The March 31, 2010 quarterly cash flow statement has been revised.

**SUCAMPO PHARMACEUTICALS, INC.**

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

**Recent Accounting Pronouncements**

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

**3. Earnings per Share**

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

The computation of net income (loss) per share for the three months ended March 31, 2011 and 2010 is shown below:

| <b>(in thousands, except per share data)</b>  | <b>Three Months Ended March 31,</b> |             |
|---|-------------------------------------|-------------|
|   | <b>2011</b>                         | <b>2010</b> |
| Basic net income (loss) per share:  |                                     |             |
| Net income (loss)   | \$ (6,909)                          | \$ 1,800    |
| Weighted average class A and B common shares outstanding                                  | 41,851                              | 41,847      |
| Basic net income (loss) per share   | \$ (0.17)                           | \$ 0.04     |
| Diluted net income (loss) per share:  |                                     |             |
| Net income (loss)   | \$ (6,909)                          | \$ 1,800    |
| Weighted average class A and B common shares outstanding for diluted net income per share | 41,851                              | 41,849      |
| Diluted net income (loss) per share   | \$ (0.17)                           | \$ 0.04     |

For the periods listed above, the potentially dilutive securities used in the calculations of diluted historical net loss per share as of March 31, 2011 and 2010 are shown below:

| <b>(In thousands)</b>      | <b>March 31,</b> |             |
|----------------------------|------------------|-------------|
|                            | <b>2011</b>      | <b>2010</b> |
| Employee stock options     | -                | 52          |
| Non-employee stock options | -                | -           |

For the periods listed above, the following securities were excluded from the computation of diluted net loss per share as their effect would be anti-dilutive as of March 31, 2011 and 2010 are shown below:

| <b>(In thousands)</b>      | <b>March 31,</b> |             |
|----------------------------|------------------|-------------|
|                            | <b>2011</b>      | <b>2010</b> |
| Employee stock options     | 1,528            | 1,092       |
| Non-employee stock options | 450              | 450         |

SUCAMPO PHARMACEUTICALS, INC.

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

4. Current and Non-Current Investments

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

|                               |                  | March 31, 2011      |                      |                  |  |
|-------------------------------|------------------|---------------------|----------------------|------------------|--|
| (In thousands)                | Cost             | Unrealized<br>Gains | Unrealized<br>Losses | Fair Value       |  |
| <i>Current:</i>               |                  |                     |                      |                  |  |
| U.S. Treasury bills and notes | \$ 1,001         | \$ -                | \$ -                 | \$ 1,001         |  |
| U.S. commercial paper         | 4,244            | 4                   | -                    | 4,248            |  |
| U.S. government securities    | 12,192           | 9                   | -                    | 12,201           |  |
| Municipal securities          | 11,265           | 2                   | (5)                  | 11,262           |  |
| Certificates of deposits      | 500              | -                   | -                    | 500              |  |
| Corporate bonds               | 6,800            | 14                  | -                    | 6,814            |  |
| Variable rate demand notes    | 12,455           | -                   | -                    | 12,455           |  |
| Total                         | <u>\$ 48,457</u> | <u>\$ 29</u>        | <u>\$ (5)</u>        | <u>\$ 48,481</u> |  |
| <i>Non-current:</i>           |                  |                     |                      |                  |  |
| Corporate bonds               | \$ 3,001         | \$ 6                | \$ -                 | \$ 3,007         |  |
| Total                         | <u>\$ 3,001</u>  | <u>\$ 6</u>         | <u>\$ -</u>          | <u>\$ 3,007</u>  |  |
|                               |                  | December 31, 2010   |                      |                  |  |
| (In thousands)                | Cost             | Unrealized<br>Gains | Unrealized<br>Losses | Fair Value       |  |
| <i>Current:</i>               |                  |                     |                      |                  |  |
| U.S. Treasury bills and notes | \$ 1,002         | \$ 1                | \$ -                 | \$ 1,003         |  |
| U.S. commercial paper         | 999              | -                   | -                    | 999              |  |
| U.S. government securities    | 16,525           | 7                   | (4)                  | 16,528           |  |
| Municipal securities          | 17,582           | 6                   | (12)                 | 17,576           |  |
| Certificates of deposits      | 750              | -                   | -                    | 750              |  |
| Corporate bonds               | 6,665            | 5                   | (2)                  | 6,668            |  |
| Variable rate demand notes    | 11,000           | -                   | -                    | 11,000           |  |
| Total                         | <u>\$ 54,523</u> | <u>\$ 19</u>        | <u>\$ (18)</u>       | <u>\$ 54,524</u> |  |
| <i>Non-current:</i>           |                  |                     |                      |                  |  |
| Corporate bonds               | \$ 5,019         | \$ 11               | \$ (2)               | \$ 5,028         |  |
| Total                         | <u>\$ 5,019</u>  | <u>\$ 11</u>        | <u>\$ (2)</u>        | <u>\$ 5,028</u>  |  |

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

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

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

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

**SUCAMPO PHARMACEUTICALS, INC.**

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

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

|  | <b>Fair Value Measurements at Reporting Date Using</b>                                |  |  |                  |
|--|---|--|--|------------------|
|  | <b>Quoted Prices in<br/>Active Markets<br/>for identical<br/>Assets<br/>(Level 1)</b> | <b>Significant<br/>Other<br/>Observable<br/>Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable<br/>Inputs<br/>(Level 3)</b> | <b>Total</b>     |
| <b>March 31, 2011</b>                      |   |  |  |                  |
| <b>(In thousands)</b>                      |   |  |  |                  |
| U.S. Treasury bills and notes              | \$ 1,001  | \$ -   | \$ -   | \$ 1,001         |
| U.S. government securities                 | 12,201  | -  | -  | 12,201           |
| U.S. commercial paper                      | -   | 4,248  | -  | 4,248            |
| Corporate bonds                            | 9,821   | -  | -  | 9,821            |
| Municipal securities                       | 11,262  | -  | -  | 11,262           |
| Certificates of deposits                   | -   | 500  | -  | 500              |
| Money market funds                         | 4,993   | -  | -  | 4,993            |
| Variable rate demand notes                 | 12,455  | -  | -  | 12,455           |
| <b>Total assets measured at fair value</b> | <b>\$ 51,733</b>  | <b>\$ 4,748</b>  | <b>\$ -</b>  | <b>\$ 56,481</b> |

|  | <b>Fair Value Measurements at Reporting Date Using</b>                                |  |  |                  |
|--|---|--|--|------------------|
|  | <b>Quoted Prices in<br/>Active Markets<br/>for identical<br/>Assets<br/>(Level 1)</b> | <b>Significant<br/>Other<br/>Observable<br/>Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable<br/>Inputs<br/>(Level 3)</b> | <b>Total</b>     |
| <b>December 31, 2010</b>                   |   |  |  |                  |
| <b>(In thousands)</b>                      |   |  |  |                  |
| U.S. Treasury bills and notes              | \$ 1,003  | \$ -   | \$ -   | \$ 1,003         |
| U.S. government securities                 | 16,528  | -  | -  | 16,528           |
| U.S. commercial paper                      | -   | 999  | -  | 999              |
| Corporate bonds                            | 11,696  | -  | -  | 11,696           |
| Municipal securities                       | 17,576  | -  | -  | 17,576           |
| Certificates of deposits                   | -   | 750  | -  | 750              |
| Money market funds                         | 780   | -  | -  | 780              |
| Variable rate demand notes                 | 11,000  | -  | -  | 11,000           |
| <b>Total assets measured at fair value</b> | <b>\$ 58,583</b>  | <b>\$ 1,749</b>  | <b>\$ -</b>  | <b>\$ 60,332</b> |

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

**5. Intangible Assets**

In April 2009, the Company entered into two agreements with R-Tech to acquire all patents and other intellectual property rights related to RESCULA for its FDA approved indication and any new indications for unoprostone isopropyl in the U.S. and Canada. Although RESCULA eye drops have been approved by the FDA since 2000, RESCULA is not currently marketed in the U.S. or Canada. The Company plans to re-launch RESCULA in the U.S. for its approved indication after approval of a commercially viable label from the FDA.

**SUCAMPO PHARMACEUTICALS, INC.**

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

Under the terms of the 2009 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 as of March 31, 2011, both of which are reflected in other non-current assets in the accompanying condensed consolidated balance sheet. 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 underlying rights and data. Amortization expense was \$85,000 for the three months ended March 31, 2011 and 2010. The annual amortization expense will be approximately \$342,000 through April 2019.

On March 22, 2011, SMR entered into a license agreement with R-Tech for unoprostone isopropyl, expanding the rights of the Company's subsidiaries beyond their previously agreed territory of the United States and Canada (those rights are held by Sucampo Pharma Americas, Inc.) to all countries in Europe and the rest of the world except the SMR Territories. This alliance ensures state of the art global development and commercialization between the Company, and all its subsidiaries, and R-Tech for all current and potential indications.

Under the terms of the 2011 SMR and R-Tech license agreement, SMR holds exclusive rights to develop, use, make, have made, export, commercialize, promote, offer for sale and sell unoprostone isopropyl in the SMR Territories. R-Tech will retain rights to unoprostone isopropyl in Japan, Korea, Taiwan and the People's Republic of China. Additionally, SMR has the exclusive right to develop unoprostone isopropyl for certain additional ophthalmic indications in the SMR Territories beyond its approved glaucoma and ocular hypertension indication as well as rights to all associated patents and other intellectual property associated with unoprostone isopropyl in these territories. R-Tech retains all other commercial and development rights.

SMR made an upfront payment to R-Tech of \$3.0 million, which is reflected in other non-current assets in the accompanying condensed consolidated balance sheet, and may be required to pay up to \$103.0 million in additional milestone payments to R-Tech based on the achievement of specified development and commercialization goals. The first milestone payment of \$3.0 million is payable upon the earlier of product approval within the SMR Territories or by March 15, 2012, which is reflected in accrued expenses in the accompanying condensed consolidated balance sheet. SMR will be responsible for all development, regulatory, and commercialization activities. The Company is amortizing the \$6.0 million over the 10-year life of the license agreement, which management believes approximates the useful life of the underlying rights and data. No amortization was expensed for the three months ended March 31, 2011. The annual amortization expense will be approximately \$600,000 through March 2021.

**6. Accrued Expenses**

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

| <b>(In thousands)</b>          | <b>March 31,<br/>2011</b> | <b>December 31,<br/>2010</b> |
|--------------------------------|---------------------------|------------------------------|
| Research and development costs | \$ 7,592                  | \$ 4,146                     |
| Employee compensation          | 1,005                     | 1,795                        |
| Selling and marketing costs    | 102                       | 305                          |
| Legal service fees             | 4,155                     | 2,620                        |
| Rescula milestone              | 3,500                     | 500                          |
| Other accrued expenses         | 826                       | 850                          |
| <b>Total</b>                   | <b>\$ 17,180</b>          | <b>\$ 10,216</b>             |

**7. Commitments**

***Operating Leases***

The Company leases office space in the United States, the United Kingdom and Japan under operating leases ranging through 2017. Total future minimum, non-cancelable lease payments under operating leases were as follows as of March 31, 2011:

**SUCAMPO PHARMACEUTICALS, INC.**

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

**(In thousands)**

|                                     |           |              |
|-------------------------------------|-----------|--------------|
| 2011 (April - December)             | \$        | 1,086        |
| 2012                                |           | 1,283        |
| 2013                                |           | 997          |
| 2014                                |           | 1,024        |
| 2015                                |           | 1,052        |
| 2016 and thereafter                 |           | 1,223        |
| <b>Total minimum lease payments</b> | <b>\$</b> | <b>6,665</b> |

Rent expense for all operating leases was approximately \$366,000 and \$340,000 for the three months ended March 31, 2011 and 2010, 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 March 31, 2011 were approximately \$15.4 million.

**8. Related Party Transactions**

**R-Tech Ueno, Ltd.**

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

The Company recorded the following expenses under its agreements with R-Tech for the three months ended March 31, 2011 and 2010:

| <b>(In thousands)</b>                   | <b>Three Months Ended March 31,</b> |              |
|---|-------------------------------------|--------------|
|   | <b>2011</b>                         | <b>2010</b>  |
| Clinical supplies                       | \$ -                                | \$ 17        |
| Other research and development services | 3                                   | -            |
| Commercial supplies                     | 123                                 | 69           |
|   | <b>\$ 126</b>                       | <b>\$ 86</b> |

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

| <b>(In thousands)</b>         | <b>March 31,</b> | <b>December 31,</b> |
|-------------------------------|------------------|---------------------|
|                               | <b>2011</b>      | <b>2010</b>         |
| Deferred revenue, current     | \$ 433           | \$ 433              |
| Deferred revenue, non-current | 5,727            | 5,839               |
|                               | <b>\$ 6,160</b>  | <b>\$ 6,272</b>     |

The Company recognized approximately \$105,000 of revenue relating to its agreements with R-Tech for each of the three months ended March 31, 2011 and 2010, which was recorded as contract and collaboration revenue in the accompanying condensed consolidated statements of operations and comprehensive income (loss).

**SUCAMPO PHARMACEUTICALS, INC.**

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

**9. Notes Payable**

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

*Subordinated Unsecured Promissory Notes*

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

The notes provide for a semi-annual repayment schedule of interest and principal over a seven-year period on each June 1st and December 1st, provided that, until December 1, 2012, all accrued and unpaid interest will not be paid in cash and will instead be added to the principal balance of the notes, and Ambrent will make only two scheduled principal payments on December 1, 2011 and December 1, 2012. For the three months ended March 31, 2011, approximately \$570,000 of interest expense was added to the principal balance of the notes as paid-in-kind.

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

Notes payable consist of the following as of March 31, 2011 and December 30, 2010:

| <b>(In thousands)</b>                                 | <b>March 31,<br/>2011</b> | <b>December 31,<br/>2010</b> |
|---|---------------------------|------------------------------|
| Loan agreement, The Bank of Tokyo-Mitsubishi UFJ, Ltd | \$ 12,022                 | \$ 12,022                    |
| Promissory notes, Sellers of SAG                      | 52,509                    | 51,939                       |
|   | <u>\$ 64,531</u>          | <u>\$ 63,961</u>             |
| Notes payable, current                                | \$ 19,522                 | \$ 19,522                    |
| Notes payable, non-current                            | 45,009                    | 44,439                       |
|   | <u>\$ 64,531</u>          | <u>\$ 63,961</u>             |



SUCAMPO PHARMACEUTICALS, INC.

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

The aggregated scheduled maturities of notes payable were as follows as of March 31, 2011:

| (In thousands)     | March 31,<br>2011 |
|--------------------|-------------------|
| Due in one year    | \$ 19,522         |
| Due in two years   | 7,500             |
| Due in three years | 7,728             |
| Due in four years  | 8,025             |
| Due in five years  | 8,337             |
| Thereafter         | 13,419            |
|                    | <u>\$ 64,531</u>  |

10. Collaboration and License Agreements

*Abbott Agreement*

In February 2009, the Company entered into the Abbott Agreement, an exclusive 19-year license, commercialization and supply agreement with Abbott to develop and commercialize lubiprostone for the treatment of CIC in Japan. 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 Abbott Agreement include a non-refundable upfront payment and non-refundable development and commercial milestone payments based on achieving specified development, regulatory and sales goals.

The Company has received a total of \$22.5 million in up-front and development milestone payments through March 31, 2011 under the Abbott Agreement. Subject to future development and commercial milestones, the Company will receive additional development milestone and commercial milestone payments under the Abbott Agreement, 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 Abbott Agreement for the three months ended March 31, 2011:

| (In thousands)   | Amount<br>Deferred at<br>December 31,<br>2010 | Cash Received<br>for the Three<br>Months Ended<br>March 31,<br>2011 | Revenue<br>Recognized for<br>the Three<br>Months Ended<br>March 31,<br>2011 | Foreign Currency<br>Effects for the<br>Three Months<br>Ended March 31,<br>2011 | Amount<br>Deferred at<br>March 31,<br>2011 |
|--|---|---|---|--|--|
| <i>Collaboration revenue:</i>  |   |   |   |  |  |
| Up-front payment associated with the Company's obligation to participate in joint committees | \$ 868  | \$ -  | \$ 13   | \$ (11)  | \$ 844                                     |
| <i>Research and development revenue:</i>   |   |   |   |  |  |
| Up-front payment   | \$ 707  | \$ -  | \$ 220  | \$ (8)   | \$ 479                                     |
| Development milestone payment  | \$ 948  | -   | 296   | (10)   | 642  |
| Total  | <u>\$ 1,655</u>                               | <u>\$ -</u>   | <u>\$ 516</u>   | <u>\$ (18)</u>   | <u>\$ 1,121</u>                            |

*Takeda commercialization and license agreement*

In October 2004, the Company entered into the Takeda Agreement, 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 the Supplemental Takeda Agreement, which supplemented 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 the Takeda Agreements, include a non-refundable up-front payment, non-refundable development and commercial milestone payments, reimbursement of certain development and co-promotion costs and product royalties.

SUCAMPO PHARMACEUTICALS, INC.

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

The Company has received a total of \$150.0 million in up-front and development milestone payments through March 31, 2011 under the Takeda Agreement. Subject to future development and commercial milestones, the Company will receive additional development milestone and commercial milestone payments under the Takeda Agreement, although there can be no assurance that the Company will receive any such payments.

On March 12, 2010, the Company submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Takeda Agreement, which specifies that New York law will govern the procedural and substantive aspects of the arbitration. The Company believes that Takeda's failure to generate an appropriate level of U.S. sales of AMITIZA is the result of its material breach of the Takeda Agreement, including, without limitation, its continuing failure to exercise its best efforts to promote, market and sell AMITIZA and to maximize its net sales revenue, and its ongoing refusal to collaborate and provide the Company with information to which the Company is entitled under the Takeda Agreement. The Company also claims 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 sent Takeda another notice of material breach in December 2010, which specifically set forth all of the claims asserted in the arbitration submission. The Company is seeking all appropriate relief, including production by Takeda of all information to which the Company is entitled, a declaration of termination of applicable agreements, and all available monetary relief, equitable relief, attorneys' fees and costs. All the arbitrators have been confirmed and the arbitration proceedings have commenced. The arbitrators have reset the hearing on the Company's claims to conclude by mid-December 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. The Company has spent and expects to spend significant resources in the dispute with Takeda, and these arbitration proceedings may require the continuing attention of the Company's senior management.

The following table summarizes the cash streams and related revenue recognized or deferred under the Takeda Agreements for the three months ended March 31, 2011:

| (In thousands)   | Amount<br>Deferred at<br>December 31,<br>2010 | Cash Received<br>for the Three<br>Months Ended<br>March 31,<br>2011 | Revenue<br>Recognized for<br>the Three<br>Months Ended<br>March 31,<br>2011 | Change in Accounts<br>Receivable for the<br>Three Months<br>Ended March 31,<br>2011* | Amount<br>Deferred at<br>March 31,<br>2011 |
|--|---|---|---|--|--|
| <i>Collaboration revenue:</i>  |   |   |   |  |  |
| Up-front payment associated with the Company's obligation to participate in joint committees | \$ 1,470                                      | \$ -  | \$ 37   | \$ -   | \$ 1,433                                   |
| <i>Research and development revenue:</i>   |   |   |   |  |  |
| Reimbursement of research and development expenses   | \$ 3,042                                      | \$ -  | \$ 1,448  | \$ 1,483   | \$ 3,077                                   |
| Product royalty revenue  | \$ -  | \$ 10,516   | \$ 9,118  | \$ (1,398)   | \$ -                                       |
| Co-promotion revenue   | \$ -  | \$ 1,037  | \$ 938  | \$ (99)  | \$ -                                       |

\* Includes billed and unbilled accounts receivable.

11. Stock Option Plans

The following table summarizes the employee stock option activity for the three months ended March 31, 2011 under the Company's 2001 Incentive Plan:

**SUCAMPO PHARMACEUTICALS, INC.**

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

|  | <u>Shares</u> | <u>Weighted Average<br/>Exercise Price Per<br/>Share</u> | <u>Weighted Average<br/>Remaining<br/>Contractual Term<br/>(Years)</u> | <u>Aggregate<br/>Intrinsic Value</u> |
|--|---------------|--|--|--------------------------------------|
| Options outstanding, December 31, 2010 | 345,100       | \$ 10.44   |  |                                      |
| Options outstanding, March 31, 2011    | 345,100       | 10.44  | 2.87   | \$ -                                 |
| Options exercisable, March 31, 2011    | 345,100       | 10.44  | 2.87   | \$ -                                 |

The following table summarizes the employee stock option activity for the three months ended March 31, 2011 under the Company's Amended and Restated 2006 Stock Incentive Plan or 2006 Incentive Plan:

|  | <u>Shares</u> | <u>Weighted Average<br/>Exercise Price Per<br/>Share</u> | <u>Weighted Average<br/>Remaining<br/>Contractual Term<br/>(Years)</u> | <u>Aggregate<br/>Intrinsic Value</u> |
|--|---------------|--|--|--------------------------------------|
| Options outstanding, December 31, 2010 | 1,201,650     | \$ 5.69  |  |                                      |
| Options forfeited                      | (13,650)      | 3.85   |  |                                      |
| Options expired                        | (5,050)       | 3.86   |  |                                      |
| Options outstanding, March 31, 2011    | 1,182,950     | 5.72   | 8.34   | \$ -                                 |
| Options exercisable, March 31, 2011    | 616,317       | 6.84   | 7.83   | \$ -                                 |

No options were granted during the three months ended March 31, 2011. The weighted average grant date fair value of options granted during the year ended December 31, 2010 was \$2.05. As of March 31, 2011, approximately \$1.1 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested awards are expected to be recognized over a weighted average period of 3.0 years.

The Company granted 510,000 stock options with an exercise price of \$5.85 per share to non-employees in August 2005 under the Company's 2001 Incentive Plan. As of March 31, 2011 and December 31, 2010, 450,000 of these options were outstanding and exercisable. These non-employee stock options vested immediately and have a weighted average exercise price per share of \$5.85 and \$5.85, respectively, and remaining contractual life of 4.09 and 5.33 years, respectively, as of March 31, 2011 and December 31, 2010.

**Employee Stock Purchase Plan**

Under the Company's 2006 Employee Stock Purchase Plan, or ESPP, a total of 765 and 1,329 shares of class A common stock were purchased during the three months ended March 31, 2011 and 2010, 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, as amended, and in accordance with GAAP guidance that requires estimates in the fair value of share-based payment awards on the date of the grant using an option-pricing model and recognizing the expense over the required service periods in the accompanying condensed consolidated statement of operations and comprehensive income (loss). The Company received \$3,052 and \$4,507 upon purchase of shares under the ESPP for the three months ended March 31, 2011 and 2010, respectively.

**12. Income Taxes**

For the three months ended March 31, 2011 and 2010, the Company recorded a tax benefit of \$2.9 million and a tax provision of \$409,000, respectively. The tax benefit for the three months ended March 31, 2011 primarily pertained to the taxable loss generated by the Company's U.S. subsidiary for which a tax benefit is being recognized, offset by the tax provision by its Swiss subsidiary. The tax provision for the three months ended March 31, 2010 primarily pertained to taxable income generated by the Company's U.S. and Swiss subsidiaries. The Company's other subsidiaries based in Europe and Japan incurred pre-tax losses for the three months ended March 31, 2011 and 2010, for which no tax benefit was recognized.

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

The Company has estimated its annual effective tax rate for the full fiscal year 2011 and 2010 and applied that rate to its income before income taxes in determining its income tax provision for the interim periods. There is no tax benefit recognized on the net operating losses incurred in the foreign jurisdictions due to the lack of evidence supporting the Company's ability to use these losses in the future.

*Uncertain Tax Positions*

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

The Company had an outstanding non-current income tax liability of approximately \$1.4 million, including interest, for uncertain tax positions as of March 31, 2011. The amount represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in the Company's condensed consolidated financial statements, and is reflected in other liabilities in the accompanying condensed consolidated balance sheets. The liability for uncertain tax positions as of March 31, 2011 mainly pertained to the Company's interpretation of nexus in certain states related to revenue sourcing for state income tax purposes, as well as uncertain tax positions related to related party interest in foreign jurisdictions.

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

**13. Segment Reporting**

The Company has determined that it has three reportable segments based on the Company's method of internal reporting, which disaggregates business by geographic location. These segments are the Americas, Europe and Asia. The Company evaluates the performance of these segments based on income (loss) from operations, as well as other factors, including the progress of its research and development activities. The reportable segments have historically derived their revenue from joint collaboration and strategic alliance agreements. Transactions between the segments consist primarily of loans and the provision of research and development services. Following is a summary of financial information by reportable geographic segment for the three months ended March 31, 2011 and 2010.

**SUCAMPO PHARMACEUTICALS, INC.**

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

| <b>(In thousands)</b>  | <b>Americas</b>   | <b>Europe</b>     | <b>Asia</b>       | <b>Consolidated</b> |
|--|-------------------|-------------------|-------------------|---------------------|
| <b>Three Months Ended March 31, 2011</b>                       |                   |                   |                   |                     |
| Research and development revenue                               | \$ 1,448          | \$ -              | \$ 516            | \$ 1,964            |
| Product royalty revenue  | 9,118             | -                 | -                 | 9,118               |
| Co-promotion revenue   | 938               | -                 | -                 | 938                 |
| Contract and collaboration revenue                             | 141               | -                 | 13                | 154                 |
| Total revenues   | <u>11,645</u>     | <u>-</u>          | <u>529</u>        | <u>12,174</u>       |
| Research and development expenses                              | 7,326             | 527               | 1,367             | 9,220               |
| Depreciation and amortization                                  | 227               | 5                 | 17                | 249                 |
| Other operating expenses                                       | 11,275            | 304               | 287               | 11,866              |
| Loss from operations   | <u>(7,183)</u>    | <u>(836)</u>      | <u>(1,142)</u>    | <u>(9,161)</u>      |
| Interest income  | 69                | 1                 | -                 | 70                  |
| Interest expense   | -                 | (570)             | (41)              | (611)               |
| Other non-operating income (expense), net                      | (4)               | (199)             | 68                | (135)               |
| Loss before income taxes                                       | <u>\$ (7,118)</u> | <u>\$ (1,604)</u> | <u>\$ (1,115)</u> | <u>\$ (9,837)</u>   |
| Capital expenditures   | <u>\$ 42</u>      | <u>\$ 6,000</u>   | <u>\$ 91</u>      | <u>\$ 6,133</u>     |
| <b>Three Months Ended March 31, 2010</b>                       |                   |                   |                   |                     |
| Research and development revenue                               | \$ 1,304          | \$ -              | \$ 2,753          | \$ 4,057            |
| Product royalty revenue  | 9,773             | -                 | -                 | 9,773               |
| Co-promotion revenue   | 855               | -                 | -                 | 855                 |
| Contract and collaboration revenue                             | 141               | -                 | 10                | 151                 |
| Total revenues   | <u>12,073</u>     | <u>-</u>          | <u>2,763</u>      | <u>14,836</u>       |
| Research and development expenses                              | 2,140             | 176               | 3,050             | 5,366               |
| Depreciation and amortization                                  | 218               | 3                 | 9                 | 230                 |
| Other operating expenses                                       | 7,268             | 310               | 273               | 7,851               |
| Income (loss) from operations                                  | <u>2,447</u>      | <u>(489)</u>      | <u>(569)</u>      | <u>1,389</u>        |
| Interest income  | 210               | 1                 | 2                 | 213                 |
| Other non-operating income (expense), net                      | (35)              | 628               | 14                | 607                 |
| Income (loss) before income taxes                              | <u>\$ 2,622</u>   | <u>\$ 140</u>     | <u>\$ (553)</u>   | <u>\$ 2,209</u>     |
| Capital expenditures   | <u>\$ 91</u>      | <u>\$ -</u>       | <u>\$ 4</u>       | <u>\$ 95</u>        |
| <b>As of March 31, 2011</b>                                    |                   |                   |                   |                     |
| Property and equipment, net                                    | \$ 1,649          | \$ 21             | \$ 323            | \$ 1,993            |
| Identifiable assets, net of intercompany loans and investments | <u>\$ 100,298</u> | <u>\$ 33,579</u>  | <u>\$ 14,826</u>  | <u>\$ 148,703</u>   |
| <b>As of December 31, 2010</b>                                 |                   |                   |                   |                     |
| Property and equipment, net                                    | \$ 1,750          | \$ 24             | \$ 251            | \$ 2,025            |
| Identifiable assets, net of intercompany loans and investments | <u>\$ 102,096</u> | <u>\$ 30,789</u>  | <u>\$ 16,388</u>  | <u>\$ 149,273</u>   |

**14. Supplemental Information**

The following is additional information for three months ended March 31, 2010 on SAG and the Company prior to the December 2010 SAG acquisition which results are now incorporated in the Company's results.

SUCAMPO PHARMACEUTICALS, INC.

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

|   | Three Months Ended March 31, |           | Consolidating Information |                            |
|---|------------------------------|-----------|---------------------------|----------------------------|
|   | 2011                         | 2010      | 2010                      | 2010                       |
|   | Consolidated Including SAG   |           | SAG                       | Consolidated Excluding SAG |
| <b>Income Statement</b>                               |                              |           |                           |                            |
| Revenues  | \$ 12,174                    | \$ 14,836 | \$ -                      | \$ 14,836                  |
| Operating expenses                                    | (21,335)                     | (13,447)  | 1,602                     | (15,049)                   |
| Non-operating income (expense)                        | (676)                        | 820       | 701                       | 119                        |
| Income (loss) before income taxes                     | (9,837)                      | 2,209     | 2,303                     | (94)                       |
| Income tax benefit (provision)                        | 2,928                        | (409)     | (204)                     | (205)                      |
| Net income (loss)                                     | (6,909)                      | 1,800     | 2,099                     | (299)                      |
| <b>Cash Flows</b>                                     |                              |           |                           |                            |
| Operating activities                                  | (6,047)                      | (179)     | 676                       | (855)                      |
| Investing activities                                  | 4,660                        | (9,453)   | 2                         | (9,455)                    |
| Financing activities                                  | 3                            | (712)     | (716)                     | 4                          |
| Effect of exchange rates on cash and cash equivalents | 499                          | (792)     | (819)                     | 27                         |
| Net decrease in cash and cash equivalents             | (885)                        | (11,136)  | (857)                     | (10,279)                   |
| Cash and cash equivalents at beginning of period      | 49,243                       | 61,420    | 34,706                    | 26,714                     |
| Cash and cash equivalents at end of period            | 48,358                       | 50,284    | 33,849                    | 16,435                     |

15. Subsequent Events

On May 2, 2011 the Company granted in the aggregate options to purchase 2,084,550 shares of its Class A common stock, consisting of 700,388 shares of time-based options and 1,384,162 shares of performance stock options to its independent directors and all eligible employees. The time-based stock options (a) vest in equal annual installments over the four-year period commencing on the first anniversary of the date of grant (i.e., the first 1/4 of the stock option grant would vest on the first anniversary of the date of grant) so long as the individual is in continuous service with the Company on each such date (subject to certain exceptions), (b) have an exercise price equal to the closing price of the Company's common stock on the Nasdaq Global Market on the date of grant, and (c) have a term of 10 years from such date. The performance-based options (a) vest in certain percentages based on the attainment of specific stock price targets over a 30 day trading period so long as the individual is in continuous service with the Company on each such date (subject to certain exceptions), (b) have an exercise price equal to the closing price of the Company's common stock on the Nasdaq Global Market on the date of grant, and (c) must vest within a term of 4 years from such date but otherwise have a term of 10 years from the date of grant. The percentages and target prices are: 40.0% at \$8.00 per share, 40.0% at \$12.00 per share, and 20.0% at \$16.00 per share. All options were issued with an exercise price equal to the fair market value of the stock price, or \$4.41 per share of common stock, on the date of the grant.

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

*This Quarterly Report on Form 10-Q contains forward-looking statements regarding Sucampo Pharmaceuticals, Inc. (the "Company," "we," "us," or "our") and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Quarterly Report Form 10-Q and in our other Securities and Exchange Commission, or SEC, filings, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2009, which we filed with the SEC on March 8, 2011. You should also read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements as of and for the year ended December 31, 2010 included in our Annual Report on Form 10-K.*

### Overview

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

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

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

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

In the United States, AMITIZA is being marketed and developed under a collaboration and license agreement, dated October 29, 2004, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda, for gastrointestinal indications. Takeda holds the same rights to AMITIZA in Canada, but it has not yet marketed AMITIZA there. Under the Takeda Agreement, Takeda is responsible for the commercialization of AMITIZA in the U.S. and Canada. Takeda currently sells AMITIZA mainly to U.S. office-based specialty and primary care physicians and reimburses us a part of our co-promotion expenses. Under a supplemental agreement with Takeda entered into on February 1, 2006, or the Supplemental Takeda Agreement, we currently co-promote AMITIZA in the U.S. through a specialty sales force which focuses on the institutional marketplace, including 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.

On March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Takeda Agreement, which specifies that New York law will govern the procedural and substantive aspects of the arbitration. We believe that Takeda's failure to generate an appropriate level of U.S. sales of AMITIZA is the result of its material breach of the Takeda Agreement, including, without limitation, its continuing failure to exercise its best efforts to promote, market and sell AMITIZA and to maximize its net sales revenue, and its ongoing refusal to collaborate and provide us with information to which we are entitled under the Takeda Agreement. We also claim 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 sent Takeda another notice of material breach in December 2010, which specifically set forth all of the claims asserted in the arbitration submission. 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. All the arbitrators have been confirmed and the arbitration proceedings have commenced. The arbitrators have reset the hearing on our claims to conclude by mid-December 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. We have spent and expect to spend significant resources in the dispute with Takeda, and these arbitration proceedings may require the continuing attention of our senior management.

In Japan, lubiprostone is developed under a license, commercialization and supply agreement, or the Abbott Agreement, with Abbott Japan Co. Ltd., or Abbott. We hold all other development and commercialization rights to lubiprostone in all other territories worldwide, including in Switzerland, where lubiprostone has received marketing approval from the Swiss authorities.

In Japan, lubiprostone is developed under a license, commercialization and supply agreement, or the Abbott Agreement, with Abbott Japan Co. Ltd., or Abbott. We hold all other development and commercialization rights to lubiprostone in all other territories worldwide, including in Switzerland, where lubiprostone has received marketing approval from the Swiss authorities.

In April 2009, we acquired the rights to unoprostone isopropyl, which allow us to commercialize the product, RESCULA, in the U.S. and Canada for its approved indication and unoprostone isopropyl for any indications developed by us or R-Tech. On March 22, 2011, Sucampo Manufacturing & Research AG, or SMR, a wholly-owned subsidiary, entered into a license agreement, a copy of which is filed as an exhibit to this Quarterly Report on Form 10-Q, with R-Tech for unoprostone isopropyl, expanding the rights of the Company's subsidiaries beyond their previously agreed territory of the United States and Canada (those rights are held by Sucampo Pharma Americas, Inc.) to all countries in Europe and the rest of the world except Japan, Korea, Taiwan and the People's Republic of China, or the SMR Territories. We are evaluating the opportunities to obtain an appropriate label in the European Union and other European countries as well as obtaining reauthorization in those countries to commercialize unoprostone isopropyl.

Our operations are conducted through subsidiaries based in Japan, the United States, Switzerland the United Kingdom and Luxembourg. 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.

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

## **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 chronic non-cancer pain, a constipation-related gastrointestinal indication. In July 2009, we reported top-line results for the two identically-designed efficacy studies, one of which met the primary endpoint by demonstrating a statistically significant change from baseline in the frequency of spontaneous bowel movements at week 8 of treatment when compared to placebo. Based on a subsequent meeting with the FDA, we decided to conduct one additional phase 3 efficacy study in order to submit a supplemental new drug application, or sNDA, for the OBD indication. This third phase 3 study of lubiprostone to evaluate its effectiveness as a treatment of OBD was initiated in December 2010, and enrollment is expected to be completed during the third quarter of 2011. If successful, the data from the trials will enable a filing of a sNDA with the FDA and the regulatory authorities in Europe.

### AMITIZA (lubiprostone) in Japan

To date, we have received a total of \$22.5 million in payments from Abbott, consisting of an upfront payment and clinical and regulatory milestone payment. We could receive additional milestone payments based on achieving other specified development and commercialization goals. We have retained the right to co-promote lubiprostone in Japan as well as its development and commercialization rights to all other therapeutic areas subject to Abbott's right of first refusal.



In September 2010, we submitted a marketing authorization application to the Japanese Pharmaceuticals and Medical Devices Agency for lubiprostone at a dosage strength of 24 micrograms for the indication of CIC. The submission includes the results of a pivotal phase 3 efficacy trial of lubiprostone in Japanese CIC patients, which met its primary endpoint with statistical significance ( $p < 0.001$ ) and demonstrated a safety profile consistent with previously reported clinical lubiprostone data. The primary endpoint of this trial was a change in the number of SBMs at the end of the first week of treatment. This pivotal, double-blinded, placebo-controlled trial evaluated 124 Japanese CIC patients each of whom received one lubiprostone 24-mcg, or placebo, capsule twice daily for 28 days. These top-line pivotal phase 3 efficacy results were reported in June 2010. The September 2010 submission was updated in December 2010 with the complete results of the phase 3 long-term, open-label multicenter safety trial in 209 Japanese CIC patients. Top-line results from that safety trial, which were reported by us in November 2010, demonstrated that lubiprostone was safe and well-tolerated. If AMITIZA is approved for sale in Japan, it will be the first new drug indicated for constipation in Japan in more than ten years. Currently, constipation patients in Japan are treated with laxatives, which generate annual sales of approximately \$326.0 million. Magnesium oxide is a leading laxative treatment for constipation in Japan and, in 2009, generated annual sales of approximately \$129.0 million. The constipation market grew by approximately 6.0% from 2008 to 2009. Future market growth is expected to continue and is fueled by an increasingly older population and changes in eating and lifestyle habits.

On December 22, 2010, Sucampo Pharma, Ltd. provided Abbott notice to initiate Abbott's 120-day negotiation rights to exercise its right of first refusal to the OBD indication for Japan, which indication in Japan will include patients with cancer treated chronically with opiates other than methadone, but may not include other OBD patients. The 120-day negotiation period expired without an agreement with Abbott on the terms and conditions for a license for the OBD indication. Sucampo Pharma, Ltd. will now negotiate with third parties, and Abbott will have 45 days to meet the terms and conditions of any third party bona fide offer.

#### AMITIZA (lubiprostone) in other countries

We 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. To file a marketing application authorization, or MAA, in Europe, an approved Pediatric Investigation Plan, or PIP, for lubiprostone in CIC, is required. We have received notice of a positive opinion from the Pediatric Committee of the European Medicines Agency, or EMA, of our PIP. As a result, we intend to file an MAA later this year.

In November 2009, we announced that Swissmedic, the Swiss Agency for Therapeutic Products, has granted Sucampo Pharma Europe, Ltd. a marketing authorization for lubiprostone for the long-term treatment of adult patients with CIC. This is the first European regulatory approval and is the first prescription medicine to be approved in Switzerland for the long-term treatment of CIC. We are currently pursuing approval of a pricing and reimbursement with the Swiss authorities and expect a decision in mid 2011. In the event of a favorable pricing decision from the Swiss authorities, Sucampo Pharma Europe, Ltd. intends to launch AMITIZA.

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

#### RESCULA (unoprostone isopropyl)

Under our 2009 and 2011 agreements with R-Tech, we hold the exclusive rights to commercialize and develop RESCULA worldwide except for Japan, Korea, Taiwan and the People's Republic of China for its approved indication and any new indication. 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 are evaluating the requirements to reactivate RESCULA's licenses in the European countries in which it has been registered, but those registrations have lapsed. In addition, we may develop RESCULA as a treatment for an array of ophthalmic diseases including dry age-related macular degeneration, or dry AMD, and diabetic retinopathy. We have initiated a phase 2a proof of concept study for the ophthalmic indication of dry AMD in the second quarter of 2011.

### **Product Pipeline**

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

| <b>Product/Product Candidate</b>         | <b>Target Indication</b>   | <b>Development Phase</b>   | <b>Next Milestone</b>   |
|--|--|--|---|
| <b>AMITIZA</b> ® (lubiprostone)          | Chronic idiopathic constipation (CIC) (adults of all ages)   | Marketed in the U.S.   | —   |
|  |  | Approved in Switzerland  | Pricing negotiations with Swiss government health agency              |
|  |  | Phase 3 efficacy and safety trials in Japanese patients results reported                             | Approval of marketing authorization in Japan                          |
|  | Irritable bowel syndrome with constipation (adult women) (IBS-C)   | Marketed in the U.S.   | —   |
|  | Chronic idiopathic constipation (CIC) (pediatric, patients with renal impairment and patients with hepatic impairment) | Phase 4 pediatric, renal impairment and hepatic impairment trials completed and submitted to the FDA | —   |
|  | Opioid-induced bowel dysfunction (OBD) in patients with chronic non-cancer pain  | Two phase 3 efficacy trials results reported   | Phase 3 safety trial and the third efficacy trial to complete in 2011 |
|  | Opioid-induced bowel dysfunction (OBD) in cancer patients  | Phase 2/3 clinical trial design underway   | Initiation of phase 2/3 clinical trial                                |
| <b>RESCULA</b> ® (unoprostone isopropyl) | Dry age-related macular degeneration (dry AMD)   | Phase 2a proof-of-concept study  | Phase 2a study completion   |
|  | Glaucoma and ocular hypertension   | Approved in the U.S.   | Limited commercialization   |
| <b>Cobiprostone</b>                      | <i>Gastrointestinal</i><br>Oral mucositis  | Preclinical  | Phase 1 trial   |
|  | Prevention of non-steroidal anti-inflammatory drug (NSAID)-induced ulcers  | Phase 2a trial results reported  | —   |
|  | <i>Pulmonary</i><br>Chronic obstructive pulmonary disease (COPD)   | Preclinical  | Finalize inhaled formulation  |
| <b>SPI-3608</b>                          | Spinal stenosis  | Preclinical  | Phase 1 trial   |

## Results of Operations

### Comparison of three months ended March 31, 2011 and March 31, 2010

#### Revenues

The following table summarizes our revenues for the three months ended March 31, 2011 and 2010:

| (In thousands)                     | Three Months Ended<br>March 31, |                  |
|------------------------------------|---------------------------------|------------------|
|                                    | 2011                            | 2010             |
| Research and development revenue   | \$ 1,964                        | \$ 4,057         |
| Product royalty revenue            | 9,118                           | 9,773            |
| Co-promotion revenue               | 938                             | 855              |
| Contract and collaboration revenue | 154                             | 151              |
| <b>Total</b>                       | <b>\$ 12,174</b>                | <b>\$ 14,836</b> |

Total revenues were \$12.2 million for the three months ended March 31, 2011 compared to \$14.8 million for the three months ended March 31, 2010, a decrease of \$2.6 million or 17.9%.

Research and development revenue was \$2.0 million for the three months ended March 31, 2011 compared to \$4.1 million for the three months ended March 31, 2010, a decrease of \$2.1 million or 51.6%. The decrease was primarily due to lower activity of our Japanese development program for lubiprostone under our agreement with Abbott. The revenue recognized under the agreement with Abbott decreased to \$516,000 for the three months ended March 31, 2011 from \$2.8 million for the three months ended March 31, 2010. We are recognizing the revenue from the payments from Abbott using a percentage-of-completion model over the estimated term of the CIC development program. The revenue recognized under the Takeda Agreement increased to \$1.4 million for the three months ended March 31, 2011 from \$1.3 million for the three months ended March 31, 2010.

Product royalty revenue represents royalty revenue earned on net sales of AMITIZA in the United States. For the three months ended March 31, 2011 and 2010, we recognized \$9.1 million and \$9.8 million, respectively, of product royalty revenue, a decrease of \$655,000 or 6.7%, reflecting a continued increase in Medicare & Medicaid rebates combined with a reduction in gross sales as reported by Takeda.

Co-promotion revenues represent reimbursement by Takeda of co-promotion costs for our specialty sales force. For each of the three months ended March 31, 2011 and 2010, we recognized \$938,000 and \$855,000, respectively, of co-promotion revenues for reimbursement of sales force costs.

### Research and Development Expenses

The following summarizes our research and development expenses for the three months ended March 31, 2011 and 2010:

| (In thousands)        | Three Months Ended<br>March 31, |                 |
|-----------------------|---------------------------------|-----------------|
|                       | 2011                            | 2010            |
| <b>Direct costs:</b>  |                                 |                 |
| AMITIZA               | \$ 6,980                        | \$ 3,774        |
| Cobiprostone          | 176                             | 145             |
| SPI-017               | 80                              | 810             |
| RESCULA               | 683                             | 117             |
| Other                 | 819                             | 61              |
| <b>Total</b>          | <b>8,738</b>                    | <b>4,907</b>    |
| <b>Indirect costs</b> | <b>482</b>                      | <b>459</b>      |
| <b>Total</b>          | <b>\$ 9,220</b>                 | <b>\$ 5,366</b> |

Total research and development expenses for the three months ended March 31, 2011 were \$9.2 million compared to \$5.4 million for the three months ended March 31, 2010, an increase of \$3.9 million or 71.8%. The increase was primarily due to expenses associated with initiating the additional phase 3 trial of lubiprostone for OBD patients.

### General and Administrative Expenses

The following summarizes our general and administrative expenses for the three months ended March 31, 2011 and 2010:

| (In thousands)                                    | Three Months Ended<br>March 31, |                 |
|---|---------------------------------|-----------------|
|   | 2011                            | 2010            |
| Salaries, benefits and related costs              | \$ 1,761                        | \$ 1,387        |
| Legal, consulting and other professional expenses | 6,604                           | 3,379           |
| Stock-based compensation                          | 124                             | 97              |
| Other expenses                                    | 1,208                           | 1,031           |
| Total   | <u>\$ 9,697</u>                 | <u>\$ 5,894</u> |

General and administrative expenses were \$9.7 million for the three months ended March 31, 2011, compared to \$5.9 million for the three months ended March 31, 2010, an increase of \$3.8 million or 64.5%. The increase in legal, consulting and other professional expenses relates primarily to costs incurred in connection with the on-going legal matters, including our dispute with Takeda and a CRO, as discussed in Item 1 of Part II of this Quarterly Report on Form 10-Q.

### Selling and Marketing Expenses

Selling and marketing expenses represent costs we incur to co-promote AMITIZA, including salaries, benefits and related costs of our sales force and other sales and marketing personnel, and represent costs of market research and analysis and other selling and marketing expenses. Selling and marketing expenses were \$2.4 million for the three months ended March 31, 2011, compared to \$2.2 million for the three months ended March 31, 2010, an increase of \$231,000 or 10.6%. The increase in selling and marketing expenses relates primarily to some pre-commercialization activities for RESCULA. Part of the AMITIZA co-promotion expenses are funded by Takeda and recorded as co-promotion revenue.

### Non-Operating Income and Expense

The following table summarizes our non-operating income and expense for the three months ended March 31, 2011 and 2010:

| (In thousands)              | Three Months Ended<br>March 31, |               |
|-----------------------------|---------------------------------|---------------|
|                             | 2011                            | 2010          |
| Interest income             | \$ 70                           | \$ 213        |
| Interest expense            | (611)                           | -             |
| Other income (expense), net | (135)                           | 607           |
| Total                       | <u>\$ (676)</u>                 | <u>\$ 820</u> |

Interest income was \$70,000 for the three months ended March 31, 2011, compared to \$213,000 for the three months ended March 31, 2010, a decrease of \$143,000, or 67.1%. The decrease was primarily due to lower prevailing interest rates earned by our investments and a shift in the composition of our portfolio from auction rate securities, or ARS, which bear higher interest rates, to other types of investments. Our investment in ARS was redeemed in June 2010.

Interest expense was \$611,000 for the three months ended March 31, 2011, including \$570,000 on the notes payable issued for the December 2010 SAG acquisition and \$41,000 on the notes payable issued on Sucampo Pharma, Ltd.'s borrowings.

Other expense was \$135,000 for the three months ended March 31, 2011, compared to other income of \$607,000 for the three months ended March 31, 2010, a decrease of \$742,000, or 122.2%. The majority of the decrease belongs to foreign exchange losses that are unrealized and non-cash and that relate to amounts held within subsidiaries.

## Income Taxes

We recorded a tax benefit of \$2.9 million and a provision of \$409,000 for the three months ended March 31, 2011 and 2010, respectively. The tax benefit for the three months ended March 31, 2011 mainly pertained to the taxable loss generated by our U.S. subsidiary for which a tax benefit is being recognized. This benefit was partially offset by the tax expense recorded for the taxable income generated by our Swiss subsidiary. Our other subsidiaries, based in Europe and Japan, incurred a pre-tax loss for the three months ended March 31, 2011, for which no tax benefit was recognized. As of March 31, 2011, we had an outstanding non-current income tax liability of approximately \$1.4 million, including interest, for uncertain tax positions which represented the aggregate tax effect of differences between tax return positions and the amounts otherwise recognized in our condensed consolidated financial statements. The liability for uncertain tax positions as of March 31, 2011 was mainly a result of our interpretation of nexus in certain states related to revenue sourcing for state income tax purposes, as well as uncertain tax positions related to related party interest in foreign jurisdictions.

## Reportable Geographic Segments

We have determined that we have three reportable segments based on our method of internal reporting, which disaggregates business by geographic location. These segments are the Americas, Europe and Asia. We evaluate the performance of these segments based primarily on income (loss) from operations, as well as other factors, including the progress of research and development activities. The financial results in these three segments based on geographic locations for the three months ended March 31, 2011 are summarized in the table below.

The financial results of our segments reflect their varying stages of development. Our Americas segment recorded a loss before taxes of \$7.1 million for the three months ended March 31, 2011 compared to income before taxes of \$2.6 million for the three months ended March 31, 2010. These results primarily reflect the expenses associated with initiating the additional phase 3 trial of lubiprostone for OBD in chronic non-cancer pain patients, a reduction in royalty revenues receivable from Takeda and the increase expenses in legal matters, including our dispute with Takeda.

Our segment in Europe recorded a loss before taxes of \$1.6 million for the three months ended March 31, 2010 compared to income before taxes of \$140,000 for the three months ended March 31, 2010. These results primarily reflect the on-going regulatory submission for AMITIZA and the interest accruing on the loan notes issued for the December 2010 SAG acquisition.

Our segment in Asia recorded a loss before taxes of \$1.1 million for the three months ended March 31, 2011 compared to a loss before taxes of \$553,000 during the three months ended March 31, 2010. These results primarily reflect the reduction of revenue recognized during the three months ended March 31, 2011 from the payments received from Abbott in 2009 and 2010.

| (In thousands)                           | Americas   | Europe    | Asia      | Consolidated |
|--|------------|-----------|-----------|--------------|
| <b>Three Months Ended March 31, 2011</b> |            |           |           |              |
| Total revenues                           | \$ 11,645  | \$ -      | \$ 529    | \$ 12,174    |
| Income (loss) before taxes               | (7,118)    | (1,604)   | (1,115)   | (9,837)      |
| <b>Three Months Ended March 31, 2010</b> |            |           |           |              |
| Total revenues                           | \$ 12,073  | \$ -      | \$ 2,763  | \$ 14,836    |
| Income (loss) before taxes               | 2,622      | 140       | (553)     | 2,209        |
| <b>Identifiable assets</b>               |            |           |           |              |
| As of March 31, 2011                     | \$ 100,298 | \$ 33,579 | \$ 14,826 | \$ 148,703   |
| As of December 31, 2010                  | 102,096    | 30,789    | 16,388    | 149,273      |

## Liquidity and Capital Resources

### Sources of Liquidity

We require cash principally to meet our operating expenses. 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, restricted cash and investments consisted of the following as of March 31, 2011 and December 31, 2010:

| <b>(In thousands)</b>     | <b>March 31,<br/>2011</b> | <b>December 31,<br/>2010</b> |
|---------------------------|---------------------------|------------------------------|
| Cash and cash equivalents | \$ 48,358                 | \$ 49,243                    |
| Restricted cash           | 15,113                    | 15,113                       |
| Investments, current      | 48,481                    | 54,524                       |
| Investments, non-current  | 3,007                     | 5,028                        |
| <b>Total</b>              | <b>\$ 114,959</b>         | <b>\$ 123,908</b>            |

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

As of March 31, 2011 and December 31, 2010, our restricted cash primarily was the collateral to Sucampo Pharma, Ltd.'s loan with The Bank of Tokyo-Mitsubishi UFJ, Ltd.

As of March 31, 2011, our short-term investments consisted of U.S. Treasury bills and notes, U.S. government agencies securities, U.S. commercial paper, municipal and corporate bonds, mutual funds, variable rate demand notes and certificates of deposits that have short-term maturities of one year or less. Our non-current investments consisted of corporate bonds.

### **Cash Flows**

The following table summarizes our cash flows for the three months ended March 31, 2011 and 2010:

| <b>(In thousands)</b>                     | <b>Three Months Ended March 31,</b> |                    |
|---|-------------------------------------|--------------------|
|   | <b>2011</b>                         | <b>2010</b>        |
| Cash provided by (used in):               |                                     |                    |
| Operating activities                      | \$ (6,047)                          | \$ (179)           |
| Investing activities                      | 4,660                               | (9,453)            |
| Financing activities                      | 3                                   | (712)              |
| Effect of exchange rates                  | 499                                 | (792)              |
| Net decrease in cash and cash equivalents | <b>\$ (885)</b>                     | <b>\$ (11,136)</b> |

### **Three Months Ended March 31, 2011**

Net cash used in operating activities was \$6.0 million for the three months ended March 31, 2011. This reflected a net loss of \$6.9 as well as changes in other operating assets and liabilities.

Net cash provided by investing activities of \$4.7 million for the three months ended March 31, 2011 primarily reflected our proceeds from the sales and maturities of investments, offset in part by purchases of investments and intangible assets.

Net cash provided by financing activities of \$3,000 for the three months ended March 31, 2011 resulted from the proceeds we received under our employee stock purchase plan.

### **Three Months Ended March 31, 2010**

Net cash used in operating activities was \$179,000 for the three months ended March 31, 2010. This reflected a net income of \$1.8 million, a decrease in deferred revenue of \$3.5 million and a decrease in accounts payable of \$1.2 million, offset in part by an increase in product royalty receivable of \$1.3 million and changes in other operating assets and liabilities.

Net cash used in investing activities of \$9.5 million for the three months ended March 31, 2010 primarily reflected our purchase of investments and property and equipment, offset in part by proceeds from the sales and maturities of investments.

Net cash used in financing activities of \$712,000 for the three months ended March 31, 2010 resulted from the issuance of notes receivable, offset in part by the proceeds we received under our employee stock purchase plan.

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

As of March 31, 2011, we did not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4) of Regulation S-K under the Securities Act of 1933, as amended.

### ***Funding Requirements***

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

- our share of the ongoing development program of AMITIZA in the U.S.;
- development and regulatory efforts in Europe and Asia for lubiprostone;
- development and regulatory activities for RESCULA in the U.S., Canada and the rest of the world except Japan, Korea, Taiwan and The People's Republic of China;
- activities to resolve our ongoing legal matters;
- research and development activities for other prostone compounds, including cobiprostone and SPI-017;
- other business development activities, including investments in or acquisitions of other businesses, products and technologies;
- the initiation of commercialization efforts in non-U.S. markets;
- the expansion of our commercialization activities in the U.S. and the initiation of commercialization efforts in non-U.S. markets;
- 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; and
- the satisfaction of the conditions of our loan note obligations.

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

- the revenue from AMITIZA and RESCULA;
- the future expenditures we may incur to increase revenue from AMITIZA or in our dispute 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 March 31, 2011, we have sufficient liquidity for 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 through the use of derivative instruments.

## ***Recent Accounting Pronouncements***

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

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

### ***Foreign Exchange Risk***

We are subject to foreign exchange risk for revenues and expenses denominated in foreign currencies. Foreign currency risk arises from the fluctuation of foreign exchange rates and the degree of volatility of these rates relative to the United States dollar. We do not believe that a hypothetical one percentage point fluctuation in the U.S. dollar exchange rate would materially affect the fair value of our foreign currency sensitive assets and investments as of March 31, 2011. We do not currently hedge our foreign currency transactions.

### ***Interest Rate Risk***

We are subject to interest rate risks associated with fluctuations in interest rates. Our interest income is more sensitive to fluctuations in the interest rates in the U.S. than to changes in interest rates in other markets. Our interest expense is more sensitive to fluctuations in LIBOR and TIBOR than to changes in other interest rates. We ensure the safety and preservation of invested funds by attempting to limit default risk, market risk and reinvestment risk. We attempt to mitigate default risk by investing in investment grade securities. A hypothetical one percentage point decline in interest rates would not have materially affected the fair value of our interest-sensitive financial instruments as of March 31, 2011.

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

### ***Credit Risk***

Our exposure to credit risk consists of cash and cash equivalents, restricted cash, investments and receivables. We place our cash, cash equivalents and restricted cash with what we believe to be highly rated financial institutions and invest the excess cash in highly rated investments. As of March 31, 2011 and December 31, 2010, approximately 28.7% and 27.6%, respectively, of our cash, cash equivalents, restricted cash and investments is issued or insured by the federal government or government agencies. We have not experienced any losses on these accounts related to amounts in excess of insured limits.

## ***Item 4. Controls and Procedures***

### ***a) Evaluation of Disclosure Controls and Procedures***

Our management, under the supervision and with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of March 31, 2011. In designing and evaluating such controls, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based upon the evaluation we carried out, our Chief Executive Officer and Principal Financial and Accounting Officer have concluded that, as of March 31, 2011, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified under the applicable rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow timely decisions regarding required disclosures.



**b) Changes in Internal Controls**

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2011 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**

As previously reported in our Quarterly Reports on Forms 10-Q, on March 12, 2010, we submitted for filing with the International Court of Arbitration, International Chamber of Commerce a demand for arbitration under the applicable provisions of the Takeda Agreements between us and Takeda, which specify that New York law will govern the procedural and substantive aspects of the arbitration. We believe that Takeda's failure to generate an appropriate level of U.S. sales of AMITIZA is the result of its material breach of the Takeda Agreements, including, without limitation, its continuing failure to exercise its best efforts to promote, market and sell AMITIZA and to maximize its net sales revenue, and its ongoing refusal to collaborate and provide us with information to which we are entitled under the Takeda Agreements. We also claim 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 sent Takeda another notice of material breach in December 2010, which specifically set forth all of the claims asserted in the arbitration submission. 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. All the arbitrators have been confirmed, and the arbitration proceedings have commenced. The arbitrators have reset the hearing on our claims to conclude by mid-December 2011; it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude. We have spent and expect to spend significant resources in the dispute with Takeda, and these arbitration proceedings may require the continuing attention of our senior management.

On December 9, 2010, we filed an amended lawsuit under seal in Circuit Court for Montgomery County, Maryland against the CRO that performed the clinical trials for the OBD indication. We have alleged that the CRO materially breached its contract with us by failing to use its best efforts to perform the services and performed the clinical trials in a careless and grossly negligent manner. We are seeking damages for, among other things, the expenses relating to the additional clinical trial that we are conducting and all available monetary relief, attorneys' fees and costs. After filing the lawsuit, we have engaged in mediation to resolve our dispute. The mediation has not been successful, so we are pursuing our claims in the lawsuit. We have spent and expect to spend significant resources in the dispute with the CRO, and these court 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, 2010, filed by us with the SEC on March 8, 2011. There have not been any material changes from the risk factors as previously disclosed in our Form 10-K.

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

On December 11, 2008, we announced a stock repurchase program pursuant to which we are authorized to purchase up to \$10.0 million of our class A common stock from time to time in open market transactions. During the quarter ended March 31, 2011, we did not purchase any shares of our class A common stock under this program.

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

None.

### **Item 4. (Removed and Reserved).**

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

None.

**Item 6. Exhibits****(a) Exhibits**

| <b>Exhibit Number</b> | <b>Description</b>  | <b>Reference</b>   |
|-----------------------|---|--|
| 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  |
| 10.1                  | Separation Agreement and Release, dated January 12, 2011, between the Company and Jan Smilek  | Exhibit 99.1 to the Company's Current Report on Form 8-K (filed February 2, 2011)              |
| 10.2                  | Consulting Agreement, dated January 21, 2011, between the Company and Jan Smilek  | Exhibit 99.2 to the Company's Current Report on Form 8-K (filed February 2, 2011)              |
| 10.3                  | License Agreement, dated March 22, 2011, between Sucampo Manufacturing & Research AG and R-Tech Ueno, Ltd.  | Included herewith  |

**SIGNATURES**

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

Sucampo Pharmaceuticals, Inc.

May 10, 2011

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

May 10, 2011

By: /s/ ANDREW P. SMITH  
Andrew P. Smith  
Principal Accounting Officer

**Sucampo Pharmaceuticals, Inc.**  
**Exhibit Index**

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EXCLUSIVE LICENSE  
FOR DEVELOPMENT AND COMMERCIALIZATION  
OF UNOPROSTONE

This Agreement made this 22nd day of March, 2011 (the "Effective Date") by and between R-Tech Ueno, Ltd., a corporation duly incorporated and existing under the laws of Japan and having its registered office at NBF Hibiya Bldg., 10F, 1-1-7 Uchisaiwaicho, Chiyoda-ku, Tokyo 100-0011, Japan ("R-Tech"), and Sucampo Manufacturing & Research AG, a corporation duly incorporated and existing under the laws of Switzerland and having its registered office at Alte Wolleraustrasse 53, 8832 Wollerau, Switzerland ("SMR"). Each of R-Tech and SMR is referred to herein as a "Party" and collectively, as the "Parties."

WITNESSETH THAT:

WHEREAS, R-Tech is the owner of all rights and title to and interest in certain Intellectual Property Rights (as defined below in Article 1) and Technology (as defined below in Article 1) relating to Unoprostone (as defined below in Article 1) and the manufacturing of Unoprostone;

WHEREAS, SMR, a corporation duly organized under the laws of Switzerland and Sucampo Pharma Americas, Inc. ("SPA"), a corporation duly organized under the laws of the state of Delaware, United States, are wholly-owned subsidiaries of Sucampo Pharmaceuticals, Inc. ("SPI"), which is duly organized under the laws of the state of Delaware, United States;

WHEREAS, SMR wishes to obtain the exclusive license to develop and commercialize Unoprostone for the Indications (as defined below in Article 1) in the SMR Territory (as defined below in Article 1), and R-Tech is willing to do so;

WHEREAS, SPA and R-Tech intend to keep in force the Unoprostone NDA Transfer, Patent and Know-how Licensing, and Data Sharing Agreement dated April 23, 2009, Unoprostone Exclusive Manufacturing and Supply Agreement dated April 23, 2009, and Technology Assignment and License Agreement dated February 2009 except to the extent those agreements are required to be modified by this Agreement;

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WHEREAS, SMR does not have the ability to develop or re-engineer the Intellectual Property Rights and Technology for the manufacturing of Unoprostone and therefore lacks the capability to manufacture Unoprostone without a license from R-Tech; and

WHEREAS, R-Tech desires that any future manufacturing of Unoprostone in SMR Territory be performed by SMR or its designee.

NOW, THEREFORE, in consideration of the covenants and obligations expressed herein , and in consideration of the execution of the Unoprostone Toll Manufacturing Agreement (the "Unoprostone Toll Agreement") (Exhibit A) to be executed between the Parties in accordance with Section 6.1 of this Agreement, and intending to be legally bound, the Parties hereto agree as follows:

## 1. DEFINITIONS

The capitalized terms in this Agreement shall have the definitions given them within this Agreement. The following terms, as used herein, shall have the following meanings:

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

"Affiliate" means any person, corporation, firm, partnership, limited liability company or other entity that controls, is controlled by or is under common control with a Party to this Agreement, except that in no event at any time during the Term of this Agreement shall SMR be considered Affiliate of RTU nor RTU be considered an Affiliate of SMR for the purpose of this Agreement. For purposes of this definition, an entity will be regarded as in "control" of another corporation if

(a) it owns or directly or indirectly controls at least fifty percent (50%) of the voting stock of the other corporation or such lesser maximum percentage permitted in those jurisdictions where majority ownership by foreign entities is prohibited, (b) it owns or has a right to at least fifty percent (50%) of the net assets of an entity without voting securities, or (c) it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the entity, whether through contract or otherwise.

“Annual Net Sales” means the cumulative Net Sales during any given calendar year.

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

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

“Clinical Studies” means a human clinical study, or other test or study in humans, with respect to a Unoprostone or a Licensed Product performed incident to an open IND, including, but not limited to Phase I Study, Phase II Study, Phase III Study, Phase IV Study, early access programs, compassionate use and single patient INDs, epidemiological studies, modeling and pharmacoeconomic studies, post-marketing studies, investigator sponsored studies, and health economics studies. “Phase I Study” means a human clinical trial of a product, the principal purpose of which is a preliminary determination of safety or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, from



time to time, pursuant to Applicable Law or otherwise. “Phase II Study” means, collectively, a Phase IIa Study and a Phase IIb Study. “Phase IIa Study” means a human clinical trial of a product, the principal purpose of which is a demonstration of proof of concept in the target patient population or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise. “Phase IIb Study” means a human clinical trial of a product, the principal purpose of which is to find the optimally safe and effective dose range in the target patient population or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise. “Phase III Study” means a human clinical trial of a product on a sufficient number of subjects that is designated to establish that such product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support marketing of such product, including all tests, studies, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise. “Phase IV Study” means clinical studies performed after obtaining the Marketing Approval for the purpose of supporting the Commercialization of the Licensed Products.

“CMC” means chemistry, manufacturing and controls.

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

“Confidential Information” means all information that is not in the public domain and is protectable by a Disclosing Party (as defined below in Section 13.1) as a trade secret under Applicable Law (including, without limitation, Regulatory Data and Information, as defined below) provided to a Receiving Party (as defined below in Section 13.1), whether oral, in writing or otherwise, including, without limitation, any information on the research, development, markets, customers, suppliers, patent applications, inventions, products, procedures, designs, formulas, business plans, financial projections, organizations, employees, consultants or any other similar aspects of a Party’s present or future business.

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

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

“DDU” means a daily dose unit, sterile and preservative-free or equivalent, of the ophthalmic preparation.

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

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

“Develop” or “Development” means, with respect to the Licensed Product, all research, all pre-clinical and clinical activities conducted relating to the Licensed Product for any Indication, including without limitation, test method development and stability testing, toxicology, animal studies, formulation, process development, manufacturing scale-up, quality assurance/quality control development for clinical studies, statistical analysis and report writing, and the Clinical Studies, including without limitation clinical trial design, operations, data collection and analysis and report writing, publication planning and support, risk assessment mitigation strategies, health economics outcomes research planning and support, clinical laboratory work, disposal of drugs and regulatory activities in connection therewith, the transfer of information, materials, the Licensed Product regulatory documentation and other Technology with respect to the foregoing, the preparation of Regulatory Filings, and obtaining and/or maintaining the Regulatory

Approvals (including regulatory affairs activities and preparation of meetings with the Regulatory Authorities). When used as a verb, "Developing" means to engage in Development and "Developed" has a corresponding meaning.

"EMA" means the European Medicines Agency that is a European agency for the evaluation of medicinal products.

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

"FASB" means the Financial Accounting Standards Board.

"Formulation" means the process in which Unoprostone is combined with chemical substances to produce the Licensed Product.

"GAAP" means generally accepted accounting principles as regularly applied under the FASB as may be promulgated from time to time.

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

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

"Improvement Intellectual Property" means any protectable intellectual or industrial (e.g. registrations) property interests that extend, improve, increase or build up the scope, value, duration, defensibility, or other value of the Licensed Product, Licensed Know-How and/or

Licensed Patents for their application in the manufacture, use or sale of human pharmaceutical products, whether by novel formulation, combination with additional substances, dosages, indications or any other form of pharmaceutical application.

“Improvement Product” means any composition of matter which shares the prostone SAR, including but not limited to BK channel and/or CIC-2 stimulation, which is discovered, developed or innovated in whole or in significant part in reference to, in imitation of, or in reliance upon the SAR already characterized with respect to lubiprostone, cobiprostone, Unoprostone, SPI-017, SPI-3608 or any other prostone molecules heretofore or hereafter developed by Dr. Ryuji Ueno and/or Dr. Sachiko Kuno or any Party or Affiliates of the Parties.

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

“Indications” means Glaucoma and Ocular Hypertension, Diabetic Retinopathy (DR), Diabetic Macular Edema (DME), dry and wet Age-related Macular Degeneration (AMD), and Retinitis Pigmentosa (RP), and other indications as noted in Exhibit X as may be agreed upon in writing between the Parties.

“Intellectual Property Rights” means: (a) any and all US and/or foreign patent applications, letters patent, patents, or any division, continuation, reissue, or extension thereof, and any applications (including provisional applications) therefor; (b) any and all trade secrets, know-how, and trade secret rights arising under the common law, state law, federal law of the United States and/or laws of foreign countries; (c) any and all copyrights, literary property and author rights, and moral rights, whether or not copyrightable, and any registrations and applications for registration therefor; (d) any and all trademarks, service marks, trade names, trade dress, designs, logos, slogans, associated goodwill, whether registered or arising under the common law, state law, federal law of the United States and/or other laws of foreign countries, and all registrations and applications for registration thereof; (e) any and all contract and licensing rights under the foregoing; and (f) all other right other intellectual property and proprietary rights as may now

exist and/or hereafter come into existence, and all renewals and extensions thereof, regardless of whether such rights arise under the laws of the United States or any other state, country or jurisdiction.

“Launch” means the first commercial sale of the Licensed Product to an unrelated Third Party.

“Licensed Know-How” means all Technology controlled by R-Tech or its Affiliates as of the Effective Date or at any time during the Term that is useful or necessary for developing, using, making, having made, offering for sale, registering, selling or importing the Licensed Product. Licensed Know-How includes those set forth in Exhibit C (Licensed Know-How), which may be amended from time to time to add additional know-how.

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

“Licensed Products” means any human or veterinary pharmaceutical product (whether prescription or over-the-counter and in any form or dosage form of a pharmaceutical composition or preparation), comprising of Unoprostone (whether as a sole active ingredient or in combination with one or more other active ingredients) for which the rights to use and to sell such product in the SMR Territory as a pharmaceutical product are granted hereunder to SMR under the Licensed Patents and the Licensed Know-How as shown on Exhibits B and C which may be amended from time to time by agreement of the Parties.

“Licensed Technology” means, collectively, proprietary information, know-how and data, technical or non-technical, trade secrets, materials (including tangible chemical, biological or other physical materials) or inventions, discoveries, improvements, processes, methods of use, methods of manufacturing and analysis, compositions of matter, or designs, whether or not patentable for which the rights to make such product in the SMR Territory as a pharmaceutical product are granted hereunder to SMR.

“Marketing Approval” means (i) the approval of an NDA in any country within the SMR Territory, and (ii) any pricing and reimbursement approvals, at a pricing and reimbursement level which is determined to be commercially reasonable, in any country within the SMR Territory, to the extent the applicable regulatory authorities having jurisdiction over such country require a pricing or reimbursement approval prior to marketing or sale of a product in such country.

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

“MDB” means a multi-dose bottle of the ophthalmic preparation.

“NDA” means a new drug application, as defined by laws and regulations for such application in any country within the SMR Territory, for the Marketing Approval.

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

- (i) trade, cash and quantity discounts;
- (ii) price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to governmental authorities;

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

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

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

(vi) the portion of management, commercialization costs or fees paid during the relevant time period to unrelated Third Parties who are distributors, co-promotion partners, group purchasing organizations and/or pharmaceutical benefit managers relating specifically to and facilitating the promotion and/or sale of the finished Licensed Product.(e.g. a fee, rebate, or charge paid to a payor/purchaser or their agent or insurer to enable, promote or compensate for any effective discount on sales payable to such payor/purchaser, benefit manager, insurer, or any other party affecting the terms of access treatment or purchase of the Licensed Product by the ultimate user.)

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

Subject to the above, Net Sales will be calculated in accordance with SMR's standard internal policies and procedures, which must be in accordance with the GAAP as determined by SMR. Net sales will not include sales between or among SMR and its Affiliates.

For purposes of calculating the Net Sales, all Net Sales will be converted into United State dollars using SMR's standard conversion methodology (as those published by [www.OANDA.com](http://www.OANDA.com)) consistent with the GAAP. The standard conversion methodology is based on monthly averages (for example, the spot rate at the end of the month immediately prior to the reporting month plus the spot rate at the end of the reporting month, divided by two) using open market rates or such other arrangements as the Parties may agree in writing.

If SMR or its Affiliates appoint Third Party distributors for the Licensed Product or grant a license or sublicense to any Third Party for selling the Licensed Product, the Net Sales will include the Net Sales invoiced and received by SMR or its Affiliates to such Third Party distributors and the royalties or other compensation of any other kind whatsoever invoiced and

received by SMR or its Affiliates to any such Third Party distributors, but it will not include any sales of the Licensed Product made by any such Third Party distributors or other Person.

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

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

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

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

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



include, without limitation, those Product Trademarks set forth in Exhibit D (Product Trademarks), which shall be updated from time to time.

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

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

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

“R-Tech Territory” means Japan, Korea, Taiwan and the People’s Republic of China.

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

“Regulatory Approval” means, in the SMR Territory, any and all approvals, licenses (including product and establishment licenses), registrations, or authorizations of any Regulatory Authority necessary to Develop, manufacture, Commercialize, Promote, distribute, transport, store, use, sell or market the Licensed Product, including, where applicable, pricing or reimbursement

approval, or pre- and post-approval marketing authorizations, labeling approvals, import and export licenses, technical, medical and scientific licenses.

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

“Regulatory Filings” means, collectively, all INDs, NDAs, diagnostic product device approval applications, establishment license applications, drug master files, and any product approvals under Section 505 (a) and (b) of the Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. § 355(b)(4)(B)) or any update thereto or all other similar filings as may be required by any Regulatory Authority for the Development, manufacture or Commercialization of the Unoprostone or the Licensed Product; and (b) all supplements and amendments to any of the foregoing.

“Rescula” means the pharmaceutical preparation containing Unoprostone for use in the indications of glaucoma and ocular hypertension.

“SAR” means structure activity relationship.

“SDU” means a single dose unit, sterile and preservative-free or equivalent, of the ophthalmic preparation.

“SMR Territory” means all countries of the world except for those within the R-Tech Territory and SPA Territory.

“SPA Territory” means the United States of America and Canada, and all of their territories and possessions and any other location where the FDA or its foreign counterparts in the SPA Territory has jurisdiction over pharmaceutical products intended for human use.

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

“Term” means the definition in Article 14.

“Third Party” means any party other than a Party to this Agreement and such Party’s Affiliates.

“Unoprostone” means the composition of matter defined chemically as isopropyl (Z)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-(3-oxodecyl) cyclopentyl]hept-5-enoate as further described in Exhibit E (Unoprostone), and its salts, metabolites, as well as any active pro-drugs, isomers, tautomers, hydrates, chelates, complexes and polymorphs and all other pharmaceutically acceptable modifications as may be projected in the public domain as motivation to an medicinal chemistry expert in the drug development field.

## 2. GRANT

2.1 Licenses. R-Tech hereby grants to SMR an exclusive license, with the right to grant sublicenses, under the Licensed Patents and the Licensed Know-How to Develop, use, make, have made, export, Commercialize, Promote, offer for sale and sell the Licensed Products for the Indications in the SMR Territory. R-Tech reserves the rights to make and have made Unoprostone and the Licensed Products within the RTU Territory and the Licensed Products within any and all areas not included in the SMR Territory. The license to make and have made the Licensed Products granted to SMR in this Section 2.1 shall be subject to the provisions of Section 6.1 and such license will be on terms no less favorable for R-Tech than those under the Unoprostone Exclusive Manufacturing and Supply Agreement dated April 23, 2009, and further such license will not result in the disclosure or unauthorized use of Licensed Technology.

2.2 Sublicenses. In the event that SMR wishes to grant sublicense to any Third Party, SMR shall inform R-Tech of the name, location and other details of such Third Party for the purpose of obtaining R-Tech’s prior written approval therefor; provided, however, that such approval shall not unreasonably be withheld or delayed. SMR may, at any time, grant sublicense to its Affiliate with a written notice to R-Tech. Any sublicense granted by SMR shall be subject to the terms and conditions of this Agreement. In no event may SMR grant a sublicense that diminishes the rights or increases the obligations of R-Tech under this Agreement without the prior written consent of R-Tech, which consent shall not unreasonably be withheld or delayed. With reasonable promptness following execution, SMR shall provide a copy of any

sublicense to R-Tech provided that the financial terms of such sublicense may be redacted. SMR shall be responsible hereunder for any failure of such Third Parties to comply with the terms and conditions of this Agreement as if they are directly applicable to such Third Parties.

2.3 License to Product Trademarks. Subject to and in accordance with the terms and conditions of this Agreement, R-Tech hereby grants to SMR an exclusive, even as to R-Tech in the SMR Territory, royalty-free license, with the right to sublicense to multiple tiers of Third Parties, to use all current and future Product Trademarks for the purpose of the Development and Commercialization by SMR of the Licensed Product; provided, however, that R-Tech shall have the right to use these future trademarks without incurring any payment obligations to SMR in the R-Tech Territory. Notwithstanding the license to the Product Trademarks granted by R-Tech in this Section 2.3, SMR shall have the right not to use the Licensed Product Trademarks or to use another trademark (each an "Alternative Trademark") for the Licensed Product in the SMR Territory, and SMR shall own all rights to such Alternative Trademark and shall be free to use such Alternative Trademark without regard to, or accounting to, R-Tech except as otherwise provided herein. R-Tech shall have the right to use these Alternative Trademarks without incurring any payment obligations to SMR in the R-Tech Territory.

2.4 NDA Transfer from NVO. R-Tech hereby agrees to transfer from Novartis Pharma AG ("NVO") directly to SMR of all regulatory approvals on records in Argentina, Ecuador and Lebanon and relevant files, which ownership were already returned from NVO to R-Tech pursuant to the License, Transfer, Settlement and Termination Agreement, dated as of June 30, 2010, by and between R-Tech and NVO, for the Licensed Products with respect to the SMR Territory, with the exception of the CMC to be retained by RTU.

### 3. PAYMENTS

3.1 Milestone Payments. In partial consideration of the acquisition of the license rights granted to SMR by R-Tech hereunder, SMR shall pay to R-Tech the following milestone amounts:

| Milestone Event                              | Milestone Payment  |
|--|--|
| Execution of this Agreement (Effective Date) | US\$3 million, as an upfront payment, within five (5) business |

|   |  |
|---|--|
|   | days of the occurrence of the Effective Date.  |
| Earlier of central approval by the EMA of Licensed Product for Glaucoma and Ocular Hypertension Indication and Other Indications within the SMR Territory by SMR or its Affiliates or March 15, 2012.                               | US\$3 million, within five (5) business days of the occurrence of the Milestone Event. |
| Acceptance for filing of the first NDA other than for Glaucoma and Ocular Hypertension Indication and Other Indications after the Launch of Licensed Product in any jurisdiction within the SMR Territory by SMR or its Affiliates. | US\$5 million within five (5) business days of the occurrence of the Milestone Event.  |
| Approval of the NDA other than for Glaucoma and Ocular Hypertension Indication and Other Indications after the Launch of Licensed Product in any jurisdiction within the SMR Territory by SMR or its Affiliates.                    | US\$10 million within five (5) business days of the occurrence of the Milestone Event. |
| 1st occurrence of Annual Net Sales in total of all Indications of US\$50 million or more in SMR Territory by SMR or its Affiliates.   | US\$5 million within five (5) business days of the occurrence of the Milestone Event.  |
| 1st occurrence of Annual Net Sales in total of all Indications of US\$100 million or more in SMR Territory by SMR or its Affiliates.  | US\$10 million within five (5) business days of the occurrence of the Milestone Event. |
| 1st occurrence of Annual Net Sales in total of all Indications of US\$200 million or more in SMR Territory by SMR or its Affiliates.  | US\$20 million within five (5) business days of the occurrence of the Milestone Event. |
| 1st occurrence of Annual Net Sales in total of all Indications US\$500 million or more in SMR Territory by SMR or its Affiliates.   | US\$50 million within five (5) business days of the occurrence of the Milestone Event. |

3.2 No Refund. Any payments made by SMR in accordance with Article 3 hereof shall, once they are paid, are not be refundable nor creditable for any reason whatsoever.

3.3 Payments to Third Party. Within the SMR Territory, SMR shall be solely responsible for royalty payments, milestone payments and any other payments to Third Parties for Intellectual Property Rights claims related to the Licensed Product.

3.4 Payment Reports. Upon making the payments under Article 3, SMR and its Affiliates shall also provide a report showing: (i) a statement identifying the Annual Net Sales of the Licensed Product in the respective countries within the SMR Territory; (ii) the withholding taxes, if any, required by Applicable Law to be deducted with respect to such Net Sales; and (iii) the exchange rates, if any, used in determining the amount of United States dollars. The Parties will agree upon a common reporting mechanism for such report.

3.5 Audit Rights. Each Party shall keep and maintain for at least three (3) years complete and accurate records in accordance with GAAP in sufficient detail to allow confirmation of any payment calculations or components thereof and made hereunder. Upon the written request of a Party (herein, the "Auditing Party") and not more than once in each calendar year, the other Party (herein, the "Audited Party") shall permit an independent certified public accounting firm of internationally-recognized standing, selected by the Auditing Party (provided that the Auditing Party shall not without the Audited Party's prior written consent select the same public accounting firm that conducts the Auditing Party's annual financial statement audit) and reasonably acceptable to the Audited Party, at the Auditing Party's expense, to have access, with not less than thirty (30) days notice, during normal business hours, to the records of the Audited Party and its Affiliates as may be reasonably necessary to verify the accuracy of the payments hereunder for any year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm will be instructed to provide its audit report first to the Audited Party, and will be further instructed to redact any proprietary information of the Audited Party not relevant to verifying the accuracy of payments prior to providing that audit report to the Auditing Party. The accounting firm's audit report shall state whether the applicable report(s) is/are correct or not, and, if applicable, the specific details concerning any discrepancies. No other information shall be shared. If such accounting firm concludes that additional monies were owed by the Audited Party to the Auditing Party, the Audited Party shall have the option to invoke the arbitration proceedings of Section 17.10.2 or pay the additional monies within thirty (30) days of the date the Audited Party receives such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by the Auditing Party; provided if an error in favor of the Auditing Party of more than ten percent (10%) of

US\$100,000 is discovered, then the Audited Party shall pay the reasonable fees and expenses charged by such accounting firm. Any audit reports provided hereunder shall be the Confidential Information of the Audited Party.

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

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

#### 4. DEVELOPMENT

4.1 Development Plan and Committee. R-Tech and SMR shall agree to a plan for the development of Unoprostone for the Indications in the SMR Territory and R-Tech Territory so that approvals may be obtained in the most effective and expeditious manner. R-Tech and SMR shall form a joint development committee ("Joint Development Committee" or "JDC") to

plan and conduct these trials in which the Parties shall cooperate on the Development of the Unoprostone. The Parties shall mutually agree upon the format, frequency and method of making decisions for the meetings of the JDC.

4.2 Funding. SMR, in its reasonable judgment, shall fund any studies necessary for the Development including local clinical trials required under ICH IES guidelines, required beyond any global pivotal trial(s), and earlier trials performed to enable such pivotal trial(s).

4.3 Records and Reports. SMR and R-Tech shall maintain records of its Development activities in sufficient detail, in good scientific manner and otherwise in a manner that reflects all work done and results achieved in the performance of the Development. SMR and R-Tech shall retain such records for at least five (5) years after the expiration of the Term or termination of this Agreement, or for such longer period as may be required by Applicable Law or agreed to in writing by the Parties. Subject to Article 13 (Confidentiality), each Party shall provide the other Party, upon reasonable request, a copy of such records to the extent reasonably required for the performance of the requesting Party's obligations and exercise of its rights under this Agreement. The Parties shall develop standard operating procedures for the submittal of written reports of their Development activities to the JDC.

4.4 Development of Formulation. Notwithstanding any other provisions of this Agreement, R-Tech shall reserve the right to Develop and control Development of any formulation of the Licensed Products in accordance with the terms of the Unoprostone Toll Agreement except that SMR may in its reasonable judgment request R-Tech to process a certain formulation and license such formulation to SMR in accordance with the terms of the Unoprostone Toll Agreement.

4.5 Regulatory Concerns. During the Term, R-Tech shall advise SMR without undue delay of any occurrences or information arising out of R-Tech's manufacturing activities that have or could reasonably be expected to have adverse regulatory compliance and/or reporting consequences concerning the Licensed Products, including actual or threatened Regulatory Authorization withdrawals or labeling changes in the SMR Territory. During the Term, and subject to the Unoprostone Toll Agreement, R-Tech shall be responsible for handling and responding to any Regulatory Authority inspections with respect to R-Tech's manufacture of the Licensed Product. R-Tech shall provide SMR with any information reasonably requested by SMR and all information requested by any Regulatory Authority concerning any governmental



inspection related to the Licensed Products and shall allow Regulatory Authorities to conduct reasonable inspections upon the request of such Regulatory Authority.

4.6 Product Concerns. During the Term, SMR shall advise R-Tech without undue delay of any written alleged violations or deficiencies relating to the Licensed Products and the corrective action to be taken. R-Tech shall as expeditiously as practicable take any such corrective action required to comply with the provisions of this Agreement and with the Unoprostone Toll Agreement. Prior to submission of any written response submitted to any applicable Regulatory Authority, SMR shall have an opportunity to review any portion of the response regarding written alleged violations or deficiencies relating to the Licensed Products.

## 5. REGULATORY

5.1 DMF and CMC. Maintenance of the NDA with respect to compliance of the Licensed Products and with the Drug Master File/Chemistry, Manufacturing and Controls elements of the NDA shall remain with and be maintained by R-Tech in R-Tech Territory and with SMR in SMR Territory, at their respective expenses.

5.2 Product Labels and Inserts; Core Data Sheets. SMR shall own and be responsible for all Product Labels and Inserts for all Licensed Products in the SMR Territory, and shall own and be responsible for all Core Data Sheets for all Licensed Products in the SMR Territory.

5.3 Adverse Event Reports. SMR and its Affiliates shall be responsible for investigating Adverse Events and other required safety information associated with the Licensed Products in the SMR Territory in accordance with the requirements of the relevant Regulatory Authority. SMR shall be responsible for the collection, review, assessment, tracking and filing of information related to Adverse Events, and R-Tech will cooperate and provide or cause any Third Party to provide such information to SMR and its Affiliates with respect thereto. Prior to any Commercialization of the Licensed Products in the SMR Territory, the Parties shall enter into an agreement to initiate a process for the exchange of Adverse Event safety data in a mutually agreed format, including, but not limited to, post-marketing spontaneous reports received by a Party or its Affiliates in order to monitor the safety of the Licensed Products and to meet reporting requirements with any applicable Regulatory Authority.

#### 5.4 Recalls and Market Withdrawals.

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

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

5.4.3 Responsibility. For all Recalls or Market Withdrawals undertaken pursuant to this Section 5.4, SMR and its Affiliates shall be solely responsible for the execution of such Recall or Market Withdrawals caused by SMR in the SMR Territory, and R-Tech shall reasonably cooperate in all such Recall or Market Withdrawal efforts. R-Tech shall be responsible for the costs associated with any Recall or Market Withdrawal caused by R-Tech.

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

## 6. MANUFACTURING AND SUPPLY

6.1 Manufacturing and Supply by R-Tech. SMR shall exclusively engage R-Tech to manufacture (or have manufactured) and supply the Licensed Products for SMR and/or its Affiliates, sublicensees or distributors for the SMR Territory for the purpose of both the Development and the Commercialization under this Agreement, subject to and pursuant to the terms and conditions of the Toll Manufacturing Agreement to be entered into for such particular purpose between the Parties, the substance and form of which will substantially be as set forth Exhibit A.

## 7. COMMERCIALIZATION AND MARKETING

7.1 Efforts. SMR shall exert its commercially reasonable efforts, at its own expense and consistent with SMR resources and capabilities and commercial viability of the Licensed Products, to Promote, market, distribute and sell the Licensed Products in the SMR Territory. SMR shall market the Licensed Products in the SMR Territory and have the sole final responsibility for decisions in the SMR Territory. Unless otherwise agreed to by the parties, within ninety (90) days following receipt by SMR or its Affiliate or its sublicensee(s), if any, of a Marketing Approval of the Licensed Product in any country within the SMR Territory, SMR shall, and shall make its Affiliate and its sublicensee(s), if any, start the marketing and sales of such Licensed Product in such country with its commercially reasonable efforts, at its own expense, and to use commercially reasonable efforts to Promote, market, distribute and sell such Licensed Product consistent with accepted pharmaceutical business practice and applicable legal requirements. The Parties shall mutually agree to form a joint commercialization committee ("Joint Commercialization Committee" or "JCC") to plan and determine which Licensed Products to Promote, market, distribute and sell in the SMR Territory. The Parties shall mutually agree upon the format, frequency and method of making decisions for the meetings of the JCC.

7.2 Promotional Materials. SMR shall produce and own all Promotional Materials for the Licensed Products in the SMR Territory. In the event R-Tech prepares Promotional Materials for the Licensed Products, R-Tech shall provide them to SMR. SMR, its Affiliates and sublicensees may use such Promotional Materials, as modified appropriately and subject to the prior written approval of R-Tech, for use in the SMR Territory for the purpose of this Agreement. SMR shall permit R-Tech to use copies of the Promotional Materials, including those so modified, within R-Tech Territory.

## 8. INTELLECTUAL PROPERTY RIGHTS

8.1 Licensed Know-How and Licensed Patents. All the Licensed Know-How and the Licensed Patents shall remain the property of R-Tech, but exclusively licensed to SMR for the SMR Territory pursuant to the terms and conditions of this Agreement.

8.2 Joint Ownership and Filing. Notwithstanding any other provisions of this Agreement, R-Tech and SMR shall jointly own any and all data, inventions and other Intellectual Property Rights, patentable and non-patentable, resulting from the Development pursuant to this Agreement, and any and all patent applications with respect to such patentable inventions shall be filed jointly in the SMR Territory under the names of R-Tech and SMR and at both parties' equal share of expense. If inventions are discovered by a Party that would be a basis for filing for an Improvement Patent, such Party shall promptly inform the other Party of such inventions, and the Parties will cooperate with each other in the filing to assure, at a lowest reasonable cost and lowest reasonable level of effort, as will assure the widest filing globally of patents most likely to be granted with the most comprehensive claims so as to best extend and improve the commercial returns from the Licensed Product and/or Improvement Product.

8.3 Formulation. Notwithstanding any other provisions of this Agreement, any and all data, inventions and other Intellectual Property Rights, patentable and non-patentable, with respect to formulation of the Licensed Products resulting from the Development shall be solely owned by R-Tech and patent applications with respect to such patentable inventions shall be filed solely under the name of R-Tech and at R-Tech's expense.

8.4 Intellectual Property Rights Owned by R-Tech. Notwithstanding any other provisions of this Agreement, SMR shall not acquire any Intellectual Property Rights or other interests whatsoever, except for those expressly provided for herein or in another agreement, in any data, invention, confidential information or know-how (including but not limited to the Drug Master File/Chemistry) that R-Tech develops or has developed at its cost and expense as part of the manufacturing of Unoprostone in the performance of this Agreement.

## 9. REPRESENTATIONS AND WARRANTIES

9.1 Mutual Representations and Warranties. SMR and R-Tech each represents and warrants to the other, as of the Effective Date, as follows:

9.1.1 Such Party is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation.

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

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

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

9.1.5 Neither it, nor any of its employees or agents that will be performing hereunder, has ever been or is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual.

## 9.2 Representations and Warranties by R-Tech.

9.2.1 R-Tech represents and warrants to SMR that it has the right to grant to SMR rights and licenses within the scope set forth in this Agreement that is free and clear of any licenses, sublicenses and all encumbrances.

9.2.2 R-Tech represents and warrants that, to the best of its knowledge, with respect to all relevant patents and patent applications, trademarks and trademark applications in relation to the Licensed Patents and Product Trademarks, that all patents are valid and in good standing,

all assignments for patents and patent applications have been appropriately obtained and recorded, all inventors have been correctly and appropriately listed, no inventorship disputes exist, and there is no claim or demand of any Person pertaining to, or any proceeding which is pending or to the best of its knowledge threatened, that challenges R-Tech's interest in or the validity of, scope of, infringement of or enforceability of the Licensed Patents or the Product Trademarks or makes any adverse claim of inventorship or ownership thereof. To R-Tech's knowledge, none of the relevant patents and patent applications, trademarks and trademark applications in the Licensed Patents and the Product Trademarks is the subject of any ongoing infringement by any Third Party or any pending or, threatened adverse claim, judgment, injunction, order, decree or agreement restricting its use in connection with the Licensed Product.

9.2.3 R-Tech represents and warrants that it maintains all patent licenses (the "Third Party Patent Licenses") having been granted by Third Parties to R-Tech that materially affect SMR's rights set forth in this Agreement. All the Third Party Patent Licenses are listed in Exhibit B (Licensed Patents) to this Agreement.

9.2.4 Notwithstanding anything to the contrary contained in this Agreement, R-Tech does not warrant that SMR can successfully develop, obtain approval for the marketing of, or market the Licensed Products in the SMR Territory.

9.3 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE MANUFACTURE OF LICENSED PRODUCT, ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY SPECIFICALLY DISCLAIMS ALL WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

## 10. COVENANTS

10.1 Compliance with Applicable Law. Each Party shall comply, in all material respects, with Applicable Law relating to such Party's rights, duties, responsibilities and obligations set forth in this Agreement.

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

10.3 Governmental Approval, Etc. R-Tech shall obtain and maintain at R-Tech's expense during the Term all authorizations, consents and approvals, governmental or otherwise, necessary for R-Tech to grant the rights and licenses granted to SMR hereunder.

10.4 Product Trademarks. R-Tech shall be responsible for the filing, prosecution, defense and maintenance at R-Tech's expense before all trademark offices of all Product Trademarks (excluding the Alternative Trademarks for the purpose of this Section 10.4) and using commercially reasonable efforts to ensure the Product Trademarks exist in the SMR Territory during the Term. If R-Tech chooses not to prepare, file, prosecute, maintain or defend the Product Trademarks in the SMR Territory, then SMR or its Affiliates shall have the right and option to do so at its own expense. SMR shall be responsible for the filing, prosecution, defense and maintenance before all trademark offices of all Alternative Trademarks.

10.5 Third Party Patent Licenses. In the event R-Tech receives a notice that it is in breach of the Third Party Patent Licenses, it shall provide prompt written notice to SMR and take all actions at its own expense to cure such breach, including at SMR's option, allowing SMR to cure such breach if possible without impairing SMR's legal rights and remedies set forth in this Agreement.

10.6 Product Trademarks. R-Tech shall use commercially reasonable efforts to ensure Product Trademarks exist in each country in SMR Territory and are kept in good standing.

## 11. INDEMNIFICATION

11.1 Indemnification by SMR. SMR agrees to indemnify, defend and hold harmless R-Tech and its Affiliates and their respective employees, agents, officers, directors and permitted assigns (the "R-Tech Indemnitees") from and against any Third Party claims, judgments, expenses (including reasonable attorneys' fees), damages and awards (collectively a "Third Party

Claim”) arising out of or resulting from: (a) improper storage or handling of Unoprostone or the Licensed Product by SMR or its Affiliates or sublicensees in SMR Territory including but not limited to failure to comply with CMC specifications, practices or procedures filed in support of the NDA for the Licensed Products; (b) SMR’s negligence or willful misconduct in regard to its performance, or non-performance, under this Agreement including but not limited to its compliance with cGMP law and regulations and filed CMC requirements of the NDA for the Licensed Products in SMR Territory; (c) a breach of any of SMR’s representations or warranties hereunder; except, in the respective events above, to the extent that such Third Party Claim arises out of or results from the gross negligence or willful misconduct of any R-Tech Indemnitee.

11.2 Indemnification by R-Tech. R-Tech agrees to indemnify, defend and hold harmless SMR and its Affiliates and their respective employees, agents, officers, directors and permitted assigns (the “SMR Indemnitees”) from and against any Third Party Claim arising out of or resulting from: (a) improper storage, handling, manufacturing, formulation or contamination of Unoprostone or the Licensed Product by R-Tech or its Affiliates Agreement including but not limited to its compliance with cGMP law and regulations and filed CMC requirements of the NDA for the Licensed Products; (b) infringement of Third Party intellectual property rights by the manufacture of the Licensed Products pursuant to the terms and conditions of this Agreement or the filing and prosecution of any Licensed Patents or Licensed Know-How or any Product Trademark; (c) failure by R-Tech or any Affiliate or subcontractor of R-Tech to manufacture and supply the Licensed Product in accordance with the specifications and Applicable Law, including but not limited to its compliance with cGMP law and regulations and filed CMC requirements of the NDA for the Licensed Products; (d) any product liability claims arising from the Licensed Product; (e) R-Tech’s and/or its subcontractors’ negligence or willful misconduct in regard to its performance, or non-performance, under this Agreement; or (f) a breach of any of R-Tech’s representations or warranties hereunder, except, in the respective events above, to the extent that such Third Party Claim arises out of or results from the gross negligence or willful misconduct of any SMR Indemnitee.

11.3 Procedures for Indemnification. The obligations of an indemnifying Party under Section 11.1 and Section 11.2 shall be governed by and contingent upon the following:

11.3.1 Notice of Claim. Each Party to be indemnified hereunder shall give the other Party prompt written notice of any Third Party Claim (an “Indemnification Claim Notice”). Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of the loss claimed (to the extent that the nature and amount of such loss is known at



such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any such Third Party Claim.

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

11.3.3 Control of the Defense. Upon the assumption of the defense of a Third Party Claim by the indemnifying Party: (a) the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party, which shall be reasonably acceptable to the indemnified Party; (b) the indemnified Party shall promptly deliver to the indemnifying Party all original notices and documents (including court papers) received by the indemnified Party in connection with the Third Party Claim; and (c) except as expressly provided in Section 11.3.4, the indemnifying Party shall not be liable to the indemnified Party for any legal expenses subsequently incurred by such indemnified Party or any Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim.

11.3.4 Right to Participate in the Defense. Without limiting Section 11.3.2 or Section 11.3.3, any Indemnitee shall be entitled to participate in, but not control, the defense of a Third Party Claim and to retain counsel of its choice for such purpose; provided that such retention shall be at its own expense unless, (a) the indemnifying Party has failed to assume the defense and retain counsel in accordance with Section 11.3.2 (in which case the indemnified Party shall control the defense), or (b) the interests of Indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under Applicable Law, ethical rules or equitable principles.

11.3.5 Settlement. The indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of any Third Party Claim, on such terms as the indemnifying Party, in its reasonable discretion, shall deem appropriate; provided that: (a) the sole relief provided is the payment of money damages; (b) the consent, settlement or other disposition does not, and will not, result in a finding or admission of

any negligence, intentional malfeasance, violation of any Applicable Law or any violation of the rights of any person and does not effect on any other claims that may be made against the indemnified Party; (c) the consent, settlement or other disposition does not, and will not, result in the indemnified Party's rights under this Agreement being adversely affected; and (d) the consent, settlement or other disposition does not, and will not, result in the indemnified Party becoming subject to injunctive or other relief or otherwise will adversely affect the business of the indemnified Party in any manner. With respect to all other Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 11.3.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Third Party Claim with the prior written consent of the indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Third Party Claim by an indemnified Party that is reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

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

11.4 Insurance. Each Party shall obtain and carry in full force and effect the minimum insurance requirements set forth herein, which shall protect Indemnitees with respect to events covered by Section 11.1 and Section 11.2. Such insurance (i) shall be primary insurance with respect to each Party's own participation under this Agreement, (ii) shall be issued by a recognized insurer rated by A.M. Best "A-VII" (or its equivalent) or better, or an insurer pre-

approved in writing by the other Party, (c) shall list the other Party as an additional named insured thereunder, and (d) shall require thirty (30) days written notice to be given to the other Party prior to any cancellation, non-renewal or material change thereof. The types of insurance, and minimum limits shall be general liability insurance with a minimum limit of Three Million United States dollars (US\$3,000,000) per occurrence and Ten Million United States dollars (US\$10,000,000) in aggregate. General liability insurance shall include, at a minimum, professional liability, clinical trial insurance and, beginning at least thirty (30) days prior to the first commercial sale] of the Licensed Product, product liability insurance. Upon request by a Party, the other Party shall provide certificates of insurance evidencing compliance with this Section. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement during any period in which such Party continues to make, to have made, to use, to offer for sale, to sell or to import a product that was the Licensed Product under this Agreement, and thereafter for a period of five (5) years. Notwithstanding the foregoing, each Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies.

## 12. LIMITATION OF LIABILITY

NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, EXCEPT IN CIRCUMSTANCES OF INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES, OR WITH RESPECT TO INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS SET FORTH IN ARTICLE 11, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS OR LOST REVENUES, OR COST/EXPENSE OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY.

## 13. CONFIDENTIALITY

### 13.1 Confidentiality.

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

13.1.2 Exceptions to Confidentiality. The Receiving Party's obligations set forth in this Agreement shall not extend to any information of a Disclosing Party or information developed in the performance of this Agreement that: (a) is or hereafter becomes part of the public domain, by public use, publication, general knowledge or the like or is made generally available in the public domain by a Third Party with right to make such publication; in each case, other than through a breach of this Agreement by the Receiving Party; (b) is received from a Third Party without restriction and with the right to disclose such information; (c) the Receiving Party can demonstrate by competent pre-existing written evidence properly maintained as a formal business record was already in its possession without any limitation on its use or disclosure prior to its receipt from the Disclosing Party; (d) the Receiving Party can demonstrate by competent written evidence properly maintained as a formal business record was independently developed by or for the Receiving Party without reference to, use of or disclosure of the Disclosing Party's Confidential Information; or (e) is released from the restrictions set forth in this Agreement by the express prior written consent of the Disclosing Party. Notwithstanding the foregoing, specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

13.1.3 Authorized Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is: (a) made in response to a valid relevant unappealed or unappealable order of a court of competent jurisdiction or other Regulatory Authority or any political subdivision or regulatory body thereof of competent jurisdiction; provided that the Receiving Party shall first have, if reasonably possible, given notice to the Disclosing Party and given the Disclosing Party, at such Disclosing Party's own expense, a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order be held in confidence by such court or Regulatory Authority or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such order shall be limited only to that information which is legally required, in the opinion of legal counsel to the Receiving Party, to be disclosed in such response to such court or governmental order; (b) otherwise required by Applicable Law or the requirements of a major national securities exchange, in the opinion of legal counsel to the Receiving Party, provided that the Party disclosing such Confidential Information shall exercise its commercially reasonable efforts to obtain a protective order or other reliable assurance that confidential treatment will be accorded and if possible give the Disclosing Party a reasonable opportunity to review and comment on any such disclosure in advance thereof (but not less than seven (7) days, if possible, prior to the date of such disclosure); (c) made to an applicable Regulatory Authority as useful or required in connection with any filing, application or request for the Marketing Approval; provided that reasonable measures shall be taken to assure confidential treatment and narrowest possible use and disclosure of such information; (d) (i) reasonably necessary in filing or prosecution of patents or other intellectual and/or industrial property rights covering the manufacture, use or sale of Unoprostone or the Licensed Product(s) or (ii) reasonably necessary in defending litigation related to the Licensed Patents if such litigation relates to this Agreement, and in each case of (i) and (ii), provided that the Receiving Party, if such disclosure is non-confidential, gives reasonable advance notice to the Disclosing Party of such disclosure; and (e) to the extent necessary, and subject to subcontracting provisions set forth in this Agreement, to its Affiliates, directors, officers, employees, consultants, sublicensees of SMR or R-Tech (or bona fide potential sublicensees of SMR or R-Tech), vendors and clinicians, under written agreements of confidentiality substantially similar or at least as restrictive as those set forth in this Agreement, who have a reasonable need to know such information in connection with a Party performing its obligations or exercising its rights under this Agreement; provided, that either Party may enter into such written agreements that provide for shorter timeframes for maintaining confidentiality than those set forth in this Agreement with the written consent of the other Party.

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

13.3 Use of Name and Disclosure of Terms. Each Party shall keep the existence of, the terms of and the transactions and the subject matter covered by this Agreement confidential and shall not disclose such information to any Third Party through a press release, publication, Promotional Material, other form of publicity or otherwise, or, except as expressly permitted in this Agreement, mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates in any manner without the prior written consent of the other Party in each instance. The restrictions imposed by this Section shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the Disclosing Party's counsel, is required by Applicable Law, rule or regulation or the requirements of a major national securities exchange or another similar regulatory body, provided that any such disclosure shall be governed by this Article and that the Disclosing Party is given a reasonable opportunity to review and comment on any such press release or public communication in advance thereof (but not less than seven (7) days prior to the date of disclosure).

#### 14. TERM AND TERMINATION

14.1 Term. With respect to each Licensed Product, the term (the "Term") of this Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to this Agreement, shall expire upon the later of (i) a period of ten (10) years, or (ii) the expiry of all Product Valid Claims in the SMR Territory with respect to such Licensed Product, or (iii) the loss of the Data Exclusivity with respect to such Licensed Product.

#### 14.2 Early Termination.

14.2.1 In the event of a material breach of this Agreement by a Party (the

“Defaulting Party”), the other Party may terminate this Agreement effective immediately, with respect to any and all Licensed Product or countries within the SMR Territory at its discretion, by providing a notice thereof to the Defaulting Party (i) if such breach is not curable, or (ii) if the Defaulting Party fails to cure such breach, only if curable, within 90 days of a notice of such breach provided to the Defaulting Party.

14.2.2 In the event any Licensed Product is withdrawn from any country within the SMR Territory as required by a Regulatory Authority of such country due to any material Adverse Event, SMR may terminate this Agreement effective immediately, by giving a written notice to R-Tech, with respect to such Licensed Product and such country.

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

14.2.4 If no Order is submitted to R-Tech by SMR, or no Clinical Study is initiated within two (2) years of the Effective Date, R-Tech may terminate this Agreement at any time by providing SMR with ten (10) days’ advance notice in writing.

#### 14.3 Consequences of Expiration of Term or Early Termination.

14.3.1 Upon expiration of the Term or upon any termination of this Agreement in its entirety by a Party pursuant to Section 14.2, (a) the licenses granted by R-Tech to SMR under this Agreement shall terminate and any and all rights and properties (including Regulatory Filings) provided to SMR hereunder shall revert to R-Tech; (b) with respect to all Clinical Studies or post approval studies for any Licensed Products being conducted as of the effective date of termination, the applicable Party shall end such Clinical Studies or post approval studies with respect to enrolled subjects in an orderly and prompt manner in accordance with Applicable Law, including any required follow up treatment with previously enrolled subjects, and all other Development, Commercialization and promotion activities under this Agreement shall promptly cease, and (c) each Party shall return, or if allowed by the other Party destroy (and soon thereafter provide to the other Party written certification evidencing such destruction), all data,

files, records and other materials in its possession or control relating to the other Party's Technology, or containing or comprising the other Party's Confidential Information.

14.3.2 Upon any termination of this Agreement with respect to a Licensed Product by a Party pursuant to Section 14.2, (a) the licenses granted by R-Tech to SMR under this Agreement shall terminate with respect to such terminated Licensed Product; (b) with respect to all Clinical Studies or post approval studies for such terminated Licensed Product being conducted as of the effective date of termination, the applicable Party shall end such Clinical Studies or post approval studies with respect to enrolled subjects in an orderly and prompt manner in accordance with Applicable Law, including any required follow up treatment with previously enrolled subjects, and all other Development, Commercialization and Promotion activities under this Agreement shall promptly cease.

14.3.3 If this Agreement terminates at the expiration of the Term but not as a result of early termination pursuant to this Agreement, the Parties shall, at R-Tech's request, negotiate in good faith the terms and conditions under which SMR may continue to Promote or co-Promote and distribute the Licensed Product, and, if both Parties fail to reach to such terms and conditions within ninety (90) days, SMR sells back to R-Tech, and R-Tech repurchases from SMR, at SMR's actual cost, remaining inventory of the Licensed Products with greater than twelve (12) months remaining shelf life.

14.3.4 In addition to any other provisions in which particularly so provided, Sections 8 and 13 hereof and other provisions of this Agreement that by their nature should survive the expiration of the Term or termination of this Agreement, and any accrued rights and remedies shall survive the expiration of the Term or termination of this Agreement.

## 15. GUARANTEE BY SPI

SMR shall, within five (5) business days of the Effective Date, cause SPI to guarantee the performance by SMR of the obligations hereunder in the form attached hereto as Exhibit F (SPI Guarantee).

## 16. SPA AGREEMENTS

16.1 SPA Agreements. SMR shall cause SPA to assign and transfer to SMR, and SMR shall assume from SPA any and all obligations under the Unoprostone NDA Transfer,



Patent and Know-how Licensing and Data Sharing Agreement, dated as of April 23, 2009, and the Unoprostone Exclusive Manufacturing and Supply Agreement, dated as of April 23, 2009, respectively by and between R-Tech and SPA (collectively, the "SPA Agreements"), as of the date hereof to the extent necessary to fulfill the obligations of SMR under this Agreement.

16.2 Scope of Application. SMR hereby confirms and agrees the SPA Agreements shall not apply, but this Agreement shall instead apply, with respect to any and all formulations of the Licensed Products that may be Developed at any time from the date hereof for use in the SMR Territory but not the SPA Territory.

## 17. GENERAL PROVISIONS

17.1 Assignment. This Agreement is personal to the Parties hereto and shall not be assignable to any Third Party by either Party without the prior written consent of the other Party; provided, however, that any Party may assign this Agreement to an Affiliate of such Party without the prior written consent, but with prior written notice. All successors and permitted assignees of a Party shall be subject to, and will be bound, by all the terms and conditions of this Agreement. Any attempted assignment made contrary to the provisions hereof will be void. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party, provided that such Party, if it survives, shall remain jointly and severally liable for the performance of such delegated obligations under this Agreement.

17.2 Entire Agreement. This Agreement shall constitute the entire agreement between the Parties concerning the subject matter hereof and shall supersede any other agreements, whether oral or written, express or implied, and may not be changed or modified or revised except as specifically agreed upon by the Parties in writing. All Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement.

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

17.4 Amendment; Waiver. This Agreement may be amended, modified, superseded or

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

17.5 No Third Party Beneficiaries. Unless otherwise set forth in this Agreement, the provisions of this Agreement are for the sole benefit of the Parties and their permitted successors and permitted assigns and none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, without limitation, any employee or creditor of either Party hereto.

17.6 Independent Contractors. The Parties are independent contractors. In making and performing this Agreement, the Parties are acting, and intend to be treated, as independent entities performing a contract, and nothing contained in this Agreement is to be construed or implied or deemed to create an agency, partnership, joint venture or an employee/employer relationship between the Parties. This Agreement is not, and will not be deemed to be, a partnership agreement or joint venture agreement, expressly or by implication.

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

recognized overnight delivery service that maintains records of delivery as soon as practicable thereafter. This Section is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to SMR: Sucampo Manufacturing & Research AG  
c/o Sucampo Pharma Americas, Inc.  
4520 East West Highway, Third Floor  
Bethesda, MD 20817  
UNITED STATES  
Attention: General Counsel  
Facsimile: 301-961-3440

If to R-Tech: R-Tech Ueno, Ltd.  
NBF Hibiya Bldg., 10F  
1-1-7 Uchisaiwaicho  
Chiyoda-ku, Tokyo 100-0011  
JAPAN  
Attention: President  
Facsimile: +81-3-3596-8011

17.8 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties under this Agreement which is not within the reasonable control of the Party affected, not due to malfeasance, and which, with the exercise of due diligence could not have been avoided ("Force Majeure"), including, without limitation, fire, explosion, flood, earthquake, war, accident, strike, riot, terrorist attacks, civil commotion, acts of God, or the like, will not excuse such Party from the performance of its obligations or duties under this Agreement, but will suspend such performance during the continuation of such Force Majeure. The Party prevented from performing its obligations or duties because of Force Majeure shall be required to, as soon as reasonably possible, notify the other Party hereto of the occurrence and particulars of such Force Majeure and shall be required to provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure and with notice of the termination thereof. The Party so affected shall use reasonable efforts to avoid or remove such causes of nonperformance. Upon termination of Force Majeure, the obligation to perform any previously suspended obligation or duty shall promptly recommence.

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

17.10 Dispute Resolution.

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

17.10.2 Arbitration. Any dispute, controversy or claim that arises out of or relates to this Agreement that is not resolved under Section 17.10.1 shall be settled by final and binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC") in effect on the Effective Date. Judgment upon the award rendered by the arbitrators may be entered in any court of competent jurisdiction. The place of arbitration shall be Paris, France unless another location is agreed upon between the parties and arbitrators. The arbitration shall be conducted in the English language by three (3) neutral arbitrators selected by mutual agreement of the parties or, if that is not possible within thirty (30) days of the initial demand for such arbitration, by the ICC. At least one (1) arbitrator shall have professional knowledge of and experience in the regulation of and terms of trade of the ethical pharmaceutical industry. Notwithstanding any provision to the contrary in the ICC's Rules of Arbitration, the arbitrators may not award or assess punitive damages against either Party; and each party shall bear its own costs and expenses of the arbitration and shall share equally the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing Party.

17.11 Equitable Relief. The Parties acknowledge and agree that the restrictions set forth in Article 13 (Confidentiality) are reasonable and necessary to protect the legitimate interests of the Parties and that neither Party would have entered into this Agreement in the

absence of such restrictions, and that any breach or threatened breach of any provision of Article 13 may result in irreparable injury to the other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of Article 13 by a Party, the other Party may be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. Nothing in this Section is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

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

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

its severance herefrom, in each case provided that the basic purpose and structure of this Agreement is not altered.

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

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

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

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

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate counterparts by their duly authorized representatives, each fully executed copy hereof to be deemed as original, as of the Effective Date.

R-Tech Ueno, Ltd.

Sucampo Manufacturing & Research AG

By: \_\_\_\_\_

Name: Yukihiro Mashima  
Title: President


By:   
Name: James J. Egan  
Title: COO, SPI on behalf of SMR

Exhibit A Unoprostone Toll Manufacturing Agreement  
Exhibit B Licensed Patents  
Exhibit C Licensed Know-How  
Exhibit D Product Trademarks  
Exhibit E Unoprostone  
Exhibit F SPI Guarantee

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate counterparts by their duly authorized representatives, each fully executed copy hereof to be deemed as original, as of the Effective Date.

R-Tech Ueno, Ltd.

Sucampo Manufacturing & Research AG

By: Y. Mashima  
Name: Yukihiro Mashima  
Title: President

By: James J. Egary  
Name: James J. Egary  
Title: COO, SPI on behalf of SMR

Exhibit A Unoprostone Toll Manufacturing Agreement  
Exhibit B Licensed Patents  
Exhibit C Licensed Know-How  
Exhibit D Product Trademarks  
Exhibit E Unoprostone  
Exhibit F SPI Guarantee



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**TOLL MANUFACTURING AGREEMENT**

**by and between**

**SUCAMPO MANUFACTURING & RESEARCH, AG**

**and**

**R-TECH UENO, LTD**

**Effective as of**

\_\_\_\_\_, 20\_\_



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## TOLL MANUFACTURING AGREEMENT

This **TOLL MANUFACTURING AGREEMENT** (together, with the exhibits, the "Agreement") dated as \_\_\_\_\_, 2011 ("Effective Date") is made between **SUCAMPO MANUFACTURING & RESEARCH, AG**, a Swiss company (hereinafter "**SMR**") and **R-TECH UENO, LTD.**, a Japanese company (hereinafter "**RTU**"). SMR and RTU hereinafter collectively referred to as "**Parties**".

### **W I T N E S S E T H:**

**WHEREAS**, SMR is or intends to be engaged in the development, marketing, distribution and sale of the Products (as defined below) pursuant to the terms and conditions set forth in the Unoprostone License Agreement (as defined below);

**WHEREAS**, SMR, for the purpose of its manufacture of the Products pursuant to the Unoprostone License Agreement, intends to use its employees in Switzerland to engage in various aspects of the manufacture of the Products as well as direct and control the manufacturing of the Products by RTU at its facility in Japan;

**WHEREAS**, RTU is engaged in the development, formulation, testing, manufacture and distribution of pharmaceutical products and manufactures the Products in Japan;

**WHEREAS**, SMR and RTU are affiliated companies through the majority ownership of the founders of Sucampo Pharmaceuticals, Inc., the parent of SMR, and RTU; and

**WHEREAS**, SMR desires RTU to toll manufacture the Products for SMR, and RTU desires to do so, on the terms and conditions set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing and of the representations, warranties and mutual covenants contained in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which each Party acknowledges, the Parties, intending to be legally bound, agree as follows:

### **I. DEFINITIONS**

"**Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder.

"**Affiliate**" means any corporation or other business entity that, directly or indirectly, is controlled by or is under common control with another corporation or business entity. For this purpose, "control" shall be deemed to mean ownership of fifty percent (50%) or more of the stock or other equity of such entity.

"**API**" means the "Active Pharmaceutical Ingredient" or the active compound present in a particular Product.

"**cGMPs**" means the current good manufacturing practices for finished pharmaceuticals as set forth in 21 C.F.R. 210, 211, and 10, as hereafter amended, applicable to the manufacture of

the Products and specified by FDA and EMEA, and similar European regulatory authorities, as applicable.

"Components" means the raw material, excipients and any other in-process material caused to be furnished by SMR necessary to formulate or make the Products (excluding, for the avoidance of doubt, API and utilities, but including all packaging materials).

"Confidential Information" means any non-public information, whether oral, written, visual or otherwise, disclosed, either directly or indirectly, by one Party or any of its Affiliates or to the other Party, including requests for proposals, requests for information, project plans, analysis, research, price lists, product lists, Product Information, technical information, processes, methods, ideas, business plans and strategies, forecasts, employee and vendor information, except any portion thereof which (a) at the time of disclosure, is public knowledge; (b) after disclosure, becomes public knowledge by publication or otherwise, except by breach of this Agreement by the recipient; (c) the recipient can demonstrate by its written records was in the recipient's possession at the time of such disclosure, and which was not acquired, directly or indirectly, from the disclosing Party or any of its Affiliates; (d) is lawfully disclosed to the recipient on a non-confidential basis by a third party who is not obligated to the disclosing Party or any other third party to retain such Confidential Information in confidence; or results from research and development by the recipient independent of such disclosure as shown by competent evidence.

"Defect" means in respect of Products, failure to conform to the applicable Specifications or failure to meet the agreed quality as set forth in the Quality Agreement or, if applicable, in a separate quality agreement.

"Delivering Schedule" shall mean the quantity of Product and anticipated delivery date set forth in the Purchase Order furnished by SMR and delivered to RTU as set forth in Section 2.3.

"Effective Date" shall mean the date stated in the first paragraph of this Agreement applicable to a particular product.

"EMA" means the European Agency for the Evaluation of Medicinal Products.

"Finished Product" means Product that has been formulated, compounded, filled into containers, labeled and placed in final commercial packaging over which SMR had exercised oversight, direction, management and control.

"FDA" means the U.S. Food and Drug Administration, or any successor entity thereto.

"Forecasted Needs" means SMR's estimate of Products to be ordered from RTU for each of the twelve (12) months following the month in which such estimate is provided.

"Governmental Entity" means any (a) government; (b) court, arbitral or other tribunal or governmental or quasi-governmental authority of any nature (including any governmental agency, political subdivision, instrumentality, branch, department, official or entity); or (c) body

exercising, or entitled to exercise, any administrative, executive, judicial or legislative, police, regulatory, or taxing authority or power of any nature pertaining to government.

"Intellectual Property" means, in addition to the definition of the Intellectual Property Rights in the Unoprostone License Agreement, Trademarks, trade dress, copyrights, Know-How, Patents, Confidential Information and other intellectual property rights related to the Products over which SMR exercises oversight, direction, management or control.

"Know-How" means, in addition to the definition in the Unoprostone License Agreement, as the term is defined in the Sucampo Agreements over which SMR exercises oversight, direction, management or control.

"Label", "Labeled", or "Labeling" means (a) all labels and other written, printed or graphic matter placed upon any Product or any container, (b) any wrapper utilized with Product, or (iii) any written material accompanying Product.

"Law" means any law (including the Act), statute or ordinance, or any rule, regulation, or published guidelines promulgated by any Governmental Entity.

"Manufacturing Fee" means the fee paid by SMR to RTU for services required to manufacture and package Products in accordance with cGMPs. The Manufacturing Fee shall be quoted in single final Product unit increments (*i.e.*, by the bottle or tube) determined in accordance with Section      below.

"Material Safety Data Sheet" or "MSDS" means written or printed material concerning a hazardous chemical which is prepared in accordance with the regulations promulgated by the U.S. Occupational Safety and Health Administration, or any successor entity thereto.

"Packaging" means all primary containers, cartons, shipping cases, inserts or any other like material used in packaging or accompanying a Product.

"Patents" means the term as defined in the Sucampo Agreements.

"Pharmaceutical Quality Agreement" means the Pharmaceutical Quality Agreement, dated on or around the Effective Date and attached hereto as Schedule     .

"Products" means the products listed on Schedule A.

"Quality Agreement" means the form of quality assurance/quality control agreement, as amended, entered into by SMR and RTU and attached as Appendix C.

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

"RTU's SOPs" means RTU's step-by-step standard operating procedures for manufacturing the Products and discharging its other obligations under this Agreement, all in compliance with Law and cGMPs.

"Similar Product" means, with respect to any Product, a product intended to be substitutable for such Product that (a) contains substantially similar ingredients in substantially similar quantities, and (b) is indicated for substantially similar purposes.

"Standard Cost" means RTU's average actual cost of raw materials *plus* incoming freight *plus* yield loss adjustment.

"Specifications" means, with respect to any Product (a) raw material specifications (including chemical, microbiology and packaging specifications), (b) sampling requirements (*i.e.*, lab, chemical and microbiology), (c) compounding module, including compounding process and major equipment, (d) intermediate specifications, (e) packaging module (including packaging procedures, torque and fill weights), and (f) finished Product specifications release criteria including RTU's Acceptable Quality Limits. Specifications shall be established by SMR or amended from time to time through the collaboration of SMR and RTU through the written agreement of the parties by way of a written Product or Process Change Request ("PCR") in accordance with Section   .

"Sucampo Agreements" means the following agreements: Unoprostone NDA Transfer, Patent and Know-how Licensing, and Data Sharing Agreement dated April 23, 2009, Unoprostone Exclusive Manufacturing and Supply Agreement dated April 23, 2009, and Technology Assignment and License Agreement dated February 2009.

"Trademarks" means the term as defined in the Sucampo Agreements.

"Unoprostone License Agreement" means the Exclusive License for Development and Commercialization of Unoprostone, dated as of March 22th, 2011, by and between RTU and SMR. "Validation Batch" means those batches of product necessary for process validation as set forth in the Guideline on General Principles of Process Validation, May 1987, as amended.

## **II. PRODUCT MANUFACTURE AND SUPPLY**

### **2.1 Grant of License**

To the extent RTU has not already done so, promptly after the date of this Agreement, RTU shall make available to SMR the Intellectual Property not previously made available to SMR, and which RTU determines is necessary for SMR to perform its obligations hereunder or which SMR reasonably requests for such purpose. Likewise, to the extent SMR has not already done so, promptly after the date of this Agreement, SMR shall make available to RTU the Intellectual Property not previously made available to RTU, and which SMR determines is necessary for RTU to perform its obligations hereunder or which RTU reasonably requests for such purpose. All Intellectual Property previously made available by RTU to SMR, and vice versa, shall be deemed to have been done pursuant to the terms of this Agreement. The Parties acknowledge and agree that the Intellectual Property made available by RTU and/or SMR in accordance with this Section 2.1, if any, belongs to the respective party furnishing the

Intellectual Property and shall continue to belong to such party during and after the Term of this Agreement. Notwithstanding the foregoing, SMR shall at all times retain general oversight and control regarding the use of the Intellectual Property as it pertains to the manufacture and distribution of the Products.

## **2.2 Manufacture**

Subject to the terms and conditions of this Agreement, RTU agrees to toll manufacture at its facility in Japan 100% of SMR's requirements for the Product to SMR on the terms and conditions set forth herein. RTU shall manufacture Products in accordance with the Specifications established by SMR, Law, cGMPs and this Agreement in sufficient quantity to meet the Delivery Schedule and in sufficient quantity to meet SMR's forecasted needs for the Term of this Agreement.

## **2.3 API and Components.**

(a) SMR will supply or cause RTU to procure, at its expense and in a timely manner, API and Components which meet the its applicable Specifications. Such API and Components shall remain SMR's property also during the time of storage by RTU in its warehouse. SMR shall provide the API and components thirty (30) days prior to scheduled use in production by RTU. All SMR applied materials shall be shipped Delivery Duty Paid (within the meaning of International Commercial Terms) to RTU's facility along with Certificates of Analysis and MSDS sheets relating to the same.

(b) RTU shall store, without charge, all API and Components purchased by SMR and delivered to RTU for use in toll manufacturing under this Agreement in RTU's warehouse segregated from all other materials. Following receipt of the API and Components from SMR at RTU's facility, RTU shall assume responsibility for the safekeeping and for safe handling, and shall reimburse SMR for the replacement cost of any API and Components that are lost, contaminated or destroyed while in RTU's possession due to RTU's negligence or willful misconduct. Legal title to all API and Components in storage at RTU will remain with SMR.

(c) RTU will store the Products safely in its warehouse and keep them ready so that SMR or its agent can pick them up during normal working hours for shipment. SMR remains the owner of the API and Components prior to use in manufacturing. Ownership in the Products shall pass to SMR after the Products have been delivered pursuant to Section \_\_\_ below. SMR shall be allowed to physically access the warehouse at any time to take custody or inventory of the Products, subject to SMR providing prior notification to RTU, which notification can be given by any reasonable means. SMR must follow all RTU policies and procedures while at the warehouse, except where they conflict with SMR's right to possession of the Products. SMR agrees to indemnify RTU for any damage caused by such access.

## **2.4 Forecasted Needs and Purchase Orders**

(a) Upon the execution of this Agreement, and at the end of each month during the Term hereof, RTU shall provide to SMR a forecast of the manufacturing costs and



capacity of the plant and SMR shall provide RTU with specific data as to its Forecasted Needs. It is understood that the forecast of the costs and capacities by RTU will allow SMR to provide RTU with advice and direction with respect to the manufacturing of the Products and its Forecasted Needs. It is understood and agreed that with respect to all Forecasted Needs issued by SMR pursuant to the terms hereof, the forecast for the first three (3) months thereof shall constitute a firm order for Products, regardless of receipt of SMR's actual purchase order. RTU may produce Product up to thirty (30) days prior to the requested delivery date in order to accommodate fluctuations in production demands.

(b) Products shall be ordered by SMR by the issuance of separate, pre-numbered purchase orders in increments of full batches. Purchase orders shall designate the Products to be shipped, the quantities of each Product, ship and delivery dates (the "**Delivery Schedule**") and destinations. Any terms proposed by RTU in any purchase order acknowledgement or confirmation that vary from, conflict with or add materially to the terms of this Agreement are hereby rejected by SMR, and the terms of this Agreement and the Purchase Orders shall govern. Should there be a conflict between this Agreement and any Purchase Order, the terms of the Purchase Order shall govern.

(c) SMR shall issue written purchase orders for Products to RTU at least ninety (90) days prior to the requested delivery dates if the requirements are at or below one hundred twenty-five percent (125%) of the applicable Forecasted Needs, and at least one hundred twenty (120) days prior to the requested delivery dates if the requirements exceed the Forecasted Needs by more than one hundred twenty-five (125%).

## **2.5 Manufacturing Fees**

(a) The Manufacturing Fees to be paid by SMR to RTU shall be listed on Schedule A, as amended from time to time upon agreement in writing by SMR and RTU. The Manufacturing Fee shall include fees for services for inspection of incoming materials, compounding of bulk, packaging Product, testing Product, accredited validation of the testing, making Product ready for shipment and Product documentation (*i.e.*, a copy of the Certificate of Analysis, Accelerated Stability Summary, Real Time Stability Summary, Certificate of Compliance, Stability Protocol, Method Validation, Deviations or Out-of-Specification (OOS), including Corrective and Preventative Action (CAPA), Batch Record Review, MSDS, all other documentation required by the FDA or cGMPs), and completion of all Stability Testing required by cGMPs or by Law, including testing required after termination of this Agreement or the production of any Product. The Manufacturing Fee shall also include, without limitation, any research & development support, package engineering studies, validation support, FDA or other Regulatory Authority audit support, extensive reporting requirements, or additional laboratory testing performed by an outside testing laboratory or testing beyond that required in the Specifications. In addition, the Manufacturing Fee includes warehousing or distribution of finished Product. All the services provided by RTU are subject to the oversight and control of SMR.

(b) The initial Manufacturing Fees to be paid by SMR to RTU are listed in Schedule A. The parties hereto agree that the Manufacturing Fees set out in Schedule A shall be

re-negotiated, in good faith, at the beginning of each calendar year. In addition, Manufacturing Fees are based on annual volumes for Products. RTU reserves the right to re-evaluate Manufacturing Fees at the beginning of the second year of the Agreement (and each year thereafter) in the event that actual volumes differ from those forecasted by more than ten percent (10%). If the parties are unable to agree on a re-negotiated price at least thirty (30) days prior to the start of a new twelve (12) month period, then this Agreement, effective the first day of January of the new twelve (12) month period, shall continue in force with prices being adjusted to reflect the change in the most recently published monthly "Producer Price Index for the Pharmaceutical Sector", issued by the Bureau of Labor Statistics, US Department of Labor ("PPI"), or comparable successor index, during the preceding twelve (12) month period until such time as to when price negotiation can be completed. Prices for new Products or new Product sizes, not initially included in Schedule A, shall be negotiated and RTU and SMR shall arrive at a mutually agreed prices at the time said new Products or new product sizes are added to Schedule A. If a negotiated price cannot be agreed upon, final pricing for any of the above will be in accordance with paragraph 13.6 (b) below. Provided however, the Manufacturing Fee charged by RTU for the toll manufacture of the Product shall not exceed the lowest manufacturing fees charged by RTU to any other customer for the Product or similar Product.

## **2.6 Invoices; Payment**

Payment for all deliveries of Product and services shall be made in U.S. dollars, net thirty (30) days. Invoices shall be dated as of the date the Product is shipped from RTU or placed in storage pursuant to Section 3.1. Total invoice shall be equal to the quantity of Product shipped multiplied by the Total Price per unit listed on Schedule A effective on the date of Product is shipped.

## **2.7 Packaging and Labeling**

SMR shall provide RTU with Specifications (including art proofs) for Packaging and Labeling, and RTU shall purchase, at the expense of RTU, Packaging and Labeling in accordance with the Specifications. SMR is responsible for the Finished Product and for the shipment of the Finished Product as noted below in Section 3.1.

## **2.8 New Product Sizes**

Prices for new Product sizes, not initially included in Schedule A, shall be negotiated in good faith by SMR and RTU. If a negotiated price cannot be agreed upon within thirty (30) days, SMR shall be permitted to retain another manufacturer to manufacture such Product.

# **III. SHIPMENT AND RISK OF LOSS**

## **3.1 Shipment/Delivery Terms**

Shipment of Product shall be in accordance with SMR instructions. Delivered Duty Paid (within the meaning of International Commercial Terms [Incoterms]) SMR's facility plant, \_\_\_\_\_ [city], \_\_\_\_\_ [state], freight collect. At SMR's request, RTU will hold Product in RTU's warehouse for a commercially reasonable fee not greater than

the lowest fee charged by RTU to any other customer for storage of products of similar size and bulk. If SMR requests RTU to make small shipments of Product, material, or other items on SMR's behalf, SMR agrees to reimburse RTU for any reasonable shipping charge incurred within thirty (30) days of invoice.

### **3.2 Claims**

The weights, tares and tests affixed by RTU's invoice shall govern unless established to be incorrect. Claims relating to quantity, weight and loss or damage to any shipment of Product sold under this Agreement shall be waived by SMR unless made within sixty (60) days of receipt of Product by SMR or SMR's designee.

### **3.3 Failure to Supply**

RTU shall notify SMR immediately if RTU is unable to supply the quantity of Product ordered by SMR in accordance with the Client Delivery Schedule, stating in such notice the reason for such inability and its reasonable estimate of the amount of Product that it will be able to supply and the anticipated schedule for delivery of such Product. SMR's receipt and acknowledgement of such notice shall not be deemed as a waiver by SMR of rights SMR may have under this Agreement.

Provided that a late delivery is not due to SMR's breach of its obligations or duties pursuant to this Agreement, if RTU fails to deliver the Products in accordance with the Delivery Schedule or otherwise agreed between the Parties in writing, SMR is allowed to invoice RTU for the following amounts of the Standard Price for the Products that have not been delivered on time at the end of the calendar year in which the Products should have been delivered: 1-2 weeks delay 5%; 2-4 weeks delay: 10%; 4-8 weeks delay: 15%; more than 8 weeks delay: 20% ("Late Fee").<sup>1/4</sup>

## **IV. TERM AND TERMINATION**

### **4.1 Term**

Except as set forth in 4.2 and 4.3 below, this Agreement shall commence on the Effective Date and shall continue for an initial term no charge of three (3) years and thereafter shall automatically renew for additional two (2) years term unless either Party provides written notice to the other Party at least one hundred eighty (180) days prior to the expiration of the then current term.

### **4.2 Termination for Convenience**

This Agreement may be terminated for convenience at any time by SMR by providing RTU at least ninety (90) days prior written notice.

### **4.3 Termination for Breach or Unfavorable Tax Treatment**

This Agreement may be terminated at any time by either Party upon the occurrence of either of the following events:

(a) Breach of this Agreement (including but not limited to breach of the Pharmaceutical Quality Agreement) that is not cured within fifteen (15) days of notice of breach by either Party if the other Party (i) declares itself insolvent or is adjudged by a court of competent jurisdiction to be insolvent, (ii) makes or attempts to make an assignment for the benefit of creditors, (iii) dissolves, liquidates or enters into receivership, (iv) becomes the subject of voluntary or involuntary bankruptcy proceedings, and such proceedings are not dismissed within sixty (60) days, or if this Agreement or the rights hereunder are conveyed out of bankruptcy, or (v) the parties are unable to obtain a favorable tax ruling on the transaction as structured. [Parties to discuss a tax ruling].

(b) This Agreement may be terminated by either party if the parties are unable to obtain a favorable tax ruling on the structure of the transactions. Furthermore, SMR shall indemnify RTU from and against any increase in its tax burden, including tax penalties or interest thereon, incurred by RTU as a result of entering into, or performing its obligations under, this Agreement in excess of RTU's tax burden for selling the Product or Similar Products under the current arrangement with Sucampo Pharma Americas, Inc., a subsidiary of Sucampo Pharmaceuticals, Inc. [Discuss a letter ruling]

Termination shall be in addition to any other rights and remedies a non-defaulting Party may have at law or in equity.

#### **4.4 Payment upon Termination**

In the event of the termination of this Agreement for any reason other than RTU's breach hereof, and without prejudice to any other rights and remedies available to RTU hereunder or at law or in equity, (a) RTU shall manufacture for SMR all Products for which RTU has open purchase orders from SMR as of the date of notice of termination, and SMR shall make payments hereunder for such Products manufactured by RTU, and (b) SMR shall reimburse RTU at Standard Cost for any raw materials ordered specifically for the manufacture of Products based on the Delivery Schedule and for which RTU can find no reasonable alternative use (but only if such orders are non-cancelable and non-refundable by the supplier thereof. Within thirty (30) days of such termination, RTU shall furnish SMR with a statement of all items to be reimbursed pursuant to this Section 4.4 and shall ship at SMR's direction and expense any such raw materials for which RTU seeks reimbursement. SMR shall pay such invoices within thirty (30) days.

### **V. REGULATORY COMPLIANCE; Pharmaceutical Quality Agreement**

#### **5.1 Certificates of Analysis**

Pursuant to the Pharmaceutical Quality Agreement, RTU shall send one (1) Certificate of Analysis to SMR at least three (3) business days prior to the time of shipment of such Product to SMR.

#### **5.2 Pharmaceutical Quality Agreement**

RTU and SMR shall comply with their respective obligations set forth in the Pharmaceutical Quality Agreement (which is incorporated by reference herein). In the

event of a conflict between this Agreement and the Pharmaceutical Quality Agreement, the terms of the Pharmaceutical Quality Agreement control.

### **5.3 Materials Testing**

The cost of all analyses and evaluations of raw materials and packaging supplies required by the Pharmaceutical Quality Agreement shall be borne by RTU, except as otherwise provided in this Agreement. RTU agrees to maintain and, if necessary, make available records of all such analyses and evaluations.

### **5.4 Material Safety Data Sheets**

Prior to RTU's use of any raw materials to be used in connection with this Agreement, RTU shall obtain a MSDS for each raw material. Any raw materials or Products requiring disposal or destruction shall be presumed to be a regulated or hazardous substance unless otherwise indicated in the MSDS.

### **5.5 FDA Inspection**

The Parties agree that any validation work outside the Validation Batches or additional testing of the Product required by any Governmental Entity will be performed by RTU pursuant to a written Project Protocol Agreement establishing methodology and pricing for such services. Such validation work and testing of the Product is subject to the oversight and control of SMR. If additional validation studies or additional testing is required by any Governmental Entity to continue to manufacture any Product and RTU and SMR cannot reach an agreement on a written Project Protocol, SMR will be under no obligation to continue purchasing such Product from RTU.

### **5.6 Regulatory Filings**

SMR agrees to provide RTU with copies of all sections of NDAs, ANDAs, 510(k)'s or other regulatory filings directly or indirectly applicable to the Products, and copies of any changes in or updates of the same as may occur from time to time.

RTU shall advise SMR if an authorized agent of the FDA or other governmental agency visits RTU's manufacturing facility and requests or requires information or changes which directly pertain to the Products. FDA audit time specific to Products will be billed to SMR from RTU at the then-prevailing QA hourly rate.

## **VI. WARRANTIES**

### **6.1 Conformity with Specifications**

RTU represents and warrants that all Products shall conform to the Specifications (or to exceptions thereto approved in writing by SMR prior to the time shipment).

## **6.2 Compliance of Specifications, Packaging and Labeling with Law**

SMR hereby represents that all Packaging and Labeling copy and artwork approved, designated or supplied by SMR shall be in compliance with Law and cGMPs. SMR represents and warrants that SMR exclusively owns or holds a valid and exclusive license to use all of the intellectual property, if any, contained in or on the Packaging and Labeling that it provides to RTU to manufacture, package and label Products. SMR further represents and warrants that SMR has full power and authority to grant to RTU the right to use such copy and artwork in accordance with this Agreement. SMR represents and warrants that all Packaging and Labeling content included in or on the Packaging and Labeling shall at all times be complete and accurate and shall comply with Law. RTU shall apply all serialized and uniquely identified labels to all Products, cartons and pallets in accordance with Law and as instructed by SMR in writing. RTU shall adhere to the shipping carton label barcode standard set forth on Schedule C.

## **6.3 Disclaimer**

**MANUFACTURER AND COMPANY MAKE NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO PRODUCT, LABELING OR PACKAGING. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED.**

## **VII. REJECTED PRODUCTS; PRODUCT RECALLS**

### **7.1 Rejected Products**

#### **(a) Rejection of Product by SMR**

SMR may reject any Product which fails to meet the Specifications or were not manufactured in accordance with the cGMPs ("Rejected Product"). For defects that are readily discernable, SMR shall, within sixty (60) days after its receipt of any shipment of Product, notify RTU in writing of any claim relating to the Rejected Product. SMR shall notify RTU within ten (10) days of SMR discovery of any defect that is not readily discernable. Such notice shall specify the reason why the Product was rejected. SMR and RTU shall each have the right to inspect or test any Rejected Product. Notwithstanding the foregoing and the other provisions in this Section 7.1, in the event that SMR determines that an accepted Product had a previously undetected defect (including a failure to meet the Specifications or the manufacturing of such Product was not in accordance with cGMPs), SMR shall be permitted to pursue its rights under the remainder of this Section 7.1 and any other remedy SMR may have at law or in equity.

#### **(b) Replacement of Rejected Product**

As to any Rejected Product, RTU shall replace such Rejected Product promptly after all materials are available to RTU. If requested, RTU shall make arrangements with SMR for the return or disposal of Rejected Product.

#### **(c) Responsibility for Costs**

In the event that any Validation Batches or any of initial three (3) registration batches intended for shipment to customers fail to meet Specifications due to SMR supplied information, formulations or materials, SMR shall bear all costs directly related to the Rejected Product, including the Manufacturing Fee and cost of destruction. In the event that any Validation Batches or any of initial three (3) registration batches intended for shipment to customers fail to meet Specifications due to RTU's negligence or error or were not manufactured in accordance cGMPs produced by RTU, RTU shall bear all costs directly related to Rejected Product, including cost of destruction. Thereafter, in the event a Rejected Product is due to the failure of RTU, RTU shall bear all costs directly related to the Rejected Product, including Manufacturing Fee and cost of destruction of Rejected Product. To the extent such failure of RTU is due to SMR supplied information, formulations or materials, SMR shall bear all costs directly related to the Rejected Product, including cost of destruction. In all other circumstances, SMR shall bear all material costs related to the Rejected Product and the cost of destruction of Rejected Product, and RTU shall bear all Manufacturing Fees related to the Rejected Product. Destruction of Rejected Product shall be in accordance with Law. The Party conducting the destruction shall also provide to the other Party all manifests and other applicable evidence of proper destruction as may be required in accordance with Law.

(d) Resolution of Conflict

In the event of a conflict between the test results of RTU and the test results of SMR with respect to any shipment of Product, a sample of such Product's batch shall be submitted by RTU to an independent laboratory acceptable to both Parties for testing against the Specifications developed by SMR employees utilizing the methods set out in the Specifications as provided by SMR. The fees and expenses of such laboratory testing shall be borne entirely by the Party against whom such laboratory's findings are made. If results from the independent laboratory are inconclusive, final resolution will be settled in accordance with Section 13.5(b).

## **7.2 Product Recalls**

As provided in Section 6.4 of the Pharmaceutical Quality Agreement, each Party shall keep the other Party promptly and fully informed of any notification or other information whether received directly or indirectly which might affect the marketability, safety or effectiveness of Products. In the event (a) any Governmental Entity issues a request, directive or order that Product be recalled or (b) SMR reasonably determines after consultation with RTU that the Product should be recalled, the Parties shall take all appropriate corrective actions reasonably requested by such Governmental Entity or the other Party. In the event that such recall is caused by a breach of this Agreement (including the Pharmaceutical Quality Agreement) by RTU, RTU shall be responsible for the expenses of the recall. In the event the recall is not caused by a breach of this Agreement (including the Pharmaceutical Quality Agreement) by RTU, SMR shall be responsible for all expenses of the recall. For the purposes of this Agreement, the expenses of the recall shall include: (i) the expenses of notification to SMR's physicians, consumers and other parties affected by the recall, (ii) the destruction or return of the recalled Product, (iii) the cost of the recalled Product, (iv) the costs of manufacturing and shipping replacement Product to SMR's physicians, consumers and other parties affected by the

recall, and (v) any other costs that the retailers and wholesalers of the recalled Product charge SMR in connection with the recall.

## **VIII. FORCE MAJEURE**

### **8.1 Force Majeure**

Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, which may include fire, floods, embargos, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God, compliance with any court order or regulation of any Governmental Entity acting with color of right or by any other cause beyond the reasonable control of the Parties, whether or not foreseeable.

## **IX. CHANGES TO PROCESS OR PRODUCT**

### **9.1 Changes by SMR**

Subject to the provisions of Section 1.2 of the Pharmaceutical Quality Agreement, any change reasonably requested by SMR (a) shall be incorporated within the manufacturing documents and Specifications by way of a written Process or PCR, subject to consent by RTU, which shall not be unreasonably withheld or delayed, (b) the Parties shall, if necessary, negotiate a commercially reasonable adjusted price for such Product conducted in good faith, and (c) SMR shall pay RTU for the costs associated with such change including any additional development work required, charged at RTU's then-prevailing research and development hourly rates in accordance with Section 11. It is understood that SMR, through its employees, will develop and provide the Specifications and any changes to the Specifications. If a negotiated price is not agreed within thirty (30) days of a request to change the Product or Process, SMR shall be permitted to retain another manufacturer to manufacture such Product.

### **9.2 Changes by RTU**

Subject to the provisions of Section 1.2 of the Pharmaceutical Quality Agreement, the Parties agree that any changes developed by RTU to be incorporated into the Product shall require the written approval of SMR by way of a PCR prior to such incorporation. SMR will oversee and control such changes. At the time of such incorporation, such changes shall become part of the Specifications and Master Batch Records. Any new pricing for such changed Product shall be negotiated in accordance with Section 9.1.

### **9.3 Changes by Regulatory Authorities**

The Parties agree that any changes required by Governmental Entity shall be incorporated into the Product or Process shall require the written approval of SMR and RTU by way of a PCR prior to such incorporation. At the time of such



incorporation, such changes shall become part of the Specifications and Master Batch Records. Any new pricing for such changed Product shall be negotiated in accordance with Section 9.1.

#### **9.4 Obsolete Inventory**

Any inventory (including raw materials, work-in-process and finished Product) rendered obsolete as a result of a Product changed pursuant to this Section 9 shall be shipped and reimbursed in accordance with Section 4.4.

### **X. CONFIDENTIALITY; INTELLECTUAL PROPERTY; NON-SOLICITATION**

#### **10.1 Confidentiality**

##### **(a) Obligations of Confidentiality**

All Confidential Information furnished by one Party to the other Party, both orally or in tangible format, during the term of this Agreement shall be kept confidential by the receiving Party, shall not be used by the receiving Party except for purposes authorized by this Agreement, and shall not be disclosed to any person or firm, unless previously authorized in writing to do so, all for a period of not less than five (5) years following the date of disclosure. Trade Secrets of a party shall not be disclosed or used by the other Party until the information is no longer a Trade Secret under applicable law. The receiving Party may, however, disclose the same to its responsible officers and employees who require such information for the purposes contemplated by this Agreement, provided that such officers and employees are subject to comparable obligations of confidentiality.

##### **(b) Exceptions**

Any other provisions hereof to the contrary notwithstanding, the confidentiality and non-use obligations herein assumed shall not apply to any information which:

- (i) is at the time of disclosure or thereafter becomes a part of the public domain through no fault of the receiving Party;
- (ii) was otherwise in the receiving Party's lawful possession prior to disclosure as shown by its written record;
- (iii) is thereafter disclosed to the receiving Party by a third party not in violation of an obligation of confidentiality to the disclosing Party relative to such information;
- (iv) is by mutual agreement of the Parties released from a confidential status; or
- (v) is required to be disclosed by any Governmental Entity pursuant to regulatory or legal requirements.

## **10.2 Intellectual Property**

### **(a) Trademarks and Trade Names**

Each Party hereby acknowledges that it does not have, and shall not acquire, any interest in any of the other Party's trademarks or trade names unless otherwise expressly agreed to in writing. Each Party agrees not to use any trade names or trademarks of the other Party in any advertising, promotions, marketing, or labeling of the Product or otherwise, except as specifically authorized by the other Party in writing both as to the names or marks which may be used and as to the manner and prominence of use.

## **XI. INDEMNIFICATION**

### **11.1 Indemnification by RTU**

RTU shall indemnify and hold SMR, its officers, directors, equity holders, employees and agents, harmless from and against any and all suits, claims, demands, liability, damage, loss, cost, or expenses (including reasonable attorney's fees) caused by, resulting from or arising out of any third party claims made or suits brought against SMR which arise out of (a) RTU's breach of the representations, warranties and covenants set forth in this Agreement or the Pharmaceutical Quality Agreement, or (b) any negligence on the part of RTU, including any suit or action brought against SMR based upon a claim that any process or technical data furnished by RTU infringes any patent, copyright or other proprietary rights of a third party.

### **11.2 Indemnification by SMR**

SMR shall indemnify and hold RTU, its officers, directors, equity holders, employees and agents harmless from and against any and all suits, claims, demands, liability, damage, loss, cost or expense (including reasonable attorney's fees) caused by, resulting from or arising out of any third party claims made or suits brought against RTU which arise out of (a) the promotion, distribution, sale or use by SMR of an item or items of the Products which RTU manufactured hereunder and which at the time of delivery to SMR complied with the Specifications and the applicable representations, warranties and covenants set forth in this Agreement or the Pharmaceutical Quality Agreement, or (b) any negligence on the part of SMR, including claims that Products or the labeling thereof or inserts therefore or the use of the Product names and any other trademarks, trade names or trade dress used by SMR in connection with Products infringes patent, copyright or other proprietary rights of a third party.

### **11.3 Indemnification Procedures**

A Party that intends to claim indemnification under Section 12.1 or 12.2 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") in writing of any claim, demand, action or other proceeding for which the Indemnitee intends to claim indemnification; *provided, however*, that the failure to provide written notice of such claim within a reasonable period of time will not relieve the Indemnitor of any of its obligation hereunder, except to the extent that the Indemnitor is prejudiced by such failure to provide prompt notice. The Indemnitor shall have the right to participate in, and to the extent the Indemnitor so desires to assume the defense thereof with counsel selected by the Indemnitor; *provided, however*, that the Indemnitee,

shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor, if representation of the Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceedings. The Indemnitor may not settle or otherwise consent to an adverse judgment in any such claim, demand, action or other proceeding, that diminishes the rights or interests of the Indemnitee without the prior express written consent of the Indemnitee, which consent shall not be unreasonably withheld or delayed, unless (a) there is no finding or admission of any violation of Law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee and (b) the sole relief provided is monetary damages that are paid in full by the Indemnitor.

#### **11.4 Evidence of Liability Insurance**

Each Party shall maintain with a financially sound and reputable insurer throughout the term of this Agreement comprehensive general liability insurance, including product liability insurance with liability limits of at least Five Million Dollars (\$5,000,000) per occurrence and in the aggregate. Each Party shall name the other Party as a vendor under the broad form vendor endorsement on its policy and provide the other Party with such evidence thereof as is reasonably requested by the other Party from time to time. Such insurers shall warrant that such insurance will not be changed or canceled without at least thirty (30) days prior written notice to the respective indemnities. The Parties agree that upon first approval by FDA for commercialization of any Products covered by this Agreement, insurance coverage will be re-evaluated and, if necessary, adjusted to levels that are acceptable to both Parties.

## **XII. GENERAL PROVISIONS**

### **12.1 Notices**

Any notices permitted or required by this Agreement shall be sent by certified or registered mail, by recognized overnight carrier or by fax and shall be effective the earlier of the date actually received or three (3) days after deposit in the U.S. mail, if sent and addressed as follows or to such other address as may be designated by either Party in writing:

If to RTU: R-Tech Ueno, Ltd  
Attention: President  
[address]

With a copy to:

[address]

If to SMR: SMR Manufacturing & Research  
Attention: President  
[address]

With a copy to:

[address]

## **12.2 Entire Agreement; Amendment**

The Parties acknowledge that this Agreement (including the schedules hereto) and the Pharmaceutical Quality Agreement set forth the entire agreement and understanding of the Parties and supersedes all prior written or oral agreements or understandings with respect to the subject matter hereof and thereof, and shall supersede any conflicting portions of RTU's quotation, acknowledgement and invoice forms and SMR's purchase orders and other written forms. No modification of any of the terms of this Agreement, or any amendments hereto, shall be deemed to be valid unless in writing and signed by the Parties. No course of dealing or usage of trade shall be used to modify the terms and conditions hereof.

## **12.3 Waiver**

No waiver by either Party of any default shall be effective unless in writing, nor shall any such waiver operate as a waiver of any other default or of the same default on a future occasion.

## **12.4 Assignment**

Neither Party may assign its rights or delegate its obligations under this Agreement without the express prior written consent of the other Party, which consent will not be unreasonably withheld; *provided, however*, that SMR's rights and obligations may succeed by operation of law to the surviving entity in a merger or consolidation in which it participates or to a successor of all or substantially all of SMR's assets or equity interests. Any unauthorized assignment or transfer of this Agreement shall be void. Subject to the foregoing, the rights and liabilities of the Parties will bind and inure to the benefit of their respective successors, permitted assigns, insurers and reinsurers. Any assignments, including sale, transfer, or license of brand or Products, shall not release the original Party from its duties and obligations under this Agreement.

## **12.5 Governing Law and Arbitration**

### **(a) Governing Law**

This Agreement shall be governed and construed in accordance with the internal laws of the State of New York, and without regard to its choice of law rules. The rights and obligations of the Parties hereunder shall not be governed by the provisions of the 1980 U.N. Consortium on Contracts for International Sale of Goods or the related convention on the Limitations Period in the International Sale of Goods.

### **(b) Arbitration**

Any controversy, dispute or claim arising out of, in connection with, or in relation to the interpretation, performance or breach of this Agreement, or any amount due hereunder,

including any claim based on contract, tort or statute shall be settled as follows: Either RTU or SMR may request that the chief executive officer of each RTU and SMR meet to attempt to resolve such dispute. If the chief executive officers cannot resolve such disputes within seven (7) days after either RTU or SMR requests such a meeting, then such controversy, dispute or claim shall be settled, solely and exclusively, by arbitration. Any arbitration pursuant to this Agreement shall be conducted in New York City, New York USA, before and in accordance with the then existing Commercial Dispute Resolution Procedures through the American Arbitration Association, using an arbitrator mutually selected by RTU and SMR from a list of those designated by the American Arbitration Association or, if the Parties disagree, otherwise appointed by the American Arbitration Association. At any time, either RTU or SMR may seek or obtain preliminary, interim or conservatory measures from the arbitrators or from any court as provided below. Any arbitration shall be final and binding. The findings shall be delivered in a written opinion with findings of fact based on the record. Any judgment upon any interim or final award or order rendered by the arbitrator may be entered by any State or Federal court having jurisdiction thereof. The Parties intend that any agreement pursuant hereto to arbitrate be valid, enforceable and irrevocable. Each Party in any arbitration proceeding commenced hereunder shall bear such Party's own costs and expenses (including expert witness and attorneys' fees) of investigating, preparing and pursuing such arbitration claim. Notwithstanding anything else contained in this Section 13.5 to the contrary, pending arbitration of the claims, either Party may seek injunctive relief in any state or federal court sitting within New York City, New York, USA, to preserve the status quo and prevent irreparable harm from breach or anticipated breach of this Agreement.

#### **12.6 Severability**

If any provision of this Agreement or portion thereof is finally held by a court of competent jurisdiction to be unenforceable, void, invalid, or otherwise contrary to law or equity, the Parties agree that such provision or portion thereof shall be reformed automatically as necessary to cure such defect, or if necessary to delete such provision or portion thereof, and that the remainder of this Agreement, and the remainder of this Agreement shall continue in full force and effect.

#### **12.7 Headings; Interpretation**

The headings, used in this Agreement are for convenience only and are not a part of this Agreement. In the event that an ambiguity or a question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement. The definitions of the terms herein shall apply equally to the singular and the plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation".

### **12.8 Counterparts**

This Agreement shall be effective upon full execution by facsimile, electronic signature (including by PDF file) or original, and a facsimile signature or electronic signature shall be deemed to be and shall be as effective as an original signature. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which taken together shall constitute one single agreement between the Parties.

### **12.9 Liability for Actions of Others**

Neither Party shall be liable to any third party for any action taken or for any failure to take any action on the part of the other Party, or for any liability, obligation or commitment incurred by the other Party, except to the extent specifically agreed in writing.

### **12.10 Independent Contractor**

In performing its services hereunder, RTU shall act as an independent contractor. Neither Party shall be the agent of the other Party for any purpose whatsoever, or shall have any power or authority to make or give any promise, warranty or representation, to execute any contract or otherwise create, issue or assume any liability, obligation or commitment in the name of or on behalf of the other Party, except to the extent specifically authorized in writing by the other Party.

*[remainder of page intentionally left blank]*

IN WITNESS WHEREOF, the Parties have each caused this Manufacturing Agreement to be executed by their duly authorized representatives as of the date first above written.

**SUCAMPO MANUFACTURING &  
RESEARCH, AG:**

**R-TECH UENO, LTD:**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_



Schedule A  
Products & Manufacturing Fees

D





**Schedule B**

**Pharmaceutical Quality Agreement**

## Schedule C

### Barcode Format Details

The barcoded date shall consist of 2 barcodes. The primary barcode contains the NDC/UPC number and case size (the case size can be from 2 to 5 digits) using the Code 128 format and just the NDC/UPC number using the interleaved 2 of 5 format. The secondary barcodes contains the case size, expiration date and lot number using the Code 128 format. RTU shall consistently barcode Products using the same length for the case size (i.e., always use either the 2 or 5 digits).

The size of the narrowest bar and the narrowest white space should be a minimum of 15 mils and the quality of the barcode should be a minimum Grade of B.

The coding technique is as follows:

Primary Code:       Either interleave 2 of 5 or Code 128 format  
                          01PUUNNNNNNNNNX3OCCCCC  
                          (with the quantity can be anywhere from 2 to 5 digits in length)

Secondary Barcode: Code 128 format  
                          22QCCCCMMYYLLLLLLLLLLZ

Where:

- P = Packaging level indicator (Use 3 if level is not known)
- U = UPC Prefix (generally 03 if your NDC number is preceded by a 3)
- N = NDC or UPC number (10 digits)
- X = Mod 10 check digit on the NDC or UPC number
- Q = 8 indicates a 2 digit case quantity; 9 indicates a 5 digit case quantity
- C = Case quantity (in eases, either 2 or 5 digits based upon the value of Q above)
- M = Expiration date month (2 digit month)
- Y = Expiration date year (2 digit year)
- L = Lot number (State the minimum number of characters/digits in the lot number)
- Z = Link character (which has the same value as "X"/Mod 10 check on the NDC/UPC number)

If the item does not have an expiration date, then fill the date with '0000'.

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**Exhibit B Licensed Patents**

| Country        | Application No | Filing Date | Publication No | Publication Date | Patent No | Issue Date | Expiration date |
|----------------|----------------|-------------|----------------|------------------|-----------|------------|-----------------|
| United Kingdom | 8830931.5      | 1988/4/29   | 289349         | 1988/11/2        | 289349    | 1992/4/29  | 2013/4/28       |
| FRANCE         | 8830931.5      | 1988/4/29   | 289349         | 1988/11/2        | 289349    | 1992/4/29  | 2013/4/28       |
| Germany        | 8830931.5      | 1988/4/29   | 289349         | 1988/11/2        | 289349    | 1992/4/29  | 2013/4/29       |
| Netherlands    | 8830931.5      | 1988/4/29   | 289349         | 1988/11/2        | 289349    | 1992/4/29  | 2013/4/28       |
| Sweden         | 8830931.5      | 1988/4/29   | 289349         | 1988/11/2        | 289349    | 1992/4/29  | 2013/4/29       |
| Spain          | 8830931.5      | 1988/4/29   | 289349         | 1988/11/2        | 289349    | 1992/4/29  | 2013/4/29       |
| Switzerland    | 88308299.2     | 1988/9/8    | 308135         | 1989/3/22        | 308135    | 1992/11/19 | 2013/9/8        |
| United Kingdom | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| FRANCE         | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Germany        | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Italy          | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Netherlands    | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Switzerland    | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Belgium        | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Austria        | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Luxembourg     | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Sweden         | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Spain          | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| Greece         | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| DEMARM         | 91304574.6     | 1991/5/21   | 458588         | 1991/11/27       | 458588    | 1994/11/30 | 2011/5/21       |
| United Kingdom | 91304576.1     | 1991/5/21   | 458590         | 1991/11/27       | 458590    | 1996/1/10  | 2011/5/21       |
| FRANCE         | 91304576.1     | 1991/5/21   | 458590         | 1991/11/27       | 458590    | 1996/1/10  | 2011/5/21       |

| Country        | Application No | Filing Date | Publication No | Publication Date | Patent No  | Issue Date | Expiration date |
|----------------|----------------|-------------|----------------|------------------|------------|------------|-----------------|
| Germany        | 91304576.1     | 1991/5/21   | 458590         | 1991/11/27       | 458590     | 1996/1/10  | 2011/5/21       |
| United Kingdom | 92301412.0     | 1992/2/20   | 501678         | 1992/9/2         | 501678     | 1996/5/1   | 2012/2/20       |
| Germany        | 92301412.0     | 1992/2/20   | 501678         | 1992/9/2         | 501678     | 1996/5/1   | 2012/2/20       |
| FRANCE         | 92301412.0     | 1992/2/20   | 501678         | 1992/9/2         | 501678     | 1996/5/1   | 2012/2/20       |
| United Kingdom | 92307700.2     | 1992/8/24   | 561073         | 1993/9/22        | 0561073    | 2001/10/24 | 2012/8/24       |
| Germany        | 92307700.2     | 1992/8/24   | 561073         | 1993/9/22        | 0561073    | 2001/10/24 | 2012/8/24       |
| FRANCE         | 92307700.2     | 1992/8/24   | 561073         | 1993/9/22        | 0561073    | 2001/10/24 | 2012/8/24       |
| Sweden         | 98945530.8     | 1998/9/30   | 0979652        | 2000/2/16        | 0979652    | 2006/5/24  | 2018/9/30       |
| Switzerland    | 98945530.8     | 1998/9/30   | 0979652        | 2000/2/16        | 0979652    | 2006/5/24  | 2018/9/30       |
| Spain          | 98945530.8     | 1998/9/30   | 0979652        | 2000/2/16        | 0979652    | 2006/5/24  | 2018/9/30       |
| HongKong       | 00103455.2     | 1998/9/30   | 1024170        | 2000/10/5        | 1024170    | 2006/10/20 | 2018/9/30       |
| Denmark        | 98945530.8     | 1998/9/30   | 0979652        | 2000/2/16        | 0979652    | 2006/5/24  | 2018/9/30       |
| Germany        | 98945530.8     | 1998/9/30   | 0979652        | 2000/2/16        | 0979652    | 2006/5/24  | 2018/9/30       |
| FRANCE         | 98945530.8     | 1998/9/30   | 0979652        | 2000/2/16        | 0979652    | 2006/5/24  | 2018/9/30       |
| United Kingdom | 98945530.8     | 1998/9/30   | 0979652        | 2000/2/16        | 0979652    | 2006/5/24  | 2018/9/30       |
| Netherlands    | 98945530.8     | 1998/9/30   | 0979652        | 2000/2/16        | 0979652    | 2006/5/24  | 2018/9/29       |
| Australia      | 2001239551     | 2001/3/23   | 2001239551     | 2005/7/21        | 2001239551 | 2005/11/4  | 2021/3/23       |
| New Zealand    | 521464         | 2001/3/23   | 521464         | 2004/9/24        | 521464     | 2005/1/13  | 2021/3/23       |
| United Kingdom | 01914192.8     | 2001/3/23   | 1267882        | 2003/1/2         | 1267882    |            | 2021/3/23       |
| FRANCE         | 01914192.8     | 2001/3/23   | 1267882        | 2003/1/2         | 1267882    |            | 2021/3/23       |
| Germany        | 60138371.0     | 2001/3/23   | 1267882        | 2003/1/2         | 1267882    |            | 2021/3/23       |
| Argentina      | P010101231     | 2001/3/16   | 029818         | 2003/7/16        |            |            |                 |
| Australia      | 20021241143    | 2001/3/15   |                |                  | 2001241143 | 2005/12/9  | 2021/3/15       |

| Country        | Application No   | Filing Date | Publication No   | Publication Date | Patent No | Issue Date | Expiration date |
|----------------|------------------|-------------|------------------|------------------|-----------|------------|-----------------|
| New Zealand    | 521325           | 2001/3/15   |                  |                  | 531235    | 2004/9/9   | 2021/3/15       |
| South Africa   | 2002/7140        | 2001/3/15   |                  |                  | 2002/7140 | 2003/4/30  | 2021/3/15       |
| Brazil         | PI0109192        | 2001/3/15   | PI0109192        | 2003/5/27        |           |            |                 |
| Mexico         | PA/A/2002/008967 | 2001/3/15   |                  |                  | 233584    | 2006/1/9   | 2021/3/15       |
| Israel         | 151683           | 2001/3/15   | 151683           | 2010.10.31       | 151683    | 2011.02.01 |                 |
| Czechoslovakia | PV2002-3092      | 2001/3/15   |                  |                  |           |            |                 |
| Norway         | 20024381         | 2001/3/15   |                  |                  |           |            |                 |
| EPC            | 0912374.4        | 2001/3/15   | 1272194          | 2003/1/18        |           |            |                 |
| Australia      | 48003/96         | 1996/3/8    | 701620           | 1999/2/4         | 701620    | 1999/5/20  | 2016/3/8        |
| New Zealand    | 286141           | 1996/3/8    | 286141           | 1999/10/28       | 286141    | 2000/7/13  | 2016/3/8        |
| Norway         | 19960974         | 1996/3/8    |                  |                  | 310178    | 2001/6/5   | 2016/3/8        |
| United Kingdom | 96301637.3       | 1996/3/11   | 730866           | 1996/9/11        | 730866    | 2003/2/19  | 2016/3/11       |
| Germany        | 96301637.3       | 1996/3/11   | 730866           | 1996/9/11        | 730866    | 2003/2/19  | 2016/3/11       |
| FRANCE         | 96301637.3       | 1996/3/11   | 730866           | 1996/9/11        | 730866    | 2003/2/19  | 2016/3/11       |
| Spain          | 96301637.3       | 1996/3/11   | 730866           | 1996/9/11        | 730866    | 2003/2/19  | 2016/3/11       |
| Italy          | 96301637.3       | 1996/3/11   | 730866           | 1996/9/11        | 730866    | 2003/2/19  | 2016/3/11       |
| Sweden         | 96301637.3       | 1996/3/11   | 730866           | 1996/9/11        | 730866    | 2003/2/19  | 2016/3/11       |
| EPC            | 04720157.9       | 2004/3/12   | 1661573          | 2006/5/31        |           |            |                 |
| EPC            | 07738306.5       | 2007/3/12   | 1994933          | 2008/11/26       |           |            |                 |
| Russia         | 2008140298       | 2007/3/12   | 2008140298       | 2010.04.20       |           |            |                 |
| India          | 5478/CHENP/2008  | 2007/3/12   |                  |                  |           |            |                 |
| Mexico         | MX/A/2008/011709 | 2007/3/12   | MX/A/2008/011709 | 2008/10/31       |           |            |                 |
| Brazil         | PI 0708891-4     | 2007/3/12   |                  |                  |           |            |                 |

| Country     | Application No    | Filing Date | Publication No | Publication Date | Patent No | Issue Date | Expiration date |
|-------------|-------------------|-------------|----------------|------------------|-----------|------------|-----------------|
| Australia   | 2007225798        | 2007/3/12   | 2007225798     | 2008/10/9        |           |            |                 |
| New Zealand | 571426            | 2007/3/12   |                |                  |           |            |                 |
| Argentina   | P0903851          | 2009/10/7   | 073781         | 2010.12.01       |           |            |                 |
| PCT         | PCT/JP2009/067586 | 2009/10/2   |                |                  |           |            |                 |
| US pro1     | 61/323338         | 2010/4/12   |                |                  |           |            |                 |
| US pro2     | 61/323342         | 2010/4/12   |                |                  |           |            |                 |
| US pro3     | 61/326811         | 2010/4/22   |                |                  |           |            |                 |
| US pro4     | 61/362945         | 2010/7/9    |                |                  |           |            |                 |
| US pro5     | 61/408237         | 2010/10/29  |                |                  |           |            |                 |

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**Exhibit C Licensed Know-How**

*TBD*

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### Exhibit D Product Trademarks

| Country                   | Class | Application No | Application date | Registration No | Registration date |
|---------------------------|-------|----------------|------------------|-----------------|-------------------|
| Argentina                 | 5     | 2899679        | 2009/3/10        | 1730932         | 1999/4/14         |
| Australia                 | 5     | 673735         | 1995/10/2        | 673735          | 1998/5/15         |
| Brazil                    | 5,20  | 819157589      | 1996/3/25        | 819157589       | 1999/9/28         |
| Chile                     | 5     | 351939         | 1996/8/9         | 571201          | 2000/7/5          |
| Colombia                  | 5     | 96041256       | 1996/8/5         | 220579          | 1999/7/23         |
| C.T.M.                    | 5     | 61531          | 1996/4/1         | 61531           | 1999/1/7          |
| Czechoslovakia            | 5     | 115704         | 1996/10/14       | 203279          | 1997/8/26         |
| Ecuador                   | 5     | 71327          | 1996/8/27        | 781-98          | 1998/2/11         |
| Egypt                     | 5     | 103180         | 1996/10/8        | 103180          | 2001/11/4         |
| Hong Kong                 | 5     | 96/12298       | 1996/10/1        | 98/05476        | 1998/6/4          |
| Hungary                   | 5     | M9603273       | 1996/10/8        | 150945          | 1998/4/22         |
| Iceland                   | 5     | 1201/1996      | 1996/10/9        | 556/1998        | 1998/4/2          |
| India                     | 5     | 725901         | 1996/10/8        | 725901          | 2006/9/29         |
| Indonesia                 | 5     | D96-22173      | 1996/10/9        | 398192          | 1997/10/10        |
| Israel                    | 5     | 107835         | 1996/10/7        | 107835          | 1997/12/4         |
| Malaysia                  | 5     | 96/12156       | 1996/10/7        | 96/12156        | 2000/5/4          |
| Mexico                    | 5     | 270728         | 1996/8/9         | 530343          | 1996/8/30         |
| New Zealand               | 5     | 254275         | 1995/10/2        | 254275          | 1998/5/15         |
| Nicaragua                 | 5     | 96-02899       | 1996/8/14        | 33638CC         | 1997/3/11         |
| Norway                    | 5     | 966148         | 1996/10/9        | 183971          | 1997/7/31         |
| Peru                      | 5     | 017422         | 1996/8/2         | 030840          | 1996/11/13        |
| Philippines               | 5     | 115005         | 1996/10/23       | 4-1996-115005   | 2001/7/10         |
| Romania                   | 5     | 41174          | 1996/10/9        | R28741          | 2000/1/6          |
| Saudi Arabia              | 5     | 36379          | 1996/11/12       | 424/36          | 1998/1/7          |
| Singapore                 | 5     | T96/10659D     | 1996/10/2        | T96/10659D      | 1996/10/2         |
| South Africa              | 5     | 96/14690       | 1996/10/15       | 96/14690        | 1999/11/11        |
| Switzerland               | 5     | 02266/1996     | 1996/3/29        | 434172          | 1997/1/16         |
| Thailand                  | 5     | 305481         | 1996/4/2         | KOR54996        | 1997/2/5          |
| UAE                       | 5     | 19299          | 1996/11/9        | 14991           | 1998/5/6          |
| Venezuela                 | 5     | 13528/96       | 1996/8/20        | 219777          | 2000/6/2          |
| Bangladesh                | 5     | 51708          | 1997/6/25        |                 |                   |
| Cyprus                    | 5     |                |                  | 48204           | 1998/5/15         |
| JORDAN                    | 5     |                |                  | 46003           | 1999/9/28         |
| Nigeria                   | 5     |                |                  | TP33736         | 1997/6/3          |
| Pakistan                  | 5     |                |                  | 142210          | 2002/9/26         |
| Switzerland               | 5     | 08646/2001     | 2001/9/3         | 489110          | 2001/9/13         |
| Int. Regist. 18 countries | 5     | 08646/2001     | 2001/9/3         | 766429          | 2001/9/13         |
| Liechtenstein             | 5     | 12614          | 2002/8/14        | 12614           | 2002/11/14        |



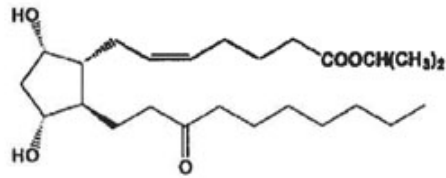
## Exhibit E Unoprostone

Generic Name: Unoprostone Isopropyl (USAN)

Chemical Names: (+) - Isopropyl (Z) - 7 - [(1R,2R,3R,5S) - 3,5 - dihydroxy - 2 - (3-oxadecyl) cyclopentyl] hept - 5 - enoate

CAS No.: 120373-24-2

Structural Formula




*Unoprostone Isopropyl*

EXHIBIT F

SUCAMPO PHARMACEUTICALS, INC. GUARANTEE

In accordance with Article 15 of Exclusive License for Development and Commercialization of Unoprostone by and between R-Tech Ueno, Ltd. and Sucampo Manufacture and Research AG dated March 22, 2011 ("Agreement"), Sucampo Pharmaceuticals, Inc. hereby guarantees the performance of Sucampo Manufacture and Research AG under the Agreement.

Dated: March 22, 2011



James J. Egan  
Chief Operating Officer  
Sucampo Pharmaceuticals, Inc.



EXHIBIT F

SUCAMPO PHARMACEUTICALS, INC. GUARANTEE

In accordance with Article 15 of Exclusive License for Development and Commercialization of Unoprostone by and between R-Tech Ueno, Ltd. and Sucampo Manufacture and Research AG dated March 22, 2011 ("Agreement"), Sucampo Pharmaceuticals, Inc. hereby guarantees the performance of Sucampo Manufacture and Research AG under the Agreement.

Dated: March 22, 2011



James J. Egan  
Chief Operating Officer  
Sucampo Pharmaceuticals, Inc.

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

I, Ryuji Ueno, certify that:

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

Date: May 10, 2011

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

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

I, Andrew P. Smith, 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 registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2011

/s/ ANDREW P. SMITH  
Andrew P. Smith  
(Principal 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 March 31, 2011 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2011

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

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

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

- (1) The Quarterly Report on Form 10-Q for the period ended March 31, 2011 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2011

/s/ ANDREW P. SMITH

Andrew P. Smith

(Principal Accounting Officer)